BEFORE THE

SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS
WORKING GROUP
OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT

REGULAR MEETING

LOCATION: OMNI SHOREHAM HOTEL
251 S. OLIVE STREET
THE BUNKER ROOM
LOS ANGELES, CALIFORNIA

DATE: TUESDAY, AUGUST 30, 2005
10 A.M.

REPORTER: BETH C. DRAIN, CSR
CSR. NO. 7152

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LOS ANGELES, CALIFORNIA; TUESDAY, AUGUST 30, 2005

10 A.M.

CO-CHAIR LANSING: HELLO. CAN I HAVE EVERYBODY'S ATTENTION, PLEASE. IT'S 10 O'CLOCK AND IN THE ATTEMPT TO BE SUPER EFFICIENT, I'D LIKE TO START RIGHT ON TIME. MY NAME IS SHERRY LANSING, AND I'D LIKE TO WELCOME ALL OF YOU TO THE SECOND MEETING OF THE STANDARDS WORKING GROUP. AND I'D LIKE TO START THIS MEETING BY MAKING A FEW INTRODUCTIONS.

FIRST, I WANT TO ACKNOWLEDGE THE DEPARTURE OF MY CO-CHAIR, HARRIET RABB, FROM THE WORKING GROUP. SHE HAD TO RESIGN FOR PERSONAL REASONS, WHICH SADDENED ALL OF US, BUT, OF COURSE, WE UNDERSTOOD. BUT I WOULD LIKE TO THANK HER FOR THE ENORMOUS CONTRIBUTION THAT SHE MADE IN GETTING THIS GROUP UP AND RUNNING AND THANK HER AGAIN. BUT WE GOT VERY LUCKY BECAUSE I'D LIKE TO INTRODUCE MY NEW CO-CHAIR, BERNIE LO. AND I KNOW YOU ALL KNOW HIM SO WELL, AND I FEEL SO GRATEFUL THAT HE'S HERE. I CAN'T TELL YOU. AND I THANK YOU IN ADVANCE FOR EVERYTHING THAT YOU'VE DONE TO MAKE THIS MEETING SO EFFICIENT.

I'D ALSO LIKE TO INTRODUCE GEOFF LOMAX, AND GEOFF IS RIGHT HERE AND HE'S RECENTLY JOINED THE STAFF. AND HE IS OUR SENIOR OFFICER FOR THE STANDARDS WORKING

GROUP AND HAS BEEN INVALUABLE TO US ALREADY IN THE SHORT TIME THAT HE'S HERE.

I THINK WE MADE A SLIGHT ERROR IN OUR FIRST MEETING, WHICH IS SOMETHING I'D LIKE TO CORRECT TODAY. WE FORGOT TO GO AROUND THE ROOM AND HAVE EVERYBODY INTRODUCE THEMSELVES, SO I'D LIKE TO DO THAT TODAY. AND FRANCISCO, WOULD YOU START. LIKE JUST TO WELCOME EVERYBODY AGAIN AND ASK YOU TO JUST A SAY FEW WORDS ABOUT YOURSELF SO THAT THE PUBLIC AND THOSE OF US WHO DON'T KNOW EACH OTHER CAN KNOW EACH OTHER A LITTLE BETTER.

DR. PRIETO: I'M FRANCISCO PRIETO. I'M A PRACTICING PHYSICIAN IN THE SACRAMENTO AREA, AND I'M ONE OF THE DIABETES ADVOCATES, PATIENT ADVOCATE, ON THE ICOC.

DR. EGGAN: MY NAME IS KEVIN EGGAN. I'M AN ASSISTANT PROFESSOR IN THE DEPARTMENT OF MOLECULAR CELLULAR BIOLOGY AT HARVARD UNIVERSITY WHERE WE DO WORK ON CLONING BY NUCLEAR TRANSPLANTATION AND MORE AND MORE EFFORTS TO TRY TO USE THE ES CELLS TO CURE NEURODEGENERATIVE CONDITIONS.

DR. TAYLOR: MY NAME IS ROD TAYLOR. I'M PROFESSOR OF GYNECOLOGY AND OBSTETRICS AT EMORY UNIVERSITY IN ATLANTA, VERY RECENTLY AT UCSF FOR 25 YEARS. I'M A REPRODUCTIVE ENDOCRINOLOGIST AND

INTERESTED IN IMPLANTATION BIOLOGY.

DR. KORDOWER: I'M JEFF KORDOWER, PROFESSOR OF NEUROLOGICAL SCIENCES AT RUSH UNIVERSITY MEDICAL CENTER. WE USE STEM CELLS IN ANIMAL MODELS OF PARKINSON'S, HUNTINGTON'S, AND ALZHEIMER'S DISEASE PRIMARILY IN NONHUMAN PRIMATE MODELS.

DR. PETERS: I'M TED PETERS. I TEACH THEOLOGY AT PACIFIC LUTHERAN SEMINARY IN THE GRADUATE THEOLOGICAL UNION IN BERKELEY. AND I'VE BEEN MONITORING AND INVOLVED IN THE ETHICAL ISSUES AROUND RESEARCH ON HUMAN EMBRYONIC STEM CELLS SINCE ABOUT 1996 WHEN THE ISOLATION WAS CONCEIVED.

MR. KLEIN: BOB KLEIN, CHAIRMAN OF THE ICOC.

DR. HALL: ZACH HALL, INTERIM PRESIDENT OF THE CIRM, CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE.

MS. LANSING: I'M SHERRY LANSING, BOARD MEMBER OF THE ICOC AND CHAIR OF STOP CANCER.

DR. LO: I'M BERNARD LO. I'M A PROFESSOR OF MEDICINE AT THE UNIVERSITY OF CALIFORNIA SAN FRANCISCO WHERE I ALSO DIRECT THE PROGRAM OF MEDICAL ETHICS. BEEN INVOLVED WITH A NUMBER OF PANELS OVER THE YEARS ON STEM CELL RESEARCH.

MR. LOMAX: GEOFF LOMAX, STAFF PERSON TO THE WORKING GROUP.

DR. KIESSLING: I'M ANN KIESSLING. I'M AN ASSOCIATE PROFESSOR AT HARVARD MEDICAL SCHOOL WHERE I MOSTLY DO HIV RESEARCH, AND I DIRECT A SMALL INDEPENDENT FOUNDATION IN SUMMERVILLE, MASS, THAT'S DEDICATED TO STEM CELL RESEARCH.

MS. CHARO: I'M ALTA CHARO. I'M PROFESSOR OF LAW AND BIOETHICS AT THE UNIVERSITY OF WISCONSIN LAW AND MEDICAL SCHOOLS. I'LL BE CHANGING AFFILIATIONS IN JANUARY AS A VISITING PROFESSOR AT BERKELEY'S LAW SCHOOL AND HAVE WORKED WITH BERNIE LO ON SEVERAL GOVERNMENTAL COMMISSIONS THAT TOUCHED ON STEM CELLS AND WAS WORKING WITH THE NAS COMMITTEE THAT DEVELOPED THE VOLUNTEER NATIONAL GUIDELINES.

DR. OLDEN: I'M KEN OLDEN. I'M FORMER DIRECTOR OF THE NATIONAL INSTITUTE FOR ENVIRONMENTAL HEALTH SCIENCES, AND NOW I'M SENIOR SCIENTIST AT THE NATIONAL INSTITUTES OF HEALTH, AND ALSO SERVE AS CHIEF SCIENTIFIC ADVISOR FOR THE MICHAEL J. FOX FOUNDATION IN NEW YORK.

MR. SHEEHY: JEFF SHEEHY, AND I'M A PATIENT ADVOCATE FOR PEOPLE WITH HIV ON THE ICOC AND DIRECTOR OF COMMUNICATIONS AT UCSF'S AIDS RESEARCH INSTITUTE.

DR. CIBELLI: I AM JOSE CIBELLI, PROFESSOR AT MICHIGAN STATE UNIVERSITY. WE ARE WORKING WITH STEM CELLS AND NUCLEAR TRANSFER CLONING.

DR. WILLERSON: I'M JIM WILLERSON. I'M THE PRESIDENT OF THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON, PRESIDENT ELECT OF THE TEXAS HEART INSTITUTE. DR. PERRIN AND I BEGAN TO TREAT PATIENTS WITH HEART FAILURE WITH THEIR OWN BONE-MARROW DERIVED STEM CELLS IN RIO DE JANEIRO, BRAZIL, IN THE YEAR 2000. AND WE TREATED 14 PATIENTS AND HAD SEVEN CONTROLS AND SHOWED THAT THEIR CELLS INJECTED DIRECTLY INTO THE HEART IMPROVED THEIR BLOOD FLOW AND THE FUNCTION OF THEIR HEARTS. WE HAVE, I BELIEVE, THE ONLY FDA-APPROVED TRIAL IN THE UNITED STATES TODAY, TREATING PATIENTS WITH HEART FAILURE WITH THEIR OWN BONE-MARROW DERIVED STEM CELLS, AND WE'VE TREATED 16 AT THE TEXAS HEART INSTITUTE IN A BLINDED RANDOMIZED STUDY.

WE'RE ALSO INVOLVED IN BASIC STUDIES TRYING TO DETERMINE WHAT STEM CELL'S THE BEST AND WHAT HAPPENS TO THESE STEM CELLS WHEN THEY'RE INJECTED INTO THE HEART.

MR. HARRISON: I'M JAMES HARRISON, COUNSEL TO THE CIRM.

CO-CHAIR LANSING: I THINK, JANET ROWLEY, ARE YOU HERE?

DR. ROWLEY: YES, I'M ON THE PHONE IN CHICAGO, UNFORTUNATELY NOT IN L.A. MY OWN RESEARCH IS IN GENETIC CHANGES IN LEUKEMIA, BUT I SERVED ON THE

PRESIDENT'S COUNCIL ON BIOETHICS AND ALSO WAS A MEMBER WITH ALTA OF THE NATIONAL ACADEMY OF SCIENCES GROUP THAT WROTE THE GUIDELINES THAT ARE AT LEAST AT PRESENT SERVING AS INTERIM GUIDELINES FOR THE STATE OF CALIFORNIA'S PROJECT.

CO-CHAIR LANSING: THANK YOU. AN EXTRAORDINARY GROUP OF PEOPLE, AND I WANT TO THANK ALL OF YOU FOR THE TIME THAT YOU HAVE GIVEN SO FAR AND THE TIME THAT I KNOW AWAITS US IN THE FUTURE. WE'VE DONE AN INCREDIBLE AMOUNT OF WORK IN A VERY SHORT AMOUNT OF TIME. AND THIS IS -- I WANT TO, ONCE AGAIN, STATE FOR ALL OF US HERE AND FOR THE PUBLIC THAT THIS IS TRULY A WORK IN PROGRESS, AND THAT WE'RE HERE TO WORK TOGETHER, BUT WE'RE ALSO HERE TO LISTEN TO THE PUBLIC, TO LISTEN TO MEMBERS OF THE SCIENTIFIC COMMUNITY, AND LAWMAKERS. AND WE'RE HERE TO LISTEN TO WHAT THEY SAY AND TAKE THEIR WORDS TO HEART. AND WE'RE GOING TO REMAIN FLEXIBLE AND MAKE CHANGES WHENEVER NECESSARY.

BUT AGAIN, I WANT TO SAY TO THE PUBLIC THAT THIS IS REALLY A WORK IN PROGRESS. WE HAVE A LONG ROAD AHEAD OF US, AND WE'RE ALL DEDICATED TO SPENDING THE TIME NECESSARY TO MAKE THE RIGHT DECISIONS.

WITH THAT SAID, I'D LIKE TO CALL THE MEETING TO ORDER AND ASK KATE IF YOU WOULD LEAD IN THE ROLL CALL.

MS. SHREVE: ALTA CHARO.

MS. CHARO: HERE.

MS. SHREVE: JOSE CIBELLI.

DR. CIBELLI: HERE.

MS. SHREVE: KEVIN EGGAN.

DR. EGGAN: HERE.

MS. SHREVE: JEFFREY KORDOWER.

DR. KORDOWER: HERE.

MS. SHREVE: ANN KIESSLING.

DR. KIESSLING: HERE.

MS. SHREVE: ROBERT KLEIN.

MR. KLEIN: HERE.

MS. SHREVE: SHERRY LANSING.

CO-CHAIR LANSING: HERE.

MS. SHREVE: BERNARD LO.

CO-CHAIR LO: HERE.

MS. SHREVE: KENNETH OLDEN.

DR. OLDEN: HERE.

MS. SHREVE: THEODORE PETERS.

DR. PETERS: HERE.

MS. SHREVE: FRANCISCO PRIETO.

DR. PRIETO: HERE.

MS. SHREVE: JANET ROWLEY.

DR. ROWLEY: HERE.

MS. SHREVE: JEFF SHEEHY.

MR. SHEEHY: HERE.

MS. SHREVE: JON SHESTACK. ROBERT TAYLOR.

DR. TAYLOR: HERE.

MS. SHREVE: JAMES WILLERSON.

DR. WILLERSON: HERE.

CO-CHAIR LANSING: I'D LIKE TO MOVE FOR APPROVAL OF THE MINUTES FROM THE JULY 6TH, 2005, MEETING. DO I HAVE A SECOND?

DR. KIESSLING: I HAVE A COUPLE OF CORRECTIONS. ON PAGE 13 AT THE BOTTOM OF THE PAGE, IT SAYS KEY ISSUES FACED BY KIESSLING, ET AL. ON THE ETHICS BOARD DEVELOPING THE FIRST IVF LAB IN OREGON. THAT'S INACCURATE. IT WAS DEVELOPING THE FIRST EGG DONOR PROGRAM FOR STEM CELL RESEARCH.

CO-CHAIR LANSING: THANK YOU. WILL YOU CORRECT THAT, PLEASE?

DR. KIESSLING: HAS NOTHING TO DO WITH THE IVF LAB IN OREGON. PAGE 13 AT THE BOTTOM OF THE PAGE IS A STATEMENT THAT SAYS KEY ISSUES FACED BY KIESSLING, ET AL. AND THE ETHICS BOARD DEVELOPING THE FIRST IVF LAB IN OREGON. THAT'S INACCURATE. HAS NOTHING TO DO WITH THE FIRST IVF LAB IN OREGON. THAT WAS 20 SOME YEARS AGO. THAT WAS DEVELOPING THE FIRST EGG DONOR PROGRAM FOR STEM CELL RESEARCH.

CO-CHAIR LANSING: MAKE THAT CORRECTION. ANY

OTHER CORRECTIONS?

DR. CIBELLI: I HAVE A DRAFT IN FRONT OF ME THAT I'M NOT SURE IS THE ONE THAT YOU ALL HAVE, BUT I HAVE IN PAGE NO. 7, THERE'S A PARAGRAPH THAT READS: THE NATIONAL ACADEMY OF SCIENCE COMMITTEE ACCEPTED AS A STARTING POINT TWO PREVIOUS NAS REPORTS THAT CALL FOR, A, A BAN ON REPRODUCTIVE CLOSING. THAT'S CLONING.

CO-CHAIR LANSING: DID YOU GET THAT?

DR. HALL: PAGE 7, IT'S TWO-THIRDS OF THE WAY DOWN; IS THAT RIGHT, JOSE?

DR. CIBELLI: YES.

DR. HALL: I DIDN'T GET -- WHAT WAS THE --

DR. PRIETO: IT'S A TYPO. CLOSING INSTEAD OF CLONING.

DR. KIESSLING: IT SAYS A BAN ON REPRODUCTIVE CLOSING.

DR. HALL: CLOSING. OKAY. GOT IT. TYPO. GOOD.

MR. KLEIN: IF THE CHAIR WOULD LIKE TO INSTRUCT THE PERSONNEL, I THINK THEY CAN RAISE ALL THE MICS IF THAT'S THE CHAIR'S PLEASURE.

CO-CHAIR LANSING: SURE. ANY OTHER CORRECTIONS FOR THE MINUTES? DO I HAVE A SECOND WITH THESE CORRECTIONS?

DR. PRIETO: SECOND.

CO-CHAIR LANSING: ALL IN FAVOR. THE MOTION PASSES.

I'D NOW LIKE TO ASK ZACH AND GEOFF IF THEY WOULD PRESENT THE CIRM REPORT FOR US.

DR. HALL: ALL RIGHT. LET ME JUST REMIND YOU THAT AT THE LAST MEETING OF THE WORKING GROUP, THE WORKING GROUP CHARGED THE STAFF WITH TAKING THE NAS GUIDELINES AND PUTTING THEM INTO REGULATORY LANGUAGE THAT WAS APPROPRIATE FOR CIRM AND THAT WAS CONSISTENT WITH PROPOSITION 71. SO JAMES HARRISON, GEOFF LOMAX, AND KATE SHREVE HAVE WORKED VERY HARD TO DO THIS IN THE INTERIM.

AND YOU HAVE -- UNDER NO. 7 YOU HAVE THE INTERIM GUIDELINES. AND SO I WOULD LIKE TO ASK -- I'M SORRY. I'VE JUMPED AHEAD. LET ME JUST SAY THAT WILL BE THE NEXT -- I JUMPED DOWN TWO ITEMS. WE'LL DO THAT IN A MOMENT.

FIRST, GEOFF LOMAX IS GOING TO BRING US UP-TO-DATE, THEN, ON WHERE WE ARE WITH OUR PROCESS AND WHAT IS PLANNED FOR THE FUTURE. SORRY, GEOFF. I SKIPPED A BEAT THERE, BUT I'M SURE YOU CAN PICK IT RIGHT UP AND GO ON.

MR. LOMAX: THANKS VERY MUCH. AM I COMING ACROSS SO PEOPLE CAN HEAR ME? THANKS. SO WHAT WE'LL DO FIRST IS DO THE REPORT-BACK. AND WHAT WE'VE DONE IS

WE'VE ORGANIZED INTO THREE PRIMARY TOPICS, WHICH ARE THE TIME LINE IN PROCESS, WHICH WE'D LIKE TO COVER IN TERMS OF THE WORK THAT'S IN FRONT OF US; THE WORKING GROUPS, AND DESCRIBE TO YOU A LITTLE BIT WHAT WE HAVE PLANNED FOR OUR PUBLIC MEETINGS BECAUSE THESE ARE ALL THREE ITEMS THAT PEOPLE EXPRESSED A NEED TO HAVE A CLEAR UNDERSTANDING OF HOW WE'RE PLANNING ON PROCEEDING.

THIS SLIDE, WHICH IS TAB 6 IN YOUR BINDER, I REALIZE THIS IS FAIRLY COMPLICATED, BUT IT GIVES YOU A COMPLETE PICTURE OF THE PROCESS BOTH IN TERMS OF WHERE WE'VE BEEN AND WHERE WE ANTICIPATE WE'LL BE HEADED. WHAT I'LL DO IS TRY TO WALK THROUGH THIS BRIEFLY, AND THEN WE HAVE A MORE SIMPLIFIED VERSION TO FOLLOW.

WHAT WE WANT TO POINT OUT ON THIS TIME LINE, THAT IN JULY THE RECOMMENDATION THAT THE GUIDELINES, THE CURRENT GUIDELINES, BE ADOPTED IN REGULATORY FORMAT, THAT THAT RECOMMENDATION THAT HAPPENED WAS FORWARDED TO THE ICOC, AND THAT CHARGE TO ADOPT REVISED GUIDELINES WAS APPROVED BY THE ICOC. BETWEEN THE LAST MEETING AND TODAY, WE'VE SPENT CONSIDERABLE TIME AND ENERGY REVISING THOSE GUIDELINES AND ATTEMPTING TO PUT THEM IN A FORMAT THAT WILL MEET THAT NEED.

THAT BRINGS US TO WHAT I'D LIKE TO DESCRIBE AS THE CRITICAL DATE IN TERMS OF PROP 71, WHICH IS WE

WANT TO TAKE THE EXISTING DOCUMENT THAT WE HAVE TODAY AND, WITH THE APPROVAL OF THIS WORKING GROUP, IT WOULD THEN GO TO THE ICOC, AND THE ICOC WOULD APPROVE THAT IN THEIR SEPTEMBER 9TH MEETING.

NOW, THAT MEETING DATE, WHAT THAT WOULD DO IS SET A CLOCK RUNNING, WHICH IS A 270-DAY CLOCK WHERE THE CIRM WOULD BE GOVERNED BY THE GUIDELINES THAT WE ADOPT TODAY. SO THAT 270-DAY PERIOD IS ILLUSTRATED BY THE BLUE BAR THAT RUNS ACROSS THE TOP OF THE TIME LINE.

I WANT TO EMPHASIZE THAT THAT TIME LINE IS EXPLICITLY PROSCRIBED BY PROPOSITION 71. SO THAT'S WHERE THAT 270-DAY NUMBER COMES FROM. SO FROM THE PERIOD WHICH ACTUALLY STARTED EARLIER THIS MONTH AND THAT WILL CARRY US THROUGH TO THE END OF OCTOBER, WHAT WE ARE ATTEMPTING TO DO IS THEN REVISE THOSE GUIDELINES TO DEVELOP A SET OF FINAL GUIDELINES WHICH WE RECOMMEND. SO THAT'S ILLUSTRATED BY THE GREEN SECTION OF THIS TIME LINE. SO WE'RE MOVING TOWARDS REDRAFTING GUIDELINES THAT WILL MEET THE LONG-TERM NEEDS OF CIRM.

THE YELLOW SET OF BOXES REPRESENT WHAT'S REFERRED TO AS THE ADMINISTRATIVE PROCEDURES ACT PHASE OR THE POINT IN TIME WHEN THE GUIDELINES RECOMMENDED BY THIS WORKING GROUP WILL THEN GO THROUGH A PUBLIC COMMENT, ADMINISTRATIVE REVIEW, AND THEN IDEALLY BE ADOPTED INTO LAW SOMETIME AT THE BEGINNING OF JUNE NEXT

YEAR.

IS THIS CLEAR IN TERMS OF THIS WALK-THROUGH?

DR. KIESSLING: I'M SORRY. WHAT IS THE 45-DAY PERIOD FOR?

MR. LOMAX: UNDER THE ADMINISTRATIVE PROCEDURES ACT RULEMAKING PERIOD, THERE'S A 45-DAY PERIOD WHICH ALLOWS FOR PUBLIC COMMENT. SO THIS WOULD BE COMMENTS THAT WOULD BE SUBMITTED FORMALLY BY EITHER MEMBERS OF THE PUBLIC OR ANYONE ELSE WHO CARES TO COMMENT ON THE FINAL DRAFT GUIDELINES AS RECOMMENDED BY THIS GROUP AND APPROVED BY THE ICOC.

DR. KIESSLING: SO THIS IS NOT PROPOSITION 71?

MR. LOMAX: NO. EXACTLY. THIS IS WHY WE TRIED TO USE A LITTLE BIT OF COLOR HERE TO CLARIFY TWO PARALLEL BUT SEPARATE PROCESSES. AND THE YELLOW INDICATES WHAT'S THE ADMINISTRATIVE PROCEDURES ACT PROCESSES, WHICH IS CALIFORNIA LAW THAT GOVERNS AN AGENCY DRAFTING AND ADOPTING REGULATIONS.

DR. HALL: LET ME JUST MAKE A COMMENT, GEOFF. WE HAVE TWO PERIODS OF PUBLIC HEARINGS, AND I WANT TO JUST DISTINGUISH THOSE. AND, JAMES, YOU CORRECT ME IF I MISSTATE HERE. ONCE THIS COMMITTEE DOES ITS WORK AND COMES UP WITH A DRAFT OF FINAL GUIDELINES TO SUBMIT FOR APPROVAL BY THE ICOC AND THEN SUBSEQUENTLY SUBMIT TO

THE OFFICE OF ADMINISTRATIVE LAW, THEN THOSE GUIDELINES BY LAW MUST BE MADE AVAILABLE FOR PUBLIC COMMENT IN A FORMAL WAY OVER A 45-DAY PERIOD.

WE WILL BE REQUIRED TO RESPOND TO ALL WRITTEN COMMENTS THAT ARE MADE DURING THAT PERIOD SAYING WE CONSIDERED THEM AND WHY WE HAD ACTED EITHER TO ACCEPT THEM OR NOT. WE ARE GOING AN ADDITIONAL STEP, HOWEVER, IN OUR PROCESS; AND THAT IS, WE ARE INCORPORATING THE PUBLIC INTO THE PROCESS OF DRAFTING THAT FINAL STATEMENT WHICH WILL BE DUE IN EARLY NOVEMBER.

SO AS YOU WILL HEAR FROM GEOFF IN JUST A MOMENT, WE'RE HAVING A SERIES OF PUBLIC HEARINGS SO THAT PEOPLE CAN ADVISE US AS WE DRAFT IT. WE ARE NOT REQUIRED BY LAW TO DO THAT AND WE DON'T HAVE TO MAKE A FORMAL RESPONSE TO THOSE, BUT WE WANT VERY MUCH TO GET INPUT FROM THE PUBLIC AS WE DO THAT. AND SO THAT IS THE FIRST PHASE OF THE PUBLIC HEARING, AND THEN THE SECOND IS THE MORE FORMAL ONE DESCRIBED THERE.

CO-CHAIR LANSING: AND THE FIRST ONE IS TOMORROW.

MR. KLEIN: I THINK IT WOULD BE APPROPRIATE TO LET YOU KNOW THAT WHILE THIS PROCESS HAS BEEN DESIGNED SPECIFICALLY FOR THIS RULEMAKING, THE INITIATIVE ACTUALLY NOT ONLY LAID OUT THE 270-DAY PERIOD, BUT CALLS OUT THE REQUIREMENT TO FOLLOW THE

ADMINISTRATIVE PROCEDURES ACT.

MR. LOMAX: I TRIED TO THEN SIMPLIFY THAT INTO A FOUR-STEP SET OF PROCEDURES, SO THIS IS A REITERATION OF WHAT WE JUST COVERED. STEP 1 IS TO ADOPT INTERIM GUIDELINES WHICH WILL BE IN EFFECT FOR UP TO 270 DAYS. THESE GUIDELINES ARE BASED ON THE NATIONAL RESEARCH COUNCIL/IOM RECOMMENDATIONS. THE ICOC WOULD THEN, AGAIN, ADOPT THOSE ON THE 9TH OF SEPTEMBER.

THE SECOND STEP WOULD BE TO THEN WORK ON REVISING THAT DOCUMENT SO THAT IT MEETS THE STANDARDS OF WHAT THIS WORKING GROUP BELIEVES SHOULD ULTIMATELY GOVERN THE CIRM.

THE THIRD STEP, AGAIN, TO SUBMIT THOSE REGULATIONS, THOSE ARE NOW FORMAL REGULATIONS, TO THE ICOC WHICH WOULD THEN APPROVE THEM, AND THEY WOULD BE FORWARDED TO THE OFFICE OF ADMINISTRATIVE LAW IN NOVEMBER. AND THAT WOULD INITIATE THE FOURTH STEP, WHICH IS TO RECEIVE AND RESPOND TO PUBLIC COMMENTS.

AND, AGAIN, IN STEP 2 I SORT OF MISSED THAT ONE POINT, AGAIN, THAT WE HAVE A SET OF WHAT WE'RE CALLING PUBLIC SESSIONS IN THE STEP 2 PHASE TO AGAIN RECEIVE AN ADDITIONAL SET OF PUBLIC COMMENTS TO FURTHER INFORM OUR WORK.

DR. TAYLOR: IS THERE ANY REASON TO BELIEVE

THAT WE WOULDN'T GET COMMENTS FROM THE PUBLIC UNTIL THAT 45-DAY PERIOD? THERE'S AN OPPORTUNITY FOR PUBLIC INPUT THROUGHOUT THE PROCESS. I'M JUST WONDERING AS THESE THINGS WORK --

DR. HALL: AS YOU WILL HEAR FROM GEOFF, WE HAVE THREE PUBLIC SESSIONS PLANNED BEFORE THAT NOVEMBER FINAL DRAFT IS SUBMITTED. SO THAT'S THE PERIOD OF INFORMAL PUBLIC COMMENT. WE'RE NOT REQUIRED TO DO THAT. WE'RE DOING IT BECAUSE WE WANT TO HAVE THE PUBLIC INVOLVED, AND WE DON'T HAVE TO MAKE FORMAL RESPONSE. THE FIRST OF THOSE, AS YOU WILL HEAR, BEGINS TOMORROW. INFORMALLY, IF ANYBODY, ANY PUBLIC MEMBER WISHES TO WRITE AND MAKE SUGGESTIONS, THAT'S ALSO A PERFECTLY GOOD WAY OF HAVING INPUT INTO THE PROCESS.

MR. LOMAX: CURRENTLY ON THE WEBSITE IN RELATION TO THE DRAFT GUIDELINES WE INVITE THAT COMMENT. SO THERE IS AN ACTIVE MECHANISM TO SAY WE'RE LOOKING FORWARD TO YOUR COMMENTS, AND HERE'S HOW YOU CAN COMMENT ON THE DRAFT REGULATIONS.

MR. KLEIN: GEOFF, IT MIGHT ALSO BE VALUABLE TO REMIND EVERYONE THAT THE MOMENT THE BOARD ADOPTS THESE INTERIM GUIDELINES, IF THAT, FOR EXAMPLE, IS ON SEPTEMBER 9TH, THOSE GUIDELINES ACTUALLY BECOME EFFECTIVE ON AN INTERIM BASIS SO THAT GRANTS CAN GO FORWARD USING THE INTERIM GUIDELINES IMMEDIATELY.

MR. LOMAX: I WANTED TO ALSO TOUCH BASE A LITTLE BIT ON HOW WE SORT OF ORGANIZED THE PROCESS IN TERMS OF DOING THE WORK BECAUSE THAT WILL INFORM HOW WE THEN EXPLAIN OUR WORK IN THESE WHAT WE'RE CALLING PUBLIC SESSIONS, AGAIN THE SESSIONS WHERE WE ARE RECEIVING COMMENT, BUT THEY'RE OUTSIDE OF THE FORMAL COMMENTING PERIOD, WHICH WAS INDICATED IN YELLOW.

WE HAVE THE FIVE STUDY GROUPS WHICH WERE AGREED ON IN THE LAST MEETING. THESE FIVE GROUPS HAVE ALL HAD AN OPPORTUNITY TO GET TOGETHER AND MEET, DO ISSUE IDENTIFICATION, AND START DISCUSSING RESOLUTION TO SOME OF THE ISSUES AND HOW TO WORK THROUGH THEM.

WE'VE STARTED TO COMPILE DOCUMENTATION OF THESE ISSUES. AND IN YOUR BINDER THERE'S A SPREADSHEET, I BELIEVE IT'S IN THE INNER LEFT POCKET, WHICH IS OUR FIRST ATTEMPT AT COMPILING AND BUILDING A RECORD OF ISSUES FOR CONSIDERATION.

AND THEN IF I CAN MOVE TO THE PUBLIC SESSIONS, YOU NOTICE THE LEVEL OF DETAIL PROVIDED IN THE TABLE IS QUITE CONSIDERABLE, SO WE'RE GOING TO NEED TO SIMPLIFY THAT MATERIAL FOR THE PUBLIC SESSIONS, THREE OF WHICH ARE PLANNED, AGAIN, ON WEDNESDAY WE'LL BE HAVING OUR FIRST PUBLIC SESSION HERE IN LOS ANGELES. WE HAVE A SESSION SCHEDULED FOR SEPTEMBER 27TH IN SAN FRANCISCO. AND I BELIEVE OUR SACRAMENTO DAY IS STILL

YET TO BE ANNOUNCED; IS THAT CORRECT? WE DON'T HAVE A DATE FOR SACRAMENTO.

SO, AGAIN, WHAT WE'VE DONE IS WE'VE TAKEN THE TOPICS FOR THE PUBLIC SESSION AND WE'VE TRIED TO -- WHAT WE HAVE PLANNED TO DO IN THE PUBLIC SESSION IS, FIRST OF ALL, GIVE THE PUBLIC A SENSE OF THE PROCESS, SO WE'LL WALK THROUGH TIME LINES, CRITICAL DATES, AND WHAT OUR WORK WILL INVOLVE. AND THEN IN ORDER TO INTRODUCE THE CONTENT OR SOME SUBSTANCE IN WHICH TO HAVE A DISCUSSION AROUND IN A FAIRLY STRUCTURED WAY THAT WILL ALLOW US TO ORGANIZE THAT FEEDBACK, WHAT WE'VE DONE IS WE'VE TAKEN THE DETAILED MATERIAL THAT IS IN THE TABLE I REFERRED TO PREVIOUSLY, AND WE PUT IT INTO A SET OF SLIDES WHICH, AGAIN, YOU HAVE COPIES OF THOSE SLIDES, AND THOSE SLIDES ARE, AGAIN, USING THE STUDY GROUP CATEGORIES, WE'VE IDENTIFIED WHAT WE'RE CALLING ISSUE AREAS, WHICH I HAVEN'T SEEN HOW THEY REPRODUCED, BUT HOPEFULLY YOU WILL SEE THIS ISSUE AREA. AND WE ALSO INTRODUCED A SET OF SORT OF KEY QUESTIONS THAT HAVE COME UP.

AND OUR HOPE IS THAT BY DOING THIS, WE'LL BE ABLE TO ORIENT THE DISCUSSION AROUND ISSUES AND ALSO PROVIDE SOME GUIDANCE IN TERMS OF IMMEDIATE QUESTIONS THAT HAVE COME UP WITHIN THOSE ISSUE AREAS. AND WE'LL HAVE A CHANCE TO SEE HOW THIS WORKS TOMORROW HOPEFULLY

WITH YOUR APPROVAL.

SO WHAT WE'RE REQUESTING AT THIS TIME IS APPROVAL FOR THE TOPICS AND QUESTIONS FOR USE IN THE PUBLIC SESSION. AND AGAIN, AS THEY'RE PRESENTED IN THE POWERPOINT DOCUMENT, NOT THE MORE EXTENSIVE TABLE IN YOUR BINDER, BUT IN THAT POWERPOINT DOCUMENT, AND THAT WOULD SERVE AS OUR TOOL FOR MOVING THE DISCUSSION FORWARD IN THE PUBLIC SESSION TOMORROW.

CO-CHAIR LANSING: ARE YOU REQUESTING A VOTE OF APPROVAL?

MR. LOMAX: YES. WE'D LIKE TO GET APPROVAL OF THE PRESENTATION.

CO-CHAIR LANSING: I MOVE APPROVAL OF THE POWERPOINT PRESENTATION, WHICH WILL BE USED IN THE PUBLIC COMMENT FOR TOMORROW, AND IT'S AT THE L.A. PUBLIC LIBRARY. I BELIEVE IT STARTS AT TEN TOMORROW TILL TWO. SO DO I HAVE A SECOND?

DR. CIBELLI: DON'T WE HAVE TO READ THIS FIRST?

CO-CHAIR LANSING: I'M SORRY. I THOUGHT YOU HAD. SO YOU SHOULD TAKE SOME TIME TO READ IT.

DR. OLDEN: I HAVE A QUESTION.

DR. HALL: WE CAN GO THROUGH THESE. LET ME JUST COMMENT QUICKLY. WE CAN GO THROUGH THESE ONE BY ONE IF YOU WISH. THESE ARE DISTILLED FROM THE

DISCUSSIONS OF EACH OF THE STUDY GROUPS AND ARE SIMPLY MEANT TO FOCUS THE SESSION TOMORROW. THEY'RE NOT MEANT TO BE PROSCRIPTIVE AND THEY'RE NOT MEANT TO LIMIT THE DISCUSSION, BUT SIMPLY TO ORGANIZE IT IN A USEFUL WAY.

CO-CHAIR LANSING: AND AT THE END THERE'S A GENERAL ONE THAT JUST SAYS ANY OTHER COMMENTS. THIS IS TO GIVE THE PUBLIC SPECIFIC POINTS. OTHERWISE PEOPLE WILL BE ALL OVER.

DR. CIBELLI: I GET IT. I JUST WANT TO READ IT FIRST.

CO-CHAIR LANSING: I THOUGHT EVERYBODY HAD. I APOLOGIZE. WHY DON'T WE TAKE A FEW MINUTES TO LET EVERYBODY READ IT WHO HASN'T HAD AN OPPORTUNITY TO AND MAKE ANY CORRECTIONS THAT YOU WOULD LIKE.

DR. OLDEN: THANK YOU. I'M NOT SURE THIS IS THE APPROPRIATE TIME TO RAISE THESE TWO ISSUES, BUT I WONDER IF WE SHOULD NOT HAVE AN EXPLICIT POLICY WITH RESPECT TO ACCESS TO THE BENEFITS OF STEM CELL RESEARCH. IT SEEMS TO ME AS I WENT THROUGH THE ACADEMIES' REPORT AS WELL, THERE WAS NO MENTION OF SOCIAL ACCESS TO THE BENEFITS. AND IT SEEMS TO ME THAT A COMPELLING CASE HAS BEEN MADE TO THE AMERICAN PEOPLE TO SUPPORT THIS RESEARCH ON THE BASIS OF THE FACT THAT EVERY SINGLE AMERICAN WILL BENEFIT FROM THIS RESEARCH, UNLIKE, FOR EXAMPLE, DEVELOPMENT OF CHEMOTHERAPY FOR

PROSTATE CANCER. EVERY AMERICAN WILL NOT BENEFIT.

SO I THINK THAT THERE NEEDS TO BE SOME ASSURANCE THAT EVERY AMERICAN WILL HAVE ACCESS TO THE BENEFITS OF STEM CELL RESEARCH IN THE STATE OF CALIFORNIA. SO THAT'S ONE CONCERN THAT I HAVE THAT WE HAVE NOT ADDRESSED.

AND THE OTHER ONE IS THE ACADEMY DID MENTION THE ISSUE OF DONOR RECRUITMENT WITH RESPECT TO DIVERSITY. I THINK THAT'S AN IMPORTANT ISSUE TO COMMENT ON TOO BECAUSE IF WE DON'T OUTREACH TO THE COMMUNITY AND MAKE SURE THAT THE DONORS ARE REPRESENTATIVE OF THE AMERICAN POPULATIONS, THE LIKELIHOOD THAT ONE WOULD FIND A HISTOCOMPATIBILITY MATCH WHEN ONE WENT TO RECEIVE THERAPY WOULD BE LESSENED. AND SO I THINK THOSE TWO ISSUES NEED TO BE DISCUSSED, MENTIONED, AND SOME RECOMMENDATIONS MADE BY THIS COMMITTEE.

CO-CHAIR LANSING: I TOTALLY AGREE WITH YOU. SO THE QUESTION IS DO WE PUT IT IN HERE, OR IS THIS THE WORK OF THE COMMITTEE TO MAKE THOSE RECOMMENDATIONS.

DR. OLDEN: I DON'T KNOW. I'M JUST RAISING THEM, AND I DON'T KNOW WHERE IT'S THE APPROPRIATE PLACE TO ADDRESS THEM.

DR. HALL: KEN, ARE YOU GOING TO BE HERE TOMORROW --

DR. OLDEN: YES.

DR. HALL: -- FOR THE PUBLIC MEETING? I THINK THAT WOULD BE IDEAL FOR YOU TO BRING THAT UP. AND THAT'S PRECISELY WHAT THE LAST OPEN SLIDE ON THIS IS MEANT TO DO; AND THAT IS, FOR AREAS THAT WE HAVE NOT COVERED IN THE WORKING GROUPS, SO THAT WOULD BE A GREAT THING.

CO-CHAIR LANSING: SOME OF IT WOULD GO UNDER DONOR RECRUITMENT. IT COULD BE VERY MUCH UNDER DONOR RECRUITMENT. SOMETHING TO ADD TO THE THING.

DR. OLDEN: YES. THANK YOU.

DR. KIESSLING: AS WE LOOK THROUGH THIS POWERPOINT, WHICH I THINK IS WHAT WE'VE BEEN HANDED, RIGHT, IT SEEMS TO ME AS THOUGH THE SLIDES THAT BEGIN DONOR RECRUITMENT AND PROTECTION, INTERSTATE AND INTERNATIONAL COLLABORATION, THAT THAT'S WHAT WE'RE DISCUSSING TODAY. SO I'M NOT SURE THAT AFTER TODAY'S DISCUSSION THESE WOULD BE THE POINTS OR THE ONLY POINTS. SOMEBODY HAS DECIDED THESE ARE THE IMPORTANT TOPICS, RIGHT?

CO-CHAIR LANSING: HERE'S WHAT HAPPENED. MAYBE I CAN ADD SOME CLARITY TO THIS. CORRECT ME IF I'M WRONG. EACH OF THE SUBCOMMITTEES BROKE DOWN, AND THE SUBCOMMITTEES CAME BACK WITH THESE AREAS. SO WE ACCEPTED THESE AREAS BECAUSE WE WEREN'T ON THE

INDIVIDUAL SUBCOMMITTEES. NOW WE'RE GOING TO DISCUSS THAT TODAY AND WE MAY MAKE CHANGES, BUT WE HAD TO HAVE SOME ORGANIZATION FOR TOMORROW. SO WE START WITH THIS ORGANIZATION.

NOW, WE HAVE TWO CHOICES. WE CAN EITHER, FOR EXAMPLE, AS KENNETH BROUGHT UP A VERY GOOD POINT, WE COULD EITHER PUT UNDER DONOR RECRUITMENT DIVERSITY AS POINT 4. I DON'T KNOW IF THE STAFF CAN GET IT READY IN TIME, SO I'M ASKING YOU THAT. AND MAYBE THEY CAN'T. SO THEN IT WOULD BE OUR RESPONSIBILITY TO BRING IT UP IN THAT MEETING. I WROTE IT DOWN NOW, BUT KEN IS GOING TO BE THERE.

THIS IS JUST REALLY AN ORGANIZATIONAL TOOL SO WE CAN START TO HAVE SOMETHING FOR THE PUBLIC.

DR. CIBELLI: JUST TO CLARIFY, THESE ARE THE POINTS OF THE STAFF? THESE ARE THE QUESTIONS THE STAFF RAISED TO THE GROUPS. IN TERMS OF THE BANKING, FOR EXAMPLE, I CAN SEE SOME OF THESE QUESTIONS WERE PUT TO US TO TRY TO ANSWER IN THIS CONFERENCE CALL THAT WE HAD A WEEK AGO. THE ANSWERS TO THE QUESTIONS ARE NOT REALLY HERE. WE HAVEN'T -- I DON'T SEE THEM.

DR. HALL: NO. NO. LET ME JUST SAY WE'RE IN AN INFORMATION GATHERING STAGE. WE ARE PREPARING TO CREATE A DOCUMENT THE FIRST OF NOVEMBER THAT WILL BE THE FINAL RECOMMENDATION OF THIS GROUP.

DR. CIBELLI: IF YOUR INTENTION IS TO SHOW THE PUBLIC WHAT THE QUESTIONS ARE, THIS IS OKAY.

DR. HALL: SO THE POINT IS, YES, WE WILL DISCUSS THESE QUESTIONS TODAY, AND WE'LL ASK INPUT ON THE SAME QUESTIONS TOMORROW. AND THESE AREN'T MEANT IN ANY WAY TO LIMIT OR TO BE PROHIBITIVE. I THINK WE WERE FACED WITH THE PROSPECT OF A PUBLIC MEETING AT WHICH PEOPLE WOULD GET UP AND AT RANDOM ADDRESS ALL SORTS OF TOPICS. AND THIS WAS JUST AN ATTEMPT TO TRY TO COORDINATE THE EFFORTS OF OUR STUDY GROUPS WITH THE PUBLIC INPUT. AND AS I SAY, WE WELCOME INPUT ON OTHER LINES OR TOPICS, BUT THIS IS JUST A WAY OF TRYING TO SAY, OKAY, LET'S TALK ABOUT THESE ISSUES IN TURN.

AND THEN WHEN WE BRING THAT MATERIAL, WE WILL ORGANIZE THE MATERIAL FROM THE PUBLIC MEETINGS BECAUSE EVERYBODY AT THIS GROUP WON'T BE THERE TOMORROW, BRING THAT BACK TO THE COMMITTEE SO THAT THE COMMITTEE, THIS WORKING GROUP, AT LEAST HAS INFORMATION OF WHAT THE PUBLIC HAS SAID ON A VARIETY OF TOPICS. AND THAT WILL BE PART OF THE INPUT ALONG WITH THE DELIBERATIONS THAT YOU UNDERGO FOR THE FINAL PROCESS OF DRAFTING THE DOCUMENT.

SO IT'S NOT -- I DON'T WANT MAKE TOO BIG A DEAL OF THIS. THIS WAS JUST AN ATTEMPT TO SORT OF GIVE A LITTLE STRUCTURE TO THE MEETING TOMORROW THAT WOULD

BE BOTH HELPFUL TO US AND THAT WOULD COORDINATE OUR TWO ACTIVITIES; THAT IS, OUR INTERNAL DISCUSSIONS AND THE DISCUSSIONS TOMORROW.

CO-CHAIR LO: IF I COULD MAKE A SUGGESTION IN LINE WITH BOTH ANN AND JOSE'S COMMENTS. IT STRIKES ME THAT JUST AS KEN OLDEN RAISED SOME POINTS THAT WEREN'T COVERED IN THESE POWERPOINTS THAT WE WILL DEFINITELY BRING TO THE PUBLIC TOMORROW, IF IN THE COURSE OF OUR DELIBERATIONS THE REST OF TODAY, ISSUES COMES UP THAT WE DEEM VERY IMPORTANT THAT WE WOULD LIKE PUBLIC INPUT ON BEFORE WE DRAFT THE FINAL DRAFT GUIDELINES, WE CAN CERTAINLY RAISE THEM ORALLY DURING THE MEETING TOMORROW TO GET PUBLIC INPUT.

MS. CHARO: SUBSTANTIVELY JUST WANTED TO POINT OUT SOMETHING ON ONE OF THE SLIDES, THE ONE THAT FOCUSES ON PRECLINICAL RESEARCH STANDARDS. PUTTING ASIDE -- BY THE WAY, THERE'S A TYPO THE WORD "CORD" JUST TO CATCH IT FOR YOU. THE SECOND AND THIRD ITEMS, 1(B) ABOUT INFORMED CONSENT, AND IT INCLUDES SOME THINGS THAT I WAS SURPRISED TO FIND. RIGHT NOW THE FOCUS HAS BEEN ENTIRELY ON EMBRYONIC STEM CELL RESEARCH. AND WHILE CIRM WILL BE FUNDING BEYOND THAT INTO OTHER AREAS OF STEM CELL RESEARCH, THAT HASN'T BEEN THE FOCUS OF ANY DISCUSSION AT ALL SO FAR. AND THIS SEEMS TO BE THE VERY FIRST TIME THAT POPS UP.

AND I WANTED TO JUST RAISE A QUESTION AS TO WHETHER OR NOT WE'RE PREPARED FOR PUBLIC COMMENT YET ON THE SOMEWHAT DIFFERENT ISSUES RAISED BY STEM CELL RESEARCH COMING FROM ADULT SOURCES, FROM FETAL TISSUE, FROM CORD BLOOD, ETC.

AND THEN SECOND, JUST AS AN ORGANIZATIONAL NOTE, BOTH THE ITEMS UNDER INFORMED CONSENT IN SOME WAYS SEEM TO FIT BETTER UNDER DONOR RECRUITMENT AND PROTECTION. PRECLINICAL RESEARCH IS REALLY ABOUT THE USE OF THE CELL LINES IN LAB OR ANIMAL TESTING. IT'S BEEN SO TERRIBLY HARD TO KEEP STRAIGHT IN EVERYBODY'S MIND THE DIFFERENT WAY RULES APPLY WHEN YOU'RE AT THE DERIVATION STAGE VERSUS AT THE USE OF CELL LINE STAGE, THAT I WANTED TO SUGGEST MAYBE PUTTING THAT BACK CLOSER TO WHERE IT BELONGS JUST FOR THE SAKE OF CLARITY.

DR. KIESSLING: I GUESS WHAT YOU'RE HEARING IS THAT THERE'S SOME CONCERNS THAT THE PUBLIC IS GOING TO FEEL THAT THESE ARE THE MOST IMPORTANT ISSUES THAT THIS COMMITTEE HAS AGREED UPON. ALTHOUGH I THINK IT'S IMPORTANT TO GUIDE THE PUBLIC DISCUSSION, I KNOW PERSONALLY THAT IT'S POSSIBLE TO REDO A POWERPOINT PRESENTATION TWO MINUTES BEFORE YOU GIVE IT. SO I THINK IT MIGHT BE -- I'M A LITTLE BIT CONCERNED THAT THE PUBLIC IS GOING TO THINK THESE FOUR POWERPOINT SLIDES REPRESENT THE THINKING OF THE CONCERNS OF THIS

COMMITTEE.

MR. LOMAX: WE'RE CERTAINLY PREPARED AND IN A POSITION TO MODIFY THE SLIDES. I HOPE WE HAVEN'T GIVEN YOU ALL THE IMPRESSION. THAT'S NOT A PROBLEM AND WE CAN MAKE ADDITIONS. SO IT REALLY COMES DOWN TO I THINK HOW WE WANT TO PROCEED.

DR. HALL: ANN, I THINK THE QUESTION IS IS THIS USEFUL OR NOT. OUR SENSE WAS RATHER THAN A COMPLETELY UNFORMED DISCUSSION, THE ALTERNATIVE WOULD BE TO LEAVE THE QUESTIONS OUT AND PRESENT THE TOPICS OR TO HAVE NOTHING AND JUST SAY ANYBODY CAN GET UP AT ANY TIME AND SAY WHAT THEY FEEL LIKE AND THEN WE'LL ORGANIZE IT LATER.

LET ME JUST EMPHASIZE THAT THIS WAS NOT AN ATTEMPT BY THE STAFF TO DO ANYTHING. THIS WAS BASED ON THE DISCUSSIONS OF THE WORKING GROUPS -- THE SUBGROUPS WHERE THEY WERE AVAILABLE. AND WE TRIED TO WORK WITH THEM TO PRODUCE THESE. SO THERE'S NOT -- AS FAR AS I KNOW, THIS REPRESENTS THE BEST THINKING. IN SOME CASES WHERE THERE WERE TOO MANY TOPICS RAISED BY ONE OF THE GROUPS, WE SAID, WELL, IT SEEMS TO US THE MOST IMPORTANT ONES ARE THESE. AGAIN, IT'S REALLY MEANT TO BE HELPFUL. IT'S NOT MEANT IN ANY WAY TO BE DIRECTIVE OR TO CUT OFF DISCUSSION OR ANYTHING OF THAT SORT.

IF IT IS THE FEELING OF THIS WORKING GROUP

THAT WE SHOULD FORGET THESE AND JUST HAVE AN OPEN DISCUSSION, PERIOD, WITHOUT STRUCTURE, WE ARE HAPPY TO DO THAT. THIS IS ONLY MEANT TO BE HELPFUL. WHATEVER YOUR WISH IS WE WILL ABIDE BY.

MR. KLEIN: ZACH, AS I UNDERSTAND IT, THIS IS A WAY TO COLLECT THOUGHTS IN AN ORGANIZED WAY SO THAT WE SYSTEMATICALLY ARE DISCUSSING ALL THOSE WHO CAN ADDRESS THE SPECIFIC CONCEPT AT ONE TIME RATHER THAN RANDOMLY SPREAD THROUGH THE DAY SO THAT WE CAN GET THE BENEFIT OF THE INTENSE FOCUS ON ONE IDEA BEFORE MOVING TO THE NEXT. AND AS HAS BEEN DISCUSSED HERE, THAT IDEAS THAT COME UP DURING THIS SESSION TODAY OR TOMORROW CAN BE ADDED AS THEY COME UP.

IN ADDITION, THE IDEAS THAT ARE BROUGHT UP FROM THE MEMBERS OF THIS COMMITTEE OVERNIGHT OR MEMBERS OF THE PUBLIC AND THE COMMITTEE TOMORROW, BUT THIS ALLOWS US A SYSTEMATIC WAY TO TRY AND COLLECT ALL THE IDEAS ON A PARTICULAR SUBJECT IN A PARTICULAR TIME PIECE WHEN WE CAN FOCUS AND SORT AND COMPARE THEM ONE AGAINST THE OTHER RATHER THAN HAVING THEM FOUR HOURS APART.

CO-CHAIR LANSING: I ALSO JUST WANT TO SAY THAT SOMETIMES IT CAN BE ACCOMPLISHED BY JUST SETTING THE TONE IN THE BEGINNING. IF WE SAY TO THE PUBLIC, SINCE I'LL BE SAYING IT, LOOK, WE ORGANIZED THIS INTO

HEADINGS. THIS IS BY NO MEANS AN ATTEMPT TO LIMIT THE DISCUSSION BECAUSE THE LAST HEADING IS GENERAL DISCUSSION. WE GAVE YOU SOME SAMPLE QUESTIONS, BUT NOT ALL SAMPLE QUESTIONS. THIS IS JUST TO HELP ORGANIZE YOUR THINKING, BUT DON'T BE LIMITED BY IT. DO YOU KNOW? EVEN IN OUR OWN GROUP WE HAD TEN OTHER QUESTIONS WE WANTED TO ADD, BUT THIS IS AN ATTEMPT TO KIND OF GUIDE YOUR THINKING. MAYBE THAT WOULD BE THE BEST.

BUT, AGAIN, IF THE COMMITTEE WANTS NO QUESTIONS, JUST THE HEADLINES, LEAVE IT THE WAY IT IS OR JUST A FREESTANDING THING. I PERSONALLY THINK THIS AT LEAST GIVES SOME ORGANIZATION.

DR. PRIETO: I THINK THIS IS USEFUL ALSO, BUT I'D HAVE TO AGREE WITH THE POINTS RAISED BY ALTA, THAT PERHAPS THE INFORMED CONSENT ISSUES DO BELONG UNDER DONOR RECRUITMENT AND THAT WE SHOULD SOMEWHERE ADD HERE, ADDRESS THE ISSUE OF STEM CELL RESEARCH ON NONEMBRYONIC STEM CELL LINES. THE INITIATIVE DOES ALLOW FOR THAT. AND QUESTIONS MAY CAME UP, AND THEY'RE CERTAINLY VALID AND IMPORTANT QUESTIONS WE'LL HAVE TO ADDRESS.

CO-CHAIR LANSING: WELL, THEN, WOULD IT BE HELPFUL TO TABLE THIS AND MAYBE AT LUNCHTIME HAVE A WORKING GROUP OF A COUPLE OF PEOPLE ADDING THIS AND CORRECTING IT IN A WAY THAT MAKES EVERYBODY HAPPY AND

REPRESENT IT? IS THAT THE FAVOR OF EVERYBODY?

DR. PRIETO: COULD WE JUST MAKE A MOTION NOW TO MAKE THOSE CHANGES AS SUGGESTED BY ALTA AND ASK STAFF TO JUST MODIFY THAT FOR TOMORROW'S DISCUSSION?

DR. HALL: LET ME JUST COMMENT ON ONE OF THE POINTS MADE BY ALTA. I THINK FRANCISCO IS PERFECTLY CORRECT. WE WILL NEED TO HAVE SOME SORT OF GUIDELINES THAT MAY NOT NEED TO BE AS ELABORATE. WE NEED TO REFER SOMETHING FOR WORK THAT'S NOT ON HUMAN EMBRYONIC STEM CELLS BECAUSE WE WILL BE INVOLVED IN THAT. THAT ACTUALLY WE SEE AS A GAP EVEN IN OUR INTERIM STANDARDS. AS YOU WILL HEAR LATER, WE HOPE TO DRAFT SOMETHING FOR YOU IN NOVEMBER THAT WILL COVER US UNTIL THE END OF THIS 270-DAY PERIOD.

BUT I WOULD HOPE THAT THE FINAL DOCUMENT THAT IS PRODUCED DOES HAVE SOME STATEMENT ABOUT THE USE OF ADULT STEM CELLS OR FETAL STEM CELLS AS APPROPRIATE. ALTHOUGH THAT HAS NOT BEEN A MAJOR TOPIC OF DISCUSSION, ALTA, I THINK IT'S NOT INAPPROPRIATE TO GET PUBLIC COMMENT ON THOSE TOMORROW. IF IT'S IN THE WRONG PLACE, WE CAN REARRANGE IT.

MS. CHARO: NO. I WOULDN'T SAY IT'S INAPPROPRIATE SO MUCH AS IT JUST SEEMS TO COME OUT OF NOWHERE, AND IT'S KIND OF BURIED IN THE MIDST OF EVERYTHING ELSE. SO LET'S JUST TELL PEOPLE, OKAY, NOW

WE'RE GOING TO MOVE ON TO A NEW TOPIC.

MR. KLEIN: I'D SECOND THE MOTION THAT FRANCISCO WAS MAKING IF THAT'S APPROPRIATE FOR THE CHAIR.

CO-CHAIR LANSING: ANY OTHER COMMENT?

DR. OLDEN: YES. I WONDER IF I COULD COMMENT ON THE PUBLIC MEETINGS THEMSELVES. THERE ARE PEOPLE WHO CANNOT PARTICIPATE IN PUBLIC MEETINGS THAT TAKE PLACE NINE TO FIVE. SO THERE OUGHT TO BE SOME MEETINGS PLANNED THAT WOULD OCCUR IN THE EVENINGS, FOR EXAMPLE. WE'VE HAD TOWN MEETINGS AROUND THE COUNTRY, AND WE'VE DONE THEM OFTEN AT AN EVENING SESSION AND A DAY SESSION NINE TO FIVE. AND THE PEOPLE WHO APPEAR IN THE EVENING TO COMMENT ARE VERY DIFFERENT FROM THE PEOPLE WHO WILL APPEAR FROM NINE TO FIVE.

SO WE WANT TO HEAR FROM ALL OF THE CITIZENS OF THE STATE OF CALIFORNIA, SO I THINK WE OUGHT TO PROVIDE AN OPPORTUNITY, A VEHICLE, FOR THAT TO OCCUR.

CO-CHAIR LANSING: I ACTUALLY THINK THAT'S A VERY GOOD POINT. NOW, WE HAVE TWO SCHEDULED, BUT WE DON'T HAVE THE SACRAMENTO ONE SCHEDULED. SO WE CERTAINLY COULD MAKE A DECISION TO DO THE SACRAMENTO ONE IN THE EVENING. I ACTUALLY THINK THAT'S A VERY GOOD POINT. I HAVE TO SAY I HAD NOT THOUGHT OF THAT. I THINK THAT'S SOMETHING FOR US IN ALL OF OUR PUBLIC

DISCUSSIONS TO BE VERY MINDFUL OF.

AND THE OTHER THING TO DO, OF COURSE, IT'S TOO LATE TO DO IT FOR TOMORROW, BUT YOU COULD START AT THREE AND YOU COULD GO TO EIGHT OR SOMETHING LIKE THAT.

DR. OLDEN: EXACTLY.

CO-CHAIR LANSING: I DON'T KNOW IF IT'S TOO LATE TO CHANGE SAN FRANCISCO TO THAT. WE COULD LOOK INTO IT. THAT'S A VERY GOOD POINT. REALLY IS. THANK YOU.

ANY OTHER COMMENT? JOSE, ARE YOU COMFORTABLE WITH THIS NOW?

DR. CIBELLI: I AM.

CO-CHAIR LANSING: ALL IN FAVOR.

MR. REED: ARE WE HAVING PUBLIC COMMENT?

CO-CHAIR LANSING: YEAH.

MR. REED: THIS MORNING AT THE AIRPORT I ASKED TWO SEPARATE WOMEN THEIR THOUGHTS ON THESE QUESTIONS. AND I READ THEM SOME OF THEM. AND THE LEVEL OF CONFUSION WAS EXTRAORDINARY, AND THESE WERE INTELLIGENT PEOPLE. ONE PERSON WAS A COMPUTER PERSON WHO WAS ACTUALLY LISTENING TO A TAPE RECORDING ON STEM CELLS. THE OTHER PERSON WAS SOMEBODY WHO WORKED AT STANFORD.

I WONDER IF WE COULDN'T STICK EVERY SO OFTEN A SENTENCE TO THE EFFECT OF WHY THIS IS NECESSARY.

WHEN YOU SAY CHIMERA, ANIMAL/HUMAN MIXES, THAT'S FRIGHTENING. IF YOU SAY IT MAY BE NECESSARY, IT MAY MEAN WE NEED TO USE LESS EGGS IF WE COULD USE SKIN OF A RABBIT EGG CELL, OR WE HAVE TO DO THIS BECAUSE THIS. JUST A SENTENCE, IT MIGHT HELP US. IN STEM CELL RESEARCH, IT MIGHT HELP TO US HELP FIGHT PARALYSIS IF WE DO THIS, SO THEY HAVE SOME IDEA AT EACH ONE OF THE HORROR THINGS WHY WE'RE DOING IT. THESE ARE PEOPLE THAT DON'T HAVE YOUR EXPERTISE.

MS. LANSING: THANK YOU. THAT'S REALLY VERY VALID FOR THE STAFF TO TAKE INTO ACCOUNT WHEN WE DO THESE POINTS. I ACTUALLY AGREE WITH YOU BECAUSE IT WILL HELP OUR COMMUNICATION TREMENDOUSLY TO THE PUBLIC IF WE DO THAT.

ANY OTHER PUBLIC COMMENT? KEN.

MR. LOMAX: ONE OTHER POINT OF CLARIFICATION BECAUSE IT CAME UP IN THE DISCUSSION, AND IT WILL AFFECT THE PROCESS AS WE MOVE THROUGH IT. BUT ONE POINT IN TERMS OF HOW THE QUESTIONS OR ISSUES WERE ARRIVED AT, AND I WANT TO POINT OUT THERE WAS ACTUALLY A REAL SPECTRUM OF PROCESS THAT VARIED BETWEEN EACH OF THE STUDY GROUPS. IN SOME CASES THE BANKING STUDY GROUP WAS AN EXTREME EXAMPLE OF THE STAFF-INITIATED SET OF QUESTIONS TO FACILITATE DISCUSSIONS. AND I THINK AT THE OTHER END OF THAT SPECTRUM, THERE WERE CHAIRS WHO

REALLY LAID OUT IN EXPANSIVE DETAIL SOME OF THE ISSUES AND QUESTIONS. SO THERE WAS A LOT OF VARIATION WITHIN THE STUDY GROUPS IN TERMS OF HOW SOME OF THESE ISSUES WERE PRESENTED, LAID OUT, AND PUT TOGETHER. AND THIS WORK REALLY REPRESENTS OUR BEST STAFF EFFORT AT TRYING TO SORT OF BRING ALL THAT TOGETHER FOR THE BENEFIT OF THIS DISCUSSION.

CO-CHAIR LANSING: AND, AGAIN, I WANT TO EMPHASIZE THIS IS A WORK IN PROGRESS. THIS IS JUST A BEGINNING. THESE QUESTIONS ARE JUST THE TIP OF THE ICEBERG. AND WITH THAT SAID, I'M GOING TO TURN IT OVER TO BERNIE.

CO-CHAIR LO: THANKS VERY MUCH, SHERRY. WE'RE GOING TO GO BACK TO ITEM 5 ON YOUR AGENDA, CONSIDERATION OF STANDARDS WORKING GROUP BYLAWS, AND I'M GOING TO ASK JAMES HARRISON, A CONSULTANT TO CIRM, TO SET THIS DISCUSSION UP FOR US.

MR. HARRISON: PROPOSITION 71 REQUIRES EACH OF THE THREE WORKING GROUPS TO PROPOSE TO THE ICOC RULES AND GUIDELINES AND PROCEDURES FOR THE OPERATION OF THE WORKING GROUP. THE ICOC THEN CONSIDERS AND ADOPTS PROCEDURES AND GUIDELINES FOR THE OPERATION OF THE WORKING GROUPS.

THESE BYLAWS ARE OUR ATTEMPT TO, IN A VERY BRIEF WAY, TO SET FORTH THE MANNER IN WHICH THIS

WORKING GROUP WILL OPERATE. WHAT THE BYLAWS DO IS SET FORTH THE MISSION OF THE STANDARDS WORKING GROUP, WHICH IS BASED ON THE TEXT OF PROPOSITION 71, THE COMPOSITION OF THE WORKING GROUP, THE APPOINTMENT OF THE CO-CHAIRS, WHO ARE DESIGNATED AS AN ICOC MEMBER WHO IS A PATIENT ADVOCATE AND A SCIENTIST, CLINICIAN, OR ETHICIST MEMBER OF THE WORKING GROUP.

THE BYLAWS ALSO SET FORTH THAT THE MEMBERS OF THE WORKING GROUP WILL BE BOUND BY CONFLICT OF INTEREST POLICIES ADOPTED BY THE ICOC. THE GUIDELINES PROVIDE FOR OPEN MEETINGS ACCORDING TO THE PROCEDURES THAT YOU ADOPTED AT YOUR LAST MEETING, AND A PROCEDURE FOR RECOMMENDING STANDARDS TO THE ICOC, DEFINING A QUORUM AS 65 PERCENT, WHICH IS SET FORTH IN PROPOSITION 71, AND PROVIDING THAT RECOMMENDATIONS WILL BE MADE BY A MAJORITY VOTE OF THE QUORUM WITH MINORITY REPORTS PRESENTED IF 35 PERCENT OF THE MEMBERS OF THE WORKING GROUP HAVE A MINORITY POSITION THEY'D LIKE TO FORWARD TO THE ICOC.

AND FINALLY, THE BYLAWS PROVIDE THAT, UNLESS THEY'RE OTHERWISE CONTRADICTED, THAT ROBERT'S RULES OF ORDER WILL GOVERN THE CONDUCT OF MEETINGS OF THE WORKING GROUP.

SO THEY'RE QUITE STRAIGHTFORWARD. WE HAVE DRAFTED THEM FOR YOUR CONSIDERATION, AND WE'D BE HAPPY

TO ANSWER ANY QUESTIONS YOU HAVE ABOUT THEM.

CO-CHAIR LO: THANK YOU. ANY QUESTIONS TO JAMES ABOUT THEM? DO WE WANT TAKE A COUPLE MINUTES JUST TO READ THROUGH THESE? I DON'T KNOW. HAVE YOU ALL READ THESE ALREADY? YES. ANY QUESTIONS, THEN, FOR JAMES ABOUT THE PROPOSED BYLAWS?

MR. SHEEHY: I'D LIKE TO COME BACK TO DR. OLDEN'S ISSUE. IT'S ALWAYS BEEN KIND OF AMBIGUOUS. WE TOOK THE LANGUAGE FOR THE RECOMMENDATIONS IN 3(B) DIRECTLY, I THINK, FROM PROP 71, BUT THERE'S BEEN AMBIGUITY AS TO WHETHER ACCESS ISSUES WOULD COME THROUGH THIS COMMITTEE AT SOME POINT OR NOT. I WONDER IF WE WANT TO STIPULATE THAT MORE DIRECTLY IN OUR BYLAWS.

MR. KLEIN: JEFF, I THINK ACCESS ISSUES ARE ABSOLUTELY RELEVANT TO STANDARDS, BUT DO YOU THINK THEY BELONG IN THE BYLAWS, OR SHOULD THEY BE ADOPTED AS A RESOLUTION OF THIS COMMITTEE TO CONSIDER TO BE WITHIN ITS JURISDICTION?

MR. SHEEHY: EITHER WAY. I JUST THINK THAT IT'S KIND OF BEEN AN ISSUE THAT HAS BEEN OUT THERE FOR THIS COMMITTEE THAT IS UNRESOLVED. THE COMMITTEE, IT SEEMS TO ME, OUGHT TO MAKE A STATEMENT ON IT AT SOME POINT, WHETHER TODAY OR WHETHER IT'S IN THE CONTEXT OF THE BYLAWS, WHETHER IN THE CONTEXT OF A RESOLUTION. I

THINK THIS IS AT LEAST THE FIRST TIME LANGUAGE DISCUSSING THE CHARGE FOR THIS SUBCOMMITTEE -- I MEAN FOR THIS WORKING GROUP THAT OFFERED AN OPPORTUNITY WHERE LANGUAGE MIGHT BE INSERTED.

DR. HALL: I DON'T KNOW THAT ONE CAN -- I CAN'T SPEAK TO INTENT. IT SEEMS TO ME THAT, AT LEAST THE WAY I HAVE THOUGHT ABOUT THE PRIMARY CHARGE OF THE COMMITTEE, IS TO SET THE GUIDELINES BY WHICH THE RESEARCH IS DONE, MEANING WHAT ARE THE PROCEDURES, WHAT MUST BE DONE IN ORDER FOR THE RESEARCH TO BE CARRIED OUT AND SO FORTH AND SO FORTH.

THE QUESTIONS OF ACCESS, WHICH HAVE COME UP IN A VARIETY OF CONTEXTS, ARE, AS YOU KNOW, COMPLICATED BOTH POLITICAL, ETHICAL, AND OFTEN HAVE TO DO NOT WITH THE WAY THE RESEARCH IS CARRIED OUT ITSELF, BUT WITH ARRANGEMENTS THAT ARE MADE SUBSEQUENT TO THE RESEARCH IN TERMS OF BRINGING IT TO THE CLINIC. IT'S AN INCREDIBLY IMPORTANT ISSUE FOR THE ICOC AS A WHOLE AND, AS YOU AND I BOTH KNOW, HAS BEEN A TOPIC OF MUCH POLITICAL AND OTHER DISCUSSION.

IT SEEMS TO ME THAT THE APPROPRIATE ROLE MIGHT BE FOR THIS COMMITTEE, AND I JUST SUGGEST THIS, TO MAKE A STATEMENT FROM THE POINT OF VIEW OF THE ETHICAL STANDARDS WHAT OUR DESIRES MIGHT BE. I THINK THAT THE DIFFICULT PART WILL BE TO SAY EXACTLY WHAT

SHOULD BE DONE TO MAKE THAT HAPPEN. THAT IS, FOR EXAMPLE, THE POINT THAT KEN MADE ABOUT HAVING THE RESULTS OF THIS RESEARCH MADE ACCESSIBLE TO THE WIDEST POSSIBLE GROUP. I THINK A STRONG STATEMENT BY THIS WORKING GROUP WOULD BE VERY VALUABLE, AND I THINK IT'S SOMETHING WE ALL WANT.

I THINK THE QUESTION IF YOU SAY THEN HOW DO WE DO THAT, THAT'S WHERE WE GET INTO WHAT I SEE AS A VERY COMPLICATED ISSUE THAT COULD ENTIRELY CONSUME THIS GROUP AND HAS RAMIFICATIONS THAT HAVE TO DO WITH INTELLECTUAL PROPERTY, HAVE TO DO WITH THE POLITICAL SITUATION, HAVE TO DO WITH PROPOSITION 71, HAVE FINANCIAL IMPLICATIONS. ALL OF THESE THINGS GET MIXED UP AND IT BECOMES QUICKLY QUITE COMPLEX.

I DON'T KNOW IF THAT'S -- I DON'T KNOW IF THAT'S SOMETHING THE WORKING GROUP IS COMFORTABLE WITH, BUT IT SEEMS TO ME THAT THAT IS, I THINK, A STATEMENT BY THIS COMMITTEE OR WORKING GROUP WOULD BE VERY VALUABLE IN TERMS OF WHAT WE WANT TO ACHIEVE, AND I WONDER ABOUT THE MECHANISMS.

MR. SHEEHY: MY SENSE IS THAT THIS PROBABLY WOULD NOT END UP PRODUCING LANGUAGE SIMILAR -- THIS WOULD NOT BE THE PLACE WHERE WE WOULD END UP WITH REGULATORY LANGUAGE, FOR INSTANCE. BUT IT SEEMS TO ME THAT IT MIGHT NOT BE A BAD IDEA TO INCLUDE SOMETHING IN

OUR CHARGE, IN OUR FUNCTIONS, SO THAT WHATEVER DOES END UP BEING PRODUCED, WHICH WILL PROBABLY BE PRODUCED BY A SEPARATE ENTITY, MAKES ITS WAY THROUGH THIS WORKING GROUP. I THINK, GIVEN THAT THIS IS A BODY THAT HAS ETHICISTS ON IT, I THINK THAT IF WE -- WE CAN MAKE A BROAD POLICY STATEMENT OR A RESOLUTION, BUT THAT DOESN'T QUITE HAVE THE SAME EFFECT IF AT SOME POINT IN THE FUTURE WE WERE ABLE TO LOOK AT THE INTELLECTUAL PROPERTY OR ACCESS ISSUE RECOMMENDATIONS THAT WOULD BE PROCEEDING TO THE ICOC AND HAVE THEM COME THROUGH HERE TO AT LEAST HAVE PEOPLE MAKE COMMENT AND HAVE THIS PARTICULAR WORKING GROUP EXERCISE SOME SORT OF ADVISORY ROLE ON THAT.

CO-CHAIR LO: WE HAVE A NUMBER OF OTHER PEOPLE WHO WANT TO COMMENT ON THIS ISSUE. I HAVE FRANCISCO, THEN ROB, AND THEN BOB KLEIN.

DR. PRIETO: I SORT OF WANT TO ECHO WHAT JEFF WAS SAYING. I THINK THAT CLEARLY UNDER 3(A) AND (B) THESE ISSUES ARE UNDER THE CHARGE OF THIS COMMITTEE, AND I THINK THAT IT'S ALMOST EXPECTED THAT WE'LL MAKE RECOMMENDATIONS TO THE ICOC. OBVIOUSLY THIS WILL TOUCH ON INTELLECTUAL PROPERTY ISSUES AND MANY OTHER ISSUES THAT ARE GOING TO COME UP AT THE LARGER COMMITTEE. BUT I DON'T KNOW WHETHER THE BYLAWS ARE THE APPROPRIATE PLACE FOR THIS, BUT I THINK SOMEWHERE WE NEED TO PUT

OUR OPINIONS OUT THERE AND OUR FEELING ABOUT ACCESS TO THERAPIES WHEN AND IF THEY BECOME AVAILABLE.

DR. TAYLOR: I FELT REALLY THE SAME WAY, AND I THINK JEFF HAS GOT A GOOD POINT, THAT 3(B), ARTICLE 3(B), IS AN OPEN OPPORTUNITY REALLY TO INSERT A GUIDING PRINCIPLE THAT DIVERSITY AND ACCESS BE PART OF THE THINGS THAT WE DISCUSS. THERE'S NOTHING REALLY THAT SPECIFIC ABOUT THE OTHER LANGUAGE IN THIS ARTICLE. AND I THINK IT WOULD BE A GREAT OPPORTUNITY TO LET PEOPLE KNOW THAT THIS IS SOMETHING THAT WE'RE THINKING ABOUT AS A PRIORITY.

CO-CHAIR LO: LET ME JUST TRY AND MAKE A CLARIFYING STATEMENT. WHAT I'M HEARING ARE SEVERAL DIFFERENT ISSUES THAT ARE ALL RELATED, BUT ARE NOT QUITE THE SAME. ONE IS DO WE WANT TO MAKE IT CLEAR THAT WE THINK THAT PART OF THE CHARGE OF THIS WORKING GROUP IS TO PROVIDE INPUT TO THE ICOC ON THESE COMPLICATED ISSUES THAT HAVE TO DO WITH ACCESS AND DIVERSITY, RECOGNIZING, AS BOB KLEIN POINTED OUT, A LOT OF OTHER PEOPLE HAVE PERTINENT EXPERTISE ON THIS, BUT THAT WE SHOULD AT LEAST BE PART OF THAT DISCUSSION AND, AS PERHAPS JEFF IS SUGGESTING, COMMENT ON ANY PROPOSALS MADE BY OTHER GROUPS. SO IT'S REALLY SAYING WE WANT TO BE PART OF THE DISCUSSIONS ON THESE IMPORTANT TOPICS.

AT THE OTHER EXTREME PERHAPS SOME

CONSIDERATION THAT IN THESE BYLAWS, WHICH ACTUALLY TO ME ARE PROCEDURAL RULES ABOUT HOW WE'RE GOING TO HOLD MEETINGS AND THINGS, THAT WE MAKE SOME SORT OF SUBSTANTIVE COMMENT ABOUT EITHER OUR BELIEF IN PRINCIPLE THAT ACCESS SHOULD BE EQUITABLE TO ALL THOSE IN NEED, OR TO EVEN BE MORE SPECIFIC THAN THAT. I'M JUST QUESTIONING WHETHER, EVEN IF WE BELIEVE THAT PART OF THE CHARGE OUGHT TO BE TO PROVIDE INPUT ON THESE ISSUES, THAT THE BYLAWS ARE THE PLACE, SO EITHER MAKE A STATEMENT OF GENERAL PRINCIPLE OR MORE SPECIFIC THINGS. I THINK WE MAY WANT TO SEPARATE OUT --

DR. PRIETO: PERHAPS UNDER PURPOSE UNDER ARTICLE 2.

CO-CHAIR LO: JUST TO SORT OF SAY THIS IS PART OF WHAT WE THINK IS OUR DOMAIN OF ADVISING.

MR. KLEIN: WELL, I THINK YOU ADDRESSED THE TOPIC WELL. THE ETHICAL ISSUES OF ACCESS ARE FUNDAMENTAL. WE SHOULD BE MAKING A STATEMENT. I IDENTIFY WITH JEFF'S POSITION ON THIS. AND THERE'S A SEPARATE STATEMENT FROM THE ISSUE OF ACCESS TO THERAPIES IN TERMS OF DIVERSITY. AS I UNDERSTAND IT, IN FACT, THERE MAY BE -- THERE ARE EXTRAORDINARY ISSUES IN HOW THESE THERAPIES ARE DEVELOPED AND WHAT KIND OF DIVERSITY OF MATERIALS, BIOLOGICAL MATERIALS, WE'RE WORKING WITH. AND THAT NEEDS TO BE SEPARATELY

ADDRESSED.

BUT MAYBE MECHANICALLY THE QUESTION IS HOW DO WE PROCEED FROM HERE? IT SOUNDS LIKE THERE'S SUPPORT FOR WHERE THIS POSITION IS. AND MY QUESTION IS DO WE SPECIFICALLY HAVE A MOTION WHERE WE PASS THESE BYLAWS WITH A DIRECTION TO MAYBE JEFF AND A COUPLE OF OTHER MEMBERS OF THIS COMMITTEE TO DRAW UP LANGUAGE TO ADD TO THE BYLAWS, EITHER UNDER ONE OR MORE SECTIONS, THAT THEY WILL BRING BACK THAT CAN BE WORKED OUT. AND I WOULD ASSUME IT'S BOTH THE ACCESS AND THE DIVERSITY ISSUE.

MR. SHEEHY: THAT SOUNDS LIKE A GREAT SUGGESTION TO ME.

CO-CHAIR LANSING: I THINK I WOULD SECOND THAT.

DR. KIESSLING: I JUST WANTED TO REMIND EVERYBODY, WHOSEVER APPLIED FOR NIH GRANTS, IS THAT WE DISCOVERED MAYBE A DECADE AND A HALF AGO THAT IF YOU SEPARATE THE FUNDAMENTAL RESEARCH AND YOU DON'T CONDUCT THE RESEARCH WITH THE POINT IN MIND THAT THIS HAS TO HAVE BROAD ACCESS AT THE END, I THINK IT IS PART OF THIS WORKING GROUP'S CHARGE BECAUSE WE'VE LEARNED THE HARD WAY THAT YOU HAVE TO HAVE THE CONCEPT THAT ALL PEOPLE ARE GOING TO HAVE ACCESS AND BENEFIT FROM THIS RESEARCH WHEN THE EXPERIMENTS ARE DESIGNED AND THE

STANDARDS TO GO FORWARD WITH THAT, AND TO MAKE -- TO BRING THAT POINT HOME SO STRONGLY THAT WE ALL THOUGHT OF IT WHEN WE APPLIED FOR A GRANT. THE NIH NOW HAS YOU JUSTIFY WHY YOU DON'T INCLUDE ALL STUDY GROUPS IN YOUR STUDIES.

SO IF YOU'RE DOING AN ADULT STUDY, YOU HAVE TO JUSTIFY WHY CHILDREN AREN'T INCLUDED. SO I THINK THAT THIS WORKING GROUP ABSOLUTELY HAS TO HAVE, AND IT MAY JUST BE A TINY PHRASE UNDER PURPOSE, IT HAS TO HAVE THE CONCEPT THAT IN ORDER TO MAKE SURE YOU ARE GOING TO HAVE TOTAL ACCESS AT THE END OF THE RESEARCH, IT'S GOT TO BE PART OF THE THINKING AT EVERY STAGE.

CO-CHAIR LO: I'M HEARING A LOT OF SUPPORT FOR SORT OF THE SPIRIT OF WHAT WE'VE BEEN SAYING. BOB, I THOUGHT THAT YOU ALMOST MADE A FORMAL MOTION. COULD I INVITE YOU TO DO SO?

MR. KLEIN: I'LL CHANGE MY QUESTION INTO A MOTION. THE MOTION IS TO APPROVE THE BYLAWS WITH THE PROVISION THAT WE SPECIFICALLY CHARGE JEFF AND DR. OLDEN AND ANY OTHER COMMITTEE MEMBERS THAT THE CHAIRS SO DESIGNATE TO BRING BACK ADDITIONAL SUPPLEMENTAL LANGUAGE TO INCLUDE WITH RECOMMENDATIONS ON THE PART OF THE BYLAWS WE INCLUDED AS WELL AS ADDRESSING BOTH ACCESS AND DIVERSITY SPECIFICALLY. AND THAT WOULD BE THE MOTION ON THE TABLE.

CO-CHAIR LO: MOTION --

DR. HALL: MAYBE FRANCISCO, I WOULD SUGGEST, MIGHT BE WILLING TO JOIN THAT EFFORT.

DR. PRIETO: SURE.

CO-CHAIR LO: THREE PEOPLE VOLUNTEER. I ASSUME THOSE WERE VOLUNTEERS. DO I HEAR A SECOND?

CO-CHAIR LANSING: SECOND.

MR. SHEEHY: AND JAMES WILL HELP US, I'M SURE.

CO-CHAIR LO: AND STAFF. ANY FURTHER DISCUSSION? ANY PUBLIC COMMENT? I'D LIKE TO JUST SORT OF FOR THE RECORD TO ASK PUBLIC COMMENTERS TO STATE THEIR NAME FOR THE RECORD, PLEASE.

MR. REED: DON REED, CALIFORNIANS FOR CURE. OBVIOUSLY THE EMOTIONS EXPRESSED HERE, A HUNDRED PERCENT EVERYBODY SHARES THEM. ACCESS AND DIVERSITY ARE IMPORTANT, BUT I THINK THERE'S A DANGER OF TRYING TO BE TOO PROSCRIPTIVE. I REMEMBER A WONDERFUL MOVIE, "EDISON THE MAN." AND EDISON AT ONE POINT TURNED ON THE LIGHTS OF TWO BLOCKS OF PHILADELPHIA, AND THE LIGHTS WENT ON; BUT BEFORE THERE COULD BE LIGHTS FOR ALL OF PHILADELPHIA, THERE HAD TO BE THE LIGHT BULB. AND I WOULD HATE TO SEE ANYTHING WHICH REQUIRED PEOPLE TO PROVE THIS IS GOING TO BENEFIT EVERYONE BEFORE THE RESEARCH GRANTS COULD GO OUT. I DON'T WANT ANYTHING TO

STOP THE LIGHT BULB FROM BEING DEVELOPED, EVEN A GUARANTEE THAT IT HAS TO BENEFIT EVERYBODY FIRST.

SO I THINK IT SHOULD BE A GENERAL CHARGE RATHER THAN SPECIFIC RECOMMENDATIONS. THAT WAS MY THOUGHTS.

CO-CHAIR LO: THANK YOU. AGAIN, LET ME STRESS THAT IT'S MY UNDERSTANDING THAT WHAT WE'RE TALKING ABOUT TODAY ARE JUST THE GROUND RULES FOR DISCUSSION. WHAT WE'RE SAYING IS WE WANT THESE TOPICS TO BE PART OF OUR DISCUSSION. WE'RE NOT SAYING ANYTHING ABOUT SPECIFIC SUBSTANTIVE RECOMMENDATIONS.

MR. REYNOLDS: HELLO. GOOD MORNING. MY NAME IS JESSE REYNOLDS. AND I'VE BEEN CONCERNED SOMEWHAT THAT OVER RECENT MONTHS I FELT THERE'S BEEN SOMETHING OF A SHIFT IN THE TONE IN THAT ORIGINALLY DURING THE PROPOSITION 71 CAMPAIGN, THE ASSERTION WAS TRUST US WITH YOUR MONEY, AND WE'LL DO OUR BEST TO GET THERAPIES AND CURES TO YOU, ALL CALIFORNIANS. BUT RECENTLY IT SEEMS THERE'S BEEN MORE OF AN EMPHASIS ON OUR JOB IS TO DO THE RESEARCH AND FUND THE SCIENCE, AND FROM THERE IT'S OUT OF OUR HANDS.

AND I THINK THE DISCUSSION WE'RE HAVING RIGHT NOW IS VERY CRITICAL TO THAT DISTINCTION. I CHECKED HERE IN PROPOSITION 71 UNDER THE STATUTORY CHARGE OF THIS WORKING GROUP. AND THERE'S A SLIGHT DIFFERENCE.

IT SAYS THE RESPONSIBILITIES ARE TO RECOMMEND TO THE ICOC STANDARDS FOR ALL MEDICAL, SOCIOECONOMIC, AND FINANCIAL ASPECTS OF CLINICAL TRIALS AND THERAPY DELIVERY TO PATIENTS. WHEREAS, THE DRAFT OF THE BYLAWS SAY THERAPY DEVELOPMENT. AND I THINK THERE'S AN IMPORTANT DISTINCTION BETWEEN THOSE TWO WORDS.

OBVIOUSLY THE STATUTORY LANGUAGE HAS PRECEDENCE OVER THE BYLAWS, BUT I ENCOURAGE YOU TO BOTH IN YOUR BYLAWS AND IN YOUR INTENTION KEEP IN MIND, AS DR. KIESSLING SAID, THE BIG PICTURE FROM FRONT TO BACK, FROM INFORMED CONSENT FOR THE GAMETE DONORS ALL THE WAY TO ISSUES OF ACCESSIBILITY FOR PATIENTS. THANK YOU.

CO-CHAIR LO: THANK YOU. THAT WAS USEFUL. IF I CAN JUST ASK YOU TO CLARIFY. SO ARE YOU SUGGESTING THAT IN 3(B), RATHER THAN SAYING THERAPY DEVELOPMENT, WE SAY THERAPY DELIVERY? WAS THAT THE TERM?

MR. REYNOLDS: IN FACT, I'D ENCOURAGE BOTH WORDS. I THINK IT PAINTS A BIGGER PICTURE OF THE PIPELINE FRONT TO BACK.

MR. KLEIN: MR. CHAIRMAN, ON MY MOTION, I WOULD TAKE A FRIENDLY AMENDMENT TO INCLUDE BOTH WORDS.

CO-CHAIR LO: SO A FRIENDLY AMENDMENT HAS BEEN ACCEPTED.

MR. KLEIN: DOES THE SECOND ALSO ACCEPT?

CO-CHAIR LANSING: YES.

CO-CHAIR LO: ANY OTHER DISCUSSION? OKAY. COULD I --

MR. HARRISON: COULD I RAISE -- I'M SORRY -- JUST ONE POINT THAT THE FRIENDLY AMENDMENT RAISED. THAT IS, IT MAY BE THAT, GIVEN THE WAY THIS WORKING GROUP OPERATES, THAT YOU WANT TO ADOPT ONE MODIFICATION TO ROBERT'S RULES OF ORDER, WHICH WOULD BE TO PERMIT FRIENDLY AMENDMENTS TO BE ACCEPTED WITHOUT HAVING TO TAKE A VOTE OF THE WORKING GROUP.

MR. KLEIN: THAT, IN FACT, IS A RULE THAT WAS ADOPTED AT THE BOARD LEVEL THAT IS IN OUR MODIFIED BYLAWS BECAUSE IT JUST EXPEDITES THE PROCESS RATHER THAN HAVING FORMALITY. AND SO I WOULD -- I WILL PROPOSE AS AN AMENDMENT TO MY ACCEPTANCE OF THE BYLAWS THAT WE ADOPT THAT MODIFICATION AS WELL.

CO-CHAIR LANSING: DO I NEED TO SECOND THAT?

CO-CHAIR LO: THANK YOU. ANY OTHER DISCUSSION? IF NOT, COULD SOMEONE PLEASE CALL THE QUESTION? ALL THOSE IN FAVOR. OPPOSED? THANK YOU.

TO RETURN TO OUR AGENDA, OUR NEXT ITEM OF BUSINESS IS NO. 7, CONSIDERATION OF INTERIM CIRM GUIDELINES BASED ON THE NATIONAL ACADEMIES OF SCIENCE'S GUIDELINES FOR HUMAN EMBRYONIC STEM CELL RESEARCH. AND, AGAIN, JUST TO SORT OF GIVE THE FULL CONTEXT HERE,

THESE ARE INTERIM GUIDELINES WHICH WE REALLY WANT TO ISSUE IN A TIMELY MANNER SO THAT WE CAN START THE 270-DAY CLOCK THAT WILL ALLOW FOR BOTH PUBLIC COMMENT ON THE DRAFT FINAL GUIDELINES AND ADMINISTRATIVE REVIEW. THE SOONER WE START THAT 270-DAY PROCESS, THE SOONER THE FINAL GUIDELINES CAN BE ADOPTED FOR GRANTEES RECEIVING FUNDING THROUGH CIRM.

SO WE CERTAINLY AS A WORKING GROUP, ONCE WE ISSUE THESE INTERIM GUIDELINES, HAVE A CONSIDERABLE OPPORTUNITY OF SEVERAL MONTHS TO DRAFT THE DRAFT FINAL GUIDELINES WHICH WOULD INCLUDE TOPICS THAT ARE NOT COVERED IN THESE NAS GUIDELINES AS TRANSLATED INTO REGULATORY LANGUAGE. AND THERE ARE A COUPLE OF THOSE THAT HAVE ALREADY BEEN MENTIONED TODAY, WORK WITH CELL LINES DERIVED WITH NON-CIRM FUNDING AND WORK WITH CELL LINES DERIVED BEFORE THE EFFECTIVE DATE OF THE GUIDELINES.

WE CAN ALSO TO DIVERGE FROM THE NAS GUIDELINES IF AFTER DELIBERATION WE COME TO A DIFFERENT SET OF RECOMMENDATIONS. AND FINALLY, IF WE THINK THERE ARE AREAS OF INCONSISTENCY OR UNCLARITY IN THE REGULATIONS THAT HAVE BEEN BASED VERY CLOSELY ON THE NAS GUIDELINES, WE ALSO HAVE AN OPPORTUNITY TO ALTER IT. SO BY CONSIDERING AND TODAY HOPEFULLY APPROVING INTERIM GUIDELINES, WE DO NOT, I THINK, IN ANY FASHION

PRECLUDE OUR MAKING QUITE SUBSTANTIVE CHANGES IN THE DRAFT FINAL GUIDELINES.

DR. HALL: JUST TO ADD TO THAT, WE ALSO NEED THEM IN THAT WE EXPECT TO APPROVE AT OUR SEPTEMBER 9TH ICOC MEETING THE FIRST ROUND OF TRAINING GRANTS. AND SO ASSUMING THAT WE WILL BE ABLE TO SEND MONEY OUT FOR THOSE BEFORE TOO LONG, WE WILL NEED THE INTERIM GUIDELINES FOR ANYTHING THAT MIGHT BE DONE UNDER THOSE GRANTS. FOR THOSE, I WOULD SAY, TWO REASONS, OUR HOPE IS THAT WE CAN HAVE A SET OF WORKABLE GUIDELINES THAT WILL GET US THROUGH THE NEXT NINE MONTHS ESSENTIALLY WHILE WE FOLLOW THE PROCESS FOR COMING UP WITH THE FINAL GUIDELINES. AS BERNIE SAYS, DOESN'T MEAN ANY OF THESE ISSUES ARE CLOSED OR NOT OPEN FOR DISCUSSION. THEY WILL BE, BUT WE JUST NEED TO HAVE SOMETHING IN THE INTERIM.

WITH THAT AS PREPARATION, MAYBE I'LL JUST SAY WHAT I STARTED TO SAY BEFORE. AND THAT IS A REMINDER THAT LAST TIME THE WORKING GROUP CHARGED THE STAFF TO BOTH PUT THE NATIONAL ACADEMY GUIDELINES INTO REGULATORY LANGUAGE AND ALSO LANGUAGE THAT WAS APPROPRIATE FOR CIRM. AND, AGAIN, JAMES, GEOFF LOMAX, AND KATE SHREVE WORKED TO PRODUCE THE GUIDELINES THAT YOU HAVE HERE, AND THERE ARE A FEW CHANGES THAT STILL NEED TO BE MADE. AND GEOFF WILL BASICALLY DESCRIBE

THOSE AND DESCRIBE WHAT'S BEEN DONE AND WHAT WE PLAN TO DO.

MR. LOMAX: THANK YOU. AGAIN, THE CHARGE AND THEN --

DR. HALL: THIS IS UNDER TAB 7; IS THAT CORRECT?

MR. LOMAX: THE COMPLETE GUIDELINES ARE IN THE FOLDER.

SO IN TERMS OF THE DRAFTING, ONE OF THE KEY POINTS WAS THAT THE GUIDELINES SHOULD BE APPROPRIATE FOR CIRM AND CONSISTENT WITH PROPOSITION 71. SO AT THE BASIC LEVEL, WE TRIED TO USE LANGUAGE THAT WOULD PUT CIRM WHERE NECESSARY TO MAKE THAT CLEAR.

IN ADDITION, PROPOSITION 71 SET A DAY 12 STANDARD FOR WHEN ONE COULD NOT USE THE CELLS THEREAFTER. SO TO DRAW YOUR ATTENTION TO SECTION 100004(1), THAT'S WHERE YOU WILL SEE THAT CHANGE. IN THE PREVIOUS DRAFT, I BELIEVE IT GAVE A TIME PERIOD, AND WE THOUGHT IT WAS APPROPRIATE TO GIVE AN EXACT DATE GIVEN THAT THE LAW DIRECTED US TO DO SO.

DR. TAYLOR: COULD I JUST MAKE A COMMENT. I THINK UNDER 100008, THOUGH, YOU STILL HAVE THAT RANGE. FOR THE PURPOSE OF BEING CONSISTENT, I WOULD SUGGEST THAT.

MR. LOMAX: THANK YOU.

CO-CHAIR LO: ARE YOU TALKING ABOUT 100008(E)?

DR. TAYLOR: THAT'S CORRECT.

MR. LOMAX: THANK YOU. IN ADDITION, I THINK THIS IS A REVISION THAT WE FELT WAS ESSENTIAL AND IS IN THE CATEGORY OF A SUBSTANTIVE AMENDMENT OR CHANGE TO WHAT WAS EXPLICITLY STATED IN THE PREVIOUS GUIDELINES. WE HAD ADDED THIS LANGUAGE. IT'S THE FINAL SENTENCE TO SECTION 06(A). AND THE INTENT OF THIS LANGUAGE, I HOPE IT'S FAIRLY CLEAR, IT'S TO ALLOW FOR A JOINT ESCRO REVIEW PROCESS SO THAT EACH INSTITUTION ISN'T REQUIRED TO HAVE IT ITS OWN ESCRO, BUT TO ENABLE THIS OPPORTUNITY FOR JOINT ESCRO'S. AND SO I HOPE THAT LANGUAGE IS CLEAR AND ACCEPTABLE.

SO AT THE MOMENT WE THEN STAND REQUESTING APPROVAL OF THE DOCUMENT GIVEN THESE ARE WHAT WE BELIEVE ARE THE AMENDMENTS THAT WE WANTED THE WORKING GROUP TO BE AWARE OF IN TERMS OF ANY SUBSTANTIVE CHANGE TO THE DOCUMENT.

CO-CHAIR LO: MAY I ASK A QUESTION OF THE STAFF IN TERMS OF IF FUNDING IS GIVEN UNDER THESE DRAFT GUIDELINES, FOR INSTANCE, TO TRAINING GRANTS, AND THEN SUBSEQUENTLY CHANGES ARE MADE TO THESE GUIDELINES IN THE DRAFT FINAL GUIDELINES OR THE FINAL GUIDELINES, WILL THE GRANTEES THAT RECEIVED FUNDING UNDER THESE

INTERIM GUIDELINES BE REQUIRED TO FOLLOW THE FINAL GUIDELINES OR THE ONES THAT WERE IN PLACE AT THE TIME THE FUNDING WAS RECEIVED?

DR. HALL: SO OUR GRANTS POLICY WILL SAY -- WE ARE IN PARALLEL PREPARING A GRANTS POLICY STATEMENT, WHICH IS BASICALLY OUTLINING THE TERMS OF THE CONTRACT BETWEEN US AND ANY GRANTEE INSTITUTION. AND ONE OF THE THINGS IS THAT THEY WILL BE REQUIRED TO FOLLOW OUR GUIDELINES FOR RESEARCH, AND WE WILL HAVE THEM FOLLOW THE INTERIM GUIDELINES UNTIL THE FINAL GUIDELINES ARE COMPLETED.

MR. LOMAX: ONE OTHER --

DR. HALL: BY THE WAY, JUST LET ME SAY THAT IT'S NOT AT ALL UNCOMMON FOR THE TERMS OF THAT, AS WE GO ALONG, AS SHERRY HAD SAID EARLIER, THIS IS SORT OF A LIVING DOCUMENT, AND IF TWO YEARS DOWN THE LINE, WE THINK WE NEED TO CHANGE THAT, WE'LL SIMPLY SEND OUT A NOTICE TO ALL THE GRANTEES SAYING THAT AS OF A CERTAIN DATE, THAT POLICY WAS CHANGED AND YOU'LL BE EXPECTED TO FOLLOW THAT POLICY AFTER THAT DATE. SO THERE'S NOTHING UNUSUAL IN THAT.

MR. LOMAX: THERE WERE AN ADDITIONAL SET OF ITEMS I DID WANT TO DRAW YOUR ATTENTION TO THAT CAME UP IN DISCUSSIONS THIS MORNING. IF I CAN TURN THE FLOOR OVER TO JAMES HARRISON FOR A MOMENT, HE CAN DRAW YOUR

ATTENTION TO THOSE ITEMS.

MR. KLEIN: BEFORE JAMES DISCUSSES THOSE, ZACH, JUST SO THERE'S CLARITY, IF I COULD ASK YOU. WOULD IT BE YOUR UNDERSTANDING THAT IF SOMEONE HAD DONE WORK UNDER THE INTERIM GUIDELINES, IF THERE'S A CHANGE, THEY WOULDN'T BE REQUIRED TO REDO THE WORK? THEY WOULD BE ALLOWED TO RELY ON THE PRIOR INTERIM GUIDELINES FOR THE WHOLE COURSE OF WHATEVER THAT RESEARCH WAS EVEN IF THAT WAS A TWO-YEAR PROJECT.

DR. HALL: SURE. THAT IS RIGHT. IF YOU DERIVE LINES, LET'S SAY, UNDER INTERIM GUIDELINES AND WE CHANGE THE RULES, WE'RE NOT GOING TO THROW OUT THE LINES.

CO-CHAIR LANSING: WE WOULD BE STARTING AT THAT POINT.

DR. HALL: ANYTHING DONE AFTER THAT POINT, BOB MAKES THE POINT THAT, PARTICULARLY IN THE CASE OF LINES, IF THEY'RE DERIVED UNDER ONE SET OF RULES AND YOU CHANGE THE RULES, THEN YOU HAVE TO GRANDFATHER THEM. I THINK WE WOULD CERTAINLY DO THAT.

MR. HARRISON: IN ADDITION TO THE CLARIFICATION THAT DR. TAYLOR MADE, THERE WERE TWO ADDITIONAL ITEMS THAT WERE BROUGHT TO OUR ATTENTION THIS MORNING, AND WE'D LIKE TO PROPOSE CHANGES TO DEAL WITH THEM. I'LL JUST REFER TO THE LAST TWO NUMBERS OF

THE SECTION.

IN SECTION 00(A), IT CURRENTLY READS THE CHAPTER COVERS ALL RESEARCH FUNDED BY THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE THAT INVOLVES THE DERIVATION OF HUMAN EMBRYONIC CELL LINES, AND IT CURRENTLY SAYS "AND." WE'D LIKE TO CHANGE THAT TO "OR" THE USE OF HES CELL LINES DERIVED FROM.

THE OTHER CHANGE IS IN THE SAME SECTION, SUBPARAGRAPH (B)(3). WE WOULD PROPOSE TO DELETE THAT LANGUAGE BECAUSE IT'S UNNECESSARY AND LIKE THE LANGUAGE IN SECTION 02, WHICH ADDRESSES THE ISSUE OF PREVIOUSLY DERIVED CELL LINES.

CO-CHAIR LO: I'M SORRY. I GOT LOST, JAMES. CAN YOU POINT US AGAIN TO WHERE THESE CHANGES ARE?

MR. HARRISON: SURE. THIS IS IN THE VERY FIRST SECTION, SECTION 100000, SUBDIVISION A. WE WOULD PROPOSE TO DELETE THE WORD "AND" IN THE FIRST SENTENCE AND REPLACE IT WITH "OR." AND THEN IN SUBPARAGRAPH (B)(3), WE WOULD DELETE SUBPARAGRAPH 3 IN ITS ENTIRETY BECAUSE THE LANGUAGE IS UNNECESSARY IN LIGHT OF THE SECTION 100002, WHICH ADDRESSES THE ISSUE OF PREVIOUSLY DERIVED CELL LINES.

CO-CHAIR LO: OKAY. GOOD. THANK YOU. OTHER COMMENTS, QUESTIONS, CONCERNS ABOUT THESE INTERIM GUIDELINES?

DR. KIESSLING: I'D LIKE TO ASK IF WE NEED TO INCLUDE SOMETHING SPECIFIC ABOUT PARTHENOTES. THIS LANGUAGE PRETTY MUCH IS EITHER EGGS THAT ARE FERTILIZED OR EGGS THAT RESULT IN NUCLEAR TRANSPLANT. I KNOW THAT THERE'S SOME WORK GOING ON -- WELL, IN THE EARLY SCOPE OF THE CHAPTER.

DR. HALL: I DIDN'T QUITE HEAR. ANN, COULD YOU --

DR. KIESSLING: I'M SORRY. THE DESCRIPTION OF THE HUMAN EMBRYONIC STEM CELL LINES THAT THIS COVERS IS PRETTY SPECIFIC IN THE FIRST SECTION.

I ALSO HAVE A TRIVIAL QUESTION. WHY ARE THERE SO MANY ZEROS?

MR. HARRISON: I CAN ANSWER THE SECOND QUESTION. IT'S JUST A PRODUCT OF THE SECTION OF THE CALIFORNIA ADMINISTRATIVE CODE THAT WAS PROVIDED TO US.

DR. KIESSLING: THEY GAVE US THE ZEROS.

MR. HARRISON: THEY GAVE US THE ZEROS. WE'VE INHERITED THEM. TELLS YOU HOW MANY REGULATIONS THERE ARE IN CALIFORNIA.

DR. KIESSLING: I'M JUST WONDERING IF THIS COMMITTEE FEELS OR IF ANYBODY BESIDES MYSELF THINKS IT WOULD BE APPROPRIATE TO ADD A 00000 SUB A, SCOPE OF CHAPTER ON NO. 4 THAT TALKS ABOUT BLASTOCYSTS DERIVED FROM PARTHENOGENICALLY ACTIVATED EGGS BECAUSE ALL THESE

GUIDELINES SHOULD APPLY THAT. OTHERWISE IT'S JUST OUT THERE SORT OF IN LIMBO.

DR. HALL: IT IS -- I THINK WE CAN EXPECT, AND CERTAINLY RECENT EVENTS MAKE THAT CLEAR, THAT IT WILL BE POSSIBLE TO DERIVE HUMAN EMBRYONIC STEM CELL LINES IN WAYS OTHER THAN THOSE THAT ARE OUTLINED HERE. AND YOU MENTIONED ONE OF THOSE. AND I WAS WONDERING EVEN IF WE COULD COME UP WITH LANGUAGE THAT WOULD LEAVE IT OPEN.

DR. KIESSLING: THAT'S THE OTHER EGG-SPECIFIC USE. THE OTHER EGG-SPECIFIC DERIVATION. THESE ARE ALL COVERING THINGS THAT COME FROM EGGS.

DR. HALL: RIGHT.

DR. KIESSLING: KEVIN'S NEW WORK MAY NOT NEED EGGS.

DR. EGGAN: THERE'S NO REASON WHY THAT WORK COULDN'T BE COVERED TOO.

DR. HALL: YES. MY QUESTION IS COULD WE COME UP WITH A GENERAL --

CO-CHAIR LO: SORT OF ALL OTHER STEM CELL RESEARCH NOT EXPLICITLY MENTIONED ABOVE.

DR. HALL: YEAH. THIS SAYS IT'S LINES THAT ARE DERIVED IN A CERTAIN WAY; WHEREAS, IN ACTUAL FACT, IT DOESN'T MATTER. WE HAVE A HUMAN EMBRYONIC STEM CELL LINE AND WE HAVE RULES ABOUT HOW IT CAN BE USED; FOR

EXAMPLE, INJECTING INTO OTHER ANIMALS OR THINGS LIKE THAT. THAT SHOULD APPLY NO MATTER HOW THAT LINE WAS DERIVED EVEN IF IT WERE DERIVED BY KEVIN'S PROCEDURE, LET'S SAY. THEN I WOULD SUGGEST THAT THAT OUGHT TO APPLY IF IT'S A HUMAN EMBRYONIC STEM CELL LINE.

AND SO THE QUESTION IS CAN WE THINK OF A TERM THAT WOULD -- THIS, AS WRITTEN, SAYS IF YOU HAVE LINES THAT ARE DERIVED IN SOME OTHER WAY, THEY FALL OUTSIDE THE GUIDELINES; WHEREAS, MAYBE EVEN A DIFFERENT KIND OF SPECIFICATION OF WHAT THE LINES ARE.

DR. CIBELLI: IS THERE ANYBODY HERE THAT WAS AT THE NATIONAL ACADEMIES WHEN THIS WAS? SO WHEN THEY TALK ABOUT THESE GUIDELINES, DO YOU HAVE A SCOPE THAT ACTUALLY NARROWED THIS --

MS. CHARO: YES. HUMAN EMBRYONIC STEM CELLS ONLY, AND IT ONLY DEALT WITH BLASTOCYSTS FROM FERTILIZATION OR NUCLEAR TRANSFER. I DON'T EVEN REMEMBER IF WE DEALT BECAUSE AT THE TIME NOBODY WAS SAYING THAT THAT WAS REALLY TECHNICALLY FEASIBLE.

DR. CIBELLI: BUT IF I REMEMBER CORRECTLY, KEVIN CALLED TO INFORM THE PANEL OF THE WORK THAT HE WAS DOING; IS THAT CORRECT? WERE YOU PART OF THIS?

DR. EGGAN: I WAS THERE, BUT WE HADN'T MADE MUCH PROGRESS IN THAT WORK. IT FOCUSED MORE ON THE NEED FOR DISEASE-SPECIFIC EMBRYONIC STEM CELLS.

MS. CHARO: THERE WAS ALSO A VERY DELIBERATE DECISION TO NARROW THE SCOPE TO THE STUFF THAT REALLY WAS THE BULK OF THE RESEARCH IN THE COUNTRY TO GET THIS PROCESS GOING. OTHERWISE IT WAS GOING TO DRAG ON. SO THERE ARE DEFINITELY OMISSIONS IN THE NAS GUIDELINES IN TERMS OF SCOPE OF WORK, NO QUESTION.

DR. HALL: THE QUESTION IS SO CAN WE THINK OF -- IT IS PROBABLY A GOOD PLACE -- FOR A 00(A), CAN WE COME UP WITH LANGUAGE THAT WOULD GIVE US THE COVERAGE WE WANT?

DR. KIESSLING: I THINK IT'S IMPORTANT IN TERMS OF JUST WORD DEFINITION AND WORD USE THAT WE REALLY MAKE IT VERY CLEAR WHEN EGGS ARE INVOLVED BECAUSE THAT IS A HUGE ISSUE TO A LARGE PERCENTAGE OF THE POPULATION IN OUR COUNTRY VERSUS OTHER KINDS OF TECHNOLOGIES. AND I THINK THE WORK THAT KEVIN HAS DONE IN USING NUCLEAR REMODELING WITHOUT USING EGGS SHOULD NOT BE LUMPED INTO THESE CATEGORIES THAT ARE SPECIFICALLY USING HUMAN EGGS FOR THEIR WORK. AND IT COMES DOWN TO THE DEFINITION OF EMBRYONIC.

DR. HALL: LET ME JUST SAY THAT IF YOU -- FOR EXAMPLE, THE RULES REGARDING PUTTING SUCH LINES NO MATTER HOW DERIVED INTO OTHER ORGANISMS, SO PRESUMABLY THE PROHIBITIONS FOR HUMAN EMBRYONIC STEM CELL LINES DERIVED FROM OOCYTES AND THOSE DERIVED IN OTHER WAYS

WOULD APPLY IN THOSE CIRCUMSTANCES.

DR. KIESSLING: YOU ARE GOING TO GET --

DR. HALL: SO THE EGG DONOR ISSUES ARE GONE BECAUSE YOU DON'T NEED THEM, BUT THE OTHER PROHIBITIONS PERHAPS, I WOULD SUGGEST, SHOULD BE THERE AND SHOULD FALL UNDER THIS.

DR. KIESSLING: BECAUSE WE MADE A DISTINCTION IN OUR WORKING GROUP BETWEEN ADULT AND FETAL LINES AND THESE, QUOTE, EMBRYONIC STEM CELL LINES. YOU HAVE THE SAME CONCERNS ABOUT PUTTING ADULT STEM CELLS INTO BLASTOCYSTS (INTERRUPTION IN PROCEEDINGS). I THINK THAT'S A SEPARATE CONSIDERATION FROM WHAT YOU WANT THIS PARTICULAR GUIDELINES TO COVER.

CO-CHAIR LO: WE HAVE A NUMBER OF PEOPLE THAT WANT TO JOIN IN HERE, SO LET ME TAKE JAMES WILLERSON AND THEN ALTA CHARO.

DR. WILLERSON: THANK YOU. WHY CAN'T WE JUST ADD THE PHRASE "OR FROM ANY OTHER SOURCE" TO THAT SENTENCE? IT DOES APPEAR -- PEOPLE ARE CLAIMING GENERATION OF EMBRYONIC CELLS FROM OTHER SOURCES. WHETHER RIGHT OR WRONG, IT ISN'T CLEAR. BUT YOU COULD JUST ADD OR FROM ANY OTHER SOURCE. IT WOULD READ 100008(A), SECOND LINE, HES CELL LINES FROM DONATED EMBRYOS OR BLASTOCYSTS OR FROM ANY OTHER SOURCE SHALL INCLUDE.

MR. KLEIN: I BELIEVE THAT DR. WILLERSON'S APPROACH IS APPROPRIATE AND BECAUSE IN ORDER TO FUND THE RESEARCH LIKE KEVIN'S, WE NEED TO BE ABLE TO HAVE STANDARDS IN PLACE. SO AS WE GO THROUGH SECTIONS, WE CAN CARVE OUT WHEN IT SHOULDN'T APPLY TO THAT RESEARCH. BUT WE'LL NEED TO HAVE IT COVER ALL SOURCES IN ORDER TO FUND ALL SOURCES.

DR. KIESSLING: I UNDERSTAND THAT.

MR. KLEIN: SO I WOULD LIKE TO SECOND DR. WILLERSON'S PROPOSAL OF ADDING THAT LANGUAGE.

DR. EGGAN: ACTUALLY COULD YOU CLARIFY WHERE THAT CHANGED LANGUAGE IS GOING TO BE BECAUSE I HAD PROPOSED THAT IT BE LISTED AS SECTION 00(A), PARAGRAPH 4, OR ANY OTHER SOURCE.

MR. HARRISON: I THINK YOU COULD ACTUALLY PUT IT IN TWO PLACES, BOTH WHERE DR. WILLERSON SUGGESTED IN SECTION 100008(A), AND THEN ALSO ADD IT IN THE GENERAL LANGUAGE IN THE FIRST SECTION THAT DEFINES THE SCOPE OF THE CHAPTER.

DR. HALL: YES. GOOD.

DR. PRIETO: QUESTION. WHERE WOULD YOU PUT IT THERE? AS A SEPARATE ITEM AT THE END OF 000?

MR. HARRISON: I WOULD SUGGEST THAT YOU ADD IT AS A NEW SUBPARAGRAPH 4 IN SUBDIVISION A, AND YOU COULD USE THE LANGUAGE "ANY OTHER PROCEDURE."

MR. KLEIN: I THINK IT WAS ANY OTHER SOURCE.

MR. HARRISON: RIGHT. THAT WAS THE LANGUAGE THAT, I THINK, WORKS FOR 1008. I'M NOT SURE THAT -- YES. ANY OTHER SOURCE IS FINE.

DR. HALL: ANY OTHER SOURCE. DOES THAT WORK, KEVIN, FOR YOU?

DR. EGGAN: FROM ANY OTHER SOURCE OR BY ANY OTHER PROCEDURE. FROM ANY OTHER SOURCE IS FINE.

MR. KLEIN: JAMES, IT'S ANY OTHER SOURCE OR ANY OTHER PROCEDURE.

MR. HARRISON: SURE.

DR. HALL: I THINK YOU JUST SAY ANY OTHER SOURCE OR BY ANY OTHER PROCEDURE. EXCELLENT.

CO-CHAIR LO: ANY OTHER COMMENTS ON THIS?

MS. CHARO: IT'S ON OTHER PARTS OF THE DRAFT.

CO-CHAIR LO: WHY DON'T WE DO THIS ONE FIRST. SO I JUST WANT TO MAKE SURE. THERE IS A MOTION THAT I THINK HAS BEEN SECONDED TO IN TWO PLACES INSERT LANGUAGE TO INCLUDE STEM CELLS DERIVED FROM OTHER SOURCES OR BY OTHER PROCEDURES.

SO I GUESS, FIRST, IS THERE ANY MORE DISCUSSION ON THAT TOPIC FROM THE WORKING GROUP?

DR. PRIETO: I'M JUST NOT CLEAR WHERE THAT WOULD GO UNDER SECTION 100008.

DR. HALL: KEVIN, YOUR NEIGHBOR THERE, MADE

THE SUGGESTION, SO MAYBE HE COULD --

DR. EGGAN: I DIDN'T MAKE THE SUGGESTION FOR 100008.

DR. HALL: NO. YOU WERE CONCERNED ABOUT (A).

CO-CHAIR LO: LET'S ASK JAMES SO WALK US THROUGH SO WE'RE ABSOLUTELY SURE. IS IT POSSIBLE TO FLIP UP ON THE OVERHEAD THE FIRST SECTION, 100000(A), AND THEN WE CAN JUST SEE EXACTLY WHERE IT GOES.

DR. HALL: GEOFF, DO YOU HAVE IT ON YOUR -- SOMEBODY HAVE IT ON THEIR COMPUTER?

CO-CHAIR LO: IF NOT, MY UNDERSTANDING IS THAT YOU TAKE THE FIRST PAGE OF THESE DRAFT GUIDELINES, IT WOULD GO RIGHT HERE AS THE FOURTH ITEM AFTER (3), RIGHT HERE (INDICATING).

DR. KIESSLING: WHAT WILL IT READ?

MR. HARRISON: IT WILL READ "ANY OTHER SOURCE OR BY ANY OTHER PROCEDURE."

DR. ROWLEY: WHERE IS THAT GOING NOW ON THE GUIDELINES?

MR. HARRISON: THAT WILL BE IN ADDITION TO THE SCOPE OF CHAPTER SECTION, WHICH IS SECTION 100000(A), AND IT WILL BE A NEW SUBPARAGRAPH 4.

DR. ROWLEY: OKAY. AFTER SOMATIC CELL NUCLEAR TRANSFER?

MR. HARRISON: CORRECT. AND THEN THE OTHER

PROPOSAL IS TO MAKE THE CORRESPONDING CHANGE IN SECTION 100008(A), WHICH CURRENTLY READS "REQUESTS TO THE ESCRO COMMITTEE FOR PERMISSION TO ATTEMPT DERIVATION OF NEW HES CELL LINES FROM DONATED EMBRYOS OR BLASTOCYSTS OR FROM ANY OTHER SOURCE OR BY ANY OTHER PROCEDURE."

DR. ROWLEY: OKAY. THAT WAS SOMETHING THAT, I GUESS, ALTA THOUGHT SHOULD BE DELETED.

CO-CHAIR LO: I'M SORRY. I DIDN'T QUITE HEAR YOU, JANET, BECAUSE OF THE CONNECTION. COULD YOU REPEAT THAT?

DR. ROWLEY: I THOUGHT THAT IN THE SUGGESTED CORRECTIONS THAT ALTA E-MAILED THAT THAT WAS GOING TO BE DELETED.

MS. CHARO: JANET, ONE OF THE THINGS THAT'S GONE ON IS THAT WE HAVEN'T DISCUSSED WHETHER OR NOT WE WANT TO MAKE ANY OF THOSE CHANGES. AND GIVEN THE TIME LINE, IT MAY TURN OUT THAT WE WANT TO SAVE DISCUSSION OF SOME OF THOSE MORE EXTENSIVE CHANGES UNTIL WE'RE PAST ADOPTION OF INTERIM GUIDELINES AND INTO REVISION TOWARD PERMANENT.

DR. ROWLEY: OKAY.

MS. CHARO: AS A RESULT, A LOT OF WHAT WAS DISTRIBUTED LAST NIGHT BY ME AS SUGGESTED AREAS FOR DISCUSSION MAY BE PREMATURE. THERE ARE STILL A FEW OTHER ITEMS I HAVE ON MY LIST.

DR. ROWLEY: THAT CLARIFIES IT. THANK YOU.

CO-CHAIR LO: ANY OTHER QUESTIONS ABOUT THESE TWO PROPOSED CHANGES? PUBLIC COMMENTS?

I'M GOING TO CALL THE QUESTION.

MS. CHARO: YOU'RE CALLING THE QUESTION JUST ON THOSE CHANGES?

CO-CHAIR LO: JUST ON THOSE TWO. I WANT TO DO THIS INCREMENTALLY.

MR. KLEIN: I'LL CALL THE QUESTION PROCEDURALLY.

CO-CHAIR LO: ALL THOSE IN FAVOR OF THOSE TWO CHANGES THAT JAMES JUST WENT OVER IN TERMS OF THE SCOPE OF OUR WORK. OPPOSED? SO IT'S UNANIMOUS.

OTHER ISSUES, QUESTIONS, CONCERNS, SUGGESTIONS?

MS. CHARO: I WARN YOU I'VE GOT A LIST, BUT THEY'RE REALLY KIND OF LITTLE. ON THE SECTION 100002, WHICH -- NO. IT'S 10000 AND THEN A TWO. RIGHT. ANYWAY, IT'S THE ONE ABOUT RESEARCH PERMISSIBLE AFTER CURRENTLY MANDATED REVIEWS. I COMPLETELY APPRECIATE THAT THIS IS INTENDED TO SIGNAL THAT WE ARE GRANDFATHERING THE NIH LINES, BUT I'D LIKE TO OPEN UP FOR DISCUSSION WHETHER OR NOT WE MIGHT WANT TO SAY IT A LITTLE BIT MORE EXPLICITLY. REMEMBER THAT THIS WILL BE READ TODAY, TOMORROW, FOUR MONTHS FROM NOW, FIVE MONTHS

FROM NOW. SO FIVE MONTHS FROM NOW IT'S READ, AND THREE MONTHS FROM NOW A NEW LINE WAS DERIVED. SO IF SOMEBODY READS IT AND THEY'RE TALKING ABOUT A PREVIOUSLY DERIVED LINE, WHICH IS ONLY AT THAT POINT TWO MONTHS OLD, I'D LIKE PEOPLE TO JUST KNOW RIGHT OFF THE BAT THAT NIH-AUTHORIZED LINES ALREADY HAVE RECEIVED THEIR IRB REVIEW, THAT THERE IS ALREADY DOCUMENTATION OF THE INFORMED CONSENT, THAT A RESEARCHER DOESN'T NEED TO RECREATE ALL THAT DOCUMENTATION.

YES, THEY STILL HAVE TO FOLLOW THE CIRM GUIDELINES FOR WHAT THEY DO WITH THE NIH LINES WHEN IT COMES TO IN VITRO EXPERIMENTS, BUT WOULDN'T IT MAKE SENSE JUST TO SAY THAT THE DOCUMENTATION FOR THE NIH LINES IS PRESUMED? I MEAN THEY'VE ALREADY PRECLEARED THEM, THEY'VE GONE THROUGH THE IRB REVIEWS, ETC. ONLY BECAUSE I KNOW THE GRANDFATHERING THING HAS DOGGED THE COMMUNITY, AND PEOPLE ARE INCREDIBLY NERVOUS THAT THEY'RE SUDDENLY NOT ALLOWED TO USE THOSE LINES.

DR. HALL: I THINK IT'S NOT ONLY THE NIH-DERIVED LINES. I THINK THOSE ARE PROBABLY NOT, AS A PRACTICAL MATTER, AND PLEASE CORRECT ME IF I'M WRONG, THE REAL ISSUE, BUT THAT OTHERS MAY BECOME AVAILABLE IN THE NEXT X MONTHS.

MS. CHARO: I WASN'T SUGGESTING DELETING THIS SECTION. I WAS SUGGESTING ADDING SOMETHING VERY

SPECIFIC. PERSONALLY I THINK THE HFEA LINES ALSO WOULD BE.

DR. HALL: WHAT WOULD YOU ADD?

MS. CHARO: THE NIH AND THE HFEA. I CAN UNDERSTAND SOMEBODY WHO WANTS TO USE DOUG MELTON'S LINES AT UCSF NEEDING TO GET SOME DOCUMENTATION FROM HARVARD THAT IT WENT THROUGH AN IRB REVIEW BECAUSE ALL WE KNOW IS FROM PRESS REPORTS THAT IT WENT THROUGH AN IRB REVIEW. BUT WITH HFEA AND NIH, IT WOULD JUST SEEM LIKE THOSE LINES WE KNOW, AND WE SHOULDN'T BE MAKING INVESTIGATORS HAVE TO RECREATE A DOSSIER THAT DOCUMENTS ALL OF THE PRIOR REVIEWS AND THE INFORMED CONSENT DOCUMENTS THAT WERE USED BY THE INDIVIDUALS BECAUSE WE KNOW HFEA AND NIH LINES, YOU COULDN'T PAY FOR THE MATERIALS, YOU HAD TO GET CONSENT.

DR. EGGAN: PERHAPS WE SHOULD OPEN THAT UP TO A NUMBER OF OTHER.

DR. ROWLEY: THIS IS JANET ROWLEY, AND I'D LIKE TO WEIGH IN AT SOME POINT.

CO-CHAIR LO: DO YOU WANT TO DO IT NOW, JANET, BECAUSE I KNOW IT'S HARD SOMETIMES ON THE PHONE TO GET RECOGNIZED?

DR. ROWLEY: WELL, I THINK IT'S IMPORTANT TO CLARIFY THAT NIH HASN'T DERIVED ANY CELL LINES. THEY ALL CAME FROM OTHER INSTITUTIONS. SO THEY'RE NIH

APPROVED, BUT WE HAVE TO MAKE SURE THAT WE DON'T -- IN THE DERIVED WE DON'T SOMEHOW LINK NIH WITH THE DERIVATION OF THOSE LINES.

CO-CHAIR LO: GOOD POINT.

DR. KIESSLING: I WOULD JUST LIKE TO ASK ALTA WHAT DO YOU WANT US TO ADD? SPECIFICALLY WHAT SHOULD WE SAY?

MS. CHARO: UNDER THIS PARTICULAR SECTION, IF YOU JUST ADDED -- IF THE ONE THAT'S THERE WAS NOW LABELED A AND THEN YOU ADDED A "B" SAYING LINES APPROVED FOR NIH FUNDING OR HFEA FUNDING WILL BE ACCEPTED AS HAVING ALREADY COMPLIED WITH DOCUMENTATION REQUIREMENTS CONCERNING COMPLIANCE WITH INFORMED CONSENT AND INSTITUTIONAL REVIEW BOARD OVERSIGHT.

DR. EGGAN: I'D MODIFY THAT IN ONE WAY TO SAY "OR DEPOSITED IN ONE OF THE FOLLOWING ACCEPTED TISSUE BANKS INCLUDING, FOR INSTANCE, THE UK STEM CELL BANK OR OTHER BANKS WHICH THIS BODY CAN AGREE PASSED THOSE LITMUS TESTS."

MS. CHARO: THAT BEGINS TO ANTICIPATE THE WORK OF THE INTERNATIONAL INTERSTATE COLLABORATIONS WORKING GROUP, WHICH IS STRUGGLING TO FIGURE OUT HOW WE WOULD CAPTURE THAT UNIVERSE. THE EASY ONES ARE HFEA, BECAUSE THEY USE LICENSING, AND THE NIH BECAUSE THEY PUBLISHED WHAT IT IS THEY WILL OR WILL NOT AUTHORIZE

FOR FUNDED RESEARCH.

MR. KLEIN: SO DOES THAT MEAN, ALTA, YOU'RE ACCEPTING KEVIN'S ADDITIONAL LANGUAGE?

MS. CHARO: IF YOU'RE TALKING ABOUT THE UK STEM CELLS, SURE. I DON'T KNOW. WITH OTHERS I THINK WE'RE GOING TO HAVE TO WAIT UNTIL WE CAN FIGURE OUT HOW WE WANT TO -- WHAT CRITERIA WE WANT TO APPLY.

DR. EGGAN: I STRONGLY AGREE.

DR. HALL: EXACTLY. I THINK THAT -- I DON'T KNOW WHAT THE PRACTICE WILL BE ABOUT CELL LINES DEPOSITED IN THE UK BANK AND WHETHER THERE WILL BE DUPLICATE DEPOSITS OR NOT. I WAS WONDERING IF WE COULD USE THAT ONE, WHICH IS VERY WELL ESTABLISHED AND WE CAN ALL AGREE ON AS A STANDARD. I THINK BEYOND THAT, IT GETS -- WE ALMOST HAVE TO CONSIDER THEM ONE BY ONE. AND IT WILL BE TIME-CONSUMING, AND I WONDERED IF WE COULD USE THE UK STEM CELL BANK. I SUPPOSE THE OTHER POSSIBILITY WOULD BE TO SAY OR ONE WITH EQUIVALENT STANDARDS.

MR. KLEIN: THAT WOULD BE SEEM TO BE -- BECAUSE ONCE YOU SET THE BENCHMARK, IF THEY'RE EQUIVALENT STANDARDS, THAT WOULD SAVE A LOT OF UNNECESSARY DOCUMENTATION.

DR. EGGAN: I'M CONTENT WITH THAT.

DR. HALL: IS THAT A REASONABLE?

CO-CHAIR LO: LET ME RAISE ONE POINT BECAUSE WE WENT THROUGH THIS AT UCSF WHEN AN INVESTIGATOR WANTED TO WORK WITH AN NIH-APPROVED STEM CELL LINE. IT TURNS OUT IF YOU GO TO THE NIH WEBSITE, THERE ARE QUESTIONS ABOUT -- IT'S NOT CLEAR -- AT LEAST ONE OF THOSE LINES WAS DERIVED WITH DONOR GAMETES, AND IT'S NOT CLEAR FROM THE WEBSITE WHAT THE LEVEL OF CONSENT WAS FROM THE GAMETE DONOR AS OPPOSED TO THE WOMAN OR COUPLE AT THE IVF ACTUALLY DONATED THE EMBRYO. SO THERE IS THAT AMBIGUITY. AND WE HAVE BEEN UNABLE AT NIH TO CLARIFY THAT.

NOW, I THINK ON THE ONE HAND THERE'S A PRINCIPLE OF GRANDFATHERING IN THINGS THAT HAVE BEEN APPROVED THAT WERE WELL CHARACTERIZED AND WORKED WITH; AND ON THE OTHER HAND, THERE'S A QUESTION OF WHAT STANDARDS WERE IN PLACE AT THE TIME THEY WERE DERIVED. I THINK JUST AS A PIECE OF INFORMATION TO PUT IN AND PERHAPS A WARNING AS WE SORT OF INCLUDE APPROVAL FOR GUIDELINES THAT HAVE BEEN DEEMED APPROPRIATE BY OTHER BODIES SO WE UNDERSTAND WHAT KIND OF PROCESS THEY WENT THROUGH AND WHAT THE STANDARDS WERE. SO THE EQUIVALENT STANDARDS CRITERION SEEMS APPROPRIATE.

DR. HALL: BERNIE, CAN I ASK YOU SPECIFICALLY DO YOU THINK IT WOULD BE A MISTAKE TO SAY THAT WE APPROVE -- THAT ANY OF THE NIH-APPROVED LINES SHOULD BE

ELIGIBLE, PERIOD? I DIDN'T QUITE UNDERSTAND.

CO-CHAIR LO: I THINK THAT'S SOMETHING WE NEED TO THINK ABOUT. THE ARGUMENT ON ONE HAND SAY LET'S SAY USE THEM BECAUSE THEY ARE APPROVED AND WELL CHARACTERIZED. THEY PROBABLY AREN'T GOING TO BE USED FOR TRANSPLANTATION FOR A VARIETY OF SCIENTIFIC REASONS, BUT THEY CERTAINLY ARE VERY VALUABLE FOR OTHER TYPES OF RESEARCH.

ON THE OTHER HAND, THERE'S A CLEAR SORT OF LACK OF CLARITY AS TO WHETHER OR NOT A COUPLE OF THESE GUIDELINES ACTUALLY MEET STANDARDS THAT WERE PUT IN PLACE ELSEWHERE, SO IT'S LIKE HOW MUCH --

DR. HALL: SO HOW DO YOU COME DOWN ON THAT DISCUSSION SINCE YOU WENT THROUGH IT? AND IS THIS A TRIVIAL MATTER OR ONE THAT YOU THINK IS SERIOUS ENOUGH THAT WE SHOULD NOT DO THIS? WE SHOULD NOT AUTOMATICALLY QUALIFY THEM.

CO-CHAIR LO: WE CAME DOWN ON THE SIDE OF APPROVING NIH GUIDELINES BECAUSE THE WORK THAT WAS BEING PROPOSED IN THAT CASE WAS PURELY VIABLE LABORATORY AND NONHUMAN. IT WAS ANIMAL.

DR. HALL: SO YOU RAISE IT AS A CONCERN, BUT NOT NECESSARILY --

CO-CHAIR LO: CORRECT.

DR. HALL: -- ONE THAT WOULD DEMAND. OKAY.

DR. KORDOWER: I'M A LITTLE CONFUSED ABOUT WHAT YOU MEAN BY NOT BEING USED IN TRANSPLANTATION EXPERIMENTS. YOU MEAN CLINICAL TRANSPLANTATION, BUT NOT PRECLINICAL? BUT THEY WILL BE USED IN PRECLINICAL TRANSPLANTATION EXPERIMENTS?

CO-CHAIR LO: ABSOLUTELY. ABSOLUTELY. I THINK THE ISSUE COMES UP IF A GAMETE DONOR WHOSE MATERIALS WERE USED IN DERIVATIONAL NIH LINES, WAIT A MINUTE. I WAS COMFORTABLE WITH IT BEING USED FOR LABORATORY RESEARCH, BUT NO ONE EVER TOLD ME THEY WERE GOING TO TRANSPLANT THIS IN HUMANS. I DID NOT AGREE TO THAT. I WOULD NOT HAVE WANTED THAT. I THINK, AS JEFF POINTS OUT, THAT FOR PRECLINICAL WORK WITH ANIMALS, I DON'T SEE --

DR. HALL: SO WHAT YOU'RE SAYING IS THAT ALTHOUGH THERE WERE QUESTIONS ABOUT THE NIH LINES, IN THE END YOU FELT THAT -- YOU WANTED TO ALERT US TO THOSE. IN THE END YOUR JUDGMENT WAS IN THE CASES THAT YOU LOOKED AT, THAT THEY WERE NOT SERIOUS ENOUGH TO DISQUALIFY THOSE LINES.

CO-CHAIR LO: FOR PRECLINICAL.

MR. KLEIN: JUST AS A QUESTION. THERE IS A PROPOSAL ON THE TABLE FOR MODIFIED LANGUAGE INCLUDING AN EQUIVALENCY USING THE STEM CELL BANK IN ENGLAND AS A BENCHMARK AND INCLUDING LANGUAGE THAT WOULD PERMIT

ADDITIONAL STEM CELL BANKS IF THEY MET AN EQUIVALENCY STANDARD OF THAT KIND OF GOLD STANDARD THAT IS SET OUT BY THE ENGLISH STEM CELL BANK; IS THAT CORRECT? IS THAT WHERE WE ARE?

DR. EGGAN: I THINK THAT'S WHERE I AM, BUT I GUESS I'M WONDERING WHETHER OR NOT WE WANT TO ACTUALLY REVIEW EACH ONE OF THOSE BANKS BEFORE WE ALLOWED THEM IN OR WHETHER OR NOT WE'RE WILLING TO MAKE A LARGE BLANKET STATEMENT LIKE THAT.

DR. HALL: EQUIVALENT STANDARDS, YOU THINK, IS NOT --

DR. EGGAN: WELL --

DR. HALL: CANADIAN, FOR EXAMPLE, OR AUSTRALIAN PROBABLY WOULDN'T.

CO-CHAIR LO: I HAVE A NUMBER OF COMMENTS.

DR. KIESSLING: I WAS JUST WONDERING HOW MUCH TROUBLE IS THIS GOING TO SAVE THE INVESTIGATOR? IS THIS SIMPLY A MATTER OF ORDERING A LINE FROM NIH AND THEY'LL PROVIDE YOU WITH ALL THE DOCUMENTATION AND YOU CAN JUST PASS IT ON, OR IS THIS DAYS OF REQUALIFYING A LINE?

DR. EGGAN: I THINK THIS IS SAYING THAT THEY WOULDN'T NEED THE DOCUMENTATION BECAUSE IT'S ALREADY BEEN DEMONSTRATED THAT THESE ARE DOCUMENTED CELL LINES, AND IT WOULD BE LIKE ORDERING SOMETHING UP FROM THE

ATCC RATHER THAN HAVING TO GENERATE THIS HUGE DOSSIER, WHICH TO A SCIENTIST IS A SUBSTANTIAL ADVANTAGE. AND THE THING IS I FEEL VERY COMFORTABLE WITH THE LEVEL OF REVIEW WHICH SEEMS TO BE GOING ON AT THE UK STEM CELL BANK. AND IT'S ONE TO SAY THAT OTHER PEOPLE ARE ADHERING TO EQUIVALENT STANDARDS, BUT IT'S ANOTHER THING FOR THEM TO ACTUALLY DO IT. SO I DO HAVE SOME CONCERN ABOUT THAT.

DR. KIESSLING: DOES THE NIH JUST PROVIDE YOU WITH ALL THE DOCUMENTATION YOU NEED, AND YOU CAN SIMPLY PASS THAT THROUGH WITH THE REQUEST?

DR. EGGAN: I DON'T KNOW.

DR. HALL: BERNIE WAS SAYING IN SOME CASES THEY ACTUALLY CAN'T.

CO-CHAIR LO: WHAT THEY DO -- THERE WAS A PIECE ON THE NIH WEBSITE, WHICH HAS ACTUALLY BEEN WITHDRAWN, WHICH DESCRIBES THE PROCESS UNDER WHICH THOSE LINES WERE APPROVED. AND THEY DETAIL THE TYPE OF MATERIALS THAT WERE REVIEWED. AND THEN YOU HAVE TO TRUST THAT THE NIH REVIEW PROCESS LOOKED AT THOSE MATERIALS CAREFULLY, THOUGHTFULLY, AND MADE A WISE JUDGMENT. YOU DO NOT ACTUALLY HAVE THE DOCUMENTS THEMSELVES, AND IT WOULD BE ACTUALLY A LOT OF DIFFICULTY FOR AN INVESTIGATOR.

THOSE OF YOU WHO ARE DOING THIS WORK, CORRECT

ME IF I'M WRONG, BUT I WAS TOLD THAT IT WOULD BE QUITE TIME-CONSUMING FOR INVESTIGATORS TO ACTUALLY PROVIDE THAT DOCUMENTATION TO THEIR IRB.

SO THE NOTION WAS THAT IT HAD BEEN REVIEWED BY A PROCESS THAT, FOR EXAMPLE, WE FELT COMFORTABLE ENOUGH THAT THE RIGHT MATERIALS WERE LOOKED AT AND IN A THOUGHTFUL MANNER, THAT THAT REVIEW NEED NOT BE REPEATED BY EACH INDIVIDUAL LOCAL IRB.

MS. CHARO: JUST TO FOLLOW UP ON THAT WITH SOME INFORMATION. FIRST, WE KNOW WHAT THE STANDARDS WERE THAT WERE BEING USED BY NIH IN DETERMINING WHICH LINES IT WOULD APPROVE FOR FUNDING. WE ALSO KNOW A LOT ABOUT WHAT THE STANDARDS WERE IN THE UNITED KINGDOM UNDER UK LAW AND HFEA POLICY FOR WHAT THEY WOULD ALLOW INTO THEIR BANK. AND INFORMATION ABOUT THAT WAS DISTRIBUTED TO THIS GROUP WHEN THE NAS REPORT WAS DISTRIBUTED AND SUMMARIZED IN THE REPORT. SO WE CAN TAKE NOTICE OF THAT INFORMATION.

AND THE KEY THINGS THAT CORRESPOND TO THE CIRM REQUIREMENTS UNDER PROP 71 INCLUDE THE NONCOMMERCIAL ASPECT OF THE MATERIAL COLLECTION AND THE VOLUNTARY INFORMED CONSENT ASPECT OF THE COLLECTION. SO TO THE EXTENT THAT PROP 71 SETS SOME ABSOLUTE BARE MINIMUM STANDARDS, WE KNOW THAT THOSE TWO COLLECTIONS MEET THOSE BARE MINIMUM STANDARDS.

NOW, LATER IN THE DISCUSSION, AS WE MOVE INTO THE DIFFERENT WORKING GROUPS, YOU WILL FIND, AND I THINK IT'S THE VERY LAST PAGE IN OUR BOOKS, THE SUMMARY OF THE CONVERSATION WITHIN THE WORKING GROUP LOOKING AT INTERSTATE COOPERATION AND INTERNATIONAL COOPERATION. AND GEOFF HAS SUMMARIZED IT FOR US THERE. AND YOU WILL BEGIN TO SEE THE OUTLINE OF HOW THAT SUBCOMMITTEE THOUGHT WE MIGHT WANT TO TACKLE THE QUESTION OF HOW TO IDENTIFY OTHER LINES OR OTHER INSTITUTIONS OR OTHER STATE AND NATIONAL LAWS AND DETERMINE WHETHER OR NOT THEY DO OR DO NOT MEET, NOT ONLY PROP 71'S BARE MINIMUM, BUT SOME OTHER MINIMUM THAT THIS GROUP IDENTIFIES AS BEING A NONNEGOTIABLE MINIMUM LEVEL OF BEHAVIOR OR PROCESS BEFORE IT WILL ALLOW A CIRM-FUNDED RESEARCHER TO COLLABORATE.

BUT IT SEEMS LIKE IT'S HARD TO GET IT ALL DONE NOW. IT'S A CHICKEN AND EGG PROBLEM. WE HAVEN'T GOTTEN TO THAT DISCUSSION, SO WE DON'T KNOW HOW TO AMEND THIS BEYOND THE TWO THINGS WE KNOW, WHICH IS THE UK STEM CELL BANK AND THE NIH COLLECTION.

DR. EGGAN: SO I WOULD MOVE THAT WE JUST AMEND IT TO INCLUDE THOSE.

DR. HALL: LET ME MAKE A SUGGESTION HERE. IF WE DO PUT THE PHRASE IN "EQUIVALENT STANDARDS" OR SOMETHING LIKE THAT, IN ESSENCE, WHAT THE NIH

GUIDELINES DO IS TO DELEGATE OR TO SUGGEST THAT THE ESCRO COMMITTEES AT THE LOCAL INSTITUTION SHOULD HAVE THE RESPONSIBILITY FOR LOOKING AT THE PROVENANCE OF THE LINES AND FOR DECIDING IN CASES PARTICULARLY OF INTERNATIONAL COLLABORATION. I THINK WHEREAS WE MAY WANT TO TALK ABOUT THAT AT A LATER TIME, IT MIGHT BE FOR THE INTERIM THAT IF WE SAY "OR APPROPRIATE STANDARDS," THEN IT BECOMES THE RESPONSIBILITY OF THE INDIVIDUAL INSTITUTION TO EXAMINE THAT, MAKE A DECISION ABOUT IT.

AND AS BERNIE'S CASE DESCRIBES, THEY ARE ALREADY DOING THIS AT MANY OF THESE INSTITUTIONS ANYHOW FOR THESE LINES. IT'S NOT TO GIVE THEM A NEW AND UNEXPECTED RESPONSIBILITY; BUT THAT IF WE SIMPLY STATE THE MINIMUM, STATE THE BROAD LEVEL OF STANDARD THAT WE EXPECT, AND THEN IT DOESN'T CLOSE THE DOOR TO USING LINES OUTSIDE OF THAT, BUT IT PUTS THE BURDEN OF PROOF ON THEM TO SHOW THAT THEY'RE OF AN EQUIVALENT STANDARD.

I DON'T KNOW IF THAT'S AN ACCEPTABLE -- THAT WOULD EASE YOUR FEELING OF UNEASE ABOUT THIS OR NOT, BUT THAT, IT SEEMS TO ME, IS ONE WAY TO THINK ABOUT DOING THIS SINCE IT'S ALREADY LAID OUT HERE.

CO-CHAIR LO: COUPLE OF PEOPLE TRYING TO GET IN, SO FRANCISCO AND ROB AND BOB.

DR. PRIETO: I'M JUST FORMING MY OWN THOUGHTS

ABOUT THIS. IT SEEMED TO ME THAT IT WOULD BE BEST TO KEEP THIS FAIRLY GENERAL STATEMENT. AND I THINK THAT'S WHAT ZACH IS SAYING RIGHT NOW. ARE YOU SUGGESTING THAT WE LEAVE THE LANGUAGE AS IS, AND THAT THAT WOULD INCORPORATE THAT, OR WOULD YOU ADD SOMETHING TO THIS LANGUAGE?

DR. HALL: NO. I THINK THE PROBLEM WITH THE LANGUAGE AS IS IS THAT IT'S -- FOR CELL LINES THAT MAY BE ANNOUNCED TOMORROW, THERE'S NO PROVISION. AND SO IT WOULD -- I THINK THE INTENT HERE IS TO TRY TO MAKE IT TO SET A MINIMUM STANDARD, TO SET A GENERAL STANDARD THAT WE EXPECT, AND THEN TO PUT THE BURDEN ON THE INDIVIDUAL INSTITUTIONS THROUGH THEIR ESCRO COMMITTEES TO THEN DEMONSTRATE THAT WHATEVER LINES ARE USED BY THEIR INVESTIGATORS WITH CIRM FUNDING WOULD FOLLOW THIS -- WOULD BE COMPATIBLE WITH OUR GENERAL STANDARDS.

DR. PRIETO: HOW WOULD YOU WORD THAT?

DR. HALL: I THINK, IF WE COME BACK TO IT, I'M A LITTLE LOST NOW WITH THE WORDING, BUT I THINK THE WORDING THAT ALTA SUGGESTED AS AMENDED BY KEVIN, AND I WOULD SUGGEST ADDING THE "OR EQUIVALENT STANDARD" AND THEN LEAVING IT, AND THEN I THINK THE GUIDELINES AS ESTABLISHED GIVE THAT ROLE TO THE ESCRO COMMITTEES TO REALLY THEN DECIDE IF THEY FIT THIS OR NOT. IS THAT A REASONABLE WAY TO GO?

CO-CHAIR LO: LET'S GET SOME MORE COMMENTS. IN THE INTERIM, IF WE COULD ASK ALTA AND/OR KEVIN TO KIND OF ACTUALLY -- WE NEED TO LOOK AGAIN, I THINK, AT THE END OF THIS NEXT ROUND OF DISCUSSIONS OF WHAT THE ACTUAL LANGUAGE IS. ROB AND THEN BOB.

DR. TAYLOR: I GUESS I SAY THIS SOMEWHAT RELUCTANTLY, BUT I'M CONCERNED THAT THE LEVELS OF STANDARDS THAT WE'RE TALKING ABOUT MIGHT NOT TRULY BE THE LEVEL OF STANDARDS THAT WE WANT TO ACHIEVE IN CIRM. AND, BERNIE, YOU MIGHT KNOW BETTER THAN I, BUT I DON'T BELIEVE THAT THE UK STEM CELL BANK HAS THE GAMETE DONOR ISSUES DISCUSSED THAT YOU RAISED IN YOUR CONCERN ABOUT THIS ONE NIH BASELINE. I'M A LITTLE BIT CONCERNED THAT WE ARE, IN FACT, GOING TO BE WATERING DOWN THE STANDARDS THAT WE WOULD REALLY WANT TO PROMULGATE.

NOW, I ACCEPT THAT GRANDFATHERING IS IMPORTANT AND THAT WE DON'T WANT TO LOSE THE OPPORTUNITY WE HAVE WITH THESE THINGS, BUT I'M A LITTLE CONCERNED ABOUT ESTABLISHING LANGUAGE THAT'S ACTUALLY GOING TO LOWER OUR STANDARDS.

DR. ROWLEY: THIS IS JANET. YOU KNOW, I WAS INVOLVED IN WRITING THE CELL LINE GUIDELINES AND READ THE UK -- THE UK GUIDELINES, I'M SURE THAT THEY MADE CERTAIN THAT THE GAMETE DONORS GAVE INFORMED CONSENT.

CO-CHAIR LO: IS THERE SOMEONE ON STAFF THAT

CAN CHECK THAT FOR US?

MR. KLEIN: JAMES, MAYBE FOR THE BENEFIT OF EVERYONE HERE, WE COULD DISCUSS HOW THIS COMMITTEE'S WORK INTERRELATES WITH THE ADMINISTRATIVE PROCEDURES ACT AND THE INTENT TO PROVIDE GRANTS IN REAL TIME. AND THAT IS, THAT IF WE HAVE AN EQUIVALENCY STANDARD IN OUR GUIDELINES AND THOSE GO THROUGH THE ADMINISTRATIVE PROCEDURES ACT, THEN, FOR EXAMPLE, WHETHER IT'S THE ESCRO COMMITTEE OR THIS COMMITTEE, THERE COULD BE A JUDGMENT ABOUT EQUIVALENCY. IF WE DON'T PUT AN EQUIVALENCY STANDARD IN, THEN WE'RE NOT GOING TO BE IN A POSITION TO APPROVE GRANTS.

MR. HARRISON: RIGHT. IF THE RESEARCH INVOLVES CELL LINES THAT AREN'T COVERED BY THIS EXCEPTION, YOU WOULD NEED TO GO THROUGH A FORMAL PROCESS IN ORDER TO AMEND THE REGULATIONS TO CREATE A NEW EXCEPTION.

MR. KLEIN: SO MY SUGGESTION WOULD BE THAT THE EQUIVALENT STANDARDS IS IMPORTANT. WHERE YOU HOUSE THAT APPROVAL IS, YOU KNOW, SOMETHING TO BE DECIDED.

BUT, JAMES, THE OTHER POINT, AND I'M GLAD DR. HALL IS BACK, IS THAT ON PREEXISTING LINES, IT SAYS, FOR EXAMPLE, RECEIVES DOCUMENTATION, AND IT PROVIDES A NUMBER OF ITEMS UNDER THE ROMANAT KEYS OF THE TYPES OF DOCUMENTATION. IT SAYS OR OTHER MANDATED REVIEW. WE

DON'T HAVE ANY PROVISION FOR A WAIVER WHERE SOMEONE CAN COME TO THIS COMMITTEE FOR A WAIVER. AND I WOULD THINK, RATHER THAN BEING FORCED ALL THE WAY BACK TO THE ADMINISTRATIVE PROCEDURES ACT, IT WOULD BE GOOD TO BE, IN THIS PROVISION AND IN OTHER PROVISIONS, TO HAVE A GENERAL CLAUSE THAT ALLOWS WAIVER IF IT COMES BACK TO A PUBLIC MEETING OF THIS COMMITTEE FOR CONSIDERATION BECAUSE THERE MAY BE A MINOR MANDATED REVIEW THAT WASN'T PERFORMED, SO YOU CAN'T PROVIDE THE DOCUMENTATION. YOU DON'T WANT TO PUT YOURSELF IN A POSITION WHERE YOU HAVE NO WAIVER PROCEDURE.

AND GIVEN THESE ARE PUBLIC MEETINGS, WE COULD COME BACK. PERHAPS THERE'S A WAIVER -- A LEVEL OF WAIVER THAT COULD HAPPEN AT THE PRESIDENT'S LEVEL AND A LEVEL OF WAIVER WHERE IT MIGHT COME BACK TO THIS COMMITTEE. BUT THAT'S A SEPARATE ITEM THAN STATING THE IMPORTANCE.

DR. HALL, WHAT I WAS SAYING IS THAT UNDER THE ADMINISTRATIVE PROCEDURES ACT, IF WE DON'T HAVE AN EQUIVALENCY STANDARD, THEN IF WE DON'T PUT IT IN THROUGH THIS PROCESS, WE'D HAVE TO GO ALL THE WAY BACK THROUGH THE ADMINISTRATIVE PROCEDURES ACT TO EVER INTRODUCE AN EQUIVALENCY STANDARD. SO THIS IS THE TIME TO INTRODUCE SUCH A STANDARD IF WE'RE GOING TO HAVE ONE.

AND BY INTRODUCING IT, IT ALLOWS THE FLEXIBILITY OF EITHER BRINGING IT BACK TO THIS COMMITTEE FOR REVIEW OR IN THE ESCRO COMMITTEE, WHATEVER YOUR DISCRETION IS, BUT AT LEAST IT GIVES A LOT OF FUTURE FLEXIBILITY WHEN OTHER STEM CELL BANKS BECOME WELL ESTABLISHED AND THEIR PROCEDURES ARE KNOWN, OR AS THE INTERNATIONAL SOCIETY DEVELOPS STANDARDS THAT ARE WELL-KNOWN.

DR. HALL: I'M SORRY. I MISSED PART OF THAT.

MR. KLEIN: I'M SUPPORTING THE NEED FOR EQUIVALENCY IN THE LANGUAGE THAT IS ADOPTED.

DR. HALL: I THINK IT WILL BE A LONG-TERM PROBLEM FOR US OF HOW WE DEAL WITH THIS. AND THAT'S OBVIOUSLY WHY THE WHOLE WORKING GROUP IS DOING THAT. THAT IS, SOMEBODY COMES UP WITH A CELL LINE FROM SOME GROUP OF INVESTIGATORS SOMEWHERE IN THE WORLD, AND THE QUESTION IS CAN CIRM INVESTIGATORS USE THAT CELL LINE AND WHO MAKES THAT DECISION, AND ARE WE GOING TO CERTIFY OR ARE OTHER PEOPLE GOING TO CERTIFY?

YOU'RE GOING TO PRESENT THE UK STANDARDS?

DR. CIBELLI: SO WE CAN MOVE ON. THE UK SAYS THEY HAVE A STEERING COMMITTEE THAT ALWAYS REVIEW THE PAPERWORK BEFORE THEY TAKE THE CELL LINES IN. IT'S IN THE WEBSITE. YOU CAN FIND IT. IT SAID THE CRITERIA ON WHICH THE STEERING COMMITTEE MAKES ITS DECISION ARE

ALSO PUBLISHED IN THE MRC WEBSITE. AND THEY HAVE TO SUBMIT ALL THE SUPPORTING DOCUMENTS, AND THE DOCUMENTS ARE BASICALLY -- THEY'RE TALKING ABOUT ETHIC COMMITTEE APPROVAL FROM THE INSTITUTION, PEER REVIEW, AND INFORMED CONSENT FOR THE WORK OF THE DERIVATION OF THE CELL LINE SHOULD BE SUBMITTED. SO THAT'S -- THAT'S SOMETHING THAT WE WILL HAVE TO DO IN THE FUTURE AS THE COMMITTEE THAT TAKES CARE OF THAT.

CO-CHAIR LO: GEOFF IS ACTUALLY TRYING TO LOOK THROUGH TO SEE IF THE INFORMED CONSENT MUST BE FROM GAMETE DONORS AS WELL AS EMBRYO.

MS. CHARO: WE'RE BOTH WORKING ON IT. AND, YOU KNOW, IT'S PROOF THAT THE WEB PAGE NEEDS TO BE IMPROVED. IT'S NOT EASY TO GET TO IT.

MR. LOMAX: WE'RE IN THE ACTUAL DOCUMENT HERE AS WELL.

DR. CIBELLI: DR. LO, IF I CAN JUST FINISH UP. I WOULD LIKE TO ECHO WHAT KEVIN EGGAN IS SAYING, THAT BEFORE WE SAY SOMETHING ALONG THE LINES OF ADOPTING SOMEONE ELSE'S GUIDELINES, I WOULD RATHER JUST SAY WE WILL MAKE SURE THAT THE CELL LINES WHEN THEY ARE SUBMITTED TO OUR BANK WILL BE THIS CRITERIA. IF WE DON'T HAVE THE CRITERIA TODAY, THAT'S FINE. WE JUST NEED TO KNOW.

MR. LOMAX: SECTION 13, A WOMAN SHALL NOT BE

PROVIDED WITH ANY TREATMENT SERVICES INVOLVING THE USE OF ANY GAMETES OF ANY PERSON, BUT THIS IS TALKING ABOUT TREATMENT. THIS IS FOR FERTILIZATION. THIS IS THE WRONG ONE.

CO-CHAIR LO: AGAIN, THERE MAY BE -- PART OF THIS IS STRATEGY. THESE ARE ISSUES WHICH WE WILL HAVE TO ADDRESS. ONE OF THE SUBCOMMITTEES IS GOING TO DO THAT. AS A WORKING GROUP WE DISCUSS THE ISSUE. FOR THESE INTERIM GUIDELINES, WHAT SHOULD WE PUT IN PLACE FOR THE NEXT NINE MONTHS AND HOW DETAILED?

DR. EGGAN: I GUESS THE IMPORTANT THING THAT BOB BROUGHT UP WAS THAT JUST BY SAYING THAT WE ALLOW THIS EQUIVALENCY STATEMENT DOESN'T MEAN THAT WE CEDE THE AUTHORITY TO JUDGE EQUIVALENCY. FOR ME, I GUESS THAT WAS THE IMPORTANT ISSUE.

CO-CHAIR LO: WHO JUDGES WHAT'S EQUIVALENT?

DR. EGGAN: IT COULD BE BOTH UP TO US AND TO THE ESCRO'S TO JUDGE THE EQUIVALENCY. AM I REGURGITATING WHAT YOU SAID CORRECTLY, BOB? WHAT YOU SAID IS THE IMPORTANT THING ABOUT THIS EQUIVALENCY STATEMENT DOESN'T SAY THAT WE CEDE OUR AUTHORITY TO JUDGE EQUIVALENCY. IT DOES NOT CEDE OUR AUTHORITY TO JUDGE EQUIVALENCY.

DR. HALL: I THINK IT SAYS AS A PRACTICAL MATTER IN THE MEANTIME, GIVEN THE REST OF THIS

DOCUMENT, THAT WE WILL LET THE ESCRO COMMITTEE DECIDE THIS. WHAT I THINK IS NOT A GOOD ROLE FOR THIS COMMITTEE, AND CERTAINLY IN THE NEXT FEW MONTHS, MAYBE NOT LONG TERM, THAT'S A SEPARATE DECISION, LONG TERM MAYBE, BUT NOT IN THE NEXT MONTH IS TO HAVE SOMEBODY COME AND SAY UCLA SAYS WE HAVE ONE OF OUR INVESTIGATORS WHO'S REQUESTED A LINE THAT WAS MADE WHEREVER YOU WANT SAY, IN COSTA RICA, AND WE WANT YOU TO CERTIFY THAT IT'S OKAY FOR US TO TAKE THAT. I DON'T THINK THAT'S WHAT THIS COMMITTEE SHOULD BE DOING.

AND I THINK WHAT WE SAY IS, LOOK, HERE'S OUR MINIMUM STANDARDS, HERE'S THE EQUIVALENT STANDARDS, AND HERE'S THE LEVEL WE SUGGEST. IT'S UP TO YOU GUYS TO DO THE LEGWORK ON THIS AND FIGURE IT OUT. IT'S YOUR PROBLEM, THEN, TO JUSTIFY TO US THAT THAT IS EQUIVALENT TO THE UK STANDARDS OR WHATEVER IT IS.

DR. EGGAN: I WOULD WANT TO SAY THAT WE MAY WANT TO ACT LIKE THE SUPREME COURT OF ESCRO'S, AND ESSENTIALLY ALMOST ALL DECISION IS BASED IN A WAY ON CASE LAW. IT COULD BE THAT WE WANT TO MAKE A GENERAL STATEMENT THROUGHOUT ALL OF CALIFORNIA ABOUT THAT CELL LINE BECAUSE IT SAYS SOMETHING ABOUT WHY THAT CELL LINE IS INCORRECT.

DR. HALL: ULTIMATELY WE MAY WANT TO DO THAT, AND WE MAY WANT TO DO THAT EITHER AS THIS COMMITTEE, OR

AN ALTERNATIVE WOULD BE TO SET UP A STATEWIDE COMMITTEE THAT WOULD THEN AGREE ON BEHALF OF ALL THE INSTITUTIONS HERE ABOUT WHICH ONES WOULD DO THAT. THAT MIGHT BE ANOTHER WAY TO HANDLE IT. I THINK TO HAVE THIS COMMITTEE AT THIS POINT HAVE TO ACT ON THOSE AND HAVE TO GET THE INFORMATION AND, IN EFFECT, ACT LIKE A LOCAL COMMITTEE, I THINK, IS PROBABLY NOT CORRECT.

I THINK WHAT WE SHOULD DO IS TO SAY, LOOK, WE'RE GOING TO GIVE YOU THE MONEY. HERE ARE THE STANDARDS WE EXPECT. AND IT'S UP TO YOU TO SHOW US THAT WHAT YOU'RE DOING MEETS THESE STANDARDS OR ITS EQUIVALENT.

DR. EGGAN: I'M COMFORTABLE WITH THAT.

DR. HALL: SO IT DOESN'T CEDE OUR AUTHORITY TO SAY WHAT THE STANDARDS ARE OR TO SAY THAT YOU HAVEN'T MET THE STANDARDS. THAT ABSOLUTELY IS NOT THE CASE, BUT IT RELIEVES US OF THE WORKING BURDEN OF PROOF. THAT'S WHAT I'M TRYING TO DO.

MR. KLEIN: SO TO MAINTAIN THE FLEXIBILITY THAT KEVIN AND YOU WERE JUST REFERRING TO, IT WOULD BE EQUIVALENCY AS DETERMINED BY THE ESCRO OR THIS COMMITTEE OR A BODY SET UP BY THIS COMMITTEE.

DR. HALL: WELL, I THINK FOR THE INTERIM, I THINK MY SUGGESTION IS THAT WILL -- I SUGGEST IT WILL REQUIRE A LONGER DISCUSSION AMONG US ABOUT HOW THAT

SHOULD BE DONE. BUT I WOULD JUST SAY FOR THE INTERIM, IF WE JUST SAY THAT IT REQUIRES IT TO DO THAT, OTHER PARTS OF THIS DOCUMENT -- I'LL HAVE TO LOOK IT UP TO FIND IT -- BUT OTHER PARTS OF THIS DOCUMENT SAY, I THINK, THAT IT IS ONE OF THE JOBS OF THE ESCRO COMMITTEE TO DO THAT.

CO-CHAIR LO: WELL, IS THIS A PLACE WHERE SOME AMBIGUITY IN THE REGULATIONS, IN THE INTERIM GUIDELINES MAY BE HELPFUL AS OPPOSED TO TRYING TO BE TOO SPECIFIC NOW FOR SOMETHING THAT MAY NOT COME UP? JUST A GENERAL QUESTION.

MR. KLEIN: WHAT WOULD HAPPEN HERE IS THAT IF YOU GIVE YOURSELF THE FLEXIBILITY NOW, YOU CAN SAY EQUIVALENCY AS DETERMINED BY THE ESCRO COMMITTEE OR THIS COMMITTEE OR A GROUP SET UP BY THIS COMMITTEE. THEN IN THESE REGULATIONS YOU CAN SAY AT THIS POINT THE ESCRO COMMITTEE DOES IT, BUT YOU LEAVE IN THE -- YOU'VE THEN AUTHORIZED YOURSELF AT A FUTURE TIME, IF YOU WANT TO SET UP A STATEWIDE BODY OR YOU WANT TO MAKE THE DECISION THROUGH THIS COMMITTEE, YOU'VE GOT THE AUTHORITY THAT'S ALREADY GONE THROUGH THE ADMINISTRATIVE PROCEDURES ACT.

DR. HALL: I WOULD ARGUE THAT FOR THE NINE MONTHS WE OUGHT TO DO THIS, AND THEN WE HAVE A DISCUSSION. JUST TO LEAVE IT TO THE ESCRO COMMITTEE,

AND THEN WE HAVE A DISCUSSION LATER ABOUT THE RIGHT WAY TO DO IT, AND MAYBE THE DOCUMENT WE PRESENT ON NOVEMBER 1ST WOULD OFFER EITHER THESE THREE ALTERNATIVES OR ONE OF THEM OR WHATEVER, BUT I THINK -- I GUESS MY POINT IS WE'VE GOT ENOUGH TO DO. I THINK IF SOMEBODY COMES AND SAYS TO US WHICH OF THOSE SHOULD WE DO, I THINK WE SHOULD JUST SAY ESCRO. IN THE NEXT NINE MONTHS, WE CAN CHANGE IT.

CO-CHAIR LO: LET ME TRY AND SEPARATE. THERE ARE A NUMBER OF ISSUES HERE. ONE IS WHAT SLIDES ARE WE GOING TO ACCEPT RIGHT OFF THE BAT? THE PROPOSAL WAS NIH AND QUESTION THE HFEA OR UK STEM CELL BANK. I'D LIKE TO SEPARATE THAT OUT JUST SORT OF LOGISTICALLY FROM THE VERY IMPORTANT QUESTION OF EQUIVALENT STANDARDS, AND DO WE WANT TO PUT IN A PROVISION ABOUT EQUIVALENT STANDARDS. AND THEN BEYOND THAT, DO WE WANT TO SPECIFY WHO DETERMINES EQUIVALENCY STANDARDS, AND SHOULD IT BE THE ESCRO FOR THE NEXT NINE MONTHS AND INTERIM GUIDELINES, OR DO WE WANT TO ADOPT BOB'S PROPOSAL, WHICH IS ESCRO OR CIRM OR SOMETHING ELSE.

LET'S TRY AND TACKLE THIS ONE AT A TIME. I THINK THEY'RE INDEPENDENT CHOICES. ALTA ACTUALLY HAS INFORMATION ON WHAT --

MS. CHARO: PEOPLE WANTED TO KNOW WHAT THE UK STANDARD IS. SO IT TURNS OUT THAT THE STANDARDS ARE

EMBODIED IN THE APPLICATION THAT YOU FILE TO DEPOSIT CELL LINES WITH THE UK STEM CELL BANK. I'LL BE HAPPY TO FORWARD THIS.

LIKE THE NIH, IT DOES NOT EXPLICITLY REQUIRE CONSENT FROM WHAT WOULD ORDINARILY BE AN ANONYMOUS EGG OR SPERM DONOR WHO WAS INVOLVED IN WHAT STARTED OUT AS A REPRODUCTIVE ENTERPRISE. SO THERE WILL BE UNCERTAINTY, I PREDICT.

THEY DO, ON THE OTHER HAND, HAVE FAIRLY EXTENSIVE AND DETAILED QUESTIONS ABOUT OTHER ASPECTS OF THE CONSENTING PROCESS AND SOME RULES THAT, INTERESTINGLY, GO BEYOND OURS THAT ARE IMPLICATED IN SOME OF THE THINGS LATER IN OUR OWN DISCUSSION ABOUT DONOR CONTROL OVER THE USE OF THEIR CELL LINES.

THE OTHER THING THAT'S INTERESTING ABOUT THE UK STEM CELL BANK IS THAT THEY WILL AUTOMATICALLY ACCEPT ANYTHING THAT WAS ON THE NIH-APPROVED LIST. SO THERE'S A KIND OF A SNAKE SWALLOWING ITS TAIL THING GOING ON HERE. UNLESS THIS GROUP RIGHT NOW AT THE OUTSET WANTS TO DRAW A LINE IN THE SAND ABOUT THE NEED FOR CONSENT FROM ANONYMOUS SPERM DONORS BACK IN THE PAST; THAT IS, RETROACTIVE APPLICATION IF ONE OF THEM WERE CONTROVERSIAL AND SOMEWHAT KIND OF TANGENTIAL NAS RECOMMENDATIONS, EXCEPT FOR THAT, IT WOULD SEEM THAT THERE WOULD BE LITTLE PROBLEM IN TAKING THE

NIH-APPROVED LINES AND UK STEM CELL BANK LINES, GRANDFATHERING THEM IN IN TERMS OF DOCUMENTATION REQUIREMENTS, AND THEN LEAVING TOTALLY SEPARATE, AS BERNIE WAS SUGGESTING, THE DISCUSSION ABOUT HOW TO SUBSTANTIVELY AND PROCEDURALLY MANAGE THE QUESTION OF EQUIVALENCY AS WE TRY TO INCREASE THIS LIST BEYOND JUST THOSE TWO SOURCES.

DR. KIESSLING: SPERM AND EGG DONORS.

MS. CHARO: SPERM AND EGG DONORS WHAT?

DR. KIESSLING: THE CONSENT DOESN'T JUST APPLY TO SPERM DONORS. IT'S ALSO TO ANONYMOUS EGG DONORS.

MS. CHARO: RIGHT. THE QUESTION IS -- I'M JUST USING IT AS THE MOST TYPICAL EXAMPLE. MOST IVF EMBRYOS, THE MOST TYPICAL EXAMPLE THAT WE DISCOVERED IS ONE WHERE THERE WAS AN ANONYMOUS SPERM DONOR THAT WAS FAR MORE COMMON. WE FOUND THAT IN ABOUT 10 PERCENT OF THE CASES, THE EMBRYOS THAT ARE FROZEN AND AVAILABLE FOR RESEARCH PROBABLY INVOLVE THE USE OF AN ANONYMOUS SPERM DONOR.

DR. CIBELLI: I WANT TO SAY THAT I AGREE THAT WE HAVE TO MOVE ON AND KEEP THINGS A LITTLE BIT GENERAL. LEAVING THIS TO THE REGIONAL OR LOCAL ESCRO'S COULD BE A PROBLEM BECAUSE WE DON'T KNOW HOW THESE ESCRO'S ARE GOING TO -- WHAT KIND OF BYLAWS THEY'RE

GOING TO HAVE ON HOW THEY'RE GOING TO OPERATE. SO YOU MAY END UP IN A SITUATION WHERE YOU DEVELOP A CELL LINE IN SACRAMENTO IT'S EASIER TO GET IT APPROVED THAN IF YOU DEVELOPED THAT IN SAN DIEGO. SO AT SOME POINT WE AS A COMMITTEE WILL HAVE TO HAVE THE STANDARDS.

DR. HALL: I THINK AS I POINTED OUT LAST TIME, I THINK ONE OF THE ROLES THAT, IN FACT, WE, CIRM, CAN PLAY IS IN COORDINATING THE ACTIVITIES OF THE ESCRO COMMITTEES AT THE VARIOUS PLACES TO BE SURE THAT, IN FACT, THEY'RE EQUIVALENT CELL LINES. I THINK -- I DON'T SEE HIM NOW. SOMEONE WAS HERE FROM THE FACULTY AT UCLA MIGHT WANT TO COMMENT, SOMEBODY WHO IS ON THE FRONT LINES OF THIS. BUT I THINK IT IS EVERYBODY'S CONCERNS IN GENERAL TO HAVE STANDARDS -- TO HAVE COMMON BEST PRACTICES AND INTERPRETATIONS. AND SO ALTHOUGH I THINK THERE IS SOME DANGER OF THAT, I DON'T THINK THERE'S VERY MUCH.

I THINK THE INSTITUTIONS, BY THE WAY, BECAUSE OF THE SENSITIVITY OF THE SUBJECT, ARE GOING TO BE VERY SERIOUS ABOUT THEIR ESCRO RESPONSIBILITIES. WE ALREADY HEARD FROM BERNIE AT UCSF. SO I THINK FOR THE INTERIM TO REFER IT TO THE ESCRO'S IS -- MY FEELING IS THAT'S THE BEST SOLUTION.

DR. CIBELLI: FOR CLARIFICATION ALSO, WE'RE TALKING ABOUT FUNDING, NOT BANKING.

DR. HALL: NO. NO. WE CAN ONLY SPEAK, WE CAN ONLY PRONOUNCE ON WHAT WE FUND. WE CAN'T SAY -- THE INDIVIDUAL -- HOWEVER, AT EACH INSTITUTION, AND THIS WAS A QUESTION THAT CAME UP IN OUR DISCUSSION LAST TIME, AND I THINK KEVIN MADE THIS POINT, INSTITUTIONS WILL NOT ONLY HAVE CIRM-FUNDED RESEARCH, BUT OTHER RESEARCH ON HUMAN EMBRYONIC STEM CELLS THAT THEY ARE RESPONSIBLE FOR. AND, OF COURSE, THEIR CONCERN IS THAT THERE BE EQUIVALENT STANDARDS ACROSS THAT. WE DON'T WANT TO HAVE UCLA, FOR EXAMPLE, TO HAVE CIRM STEM CELL WORK ON ONE STANDARD AND THEN BE ABLE TO DO SOMETHING WITH PRIVATE FUNDS THAT'S MUCH LESS.

SO ALL OF THAT, I THINK, IS A PROBLEM TO BE WORKED OUT, BUT ALL I'M POINTING OUT IS THAT I THINK INSTITUTIONS HAVE A VERY HEAVY INVESTMENT IN DOING THIS RIGHT. WE CAN SAY TO THEM WHAT WE EXPECT, AND I THINK THEY WILL TRY TO MATCH THAT. AND, OF COURSE, WE HAVE A VERY BIG STICK IN THE END, WHICH IS OUR FUNDING.

CO-CHAIR LO: LET ME AGAIN TRY TO HOPEFULLY HELP US WORK TOWARDS RESOLUTION BY ASKING US TO SEPARATE THE ISSUES. LET'S FIRST TRY AND DECIDE ARE WE GOING TO SORT OF GRANDFATHER IN NIH, HFEA, AND UK STEM CELL LINES? AND ONCE WE'VE DECIDED THAT, THEN LET'S GET TO, I THINK IT'S ACTUALLY A MORE COMPLICATED QUESTION FOR THE INTERIM GUIDELINES, WHAT WE WANT TO DO

ABOUT EQUIVALENT STANDARDS. BUT IF IT'S OKAY WITH YOU, I'D LIKE TO SORT OF ADDRESS THE NIH AND UK DOCUMENTS FIRST.

DR. EGGAN: SO I THINK WE SHOULD GRANDFATHER THOSE IN BECAUSE IF WE DON'T, NOTHING IS GOING TO GET DONE BY THE SCIENTISTS FOR ANOTHER NINE MONTHS ANYWAY. IT TAKES SO LONG FOR THEM TO GATHER THOSE DOCUMENTS AND GET THEM TO THE ESCRO'S, THAT IF WE DON'T TAKE ALTA'S ADVICE, IT'S NOT GOING TO MATTER. I AGREE THAT WE SHOULD SEPARATE THEM AND THAT WE SHOULD ADOPT, WE SHOULD GRANDFATHER IN THE LINES FROM NIH AND FROM THE UK ACT AND THE STEM CELL BANK, AND THEN LEAVE THESE OTHER ISSUES FOR LATER.

CO-CHAIR LO: LET'S DO THAT. LET'S TRY AND RESOLVE THAT ONE FIRST.

DR. KIESSLING: I THINK THE BASIC QUESTION HERE IS FOR MOST OF THE CELL LINES THAT ARE ALREADY BANKED, AND THIS IS TRUE OF THE UK AS WELL AS HERE, THE CONSENT BY THE ANONYMOUS DONORS, EITHER EGG OR SPERM, IS PROBLEMATIC BECAUSE EVEN IF THEY WERE CONSENTED THAT THEY COULD USE ANYTHING RESULTING FOR RESEARCH, IT WASN'T NECESSARILY STEM CELL RESEARCH. SO I THINK THE CHARGE TO THIS COMMITTEE IS TO DECIDE IF WE ARE WILLING TO ALLOW CALIFORNIA FUNDING FOR CELL LINES THAT ARE DEPOSITED THAT HAVE BEEN APPROVED BY BOTH THE NIH AND

THE UK LICENSING BOARD FROM PEOPLE WHO DID NOT CONSENT TO HAVE THEIR GAMETES USED FOR STEM CELL RESEARCH.

I THINK IT'S A PRETTY SMALL PERCENTAGE OF LINES THAT ARE BANKED; BUT I THINK IF WE ARE GOING TO GRANDFATHER THESE LINES IN, WE HAVE TO ACCEPT THAT WE'RE GRANDFATHERING IN SOME AMBIGUITY FOR THE ANONYMOUS DONORS WITH RESPECT TO THE OUTCOME OF THEIR DONATION.

DR. KORDOWER: ARE THERE ANY PARTICULAR ITEMS THAT THEY HAVE EXCLUDED? HAVE THEY SAID YOU CAN'T USE IT FOR OTHER RESEARCH?

DR. KIESSLING: THE WAY -- THIS IS SO HISTORIC, THAT THE WAY THIS HAS WORKED OUT, SOMEBODY DONATED THEIR EGGS OR THEIR SPERM FOR INFERTILITY. THAT WAS -- MOST INFERTILITY CLINICS HAVE IN PLACE THAT IT'S POSSIBLE IF THESE EMBRYOS ARE NOT GOING TO BE USED FOR FAMILY BUILDING, THAT THEY WILL BE DONATED FOR RESEARCH. NOBODY -- ALMOST NO CONSENT FORMS PRIOR TO LIKE THREE OR FOUR YEARS AGO HAD IN THERE THAT THE RESEARCH WAS GOING TO BE STEM CELL RESEARCH. SO THIS IS A GRAY AREA THAT ENCOMPASSES ALMOST ALL, BUT I THINK IT'S A FAIRLY SMALL PERCENTAGE OF THESE LINES THAT ACTUALLY HAVE BEEN DERIVED FROM ANONYMOUS DONORS.

THE LINES THAT HAVE BEEN DERIVED FROM COUPLES, I THINK THE CONSENTING PROCESS, THEY'VE GONE

BACK TO THOSE COUPLES, AND I THINK THAT THOSE PEOPLE CONSENTED. I THINK THAT'S PRETTY CLEAR. SO IF WE'RE WILLING TO LIVE WITH AMBIGUITY FOR THE SMALL PERCENTAGE OF THESE LINES THAT CAME FROM ANONYMOUS DONORS THAT DID NOT GIVE CONSENT, AND THERE'S PROBABLY NO WAY TO GET THIS, GIVE CONSENT FOR STEM CELL RESEARCH, THEN WE'RE FINE. IF WE'RE UNCOMFORTABLE WITH THAT, THEN WE MAY NEED TO FIND OUT WHICH LINES ARE FROM ANONYMOUS DONORS.

CO-CHAIR LO: LET ME JUST SAY THAT THE NIH PROCESS IS A PUBLIC GOVERNMENTAL PROCESS. I THINK THERE WAS A POLICY DECISION MADE AT NIH AND BY THE ADMINISTRATION TO ALLOW THOSE LINES TO BE USED FOR RESEARCH. SO IN A SENSE THERE'S SOME PRECEDENT FOR SAYING THAT IN LIGHT OF THIS AMBIGUITY, GIVEN THAT THE LINES WERE DERIVED AT A HISTORICAL POINT IN TIME, THAT THE PROCESS WAS DEEMED ACCEPTABLE BY THE FEDERAL GOVERNMENT.

DR. EGGAN: I WONDER IF HFEA HAS ALSO SPECIFICALLY TAKEN UP THIS QUESTION. DO YOU KNOW, ALTA?

MS. CHARO: THAT'S WHAT I WAS SAYING. THE APPLICATION TO DEPOSIT CELL LINES INTO THE UK STEM CELL BANK IS BASICALLY AN APPLICATION THAT SAYS DID YOU DERIVE THESE UNDER AN HFEA LICENSE? OKAY, FINE. IF NOT, CAN YOU PROVE THAT YOU MET EQUIVALENT STANDARDS TO

HFEA? SEE, EVERYBODY IS DOING THE SAME THING. EVERYBODY IS PLAYING THE EQUIVALENCY GAME. AND THEN IN THEIR OWN SET OF QUESTIONS TO DETERMINE EQUIVALENCY, ALL I CAN TELL YOU IS THAT THEY OMITTED ANY QUESTION ABOUT SPECIFICALLY OBTAINING CONSENT FROM BACKGROUND PROBABLY ANONYMOUS EGG AND SPERM DONORS, WHICH SUGGESTS THEY DID NOT SEE IT AS AN ABSOLUTELY CRUCIAL ELEMENT IN MAKING THE DERIVATION PROCESS ETHICALLY EQUIVALENT TO THE ONE THAT IS USED IN THE UK.

THE UK HAS HAD ANONYMOUS DONATION OF GAMETES UP UNTIL 2004, SO THE EMBRYO SUPPLY THEY WOULD HAVE BEEN WORKING WITH LOCALLY FOR THEIR OWN DERIVATIONS WOULD HAVE INCLUDED ANONYMOUS DONORS. SINCE 2004, THEY HAVE INSTITUTED A RECORDKEEPING PRACTICE THAT ALLOWS PEOPLE TO GO BACK TO THE DONORS IN A REPRODUCTIVE CONTEXT WITH ALL SORTS OF PROTECTIONS, ETC., BUT IT MEANS THEORETICALLY THEY COULD CHANGE THEIR POLICY, BUT ONLY PROSPECTIVELY, RIGHT, ONCE THEY ARE USING ONLY SOURCES OF GAMETES THAT WERE COLLECTED POST 2004 UNDER THE NEW REGIME.

AND THAT'S PRETTY MUCH WHERE THE NAS WAS KIND OF COMING FROM TOO; THAT IS, PROSPECTIVELY LET'S NOT -- LET'S START ASKING SPERM DONORS AND EGG DONORS IF THEY WANT TO ALLOW FOR SUBSEQUENT RESEARCH USE OF UNUSED EMBRYOS. NOBODY HAS COMMITTED A FRAUD AGAINST THESE

ANONYMOUS DONORS. NOBODY ACTUALLY TOOK THEIR GAMETES AND THEN DIVERTED THEM AWAY FOR REPRODUCTIVE PURPOSES. THEY WERE ALL USED IN AN ATTEMPT AT A REPRODUCTIVE PURPOSE. THERE'S BEEN AN ABANDONMENT OF THE ATTEMPT FOR SINCERE REASONS, AND NOW IT IS ABOUT WHAT YOU DO WITH THE DISCARDED MATERIAL. IT'S ALMOST LIKE THE QUESTION OF WHAT YOU CAN DO WITH -- I'M ALMOST SCARED TO SAY THIS. I'M ON A TRANSCRIPT. MAYBE I WON'T SAY IT -- BUT THERE ARE LOTS OF THINGS THAT WE DISCARD, AND WE LOSE CONTROL AT A CERTAIN POINT OF WHAT WE DISCARD.

DR. WILLERSON: I DON'T KNOW IF IT'S GOING TO HELP OR NOT, BUT WE COULD GRANDFATHER THOSE CELL LINES THAT WERE APPROVED FOR HUMAN RESEARCH OR CELL-BASED RESEARCH WHERE THAT WAS SPECIFICALLY PROVIDED OR WHERE STEM CELL RESEARCH OR CELL-BASED RESEARCH WAS NOT SPECIFICALLY EXCLUDED. THAT WOULD BE ONE WAY TO DO THIS. I THINK WE SHOULD GRANDFATHER THESE CELLS.

MS. CHARO: BY THE WAY, FOR THE UK, THEY WILL NOT PERMIT THE DEPOSIT OF ANY LINE IN WHICH THE DONORS HAVE ANY CONTROL OVER THE SUBSEQUENT NATURE OF THE RESEARCH. SO THERE COULDN'T HAVE BEEN ANY EXCLUSIONS ATTACHED TO ANY OF THOSE LINES BECAUSE THEY WON'T ACCEPT THE LINE TO BEGIN WITH IF THE DONORS TRY TO EXERCISE THAT DEGREE OF CONTROL.

DR. WILLERSON: BUT IF WE'RE FAIRLY SPECIFIC

ABOUT THAT, WE CAN STAY ON THE SAME GROUND, I THINK.

MR. KLEIN: AS I UNDERSTAND IT, OUR QUESTION POSED AT THE MOMENT IS WHETHER WE'RE GOING TO GRANDFATHER THE NIH LINES, IS IT THE HARVARD LINES AND THE ENGLISH STEM CELL BANK?

DR. EGGAN: WELL, THE MELTON LINES ARE IN THE PROCESS OR ALREADY ARE DEPOSITED IN THE UK STEM CELL BANK.

MR. KLEIN: I'D LIKE TO MAKE A MOTION TO APPROVE THE GRANDFATHERING OF THE NIH AND LINES DEPOSITED IN THE ENGLISH STEM CELL BANK.

DR. OLDEN: I'D SECOND THAT MOTION.

CO-CHAIR LO: ANY FURTHER DISCUSSION OF THIS? ANY PUBLIC COMMENT ON THIS? OKAY. STEVE, WHY DON'T YOU FORMALLY INTRODUCE YOURSELF TO THE COMMITTEE.

MR. PECKMAN: GOOD MORNING. I'M STEVE PECKMAN -- WELL, ACTUALLY IT'S AFTERNOON NOW -- WITH UCLA INSTITUTE FOR STEM CELL BIOLOGY AND MEDICINE, FORMERLY ASSOCIATE DIRECTOR OF THE UCLA IRB PROGRAM.

AND I THINK THIS HAS BEEN A VERY IMPORTANT DISCUSSION, BUT I'M A LITTLE CONFUSED AS A MEMBER OF THE PUBLIC AS EXACTLY WHAT IT IS YOU'RE GRANDFATHERING AND HOW YOU ARE GOING TO DO IT.

IF THE QUESTION IS AS ALTA CHARO ORIGINALLY POSITED, WHICH WAS THAT THERE ARE CERTAIN CELLS IN

BANKS OR CELL LINES IN BANKS FOR WHICH IT WOULD NOT BE NECESSARY FOR AN INVESTIGATOR TO FORWARD A 3-INCH BINDER WORTH OF DOCUMENTATION TO AN IRB OR AN ESCRO, THAT WOULD SEEM VERY APPROPRIATE. HOWEVER, THERE'S BEEN A LOT OF DISCUSSION ABOUT EQUIVALENCY AND OTHER THINGS THROWN INTO THE BARREL HERE WHICH TEND TO DIVERT FROM THAT ONE VERY SPECIFIC TOPIC. I WOULD HOPE THAT YOU WOULD FOCUS WHATEVER MOTION YOU'RE GOING TO HAVE SPECIFICALLY ON THE TOPIC OF THE DOCUMENTATION AN INVESTIGATOR WHO WANTS TO USE LINES FROM A SPECIFIC BANK NEEDS TO FORWARD TO A REVIEW COMMITTEE.

CO-CHAIR LO: YES. THAT WAS MY UNDERSTANDING OF MR. KLEIN'S MOTION.

MR. KLEIN: THE MOTION IS SPECIFICALLY, AS THE QUESTION SEGMENTED BY DR. BERNARD LO, THAT THESE NIH-APPROVED LINES AND LINES APPROVED FOR THE ENGLISH STEM CELL BANK WOULD BE EXEMPTED FROM THE DOCUMENTATION REQUIREMENT. AND THEN THERE'S GOING TO BE A SEPARATE DISCUSSION OF THE EQUIVALENCY ISSUE.

CO-CHAIR LO: YES. ANOTHER PUBLIC COMMENT.

MR. REED: I HAVE A PUBLIC COMMENT. I'M JUST A LITTLE FRIGHTENED OF LAWSUITS. AND IS THERE ANY WAY THAT OPPONENTS OF THE RESEARCH COULD SAY -- THEY FIND SOMEONE WHO SAYS, "OH, I WANTED MY GAMETES TO BE USED ONLY FOR MAKING BABIES. I HAD NO IDEA USED THAT THEY

WERE GOING TO BE THIS WAY." IS THERE A LEGAL THREAT THAT WE COULD BE HARMED BY THIS?

MR. PECKMAN: I'D LIKE TO REMIND EVERYONE THAT THE NIH STEM CELLS, APPROVED STEM CELLS AT NIH, SUPPOSEDLY ALREADY MEET THE CRITERIA SET FORWARD BY PRESIDENT BUSH IN HIS AUGUST SPEECH OF, I BELIEVE IT WAS, 2001, WHICH REQUIRED THERE BE CONSENT FOR RESEARCH FOR THE USE OF THOSE CELLS. ACKNOWLEDGING WHAT BERNIE'S POSITION WAS AT UCSF, THAT IT MAY BE DIFFICULT FINDING SUCH DOCUMENTATION, IT'S SOMETHING OUR OWN FEDERAL GOVERNMENT HAS ALREADY SAID MEETS THOSE STANDARDS.

MS. CHARO: STEVE, THE NIH REQUIRED CONSENT FROM THE PEOPLE WHO WERE, IN A SENSE, THE, QUOTE, UNQUOTE, OWNERS OF THE EMBRYOS. BUT IN MANY CASES, IF THAT WAS A COUPLE, THERE MIGHT BE IN THE BACKGROUND AN ANONYMOUS SPERM OR EGG DONOR THAT WAS NOT CONSENTED. AND THE NIH DID NOT REQUIRE THAT BACKGROUND THIRD PARTY TO BE CONTACTED. IN MANY CASES IT WOULD HAVE BEEN IMPOSSIBLE.

SO BERNIE'S RIGHT. IT'S NOT JUST THAT THE DOCUMENTATION IS LACKING. IT'S THAT THERE'S GENUINE UNCERTAINTY. WE'RE NOT REALLY SURE WHICH, IF ANY, OF THE EMBRYOS FROM WHICH THOSE NIH-APPROVED LINES WERE DERIVED ACTUALLY INVOLVED AN ANONYMOUS GAMETE DONOR.

WE JUST DON'T KNOW.

MR. PECKMAN: WE'RE INTO A TERRITORY WHICH IS EQUIVALENT TO ANY STORED TISSUE THAT'S IN A REFRIGERATOR OR REPOSITORY OR BANK ANYWHERE IN THIS WORLD WHERE A PATIENT HAS HAD TISSUE EXTRACTED THAT MAY BE USED FOR FUTURE RESEARCH. TO ME IT'S HARD TO DIFFERENTIATE BETWEEN THE TWO.

MR. REED: IS THERE A WAY THAT WE COULD SAY THAT INSOFAR AS LEGAL PRECEDENT HAS BEEN ESTABLISHED, THAT THE UNITED STATES HAS DETERMINED THAT THESE MAY BE USED FOR RESEARCH THAT WE COULD DO SO? BUT IF THERE IS CHANGE IN THAT, THAT --

MR. KLEIN: WE'RE GOING THE DIRECTION OF CREATING MORE LEGAL PROBLEMS. THIS IS -- WE'RE CREATING HERE A PROCESS THAT WOULD GO THROUGH THE ADMINISTRATIVE PROCEDURES ACT AND BE ADOPTED. IT GIVES US THE BEST LEGAL PROTECTION THERE IS. IT IS NOT FOOLPROOF, BUT IT IS THE BEST SYSTEM WE CAN USE. AND THIS ACTUALLY, BY EXEMPTING THESE LINES FROM DOCUMENTATION, WOULD AVOID LEGAL CONTEST OVER THAT DOCUMENTATION.

CO-CHAIR LO: SO SHALL WE CALL THE QUESTION ON MR. KLEIN'S MOTION TO EXEMPT THE NIH, HFEA, AND UK STEM CELL BANK LINES FROM THE DOCUMENTATION REQUIREMENTS? ALL THOSE IN FAVOR. ANY OPPOSED? SO

THAT'S CARRIED UNANIMOUSLY.

NOW WE HAVE A POINT WHERE WE CAN GO ON WITH THIS DISCUSSION, AND I THINK THE NEXT ISSUE WOULD BE THE EQUIVALENCY STANDARDS WITH REGARD TO THE INTERIM GUIDELINES, OR IT'S, AS SOMEBODY POINTED OUT, IT'S ALREADY AFTER 12. I DON'T KNOW WHEN THE TIME FOR LUNCH IS.

MS. CHARO: BERNIE, MAY I ALSO OFFER A THIRD OPTION. VERY QUICK QUESTION. MAYBE IT WON'T TAKE LONG. IS IT POSSIBLE TO FIND OUT WHY THERE WAS A SECTION THAT SPECIFICALLY SAID THAT THE ESCRO CANNOT BE A SUBCOMMITTEE OF AN IRB? THAT WAS IN THE -- AND IF YOU THINK THAT'S GOING TO BE A LONG DISCUSSION, THEN THAT WOULD BE ON THE LIST OF THINGS YOU MIGHT TO DO AFTER LUNCH. IF IT WERE AN EASY QUICK ONE, IT MIGHT BE ONE WE CAN JUST GET OUT OF THE WAY BEFORE A LONG DISCUSSION ABOUT EQUIVALENCY.

CO-CHAIR LO: I'VE BEEN CRITICIZED FOR CHAIRING OTHER MEETINGS THAT DID NOT ALLOW APPROPRIATE BREAKS. SO I'M VERY SENSITIVE OF THE PHYSICAL NEEDS OF OUR HARDWORKING COMMITTEE. IS THERE ANYONE WHO REALLY WANTS US TO SORT TO GO AHEAD AND TRY AND DO MORE BUSINESS BEFORE LUNCH? OTHERWISE, I THINK MAYBE WE'LL START WITH ALTA'S QUESTION AFTER LUNCH TO GET US ROLLING AFTER OUR NOON BREAK. TAKE A LITTLE BREAK. I

THINK WE'VE HAD A PRODUCTIVE COUPLE HOURS THIS MORNING. LET'S GET SOME FOOD.

DR. HALL: COULD I ASK THAT WE JUST GET A SUMMARY OF WHERE WE ARE MAYBE FROM KATE OR OTHERS? WE MADE THE CHANGES ORIGINALLY SUGGESTED BY -- THROUGH THE DISCUSSION OF JAMES HARRISON; THAT IS, WE CHANGED "AND" TO "OR," AND WE INSERTED ANY OTHER SOURCE OR BY ANY OTHER PROCEDURE, AND WE ELIMINATED THAT ONE THAT SAYS NUMBER 00(B)(3). SO THAT WAS DONE. RIGHT? AND --

CO-CHAIR LO: SO WE CLARIFIED THE SCOPE OF TO WHOM THESE REGULATIONS APPLY THROUGH JAMES.

DR. HALL: TO WHICH LINES. AND THEN THE OTHER -- IS THIS THE ONLY OTHER CHANGE THAT'S BEEN MADE?

AND THEN THE QUESTIONS TO BE ADDRESSED AFTER LUNCH WOULD INCLUDE EQUIVALENCE.

CO-CHAIR LO: ALTA'S QUESTION ABOUT MAY THE ESCRO BE A SUBCOMMITTEE OF THE IRB. AND, AGAIN, THOSE WILL BE DISCUSSED IN THE CONTEXT FIRST OF THE INTERIM GUIDELINES.

DR. HALL: THE INTERIM. THE AIM IS TO GET THE INTERIM GUIDELINES.

CO-CHAIR LO: I THINK IT WOULD BE VERY IMPORTANT FOR US TO MAKE RECOMMENDATIONS ON THE INTERIM GUIDELINES AT TODAY'S MEETING. I'D LIKE TO GET TO

STUDY GROUP PROGRESS REPORTS JUST TO GET A SENSE OF WHAT ISSUES THEN WE NOW HAVEN'T ADDRESSED AS A WORKING GROUP GOING FORWARD TO THE DRAFT.

DR. HALL: OKAY. THAT SOUNDS GOOD.

CO-CHAIR LO: WE HAVE A LOT OF THINGS TO DO, SO I WANT YOU TO EAT WELL AND SORT OF RELAX AND COME BACK AND WORK HARD.

(A LUNCH RECESS WAS TAKEN.)

CO-CHAIR LO: GOOD AFTERNOON. WELCOME BACK. I'D LIKE TO RECONVENE US HERE FOR THE AFTERNOON SESSION OF OUR SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS WORKING GROUP. AS I SEE IT, OUR TASK AT HAND IN THE AFTERNOON IS TWOFOLD. FIRST, I THINK IT WOULD BE HIGHLY DESIRABLE FOR US TO COME TO CLOSURE ON INTERIM CIRM GUIDELINES IN ORDER TO MAKE A RECOMMENDATION TO THE ICOC SO THAT THEY CAN ADOPT AND, THEREFORE, START THE 270-DAY CLOCK RUNNING AND ALLOW THE PLANS FOR FUNDING OF TRAINING GRANTS TO PROCEED.

AGAIN, I WANT TO REMIND US THAT IF WE DO ADOPT INTERIM GUIDELINES TODAY, WE DO NOT NEED TO RESOLVE BIG IMPORTANT ISSUES. THOSE WE CAN ADDRESS LATER AS WE WORK ON DRAFT FINAL GUIDELINES WHICH WILL GO THROUGH AN EXTENSIVE PUBLIC REVIEW PROCESS. SO I THINK THAT ONE OF THE KEY SORT OF BACKGROUND CONTEXTUAL ISSUES WE NEED TO DEAL WITH IS WHAT DO WE NEED TO DO

THIS AFTERNOON TO APPROVE INTERIM CIRM GUIDELINES VERSUS WHAT ISSUES ARE WE REALLY FLAGGING TO COME BACK TO LATER OVER THE COURSE OF THE NEXT SEVERAL MONTHS AS WE DRAW UP DRAFT FINAL DOCUMENTS.

NOW, FROM THIS MORNING'S DISCUSSION, I THINK THERE WAS A CLEAR SENSE THAT AN ISSUE WE DID NEED TO TRY AND ADDRESS FOR THESE INTERIM GUIDELINES WAS THE ISSUE OF EQUIVALENT STANDARDS, THAT WE WANTED TO ADDRESS THE ISSUE OF HAVING SOME WAY OF ALLOWING ESCRO'S TO ALLOW RESEARCH TO BE DONE UNDER CIRM FUNDING, PRESUMING UNDER THESE TRAINING GRANT MECHANISMS, FOR STEM CELL LINES THAT WERE DERIVED PRIOR TO THE NAS GUIDELINES THAT WERE ISSUED IN MAY '05.

SO BOB KLEIN BEFORE LUNCH HAD MADE A PROPOSAL ABOUT EQUIVALENT STANDARDS, AND STRUCTURALLY THERE WERE TWO ISSUES. ONE, SHOULD WE PUT A PROVISION IN TO FOLLOW WHAT WE DECIDED BEFORE LUNCH ABOUT GRANDFATHERING IN NIH, HFEA, AND UK STEM CELL BANK GUIDELINES. DO WE ALSO ADD GUIDELINES DERIVED UNDER EQUIVALENT -- SOMETHING LIKE EQUIVALENT STANDARDS. AND IF WE AGREE TO THAT, THE ISSUE OF SHOULD WE SPECIFY WHO MAKES THAT DETERMINATION OF WHETHER IT'S EQUIVALENT.

DR. HALL: LET ME JUST MAKE A POINT, AND THAT IS I THINK IT'S OBVIOUS TO ALL OF US THAT ONE OF THE -- ACTUALLY ONE OF THE BIG CHALLENGES WE'LL FACE IN THIS

AREA OVER THE NEXT TWO MONTHS IN DISCUSSING WHAT THE FINAL RECOMMENDATION IS IS HOW TO HANDLE CELL LINES DERIVED IN DIFFERENT PLACES AND UNDER DIFFERENT STANDARDS, AND TO WHAT EXTENT SHOULD CIRM FUNDING -- WE CAN CERTAINLY MAKE STANDARDS FOR OUR OWN, AND HOW SHOULD WE HANDLE THE QUESTION OF WHETHER SCIENTISTS UNDER CIRM FUNDING CAN USE THESE OTHER LINES OR NOT.

AND I THINK -- LET ME JUST SAY THAT HOWEVER THAT COMES OUT, I THINK ALL OF US UNDERSTAND THAT IT WILL BE HARD TO HAVE VERY TIGHTLY PROSCRIBED STANDARDS AND SAY THESE ARE THE ONLY STANDARDS THAT WE ACCEPT BECAUSE I THINK THEN IT MAY BE VERY DIFFICULT FOR PEOPLE IN OTHER PLACES THAT MAY HAVE LEGITIMATE DIFFERENCES TO HAVE CELL LINES THAT WOULD BE ELIGIBLE FOR WORK HERE.

ON THE OTHER HAND, WE WILL NEED SOME MINIMAL LEVEL. SO I THINK THE QUESTION IS TO WHAT EXTENT WE ACCEPT -- WHAT AMOUNT OF DIFFERENCE WILL WE ACCEPT WILL BE A VERY DIFFICULT JOB FOR US TO WORK OUT, TO TALK ABOUT, AND TO FIGURE OUT.

IN THE MEANTIME WE DO HAVE THIS ISSUE OF NOT ONLY, BERNIE, NOT JUST CELL LINES THAT WERE DERIVED BEFORE THE NAS STANDARDS, BUT OF CELL LINES THAT ARE DERIVED EVEN UP UNTIL THESE STANDARDS GET ACCEPTED AS INTERIM STANDARDS OR IN THE INTERIM PERIOD. THAT IS,

HOW DO WE HANDLE CELL LINES DERIVED ALL THE WAY UP TO NEXT JUNE WHEN WE WILL HAVE OUR PERMANENT STANDARDS? AND THAT IS BASICALLY, I THINK, THE IMMEDIATE PROBLEM IS HOW TO GIVE OUR SCIENTISTS AS MUCH LATITUDE AS POSSIBLE TO WORK WITH HIGHLY DESIRABLE LINES THAT ARE BEING DEVELOPED NOW ALL OVER THE WORLD WITHOUT VIOLATING OUR OWN ETHICAL STANDARDS. AND WE DO NEED SOME WAY TO HANDLE THIS BETWEEN NOW AND JUNE.

MR. SHESTACK: ARE THERE REALLY A LARGE AMOUNT OF HIGHLY DESIRABLE CELL LINES FROM AROUND THE WORLD THAT WILL ULTIMATELY BE MADE AVAILABLE TO CIRM SCIENTISTS? DO WE KNOW THAT?

DR. HALL: ONE OF THE THINGS I LEARNED AT LUNCH WAS SOME OF THE RECENTLY DEVELOPED CELL LINES ARE ALREADY BEING USED IN THE UNITED STATES BY INVESTIGATORS. AND I'M SURE CALIFORNIA INVESTIGATORS WILL WANT TO USE THEM AS WELL.

MR. SHESTACK: THESE ARE LINES DEVELOPED IN WHAT COUNTRY?

DR. HALL: THE ONES I KNOW ABOUT ARE PREEMINENTLY SOUTH KOREA, ALSO --

MR. KLEIN: ISRAEL.

DR. HALL: -- ISRAEL. AUSTRALIAN CELL LINES, I DON'T KNOW -- THEY'RE CONTINUING TO DEVELOP THEM. I DON'T KNOW THAT ANY ARE CURRENTLY BEING USED HERE NOW.

I JUST DON'T KNOW THAT.

MR. KLEIN: SWEDISH.

DR. HALL: A NUMBER OF COUNTRIES ARE DOING THIS. SWEDEN, BRITAIN. I THINK THE ONE THAT'S ON EVERYBODY'S MIND IN PARTICULAR ARE THE SOUTH KOREAN LINES BECAUSE THEY ARE SO FAR ADVANCED WITH SCNT. THESE APPEAR TO BE, FROM WHAT I KNOW AND HAVE HEARD, DESIRABLE LINES.

MR. SHESTACK: AND THEY ARE MAKING THOSE AVAILABLE TO AMERICAN COLLABORATORS.

DR. HALL: THEY ARE MAKING THEM AVAILABLE APPARENTLY. SOME OF YOU MAY HAVE MORE INFORMATION ABOUT THIS.

MR. SHESTACK: COLLABORATORS OR PURCHASING THEM?

DR. HALL: I DON'T KNOW THE ANSWER TO THAT.

DR. KORDOWER: I KNOW COLLABORATORS IN PITTSBURGH ARE GETTING THOSE LINES.

DR. EGGAN: CERTAINLY WE'RE TRYING TO ESTABLISH A COOPERATIVE AGREEMENT WITH THEM TO GET THEIR LINES.

MR. SHESTACK: THAT'S SOMETHING I THINK WE ALL JUST WANT TO KNOW IS LIKE HOW MUCH ACTUAL, BEFORE WE COME INTO IT, HOW MUCH COOPERATION IS THERE ALREADY OUT THERE.

DR. HALL: I THINK THEIR SIGNALS TO US HAVE BEEN THAT THEY WANT TO SHARE THEIR CELL LINES. I DON'T THINK THAT'S GOING TO BE A PROBLEM.

DR. EGGAN: THIS IS A GENERAL PHENOMENON. MORE AND MORE GROUPS ARE BEGINNING TO DERIVE THEIR OWN LINES.

MS. CHARO: MORE AND MORE -- I'M SORRY.

DR. EGGAN: MORE AND MORE GROUPS ARE BEGINNING TO OR CONTINUE TO DERIVE THEIR OWN LINES. SO THIS IS NOT JUST LIMITED TO -- I MEAN, FOR INSTANCE, THE GROUP IN CHICAGO UNDER HERLINSKY HAS DERIVED A NUMBER OF LINES THAT WOULD BE OF GENERAL INTEREST.

MR. KLEIN: AS A, I THINK, KEVIN, THE PROPER NUMBER IS THAT THE INTERNATIONAL STEM CELL FORUM IS LOOKING AT CHARACTERIZING 75 LINES AT THIS TIME THAT HAVE BEEN INDIVIDUALLY IDENTIFIED AND ARE THOUGHT TO BE OF A VERY HIGH STANDARD, SO THEY'RE TRYING TO QUALIFY 75 LINES UNDER THEIR STANDARDS AND PROTOCOLS.

DR. HALL: DOES THAT INCLUDE THE SOUTH KOREAN LINES? DOES ANYBODY KNOW? THEY WERE NOT AT THE RECENT INTERNATIONAL FORUM MEETING IN BAR HARBOR, I KNOW. DOES THAT INCLUDE --

DR. EGGAN: I DON'T THINK THE 73 OR 75 LINES INCLUDE THE KOREAN LINES. THEY DO NOT.

DR. HALL: SO THAT --

MR. KLEIN: BUT KOREA IS ON THE LIST TO BE APPROVED AT THE NEXT INTERNATIONAL FORUM MEETING; IS THAT CORRECT, KEVIN?

DR. EGGAN: (NODS.)

DR. TAYLOR: I GUESS I HAVE A QUESTION A BIT ABOUT THE CONCERN FOR SORT OF A TWO-TIERED CELL LINE SUPPLY. MY FEELING IS THAT TO GO FORWARD, AND WE HAVE A GREAT OPPORTUNITY TO DO THAT HERE IN THIS PROGRAM, WITH CELL LINES WITH CELLS THAT HAVE NOT ONLY BEEN SORT OF OBTAINED WITH ALL OF THE DOCUMENTATION AND CONSENT, BUT ALSO THE ABILITY TO SORT OF TRACK THE DONORS INTO THE FUTURE. AND TO HAVE THERAPEUTICALLY VALUABLE LINES, I THINK THAT'S GOING TO BE THE WHOLE DEAL.

SO IF WE CAN CREATE A SYSTEM WHERE WE'VE GRANDFATHERED IN CELLS THAT ARE OF VERY HIGH QUALITY AND PROBABLY WONDERFUL CELLS TO STUDY, BUT NOT NECESSARILY THE KINDS OF CELLS WE'D WANT TO USE THERAPEUTICALLY, ARE WE SORT OF PAINTING OURSELVES INTO A BIT OF A CORNER BY HAVING THIS KIND OF POTENTIALLY, I WOULD PREDICT, WOULD BE A BIT OF TWO CLASSES OF CELLS, ONE THAT ARE HIGH QUALITY THAT WE CAN LEARN A LOT FROM, BUT MIGHT NOT BE THE WAY WE WANT TO HAVE CELLS DERIVED GOING FORWARD IN THE PROGRAM. IF PEOPLE FEEL COMFORTABLE THAT THAT'S NOT A CONFLICT --

DR. HALL: REMEMBER, WE'RE TALKING ABOUT NINE

MONTHS HERE. WE'RE TALKING ABOUT STANDARDS FOR THE NEXT NINE MONTHS. WE WILL THEN SEPARATELY ADDRESS THE QUESTION OF HOW WE WANT TO --

DR. TAYLOR: DIDN'T WE SAY BEFORE THIS, THOUGH, THAT GRANDFATHERED CELLS WOULD BE IN THE POT, RIGHT? SO I SEE THIS AS REALLY MORE THAN NINE MONTHS. IT'S A WAY TO GET US THROUGH THE NINE MONTHS.

DR. HALL: I GUESS MY THOUGHT ABOUT THAT WAS THAT IT'S UNLIKELY THAT WE WILL HAVE CLINICAL TRIALS COMING THROUGH BEFORE THESE ARE DONE. AT A SUBSEQUENT TIME, IF SOMEBODY PUTS IN A GRANT FOR A CLINICAL TRIAL, I THINK FOR THEM TO SAY, OH, NO, THIS IS A CELL LINE THAT WAS APPROVED A LONG TIME AGO, I THINK THAT IT HAS -- IT WILL HAVE TO MEET THE NEW STANDARDS.

MR. SHESTACK: THE QUESTION IS IS IT -- OBVIOUSLY YOU WANT TO GET WORK DONE NOW. THERE'S A LOT OF DISCOVERY BEFORE THERE'S THERAPEUTICS. IF YOU DO THAT, YOU'LL PROBABLY ULTIMATELY HAVE TWO STANDARDS. WE'LL HAVE TWO STANDARDS. WE'LL HAVE CIRM-DERIVED CELLS AND WHATEVER EVERYONE ELSE DOES. YOU'RE ASKING DOES THAT CREATE A PROBLEM? THERE MAY BE A PERCEPTION, BUT IT'S THE ONLY WAY THAT GETS THAT WORK DONE. IT WILL BE AWHILE BEFORE YOU HAVE GOOD CELL LINE PRODUCTION HERE.

CO-CHAIR LO: ALTA AND THEN SHERRY.

MS. CHARO: I THINK WE'RE GOING TO RUN INTO THIS DILEMMA REGARDLESS, ROB, OF WHAT WE DO. AND IT'S NOT ONLY BECAUSE THERE WILL BE SOME CELL LINES WHERE WE'VE GOT THE PERFECT TRACKING INFORMATION THAT THE FDA PREFER, ALTHOUGH NOT NECESSARILY REQUIRE. EVEN IF YOU HAD PERFECT TRACKING INFORMATION, HOW YOU MANAGE THE CELL LINES IN YOUR LABORATORY IS UNLIKELY TO MEET THE GMP, GOOD MANUFACTURING PRACTICES, STANDARDS THAT THE FDA REQUIRES WHEN YOU TAKE TISSUE FOR THERAPEUTIC TRANSPLANTATION IF ALL YOU'RE DOING IS BASIC LAB WORK. SO IN MANY CASES EVEN PERFECTLY IDENTIFIED LINES STILL WOULD WIND UP BEING NONUSABLE FOR THERAPEUTIC TRANSPLANTATION, AND YOU'D HAVE TO GO BACK TO A DIFFERENT SOURCE AND START AGAIN TO DEVELOP YOUR TRANSPLANTABLE TISSUE.

SO MAYBE WE SHOULDN'T FOCUS TOO MUCH ATTENTION ON TRYING TO MAKE SURE ALL THE LINES ARE POTENTIALLY USABLE FOR THERAPEUTIC TRANSPLANTATION BECAUSE I DON'T KNOW THAT WE'LL EVER BE ABLE TO GET THERE UNLESS EVERY BASIC SCIENCE EXPERIMENT IS DONE IN A GMP FACILITY, WHICH IS FINANCIALLY NOT FEASIBLE.

CO-CHAIR LANSING: I JUST WANT TO KIND OF SECOND WHAT ZACH WAS SAYING BECAUSE I THINK WE'RE GETTING -- I THINK ALL OF THIS IS REALLY IMPORTANT. I THINK WE'RE KIND OF DOING THE WORK THAT WE WERE

SUPPOSED TO DO IN THE COMMITTEE. ALL THESE INTERIM GUIDELINES ARE INTERIM AND THEY ARE FOR NINE MONTHS, AND THEY'RE REALLY JUST ALLOWING US TO GIVE OUT THE TRAINING GRANTS. AND UNLESS THERE'S SOMETHING EGREGIOUS IN THEM, WHICH I DIDN'T THINK THERE WAS, BUT MAYBE THERE IS, UNLESS THERE'S SOMETHING EGREGIOUS IN THEM, I THINK THAT WE SHOULD ADOPT THEM BECAUSE WE WON'T IN NINE MONTHS -- WE'LL BE LUCKY IF WE CAN GIVE OUT OUR GRANTS AND START ANY KIND OF REAL EXPERIMENTATION. RIGHT NOW WE'RE GIVING OUT OUR TRAINING GRANTS.

AND THEN WE'RE SUPPOSED TO THESE ATTACK GUIDELINES AND REALLY, YOU KNOW, ADDRESS THE MINOR PROBLEMS AND ANY BIG PROBLEMS AS WELL.

MR. KLEIN: SO SPECIFICALLY GETTING BACK TO OUR DISCUSSION OF WHERE WE'RE GOING, THE NIH LINES AREN'T REALLY USEFUL CLINICALLY THEMSELVES, BUT WE NEED TO HAVE THOSE INCLUDED IN OUR STUDIES BECAUSE THEY COMPRISE SO MUCH OF THE BODY OF WORK THAT'S EXISTENT. SO I WOULD LIKE TO MAKE A MOTION THAT CELL LINES THAT MEET AN EQUIVALENT STANDARD TO ENGLAND'S STEM CELL BANK OR SUCH OTHER -- AND SUCH OTHER BENCHMARK ORGANIZATION THAT THIS GROUP MAY LATER DESIGNATE, INCLUDING, FOR EXAMPLE, THE INTERNATIONAL STEM CELL FORUM, WOULD QUALIFY UNDER THIS SECTION FOR THE WAIVER OF

DOCUMENTATION.

THIS IS RELEVANT DURING THE NEXT NINE MONTHS BECAUSE, FOR EXAMPLE, THOSE 75 STEM CELL LINES THAT THE INTERNATIONAL FORUM IS DESIGNATING, I'M SUGGESTING THAT WE ADOPT THEM AS A BENCHMARK TODAY; BUT IF WE PUT IT INTO OUR INTERIM REGULATIONS, WE'LL HAVE THE ABILITY TO COME BACK AT A LATER STANDARDS MEETING AND DECIDE IF THEY'RE A BENCHMARK. IF WE DON'T PUT THEM INTO OUR INTERIM REGULATIONS, WE DON'T HAVE THE PLACEHOLDER AND WOULD HAVE TO GO BACK THROUGH THIS PROCESS. AND WE NEED TO SIGNAL, I THINK, TO THE INTERNATIONAL FORUM THAT WE'RE GOING TO SERIOUSLY LOOK AT THEIR LINES BECAUSE THEY'RE UNDERTAKING A TREMENDOUSLY BENEFICIAL ACTIVITY.

DR. HALL: SO THE QUESTION THOUGH, AS I UNDERSTAND IT, IS THE SOUTH KOREAN LINES RIGHT NOW ARE NOT INCLUDED IN THOSE 75. AND I GUESS THE ISSUE IS IS THERE A WAY IN WHICH WE CAN PROVIDE SOME MECHANISM THAT WOULD ALLOW THOSE LINES TO BE USED IF THEY MEET A CERTAIN STANDARD?

MR. KLEIN: THEY CAN BE USED. WE'RE JUST DEALING WITH WHETHER THEY NEED THE DOCUMENTATION.

DR. EGGAN: I THINK WHAT WE'RE SAYING IS THEY COULD BE USED, BUT THEY WOULD HAVE TO GO THROUGH THE ESCRO REVIEW MORE CAREFULLY. THEY'RE NOT AUTOMATICALLY

GRANDFATHERED IN AT THIS TIME.

CO-CHAIR LO: I THINK IT'S AN IMPORTANT DISTINCTION, BOB. WHAT THIS IS ABOUT IS WAIVING THE REQUIREMENT FOR DOCUMENTATION THAT ESCRO'S WOULD OTHERWISE HAVE TO HAVE.

DR. HALL: FOR THOSE TWO LINES. OTHER LINES ARE PERMISSIBLE WITH THAT DOCUMENTATION. OKAY. VERY IMPORTANT POINT.

CO-CHAIR LO: WE'RE GOING TO WAIVE DOCUMENTATION --

DR. HALL: SO WE HAVE LANGUAGE.

MR. SHESTACK: COULD YOU RESTATE IT, ZACH? RESTATE THIS CONVERSATION BECAUSE YOU'RE THE ONLY MIC THAT SEEMS TO WORK WELL.

MR. KLEIN: YOU WOULD LIKE ME TO RESTATE IT?

DR. HALL: LET ME JUST ASK TO REPEAT THE WHOLE SECTION. I'D LIKE TO HAVE A READING OF THE WHOLE SECTION THAT DEALS WITH THAT SO WE KNOW WHAT LINES CAN BE USED.

CO-CHAIR LO: CAN WE PUT THE TEXT ACTUALLY UP ON THE SCREEN?

MR. KLEIN: WHY DON'T I TRY TO NARRATIVELY RESTATE THAT. THE MOTION IS TO MODIFY SECTION 100002, WHICH PROVIDES FOR A WAIVER OF DOCUMENTATION REQUIREMENTS ON STEM CELL LINES. THE MOTION

SPECIFICALLY PROPOSES THAT STEM CELL LINES THAT ARE DEVELOPED UNDER STANDARDS EQUIVALENT TO THE ENGLISH STEM CELL BANK -- UK STEM CELL BANK, AND OTHER BENCHMARK ORGANIZATIONAL STANDARDS, SUCH AS THE INTERNATIONAL STEM CELL FORUM, IF LATER APPROVED BY THE STANDARDS COMMITTEE AS AN EQUIVALENT, WOULD QUALIFY FOR THE WAIVER OF THE DOCUMENTATION.

MS. CHARO: ON THE LANGUAGE UP THERE, JUST BECAUSE I SEE THERE'S A QUESTION MARK THERE ABOUT WHERE THE WORD "LICENSE" COME IN, AS I UNDERSTAND IT, THE STEM CELL LINES ARE NOT LICENSED BY THE HFEA. THE HFEA LICENSES CENTERS TO DO RESEARCH AND APPROVES RESEARCH PROTOCOLS, BUT IT DOESN'T LICENSE STEM CELL LINES. SO I THINK WHAT YOU MIGHT BE REFERRING TO THERE IS TWO SEPARATE THINGS. ONE IS LINES THAT HAVE BEEN DEPOSITED IN THE UK STEM CELL BANK BECAUSE THOSE LINES NOW HAVE MET CERTAIN CRITERIA. AND I THINK ALSO LINES THAT HAVE BEEN APPROVED FOR USE BY AN HFEA LICENSEE, BECAUSE THE LICENSEES MAY BE USING NONSTEM CELL BANK LINES, BUT PART OF THE LICENSING PROCESS INVOLVES CHECKING THAT THE LINES THEY'RE WORKING WITH ARE ACCEPTABLE. SO IT'S ACTUALLY TWO SUBTLY DIFFERENT CATEGORIES, RIGHT?

SO IT REALLY CREATES THREE THINGS THAT WE'RE TRYING TO -- ESSENTIALLY WE'RE TRYING TO SAY THAT THEY ARE DEEMED TO HAVE COMPLIED SUBSTANTIVELY WITH THE

INFORMED CONSENT AND DONOR COMPENSATION REQUIREMENTS, AND, THEREFORE, WE WILL WAIVE THE REQUIREMENT THAT THEY SUPPLY DOCUMENTATION ON THOSE TWO ISSUES, RIGHT, FOR THREE THINGS. ONE ARE THE LINES THAT THE NIH SAYS YOU CAN WORK WITH WITH NIH MONEY, OTHER LINES WHERE YOU CAN -- LINES WORKED WITH BY HFEA LICENSEES, AND THIRD, LINES THAT COME FROM THE STEM CELL BANK IN THE UK.

MR. KLEIN: ACTUALLY THIS LANGUAGE FALLS SHORT OF PROVIDING A WAIVER OF THIS SECTION 100002. AND THE INTENT WAS THEY WOULD HAVE A WAIVER OF THAT SECTION OF ALL THE DOCUMENTATION REQUIREMENTS.

MS. CHARO: THEN WE WAIVE THE DOCUMENTATION STUFF ABOUT THE PROVENANCE AND THE INFORMED CONSENT, BUT YOU WOULD STILL PROBABLY WANT -- YOU ARE STILL GOING TO NEED TO SUBMIT TO THE ESCRO THAT YOU COMPLIED WITH ANY IACUC OR IBC REVIEWS, RIGHT? THAT'S TOTALLY SEPARATE, AND THAT'S NOT GOING TO BE COVERED ELSEWHERE.

DR. CIBELLI: THAT'S ROUTINELY DONE FOR ANY PROJECT.

MS. CHARO: RIGHT. IT'S A CHECKOFF SHEET. BECAUSE THE ESCRO IS STILL GOING TO BE KEEPING TRACK OF THE WORK GOING ON IN THE INSTITUTION. IT'S JUST WE DON'T WANT THEM TO HAVE TO RECREATE THE DOSSIER ON WHERE THE DONORS CAME FROM, AND HERE'S A MODEL CONSENT FORM THAT THEY LOOKED AT, ETC.

MR. KLEIN: DO THEY ALSO NEED TO SEPARATELY DOCUMENT THAT THEY COMPLIED WITH INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE?

MS. CHARO: THAT'S THE THING I DON'T THINK YOU CAN WAIVE OUT BECAUSE THE FACT THAT IT COMES FROM THE STEM CELL BANK DOESN'T TELL US ANYTHING ABOUT THE ACTUAL WORK THAT THEY'RE PLANNING TO DO WITH THE LINES, AND THE ESCRO IS GOING TO WANT TO KNOW --

DR. HALL: INSTITUTIONS WOULD DEMAND THAT.

MS. CHARO: EXACTLY. THE INSTITUTIONS ARE GOING TO DEMAND. WE'RE JUST REIFYING WHAT THEY ALREADY REQUIRE.

CO-CHAIR LO: CAN SOMEONE ACTUALLY TYPE IN ON THE SCREEN WHAT BOB JUST PROPOSED SO WE CAN SEE IT FOR CONTEXT?

DR. EGGAN: A POINT TO CLARIFY WHAT ALTA SAID. IF AN HFEA LICENSEE IS WORKING WITH A STEM CELL LINE, YOU ACTUALLY HAVE TO HAVE AN HFEA LICENSE IN THE UK TO WORK WITH EMBRYONIC STEM CELLS; IS THAT CORRECT?

MS. CHARO: I BELIEVE THAT IS CORRECT, YES.

DR. EGGAN: THIS IS THE HUMAN EMBRYO FERTILIZATION ACT.

MS. CHARO: YOU ABSOLUTELY DO TO DERIVE A NEW LINE.

DR. EGGAN: I KNOW YOU DO TO DERIVE.

MS. CHARO: I'M ALMOST A HUNDRED PERCENT SURE THAT YOU NEED IT JUST TO WORK WITH.

WHILE HE'S TYPING, THOSE OF US WITH WORKING INTERNET CONNECTIONS CAN SEE IF WE CAN CLARIFY FOR YOU, BUT I'M PRETTY SURE YOU DO, YEAH.

DR. EGGAN: CERTAINLY IT COULD READ THAT STEM CELLS DERIVED UNDER HFEA LICENSES WOULD ALL CERTAINLY BE ACCEPTABLE. THAT'S DESIRABLE BECAUSE IF THE ENROLLMENT TOMORROW TURNS AROUND AND MAKES A NUCLEAR TRANSPLANTATION ES CELL LINE, THEN, BAM, THAT'S IMMEDIATELY GRANDFATHERED IN TO BE ABLE TO BE USED IN CALIFORNIA. AND NEW LINES MADE IN THE UK WOULD ALL THEN BE ACCEPTABLE.

IT WOULD ALSO BE -- IF THAT'S TRUE, WHAT YOU'RE SAYING IS TRUE, THEN ANY CELL LINE -- FOR INSTANCE, IF DR. WILMOT SUCCEEDS IN IMPORTING THE KOREAN CELL LINES AND THAT PASSES MUSTER WITH RESPECT TO HFEA, THEN ANYTHING THAT COMES THROUGH THAT FILTER WE'RE ALSO SAYING IS OKAY. I THINK THOSE ARE TWO -- I THINK WE WANT TO CLARIFY THAT BECAUSE THAT'S TWO DIFFERENT, I THINK, LEVELS --

DR. HALL: BOTH VERY IMPORTANT.

MR. SHESTACK: WOULD THAT BE THIRD-PARTY REDISTRIBUTION?

DR. EGGAN: YES, THAT IS LIKE THIRD-PARTY

REDISTRIBUTION.

MR. SHESTACK: FROM THE AMERICANS.

DR. EGGAN: SAYING ESSENTIALLY WHAT WE NEED TO KNOW IS WHAT IS THE STRINGENCY FOR THE UK SCIENTIST TO WORK WITH ANY STEM CELL LINE. I THINK IT'S WELL ESTABLISHED WHAT'S REQUIRED FOR THEM TO DERIVE A STEM CELL LINE UNDER HFEA, AND WE'RE ALL COMFORTABLE WITH THAT. NOW THE QUESTION IS IF THEY WERE TO IMPORT A STEM CELL LINE, WHAT WOULD BE REQUIRED? IS THAT THE SAME AS REQUIREMENTS AS FOR DEPOSITING THAT IN --

DR. HALL: SORT OF LIKE WHAT WE WOULD ASK THE LOCAL ESCRO TO DO. WE'RE GOING TO GET HFEA TO DO, IN FACT, FOR US. THAT'S GREAT.

MR. SHESTACK: THEN YOU'RE TALKING ABOUT REIMPORTING THOSE LINES FROM ENGLAND?

DR. HALL: WE DON'T HAVE TO GET THE LINES FROM BRITAIN. WE JUST ACCEPT THEIR STANDARDS THAT THE LINES ARE ACCEPTABLE. THAT'S A GREAT IDEA. THANKS, ALTA, FOR POINTING THAT OUT. I THINK THAT MAKES A VERY STRONG ADDITION TO THE POLICY.

MS. CHARO: THE HFEA ACT OF 1990 WAS AIMED AT CREATION, STORAGE, AND USE OF EMBRYOS IN RESEARCH, BUT WAS AMENDED IN 2001 TO COVER STEM CELL RESEARCH. CONSEQUENTLY, THE HFEA HAS RESPONSIBILITY FOR REGULATING ALL EMBRYONIC STEM CELL RESEARCH IN THE

UNITED KINGDOM.

I'LL KEEP GOING DOWN TO SEE IF THERE'S ANY EXEMPTIONS, BUT IT SOUNDS LIKE, YEAH, IT'S COMPREHENSIVE.

DR. TAYLOR: I'M JUST KIND OF CURIOUS. I CAN SEE HOW WAIVERS CAN GET US THROUGH SOME OF THE DOCUMENTATION PROCESS, BUT IT WOULD SEEM TO ME THAT IACUC, IRB, AND CERTAINLY GCRC'S ALL HAVE AS PART OF THEIR MANDATE TO REVIEW THESE THINGS. SO AT SOME LEVEL I THINK WE'RE GOING TO AVOID SOME OF THE UP-FRONT HASSLES. I JUST WANT EVERYBODY TO BE ON THE SAME PAGE IN TERMS OF THE MANDATE OF REVIEW THAT'S GOING TO HAVE TO OCCUR.

DR. HALL: AS WAS SAID BEFORE, IT'S NOT OUR OPTION. THOSE ARE -- ACTUALLY THE OTHER THING YOU MIGHT ADD IS WHERE IT SAYS "OTHER MANDATED REVIEW" PROBABLY SHOULD BE INSTITUTIONAL REVIEW. THESE ARE ALL THINGS THAT ARE REQUIRED BY THE INSTITUTION, AND IT'S NOT OUR PREROGATIVE TO SAY YOU DON'T HAVE TO GO THROUGH YOUR INSTITUTIONAL COMMITTEES TO DO THIS. SO I THINK -- I DON'T THINK THE WORDING WILL IMPLY THAT THOSE AREN'T NECESSARY.

AND AS WE POINTED OUT FOR THE PIECE THAT'S UP THERE NOW, THAT IT DOES NOT EXEMPT FROM THE INSTITUTIONAL REVIEW. I DON'T THINK WE CAN DO ANYTHING

ABOUT THAT.

DR. KORDOWER: YOU WANT TO STATE THAT EXPLICITLY?

DR. HALL: WELL, WE CAN. I CAN'T SEE HOW THE WORDING IS GOING TO COME OUT. IT'S IMPLIED.

MR. SHEEHY: HUMAN STEM CELL RESEARCH REQUIRES IRB APPROVAL.

DR. HALL: THEY'RE DEEMED TO HAVE COMPLIED WITH THE REQUIREMENTS FOR INFORMED CONSENT AND -- WHAT'S THE OTHER -- DONOR COMPENSATION, BUT IT DOES NOT SAY THAT IT'S DEEMED THEY'VE COMPLIED WITH THE INSTITUTIONAL. THAT'S A SEPARATE THING THAT STILL HAS TO BE DONE. IF YOU THINK IT'S USEFUL TO ADD IT EXPLICITLY, WE CERTAINLY CAN.

CO-CHAIR LO: JEFF.

MR. SHEEHY: ACCORDING TO STATE LAW, ALL HUMAN EMBRYONIC STEM CELL RESEARCH IN CALIFORNIA REQUIRES IRB APPROVAL ANYWAY.

MS. CHARO: PROP 71-FUNDED RESEARCH IS EXEMPTED FROM THAT REQUIREMENT, I THOUGHT.

MR. SHESTACK: I'M SORRY, WHAT?

MS. CHARO: I THOUGHT RESEARCH FUNDED BY PROP 71 IS EXEMPTED FROM THAT STATE LAW REQUIREMENT THAT ALL EMBRYONIC STEM CELL RESEARCH GO THROUGH AN IRB.

MR. SHEEHY: SO YOU'RE GOING TO HAVE TWO

DIFFERENT ENFORCEMENT TRACKS IN THE INSTITUTION.

MS. CHARO: WELCOME TO CALIFORNIA.

MR. SHEEHY: DEPENDING ON WHETHER IT'S PROP 71 FUNDED.

CO-CHAIR LO: JEFF, AGAIN, I THINK WE NEED TO DISTINGUISH BETWEEN WHAT REVIEW IS REQUIRED AND WHAT DOCUMENTATION NEEDS TO BE DONE. SO MY UNDERSTANDING IS WHAT WE'RE WORKING ON NOW REALLY JUST HAS TO DO WITH TWO PARTS OF APPROVAL, WHICH IS THE CONSENT AND THE COMPENSATION, AND IT'S REALLY THE DOCUMENTATION THAT THEY HAVE COMPLIED IS BEING WAIVED. ALL THE OTHER TYPES OF REVIEW THAT THE INSTITUTION OR THAT THE REST OF THESE GUIDELINES MAY IMPOSE STILL REMAIN IN PLACE.

DR. EGGAN: I THINK THAT AFTER THE DISCUSSION WE HAD A MOMENT AGO, IT WOULD BE DESIRABLE TO REPLACE THE WORD "DERIVED" IN SECTION B WITH "APPROVED FOR USE."

MS. CHARO: OR APPROVED FOR USE BY A LICENSEE OF THE HFEA. DERIVED OR APPROVED FOR USE.

DR. EGGAN: OR DERIVED.

MS. CHARO: BECAUSE YOU WANT BOTH.

DR. EGGAN: YES, I THINK SO.

DR. HALL: IF IT'S APPROVED FOR USE, YOU DON'T NEED THE DERIVED, RIGHT? EITHER ONE.

DR. PRIETO: PROCURED OR DERIVED. JUST

APPROVED FOR USE WOULD BE BETTER.

CO-CHAIR LO: LET'S TAKE A MINUTE TO MAKE SURE WE HAVE THE LANGUAGE CLEAR SO WE KNOW WHAT WE'RE ACTUALLY APPROVING.

DR. HALL: SO WE'RE TALKING ABOUT THIS, (INDICATING), RIGHT?

DR. PRIETO: QUESTION. DO WE WANT THAT TO BE IN THE THIRD SENTENCE WHERE IT ALSO SAYS DERIVED, WE WANT TO HAVE CONSISTENT LANGUAGE.

CO-CHAIR LO: BY THE WAY, LET ME SORT OF HIGHLIGHT FOR THOSE OF YOU IN THE WORKING GROUP THAT THIS ISSUE OF EQUIVALENT STANDARDS, WHO GETS TO DECIDE WHAT'S EQUIVALENT, WILL NEED TO BE ADDRESSED IN THE FINAL GUIDELINES. SO THE ISSUE IS WE'RE NOT DOING THIS TODAY. WE GOING TO NEED TO ADDRESS BETWEEN NOW AND NOVEMBER. EVEN THOUGH WE'RE NOT SETTLING SOME OF THESE DIFFICULT ISSUES IN MORE DETAIL, WE WILL HAVE TO ADDRESS THEM FOR THE FINAL GUIDELINES. SO THIS MAY BE A STIMULUS TO START THINKING THROUGH HOW WE WANT THOSE FINAL GUIDELINES TO LOOK.

DR. CIBELLI: WILL THAT BE SPECIFIED FOR THE PUBLIC TOMORROW OR WHATEVER?

CO-CHAIR LANSING: YES. AT THE BEGINNING OF EVERYTHING, THAT THESE ARE SIMPLY INTERIM SO THAT WE CAN GIVE OUT THE TRAINING GRANTS. AND THAT'S PROBABLY

ALL WE'LL BE ABLE TO DO. THAT'S THE JOB OF THIS COMMITTEE, TO CHANGE THIS.

DR. HALL: MAYBE WE COULD PARTICIPATE IN THE INTERESTING DISCUSSION THAT'S GOING ON AT THE PODIUM.

CO-CHAIR LO: WHY DON'T YOU PUT UP WHAT YOU'VE GOT AND LET'S EXPLAIN. WHILE THEY ARE WORKING, FOR THE REST OF THE COMMITTEE, ARE THERE BURNING ISSUES IN THESE INTERIM GUIDELINES THAT WE THINK WE NEED TO ADDRESS BEFORE THE END OF THE DAY TODAY THAT WE WOULD NOT WANT TO SEE EVEN IN THE INTERIM FORM?

DR. PRIETO: I DON'T KNOW THAT IT'S A BURNING ISSUE, BUT I THINK IT'S A VERY VALID POINT IN THE E-MAIL THAT WE RECEIVED FROM ALTA YESTERDAY, THAT JUST THE WORDING THAT RESEARCH IS PERMISSIBLE OR PROHIBITED, TO CHANGE THAT LANGUAGE AS SHE SUGGESTED TO ELIGIBLE FOR CIRM FUNDING OR NOT ELIGIBLE FOR CIRM FUNDING SINCE WE ARE A FUNDING AGENCY. WE'RE NOT CONDUCTING THE RESEARCH OR --

CO-CHAIR LO: THAT'S SOMETHING WE WANT TO JUST MAKE A GENERAL --

DR. PRIETO: I WOULD MAKE A MOTION THAT WE MAKE THAT AS A GENERAL CHANGE THROUGHOUT THESE INTERIM REGULATIONS.

CO-CHAIR LO: AND ALLOW STAFF TO GO THROUGH AND MAKE THOSE CHANGES.

DR. EGGAN: I SECOND THAT.

DR. HALL: HERE, IT WOULD BE DERIVED BY OR APPROVED.

MS. CHARO: DERIVED BY OR APPROVED FOR USE BY.

DR. HALL: OR APPROVED FOR USE BY.

MS. CHARO: JUST TO RESPOND TO FRANCISCO, I MADE THOSE SUGGESTIONS, AND THEN ZACH HALL REMINDED ME THAT WE'RE NOW JUST ADOPTING INTERIMS. I SUSPECT WE CAN GO EITHER WAY; THAT IS, IF WE THINK IT'S ENTIRELY FEASIBLE TO JUST SUBSTITUTE ELIGIBLE FOR WHEREVER IT SAYS PERMISSIBLE, ETC., GLOBALLY, THAT'S FINE. IF WE DON'T DO IT, A SENTENCE AT THE TOP THAT JUST SAYS ALL REFERENCES HERE TO PERMISSIBILITY AND PROHIBITION ARE REFERENCES TO FUNDING CRITERIA ONLY WILL HELP US ALONG FOR NINE MONTHS UNTIL WE ACTUALLY CLEAN UP ALL THE LANGUAGE.

CO-CHAIR LANSING: ALL YOU NEED IS A SENTENCE.

DR. PRIETO: IT SEEMS TO ME THAT YOU DID THE WORK ALREADY. WE MIGHT AS WELL TAKE ADVANTAGE.

MS. CHARO: YOU CAN THANK NORTHWEST AIRLINES.

CO-CHAIR LANSING: WE'RE TALKING ABOUT THAT WE'RE A FUNDING ORGANIZATION. SO ALTA'S LINE ABOUT APPROVED FOR FUNDING, YOU KNOW, THE MEMO THAT WE GOT.

DR. PRIETO: ELIGIBLE FOR FUNDING.

CO-CHAIR LANSING: JUST DO A BLANKET STATEMENT WITH THAT AND HAVE IT GO THROUGH EVERYTHING.

DR. HALL: SO THE POINT IS --

CO-CHAIR LO: LET'S HOLD THAT FOR A MINUTE AND COME BACK. LET'S DEAL WITH THIS FIRST, AND THEN COME BACK TO THAT AND SEE HOW WE WANT TO DEAL WITH IT.

SO THIS IS BOB KLEIN'S PROPOSAL WITH A LOT OF FRIENDLY AMENDMENTS. LET'S ALL JUST TAKE A MINUTE TO LOOK AT THAT AND SEE WHAT'S ON THE TABLE.

DR. HALL: I HAVE ONE QUESTION. WHEN YOU SAY DOCUMENTATION HERE, IS IT UNDERSTOOD THAT IT'S DOCUMENTATION FOR INFORMED CONSENT AND DONOR COMPENSATION ONLY? IF NOT, PERHAPS WE SHOULD RESTATE IT TO BE ABSOLUTELY CLEAR.

MR. KLEIN: I THINK JAMES IS ADDING THE WORDS AT YOUR SUGGESTION. AND THERE WAS A SUGGESTION FROM THE FLOOR, MR. CHAIRMAN, IF WE COULD HEAR THE SUGGESTION FROM THE FLOOR FROM UCLA.

CO-CHAIR LO: STEVE, YOU WANT TO COME UP TO THE MIC AND JUST INTRODUCE YOURSELF AGAIN.

MR. PECKMAN: STEVE PECKMAN, UCLA. THE MAIN ISSUE HERE IS WHO HAS TO MAINTAIN THE DOCUMENTATION OR WHO IS BEING WAIVED FROM MAINTAINING THE DOCUMENTATION. THAT'S THE AWARDEE ORGANIZATION. AND SO I THINK THIS

HAS TO EXPLICITLY STATE THAT YOU'RE WAIVING THE REQUIREMENT OF THE AWARDEE ORGANIZATION FROM MAINTAINING THIS DOCUMENTATION. OTHERWISE YOU JUST HAVE DOCUMENTATION MAINTENANCE HANGING. WHO IS SUPPOSED -- WHO IS RESPONSIBLE FOR THIS WAIVER AND WHO IS EXEMPT FROM IT?

MR. KLEIN: SPECIFICALLY YOU WOULD SUGGEST THAT WHERE IT SAYS REQUIRE DOCUMENTATION, THAT I THINK YOUR PROPOSAL WAS IT BE AMENDED TO SAY SOMETHING LIKE --

MR. PECKMAN: THEREFORE, THE AWARDEE NEED NOT MAINTAIN OR REQUIRE THE DOCUMENTATION.

DR. HALL: (A) SAYS THE ESCRO COMMITTEE OR EQUIVALENT BODY RECEIVES DOCUMENTATION. AND SO IT PRESUMABLY IS THAT SAME GROUP THAT IS RELIEVED OF THE OBLIGATION.

MR. PECKMAN: I WOULDN'T PRESUME THAT. I WOULDN'T NECESSARILY PRESUME THAT.

DR. HALL: THAT IF YOU WANT TO SAY IT EXPLICITLY, IT CERTAINLY DOESN'T HARM ANYTHING TO DO THAT. I WOULD SUGGEST THAT YOU USE THE SAME LANGUAGE, HOWEVER, IN (B) THAT YOU USE IN (A) TO MAKE THAT VERY, VERY CLEAR. I'M NOT QUITE SURE WHERE IT WOULD GO IN.

CO-CHAIR LO: JAMES, AS THE REGULATIONS PERSON, DO YOU WANT TO SORT OF INSERT INTO (B) A SORT

OF WHO GETS TO HAVE IT WAIVED USING THE SAME LANGUAGE?

MR. KLEIN: FIVE LINES DOWN WHERE IT SAYS "AND THEREFORE DO NOT REQUIRE DOCUMENTATION," IT WOULD BE AND THEREFORE THE --

DR. HALL: BY THE ESCRO COMMITTEE OR EQUIVALENT BODY DESIGNATED BY THE INVESTIGATOR'S INSTITUTION.

MR. KLEIN: EXACTLY. HE'S A LAWYER IN THE MAKING.

CO-CHAIR LO: OKAY. SO THIS IS WHAT WE NOW HAVE AS AMENDED. AGAIN, THIS IS JUST FOR INTERIM GUIDELINES. ADDITIONAL CHANGES, DISCUSSION ON THIS? I THINK IT SUMMARIZES THE DISCUSSION WE HAD. OKAY.

LET'S MOVE THE QUESTION THEN. ALL THOSE IN FAVOR. THOSE OPPOSED? AGAIN, WE HAVE UNANIMOUS PASSAGE. THANK YOU VERY MUCH TO ALL OF YOU WHO WORKED ON THIS.

OKAY. THE NEXT ISSUE IS ONE THAT ALTA BROUGHT UP AND SHERRY COMMENTED ON -- FRANCISCO, ALTA, AND SHERRY HAVE ALL COMMENTED ON. THE WAY THESE INTERIM GUIDELINES ARE PHRASED, SOMETIMES IT SAYS MAY BE APPROVED OR SOMETHING, AND IT SEEMS LIKE WE'RE APPROVING THE RESEARCH, WHERE, IN FACT, ALL WE'RE DOING IS SAYING IT'S ELIGIBLE FOR FUNDING.

SO ONE PROPOSAL THAT SHERRY MADE WAS JUST TO

PUT IN A SENTENCE EARLY ON SAYING EVERY TIME WE USE LANGUAGE OF IS APPROVABLE OR MAY BE APPROVED, WE HAVE A SENTENCE THERE SAYING WHAT WE MEAN BY THAT IS ELIGIBLE FOR FUNDING. AND THEN WAIT TILL THE FINAL GUIDELINES TO KIND OF CRAFT THE LANGUAGE.

AN ALTERNATIVE APPROACH, WHICH IS FRANCISCO'S PROPOSAL, TO JUST DO A SEARCH AND REPLACE WITH A WORD PROCESSOR. I THINK ALTA MAY HAVE ALREADY DONE THAT.

DR. HALL: I THINK A SENTENCE AT THE BEGINNING THAT SAYS ADHERENCE TO THESE GUIDELINES WILL BE REQUIRED OF ALL CIRM GRANTEES AS A CONDITION OF FUNDING. I THINK THAT'S ALL YOU HAVE TO PUT.

AND IT COVERED IN A SECOND WAY, AS ALTA AND I WERE DISCUSSING, WE ARE PREPARING ALSO A SO-CALLED CIRM GRANTS POLICY STATEMENT, WHICH WILL BE A VERY THICK DOCUMENT THAT BASICALLY IS SORT OF MODELED ON THE NIH STATEMENT. AND, IN FACT, KEN WILL BE INTERESTED TO KNOW THAT DIANA JAEGGER IS THE PERSON WHO IS HELPING US PUT THIS TOGETHER. BUT AT ANY RATE, IT IS THE TERMS OF CONDITIONS OF OUR AWARD, AND IT STIPULATES IN ALL SORTS OF AREAS WHAT HAS TO BE DONE, WHAT THE PENALTY IS IF IT'S NOT DONE, AND WHAT THE RESPONSE WILL BE.

SO THIS IS OUR SORT OF ALMOST LIKE OUR CONTRACT CONDITIONS. AND SO THERE WE WILL STATE VERY CLEARLY THAT ANY GRANTEE IS EXPECTED TO ADHERE TO THESE

GUIDELINES AS A CONDITION OF FUNDING. SO I DON'T THINK IT'S NECESSARY AT EVERY STAGE TO SAY THAT. THOSE TWO THINGS TAKES CARE OF IT.

DR. PRIETO: IF YOU'RE SUGGESTING THAT AS AN ALTERNATIVE, I'LL WITHDRAW MY MOTION.

CO-CHAIR LANSING: MEANING TO NOW SAY THAT'S WHAT WE WANT TO DO. I MAKE THAT A MOTION, THAT WE JUST PUT ONE SENTENCE IN THE FRONT.

MR. KLEIN: I SECOND IT.

CO-CHAIR LO: ANY DISCUSSION OF ZACH'S PROPOSAL?

MS. CHARO: WE CAN REVISIT THE MAIN BODY LANGUAGE AFTER WE'VE ADOPTED THESE INTERIMS, RIGHT?

DR. HALL: THAT CAN BE RIGHT IN THE FIRST OR THE SECOND SENTENCE OF THE WHOLE THING. I THINK THAT WOULD BE A VERY USEFUL, STRONG STATEMENT AND CLARIFYING.

DR. CIBELLI: JUST TO POINT OUT THAT MANY OF THESE LABORATORIES WILL BE WILLING AND ANXIOUS TO WORK WITH CELL LINES THAT THE INSTITUTE WILL NOT APPROVE. SO AT SOME POINT YOU HAVE TO HAVE IN PLACE A POLICY.

DR. HALL: THAT'S UP TO THEM. THAT'S UP TO THE INSTITUTIONS. THEY WON'T DO IT WITH CIRM FUNDING.

DR. CIBELLI: NO. NO. NO. SAY THE SAME PI HAS ALREADY A PROJECT FUNDED THROUGH THE INSTITUTE AND

WANTS TO WORK WITH A DIFFERENT CELL LINE AT THE INSTITUTE DOES NOT APPROVE. SO HOW YOU GOING TO DIVIDE THE FUNDS? HOW ARE YOU GOING TO MAKE SURE THAT THE FUNDS ARE NOT USED IN DIFFERENT PROJECTS THAT ARE NOT ALLOCATED?

DR. HALL: I SUPPOSE IF WE THINK THERE'S A PROBLEM, WE GO IN AND AUDIT IT.

DR. EGGAN: THERE'S NO REASON WHY WE CAN'T ADOPT THE SAME SORTS OF GUIDELINES WHICH ONE WOULD ACCEPT FOR NIH FUNDING. THERE ARE WELL-PROSCRIBED RULES FOR SPONSORED RESEARCH AND PROPER SPENDING OF SPONSORED RESEARCH DOLLARS AND KEEPING ONE SPONSORED PROJECT SEPARATE FROM ANOTHER. JUST RECENTLY A NUMBER OF UNIVERSITIES HAVE GOTTEN TOGETHER AND INTERPRETED THOSE CIRCULARS RELEASED BY THE NIH AND ESTABLISHED STEM CELL FACTS AND RULES OF THE ROAD FOR DOING ELIGIBLE VERSUS INELIGIBLE RESEARCH. THERE'S NO REASON THAT SIMILAR GUIDELINES COULDN'T BE USED FOR CIRM OKAY VERSUS INELIGIBLE RESEARCH AS WELL.

DR. HALL: THAT WOULD ALSO COME INTO GRANTS POLICY WOULD SAY WHAT OUR POLICY WAS ABOUT THE DIVISION OF FUNDS. ACTUALLY I'D BE INTERESTED IN KNOWING MORE ABOUT THAT.

DR. EGGAN: I CAN E-MAIL THOSE, DEFINITELY.

MR. KLEIN: JAMES, CORRECT ME IF I'M WRONG,

BUT THOSE RULES FOR GOVERNING NIH RESEARCH, FOR EXAMPLE, TO ENSURE THERE'S ACCOUNTABILITY, WE CAN ADOPT THOSE AS CONTRACT PROVISIONS AS VERSUS REGULATIONS SO THAT THEY CAN BE MORE FLEXIBLE. THEY DON'T HAVE TO GO THROUGH THE ADMINISTRATIVE PROCEDURES ACT BECAUSE THERE ARE SPECIFIC CONTRACT CONTROLS TO SEE THAT WE HAVE COMPLIANCE WITH OUR POLICIES; IS THAT RIGHT?

MR. HARRISON: YOU CAN PUT THINGS LIKE THAT IN THE GRANT AGREEMENTS, CERTAINLY.

CO-CHAIR LO: THIS IS THE --

DR. HALL: SO I WOULD PUT IT RIGHT HERE AT THE TOP. ALL RESEARCH FUNDED BY THE CIRM. I'D PUT IT RIGHT THERE.

LET ME MAKE ANOTHER TYPO COMMENT, WHICH IS CONFUSING TO ME, JAMES. THIS (B) AND THAT (A) APPEAR IN DIFFERENT PLACES AND IN DIFFERENT WHATEVERS IN THIS. I DIDN'T UNDERSTAND AT FIRST. THAT'S JUST A SMALL THING YOU CAN WORK OUT LATER.

I WOULD PUT THIS RIGHT AT THE TOP.

CO-CHAIR LO: TAKE A MINUTE TO LOOK AT THAT.

DR. HALL: ALL CIRM GRANTEES.

CO-CHAIR LO: ANY FURTHER DISCUSSION OF THIS MOTION?

MR. KLEIN: CALL FOR THE QUESTION.

CO-CHAIR LO: PUBLIC COMMENT?

MR. PECKMAN: STEVE PECKMAN AGAIN. THE NEW SENTENCE, I THINK THE INTENT OF IT IS REALLY GOOD. I THINK THAT IF YOU READ IT CAREFULLY, WHAT IT'S DOING IS THE EXACT OPPOSITE OF WHAT YOU WANT IT TO DO. NOT THAT I DISAGREE WITH WHAT IT'S DOING. AS IT READS RIGHT NOW, YOU'RE HOLDING ALL GRANTEE RECIPIENTS TO THE LETTER AND SPIRIT OF THESE GUIDELINES FOR ALL THEIR EMBRYONIC STEM CELL RESEARCH AND NOT JUST FOR CIRM-SPONSORED RESEARCH. ALL CIRM GRANTEES SHALL BE REQUIRED TO ADHERE TO THIS CHAPTER AS A CONDITION OF THE RECEIPT OF FUNDING FROM THE CIRM.

IF YOU WANT TO MAKE THAT APPLICABLE TO ALL STEM CELL RESEARCH IN CALIFORNIA, THAT'S CERTAINLY YOUR PREROGATIVE, BUT IT DOESN'T READ THAT WAY RIGHT NOW.

DR. HALL: THAT'S SIMPLE. ALL YOU HAVE TO DO IS SAY ALL CIRM GRANTEES WILL BE REQUIRED TO ADHERE TO THIS CHAPTER FOR CIRM-SPONSORED RESEARCH.

DR. EGGAN: WE TALKED ABOUT THIS LAST TIME, RIGHT, AND THIS IS A QUESTION THAT WE DISCUSSED, WHETHER OR NOT WE WANT TO FORCE OTHER PEOPLE TO BE BOOTSTRAPPED INTO ADHERING TO WHAT WE THINK BY USING THE POWER OF THE CIRM WALLET. SO I THINK WE SHOULD TAKE A SECOND TO DISCUSS THAT. DO WE WANT TO DO THAT? I THINK THAT PEOPLE COULD DIVERGE DRAMATICALLY ON THIS ISSUE. PEOPLE CAN SAY THAT IT'S NONE OF OUR BUSINESS

TO TELL PEOPLE HOW THEY SHOULD BEHAVE IF THEY'RE NOT SPENDING OUR DOLLARS.

THE OTHER WAY TO SAY THAT IS THAT IF YOU ARE GOING TO SPEND OUR DOLLARS, THEN YOU HAVE TO BEHAVE THE WAY WE WANT YOU TO BEHAVE ALL THE TIME.

CO-CHAIR LANSING: BUT ONLY WHEN YOU RECEIVE OUR DOLLARS. I DON'T THINK WE'RE SAYING ALL THE TIME UNLESS I'M MISUNDERSTANDING. WHAT WE'RE SAYING IS --

DR. HALL: OTHER GRANTING AGENCIES HAVE THE SAME RIGHT THAT WE DO TO SPECIFY THE RULES FOR SPENDING THEIR MONEY.

DR. EGGAN: NO. NO. NO. YOU'RE MISCONSTRUING WHAT I WAS SAYING. THERE'S TWO WAYS TO LOOK AT THIS. THERE'S WE CAN TELL YOU HOW TO SPEND OUR DOLLARS, OR WE CAN SAY IF YOU WANT OUR DOLLARS, WE CAN TELL YOU HOW TO ACT ALL THE TIME.

CO-CHAIR LANSING: NO, WE DON'T WANT THAT.

DR. EGGAN: THAT'S WHAT THE SENTENCE SAYS RIGHT NOW.

DR. HALL: WE CHANGED IT.

DR. PRIETO: YOU DID CHANGE IT.

DR. HALL: THE INTENT IS THE FIRST, NOT THE SECOND. IF NIH FOLLOWED THE SECOND, WE WOULDN'T BE HERE RIGHT NOW.

CO-CHAIR LANSING: ALL WE'RE SAYING IS THAT

IF YOU WANT OUR MONEY, THESE ARE THE RULES. YOU CAN DO ANYTHING ELSE YOU WANT WITH SOMEBODY ELSE'S MONEY.

DR. HALL: I THINK WE COULD END THE SENTENCE ACTUALLY RIGHT WHERE THE MARKER IS.

MR. SHEEHY: I THINK KEVIN HAS A POINT. THIS IS A DISCUSSION THAT WE KIND OF TOUCHED ON AT THE LAST MEETING. AND DO WE -- I PERSONALLY DIDN'T MAKE UP MY MIND ON THAT POINT, AND DO WE WANT TO DECIDE THAT TODAY? BUT, YOU KNOW, I THINK IT'S A VERY IMPORTANT POINT. ARE WE SETTING STANDARDS FOR STEM CELL RESEARCH IN CALIFORNIA? I THINK THE PUBLIC PROBABLY ASSUMES THAT WE ARE.

MR. KLEIN: JEFF, THE POINT THAT WAS JUST MADE BY ZACH OR BY EVEN KEVIN WAS THAT IF WE STAND UP AND SAY WE'RE TRYING TO USE OUR DOLLARS TO TELL ALL INSTITUTIONS HOW THEY BEHAVE REGARDLESS OF THE SOURCE OF FUNDING, THE NIH COULD TURN RIGHT AROUND AND SAY IF YOU ARE GOING TO RECEIVE OUR DOLLARS, YOU'RE NOW GOING TO FOLLOW OUR RULES.

MR. SHEEHY: I'M NOT ARGUING EITHER WAY. I DON'T THINK WE SHOULD JUST WORDSMITH THIS. I THINK WE SHOULD PROBABLY COME TO A CONCLUSION ON THIS. IF EVERYBODY FEELS LIKE THAT WE OUGHT NOT TO GO THAT WAY, THEN WE OUGHT NOT TO GO THAT WAY.

CO-CHAIR LANSING: IF THIS IS A BIG ISSUE,

THEN WE SHOULD RESERVE THIS ISSUE, WHICH IS OUR SECOND THING, FOR OUR REAL GUIDELINES.

DR. EGGAN: UNLESS WE CAN JUST SETTLE IT NOW.

DR. HALL: LET ME ASK ABOUT THE SENTENCE THAT'S ON THE BOARD. I HOPE -- I WILL ASK STEVE PECKMAN IF THIS MEETS HIS OBJECTION. I THINK IT'S THE SAME ONE KEVIN IS TALKING ABOUT. ALL CIRM GRANTEES SHALL BE REQUIRED TO ADHERE TO THIS CHAPTER FOR CIRM-SPONSORED RESEARCH. ANYTHING ELSE NEEDED?

CO-CHAIR LO: I THINK THAT'S CLEAR WHAT THAT SAYS. I THINK KEVIN IS RAISING THE QUESTION OF, IN FACT, DO WE WANT TO DO SOMETHING DIFFERENT THAN THAT? AND I THINK THAT'S AN ISSUE THAT I GUESS WE SHOULD DECIDE WHETHER WE WANT TO TACKLE THAT FOR THE INTERIM GUIDELINES AS OPPOSED TO SAYING IT'S PART OF THE DISCUSSION FOR THE FINAL GUIDELINES.

DR. EGGAN: I CAN TELL YOU MY POINT OF VIEW IS THAT, NO, WE DON'T WANT TO DO THAT. AND I'M WITH BOB ON THIS FOR EXACTLY THE REASON THAT HE SAID. MAYBE WE CAN JUST TAKE A LITTLE QUICK POLL. DOES ANYONE DISAGREE WITH THAT? DOES ANYONE STRONGLY BELIEVE THAT WE SHOULD TRY TO CONTROL WHAT EVERYBODY IS GOING TO DO?

DR. CIBELLI: WE'RE STILL CONTROLLING. WE'RE SETTING UP THE GUIDELINES. HOW ARE YOU GOING TO ENFORCE IT?

DR. EGGAN: THE WAY YOU ENFORCE IT IS TO SAY IF YOU'RE NOT GOING TO BEHAVE THAT WAY IN ALL OF YOUR RESEARCH, THEN YOU GET NO CIRM DOLLARS.

DR. KIESSLING: IN FACT, KEVIN, THE NIH ACTUALLY DOES THAT TO US. IF YOU'RE AN INSTITUTION RECEIVING NIH FUNDS, YOU ABSOLUTELY HAVE TO HAVE, FOR ALL THE RESEARCH YOU DO, NO MATTER HOW IT'S FUNDED, YOU HAVE TO HAVE HUMAN SUBJECTS REVIEW THAT FOLLOW THEIR GUIDELINES. SO THE NIH DOES HAVE THAT HEAVY HAND. THAT'S WHY WE'RE HERE.

DR. EGGAN: NO, BUT IT DOESN'T DO IT IN ALL THINGS.

MS. CHARO: ACTUALLY TECHNICALLY THEY DO NOT. THEY GIVE YOU SUCH A STICK, RIGHT, IF YOU DON'T HAVE AN AGREEMENT TO HAVE ALL OF YOUR NON-NIH FUNDED RESEARCH GO THROUGH AN IRB, THEN EACH PROTOCOL HAS TO HAVE A NEW SINGLE PROJECT ASSURANCE. THEY BASICALLY EXTORT FROM YOU A LEVEL OF COOPERATION THAT YOU MIGHT NOT HAVE OTHERWISE VOLUNTEERED.

DR. HALL: WAIT A MINUTE. FOR STEM CELL RESEARCH, RIGHT NOW FOR STEM CELL RESEARCH, THE NIH DOES NOT SAY YOU CAN'T HAVE ANY NIH MONEY IF YOU HAVE ANY RESEARCH THAT IS OUTSIDE THE FEDERAL GUIDELINES IN YOUR INSTITUTION.

DR. TAYLOR: AS LONG AS IT'S NOT GOING ON

WITHIN THE SPACE.

DR. HALL: THAT'S FAIR ENOUGH. THEY SAY WE DON'T PAY FOR IT. WE DON'T PAY FOR IT EITHER WITH DIRECT DOLLARS OR INDIRECT DOLLARS. WHAT THEY DON'T SAY, WHICH IS I THINK THE POINT THAT KEVIN IS MAKING, IS THAT IF YOU DO THIS, YOU LOSE YOUR ELIGIBILITY FOR NIH FUNDING ALTOGETHER.

I THINK THE POINT THAT WE'RE ALL TRYING TO MAKE IS THAT AS WISE AND OBJECTIVE AND SENSIBLE AS THIS BODY IS, ONE COULD IMAGINE A CIRCUMSTANCE IN WHICH WE MIGHT TAKE A POSITION THAT SOMEBODY ELSE MIGHT DISAGREE WITH. AND THE QUESTION IS WHETHER THERE'S ROOM FOR THAT TO HAPPEN OUTSIDE OUR FUNDING BASE OR NOT. I THINK WE HAVE A RIGHT, IF WE PAY THE DOLLAR, WE HAVE THE RIGHT TO CALL THE SHOTS. OTHER THAN THAT, I THINK IT'S VERY DANGEROUS IF WE TRY TO EXTEND THAT CONTROL.

CO-CHAIR LANSING: I WANT TO SECOND THAT BECAUSE I THINK ALL THE TAXPAYERS EXPECTED US TO DO IS TO SET UP GUIDELINES FOR HOW THEIR MONEY WAS GOING TO BE SPENT. I DON'T THINK WE'RE SUPPOSED TO BE THE POLICE DOG OF THE WORLD. WE'RE SUPPOSED TO BE FOR OUR $3 BILLION. I THINK IT WOULD BE A TERRIBLE MISTAKE TO TRY AND DO MORE THAN THAT.

CO-CHAIR LO: JEFF, YOU ORIGINALLY RAISED THIS.

MR. SHEEHY: I REALLY AM NOT -- I DON'T KNOW IF I'LL BE ABLE TO COME TO A CONCLUSION ON HOW I FEEL ABOUT IT TODAY, BUT JUST TO BE A LITTLE BIT OF A DEVIL'S ADVOCATE, I KIND OF DISAGREE. I THINK THE PUBLIC HAS AN UNDERSTANDING THAT STEM CELL RESEARCH IS HAPPENING IN CALIFORNIA NOW BECAUSE THEY VOTED MONEY TO THE CIRM. AND IF RESEARCH TAKES PLACE THAT THE PUBLIC DOESN'T FEEL COMFORTABLE WITH, THEN AT A MINIMUM WE'RE INVITING THE LEGISLATURE TO COME IN AND CREATE ANOTHER SET OF GUIDELINES, WHETHER THEY APPLY TO OUR FUNDING OR NOT. IT MIGHT BE SIMPLER TO TRY TO, I DON'T KNOW, BUT TO TRY TO EXERCISE BECAUSE WHO ELSE IS SITTING AROUND LOOKING AT THIS THOUGHTFULLY, METHODICALLY TRYING TO SET UP GUIDELINES FOR STEM CELL RESEARCH IN CALIFORNIA? WE'RE KIND OF OUTSIDE THE REALM. USUALLY THE GUIDELINES FOR THIS TYPE OF STUFF TAKES PLACE AT THE NIH.

SO WE BASICALLY ARE ALLOWING THIS KIND OF SIDE THING GOING ON, SO YOU CAN HAVE TWO DIFFERENT RESEARCH PROJECTS, ONE FUNDED BY US UNDER CERTAIN ETHICAL GUIDELINES AND ANOTHER FUNDED PRIVATELY THAT DOESN'T HAVE OUR -- YOU KNOW, THEY CAN BE COMPENSATING DONORS, FOR INSTANCE, OR DOING OTHER THINGS THAT WE'RE NOT DOING THAT WE DON'T APPROVE OF. AND I THINK, YOU KNOW, HOW ARE WE GOING TO MAKE SURE THOSE FUNDS AREN'T

MIXED? HOW ARE WE GOING TO MAKE SURE THAT THAT SEPARATION TAKES PLACE? ARE WE GOING TO RELY ON INSTITUTIONAL REGULATORY BODIES SUCH AS ESCRO'S AND IRB'S TO DETERMINE THAT? I DON'T KNOW. I DON'T KNOW HOW TO RESOLVE THIS, BUT I DON'T THINK IT'S AS SIMPLE AS SAYING, WELL, YOU KNOW, ALL WE CAN CONTROL IS OUR FUNDS. WE'RE STIMULATING STEM CELL RESEARCH IN CALIFORNIA. THAT'S THE WHOLE POINT OF THE EXERCISE. WE KNOW THAT WE'RE NOT GOING TO BE ABLE TO ACCOMPLISH EVERYTHING WITH OUR THREE BILLION, BUT WE ARE GOING TO PUT THE CONTOURS ONTO WHAT TO STEM CELL RESEARCH IN CALIFORNIA LOOKS LIKE.

CO-CHAIR LANSING: JEFF, YOU'RE GOING TO BE GETTING GRANTS FROM ALL OVER THE WORLD. SO WHAT YOU'RE BASICALLY SAYING IS THAT IN ALL THE INSTITUTIONS ALL OF THE WORLD, IN KOREA AND ISRAEL, WHATEVER, IF THEY DON'T ADHERE EXACTLY TO OUR GUIDELINES --

MR. SHESTACK: NO, WE'RE NOT GETTING -- WE'RE GETTING PROPOSALS FROM CALIFORNIA.

CO-CHAIR LANSING: NO. YOU'RE GETTING PROPOSALS -- THEY HAVE TO DO THE WORK HERE, BUT YOU CAN GET PROPOSALS FROM OTHER PLACES. THEY HAVE TO COME HERE TO DO THE WORK.

DR. HALL: WELL, THEY HAVE TO BE A CALIFORNIA RESEARCH INSTITUTION IN ORDER TO GET FUNDS.

MR. SHESTACK: YOU MIGHT HAVE COLLABORATIONS. I DON'T THINK SO.

DR. HALL: THAT'S A LITTLE BIT SEPARATE ISSUE. LET ME JUST SAY, JEFF, LET ME PROPOSE A THING. THAT IS, ARE YOU SAYING THAT, FOR INSTANCE, IF WE DISAGREE ABOUT COMPENSATION OF DONORS AND JDRF HAS A PROJECT SPONSORED IN CALIFORNIA, THAT WE SAY YOU CAN'T WORK ON THAT PROJECT IF THEY HAVE A DIFFERENT INTERPRETATION FROM US?

MR. SHEEHY: ZACH, I JUST DON'T KNOW.

MR. SHESTACK: THAT'S WHAT YOU HAVE TO DO IS FIGURE OUT -- WHAT I'M LISTENING TO, AND I FEEL AS MUCH AS ANYBODY ELSE, LIKE, YEAH, DO IT MY WAY. I DON'T KNOW WHAT THAT WAY IS. I'M TRYING TO FIGURE OUT WHAT A SCENARIO IS THAT YOU WOULD LIKE THIS BODY TO BE SO PROSCRIPTIVE ABOUT. WHAT IT IS -- GIVE US A SPECIFIC THING YOU WOULD LIKE TO ACCOMPLISH BY BEING PROSCRIPTIVE, AND MAYBE WE'D WANT IT TO BE THAT.

MR. SHEEHY: THERE'S GOING TO BE A DE FACTO REGULATORY KIND OF AIR THAT HAPPENS WITH WHATEVER WE APPROVE. IT'S GOING TO COLOR HOW AN INSTITUTION OPERATES. BUT I THINK KEVIN HAS RAISED A GOOD POINT. THE WAY THE LANGUAGE WE ORIGINALLY PUT UP THERE WAS KIND OF PROSCRIPTIVE, AND I'M NOT CONVINCED THAT THAT'S A BAD THING. I'M NOT CONVINCED IT'S A GOOD THING. BUT

I THINK, YOU KNOW, STATES USUALLY DON'T SET UP ENTERPRISES LIKE THIS TO DO RESEARCH LIKE THIS. AND I DON'T KNOW WHO IS GOING TO REALLY GOVERN THIS. WE'RE REALLY GOING TO FLOOD RESEARCH COFFERS WITH MONEY, AND A LOT OF STUFF IS GOING TO SPIN OFF OUT OF THIS WHAT WE'RE DOING. AND PEOPLE WILL JUST SAY, YEAH, WE GOT MONEY FROM CIRM TO START THIS. NOW WE'RE GETTING MONEY FROM SOMEWHERE ELSE TO DO THIS, THIS, AND THIS, WHICH WOULD NOT HAVE BEEN APPROVED FOR CIRM FUNDS. THIS IS THE SCENARIOS THAT I CAN SEE. WE CAN SEE THINGS THAT HAPPEN. SO I JUST THINK -- MAYBE IT'S NOT A PROBLEM.

CO-CHAIR LO: LET ME JUST RAISE A POINT.

DR. HALL: LET ME JUST ASK IF THIS DISCUSSION CAN BE DEFERRED.

MR. SHEEHY: THAT MAY BE THE POINT TOO. I DON'T KNOW IF IT'S SOMETHING WE CAN RESOLVE TODAY.

CO-CHAIR LO: I THINK, AGAIN, THIS MAY BE IMPORTANT FOR US TO COME BACK TO AS WE DRAFT OUR -- AS WE WRITE OUR FINAL INTERIM GUIDELINES.

LET ME JUST ALSO SAY THERE IS ANOTHER BODY THAT IS CHARGED WITH SETTING STANDARDS FOR RESEARCH ON STEM CELLS DONE IN CALIFORNIA NOT FUNDED BY CIRM.

MR. SHESTACK: WHAT IS THAT?

CO-CHAIR LO: THAT'S A BODY THAT WAS REQUIRED BY THE SECOND BILL THAT SENATOR ORTIZ SPONSORED. THAT

COMMITTEE HAS NOT YET FINALLY BEEN APPOINTED. I WAS ASKED TO BE A MEMBER OF IT. THE COMMITTEE HAS NEVER MET. THE FORMAL LETTERS OF APPOINTMENT HAVE NOT GONE OUT. I DON'T KNOW WHERE THAT PROCESS IS. BUT THERE IS CONTEMPLATED AN OVERSIGHT MECHANISM FOR THE NON-CIRM FUNDED RESEARCH. THERE'S QUITE A GOOD CHANCE THE WORK OF THIS COMMITTEE WILL BE MONTHS AND MONTHS AHEAD OF THAT OTHER PANEL. WHAT WE DO IS LIKELY TO HAVE AN INFLUENCE ON THAT OTHER PANEL SO THAT I THINK THE GOAL WOULD BE TO HAVE SOME SORT OF HARMONIZATION BETWEEN THE TWO SETS OF GUIDELINES. BUT HOW THAT'S GOING TO WORK OUT IS UNCLEAR AT THIS POINT.

MY SENSE WAS THAT THIS IS SOMETHING TO KEEP IN MIND TO COME BACK TO, BUT NOT SOMETHING WE WANT TO DO FOR THE INTERIM GUIDELINES. I DON'T THINK THERE'S ANYTHING WRONG WITH PERHAPS ASKING AT THESE PUBLIC MEETINGS TOMORROW AND IN SACRAMENTO IF THERE ARE STRONG FEELINGS FROM PEOPLE IN THE PUBLIC ABOUT THAT. BUT I THINK THE INTERIM GUIDELINES IS SOMETHING WE'RE CLEARLY SAYING WITH THE RESEARCH THAT CIRM FUNDS, THESE GUIDELINES ARE --

DR. HALL: THIS IS A MINIMUM STATEMENT. I DON'T THINK WE WANT TO SAY LESS THAN THIS. I THINK THE QUESTION OF WHETHER WE WANT TO SAY MORE OF IT WOULD DESERVE A LONGER DISCUSSION.

MR. SHEEHY: I THINK THE POINT -- IF IT'S STILL A LIVE QUESTION, I THINK THAT GETS TO WHERE WE NEED TO GO WITH IT.

CO-CHAIR LO: SO LET ME JUST ASK ARE THERE OTHER BURNING ISSUES IN THE INTERIM CIRM GUIDELINES THAT WE FEEL NEED TO BE ADDRESSED TODAY?

MR. SHESTACK: SPEAK INTO THE MICROPHONE.

CO-CHAIR LO: DOES ANYONE HAVE ANY PRESSING ISSUES THAT HE OR SHE FEELS WE NEED TO RESOLVE IN THE INTERIM GUIDELINES AS OPPOSED TO THE DRAFT FINAL GUIDELINES?

MR. SHEEHY: I DON'T UNDERSTAND WHY THE ESCRO COMMITTEE IS NOT A SUBCOMMITTEE OF THE IRB, THAT ONE LINE.

MR. SHESTACK: IT CAN BE. MY UNDERSTANDING IS AN ESCRO COMMITTEE CAN BE THE SAME AS AN IRB, BUT DOESN'T HAVE TO BE.

MR. SHEEHY: IN SECTION 100006, NO. B, BECAUSE WE KIND OF ALREADY ESTABLISHED -- I MEAN IRB'S ARE APPROVING STEM CELL RESEARCH THAT IS NOT FUNDED AT CALIFORNIA INSTITUTIONS PER CALIFORNIA STATE LAW. SO WHY DO WE TELL THEM THAT THE ESCRO HAS TO BE COMPLETELY SEPARATE FROM THE IRB? WE SHOULD JUST STRIKE THAT AND WE CAN REFINE THAT LATER.

DR. HALL: THIS WAS A NATIONAL ACADEMY

RECOMMENDATION, AND WE WERE INSTRUCTED TO -- THOSE WERE THE GUIDELINES THAT THE ICOC APPROVED, AND WE WERE INSTRUCTED TO FIND REGULATORY LANGUAGE FOR THEM. I THINK, AGAIN, THIS IS AN ISSUE THAT COULD BE DISCUSSED. IT'S NOT JUST A TECHNICAL ISSUE BECAUSE THERE ARE GENUINE ISSUES THAT CAN COME TO THE ESCRO COMMITTEE THAT MAY NOT -- THAT ARE NOT UNDER THE NORMAL PURVIEW OF THE IRB'S. FOR EXAMPLE, THE ISSUE WE REFERRED TO BEFORE, IF YOU HAVE A HUMAN CELL LINE AND SOMEBODY WANTS TO PUT IT INTO A MOUSE BLASTOCYST.

MR. SHEEHY: ALL EMBRYONIC STEM CELL RESEARCH IN CALIFORNIA BY STATE LAW HAS TO GO THROUGH AN IRB.

MS. CHARO: NOT IF IT'S FUNDED BY CIRM.

MR. SHEEHY: BY CIRM. I KNOW, BUT WHY DO WE -- I WOULD JUST TAKE OUT THAT SENTENCE. WHY ARE WE DICTATING ESCRO COMPENSATION? I JUST MEAN FOR THESE INTERIM GUIDELINES. I THINK IT'S A VERY COMPLICATED AND DIFFICULT ISSUE, BUT IT SEEMS WEIRD THAT WE WOULD SEPARATE THEM OFF.

MS. CHARO: YOU KNOW, I COULDN'T EVEN REMEMBER WHERE THIS CAME FROM, AND I HAD A LITTLE QUESTION GOING WHERE IS IT FROM. AS SOON AS I WAS REMINDED, I REMEMBERED WHY IT WAS PUT IN THERE. ONE OF THE PROBLEMS IS THAT THE CALIFORNIA LEGISLATION MADE A MISTAKE. AND IT PLACED WITHIN THE IRB'S RESPONSIBILITY

FOR REVIEWING THINGS THAT HAD NOTHING TO DO WITH HUMAN SUBJECTS. THEY DON'T HAVE THE RIGHT EXPERTISE TO BE REVIEWING BASIC SCIENCE LABORATORY RESEARCH THAT DOES NOT INVOLVE HUMAN SUBJECTS.

AND IT HAS A POLITICAL -- IT HAS A POLITICAL LAND MINE HIDDEN WITHIN IT BECAUSE THERE'S BEEN A STRUGGLE OVER THE YEARS FROM THE REAGAN TO THE BUSH SR. TO THE CLINTON TO THE CURRENT BUSH ADMINISTRATIONS OVER WHETHER OR NOT EMBRYOS SHOULD BE CONSIDERED HUMAN SUBJECTS.

AND UP UNTIL NOW, THEY ARE NOT, BUT THIS ADMINISTRATION SET UP A COMMITTEE SPECIFICALLY TO LOOK AT AMENDING THAT. AND BY PLACING EMBRYONIC STEM CELL RESEARCH, WHETHER IT'S THE STEM CELL LINES, WHICH ARE NOT EVEN EMBRYOS, OR JUST EMBRYOS UNDER THE IRB'S JURISDICTION, YOU'RE TAKING A STEP TOWARD EASING THE WAY TOWARD CLASSIFYING EMBRYOS AND EVEN EMBRYO BY-PRODUCTS AS HUMAN SUBJECTS, WHICH IMPLICATES A WHOLE NEW LEVEL. NO, THIS IS A REAL POLITICAL ISSUE. AND IF IT'S NOT NECESSARY, WHY HELP THE IRB'S TO GO BEYOND THEIR ACTUAL EXPERTISE AND THEIR CURRENT JURISDICTIONAL LINES?

MR. SHESTACK: THAT'S EXACTLY WHAT THESE INTERIM GUIDELINES DO.

MS. CHARO: THE INTERIM GUIDELINES SAY THAT

THE ESCRO COMMITTEE CAN HAVE A LOT OF MEMBERS ON IT THAT ARE THE SAME AS THE IRB MEMBERS; BUT BY NOT BEING A FORMAL SUBCOMMITTEE, IT MEANS THAT IT DOES NOT HAVE TO REPORT TO THE IRB. THE IRB DOES NOT HAVE TO SIGN OFF ON ITS DECISIONS.

NOW, IF YOU'RE A NON-CIRM FUNDED RESEARCH, YOU'RE STUCK WITH CALIFORNIA LAW, BUT WHY EXPAND CALIFORNIA LAW?

MR. SHESTACK: THERE ARE MANY THINGS IN THESE GUIDELINES WHERE YOU HAVE TO -- UNLESS I READ THEM INCORRECTLY, THERE ARE MANY INSTANCES WHERE RESEARCHERS HAVE TO REPORT BACK TO AN IRB.

MS. CHARO: FOR THINGS INVOLVING HUMAN SUBJECTS. THAT WOULD BE THE BIOLOGICAL MATERIAL DONORS, EGG, SPERM, SOMATIC CELL EMBRYOS. BUT IT'S THE ADULT INDIVIDUALS WHO ARE DONATING CELLS THAT ARE HUMAN SUBJECTS THAT HAVE TO BE PROTECTED. IT'S NOT THE CELLULAR MATERIAL THAT HAS TO BE PROTECTED.

MR. SHEEHY: MY POINT WOULD BE IT'S IRRELEVANT WHETHER THE CALIFORNIA LAW IS GOOD OR BAD. THE CALIFORNIA LAW EXISTS AND IT GOVERNS INSTITUTIONS IN CALIFORNIA. THIS PROHIBITION ON -- THIS DESCRIPTION OF THE RELATIONSHIP BETWEEN AN ESCRO AND AN IRB IS NOT SOMETHING THAT WE NEED TO PUT INTO OUR INTERIM GUIDELINES BECAUSE THEY ARE ALREADY HAVING TO GET IRB

APPROVAL FOR STEM CELL -- HUMAN EMBRYONIC STEM CELL RESEARCH ACCORDING TO STATE LAW. SO BY DEFINING THAT RELATIONSHIP IN THIS PARTICULAR THING FOR THESE INTERIM GUIDELINES JUST DOESN'T MAKE A LOT OF SENSE FOR ME. I DON'T KNOW WHY WE CAN'T LEAVE THAT SENTENCE OUT.

DR. EGGAN: I CAN GIVE YOU ONE REASON, AND THAT IS THAT YOU WANT CALIFORNIA INSTITUTIONS TO BE STANDARDIZED WITH OTHER INSTITUTIONS ACROSS THE UNITED STATES. AND ACROSS THE UNITED STATES PEOPLE ARE GOING TO ADOPT THE NAS GUIDELINES, NOT CALIFORNIA STATE LAW, AND THEY'RE GOING TO HAVE ESCRO'S WHICH ARE SEPARATE FROM IRB'S, AND YOU WANT TO HAVE A SIMILAR SITUATION HERE. AND IF WE, THROUGH CIRM, CAN HELP ACCOMPLISH THAT, AND I THINK THAT'S A DESIRABLE THING, AND THAT IN AND OF ITSELF FOR ME AS A SCIENTIST WOULD BE ENOUGH MOTIVATION TO REALLY WANT THAT.

BESIDES THE FACT THAT I COMPLETELY AGREE WITH EVERY SINGLE THING THAT ALTA JUST SAID, AND THAT IT'S CRITICAL THAT EMBRYOS NOT BE PERCEIVED AS HUMAN SUBJECTS.

CO-CHAIR LO: ANN AND FRANCISCO.

DR. PRIETO: I THINK, JEFF, THAT THE CHANCES ARE IF THIS BECOMES THE STANDARD ACROSS THE COUNTRY, I THINK THE CHANCES ARE BETTER THAT CALIFORNIA LAW COULD BE CHANGED TO CONFORM WITH THAT THAN THE FEDERAL LAW

WOULD BE CHANGED.

MR. SHEEHY: I'M JUST TRYING -- I'M JUST WONDERING, AND MAYBE STEVE CAN ILLUMINATE PART OF THIS, I'M JUST WONDERING HOW AN INSTITUTION IS TRYING TO IMPLEMENT THIS. AND IT JUST -- THESE ARE INTERIM GUIDELINES. THIS ISN'T THE FINAL STATEMENT ON IT, BUT WE DO HAVE STATE LAW THAT REQUIRES THIS RESEARCH --

DR. KIESSLING: FROM OUR DISCUSSIONS IN OUR STUDY GROUP, ESPECIALLY WITH JEFF, WHO HAS HAD A LOT OF EXPERIENCE DOING STEM CELL WORK IN ANIMAL MODELS, I REALIZE THAT THE ESCRO IN CIRCUMSTANCES WHERE HUMAN SUBJECTS WERE NOT INVOLVED COULD BE COMPRISED OF MEMBERS OF THE ANIMAL CARE AND USE COMMITTEE. I THINK WHAT WE'RE TRYING TO DO IS, FOR INSTANCE, IF YOU DO THE KIND OF WORK THAT JEFF DOES EVERY DAY, IT'S POSSIBLE THAT HE WOULD HAVE TO GO THROUGH AN IRB, AN ANIMAL INSTITUTIONAL COMMITTEE, AND A SEPARATE ESCRO.

SO WHAT YOU DON'T WANT TO DO IS PROVIDE ANOTHER LAYER OF ADMINISTRATIVE OVERSIGHT. WE'RE TRYING TO AVOID THAT AND GET THE WORK GOING. SO IT'S POSSIBLE THAT THE WAY TO FIX THIS PROBLEM IS TO NOT WORRY ABOUT WHETHER THE ESCRO IS PART OF AN IRB OR PART OF ANOTHER COMMITTEE IN THAT INSTITUTION THAT HAS THE EXPERTISE. SO YOU WOULD SIMPLY GET RID OF THE LAST TWO SENTENCES HERE IN SECTION B AND ALLOW AN INSTITUTION,

IF THERE'S NO HUMAN SUBJECTS INVOLVED, THEN THE ESCRO CAN BE SERVED BY MEMBERS OF THE IACUC. WOULD YOU AGREE WITH THAT, JEFF?

DR. KORDOWER: I AGREE WITH THAT.

DR. HALL: LET ME SAY THAT I WOULD STRONGLY URGE THAT WE AT THIS STAGE FOLLOW THE NATIONAL ACADEMY GUIDELINES HERE. IF WE WISH TO CHANGE IT LATER AFTER A LONG DEBATE, BUT I THINK THERE'S QUITE A SERIOUS MATTER INVOLVED IN CHANGING THIS, PARTLY FOR THE REASONS THAT KEVIN SAID. AND THAT IS THAT WE DO WANT TO BE IN TUNE WITH WHAT'S GOING ON NATIONALLY. AND THERE'S BEEN A HUGE EFFORT WITH THE NATIONAL ACADEMY GUIDELINES, I THINK, TO TRY TO ESTABLISH SOMETHING THAT MANY PEOPLE CAN AGREE ON AND THAT WILL BE USEFUL ACROSS THE COUNTRY. I DO NOT WANT TO SEE US PREMATURELY GO OFF IN ANOTHER DIRECTION. AS ALTA INDICATED, THIS IS A VERY, VERY SENSITIVE AND IMPORTANT POINT.

DR. KIESSLING: I THINK IF YOU READ SECTION 6, SECTION B, IT CALLS FOR THE ESTABLISHMENT OF AN ESCRO COMMITTEE. IT ELIMINATES THE TWO SENTENCES THAT REFER TO IRB.

MR. SHESTACK: BUT THOSE TWO SENTENCES ARE ACTUALLY GOOD PROTECTIVE SENTENCES. YOU MEAN THE ESCRO COMMITTEE, HOWEVER, SHALL NOT BE A SUBCOMMITTEE OF THE IRB?

DR. KIESSLING: NO. NO. NO. JUST READ IT. A PREEXISTING COMMITTEE MAY SERVE THE FUNCTIONS OF THE ESCRO COMMITTEE PROVIDED THAT IT HAS THE RECOMMENDED EXPERTISE AND REPRESENTATION TO MEET THE REQUIREMENTS OF THIS SECTION. AND NOT TALK ABOUT HUMAN SUBJECTS REVIEW.

MR. SHESTACK: I THINK -- I WOULD ASSUME THAT THE RATIONALE WAS ACTUALLY SPECIFIED VERY INTENTIONALLY THAT AN ESCRO CANNOT BE SUBJECT TO THE AUTHORITY OF AN IRB FOR THE REASONS ALTA SUGGESTED. I'M ASSUMING THAT'S WHY THAT LANGUAGE IS IN THERE.

DR. KIESSLING: NO. I THINK THAT LANGUAGE IS IN THERE TO TRY TO AVOID A SECOND COMMITTEE. BUT, IN FACT, IF YOU JUST GET RID OF THE LAST TWO SENTENCES --

DR. TAYLOR: IT'S IN THERE TO --

MR. SHESTACK: WHO WROTE THE LANGUAGE? IS THAT EXACTLY ADOPTED FROM NAS, OR IS THAT SOMETHING THAT WE DRAFTED WHEN WE PUT IT IN REGULATORY LANGUAGE?

CO-CHAIR LANSING: IT'S PUT IT IN OUR LANGUAGE, BUT IT'S PRETTY MUCH THE SAME.

DR. PRIETO: I THINK THE INTENT SOUNDS LIKE IT WAS INTENDED TO BRING IT OUT FROM UNDER THE AUTHORITY OF THE IRB.

MS. CHARO: IT WAS INTENDED VERY SPECIFICALLY TO CLARIFY THE DIFFERENCE BETWEEN HUMAN SUBJECTS

RESEARCH AND NONHUMAN SUBJECTS RESEARCH BECAUSE EMBRYONIC STEM CELL RESEARCH INVOLVES BOTH. AND THERE HAD BEEN A TENDENCY TO LUMP ALL EMBRYONIC STEM CELL RESEARCH, THEREFOR, UNDER THE HEADING OF HUMAN SUBJECTS, AND IT LED TO SOME LOGICAL INCONSISTENCIES AND SOME POLITICAL CONCERNS LIKE I MENTIONED BEFORE.

WITH REGARD TO CALIFORNIA'S SPECIAL SITUATION, JEFF, ONE OF THE THINGS THAT A NUMBER OF PEOPLE HAVE ANTICIPATED MIGHT BE THE WAY TO COMPLY WITH CALIFORNIA LAW WAS TO DO WHAT IRB'S OFTEN DO WHEN THEY FRANKLY DO NOT HAVE THE EXPERTISE TO HANDLE SOMETHING. IF AN IRB IS PRESENTED WITH A PROTOCOL THAT HAS TO DO WITH A VERY SPECIALIZED AREA OF NEUROLOGICAL RESEARCH AND NOBODY THERE KNOWS HOW TO REVIEW IT, THEY CAN CONSTITUTE AD HOC ADVISORY GROUPS THAT WILL INCLUDE MEMBERS AND NONMEMBERS OF THE IRB THAT REVIEW THE PROTOCOL AND THEN ADVISE THE IRB.

SO WE HAVE BEEN ASSUMING THAT INSTITUTIONS SUBJECT TO CALIFORNIA LAW THAT REQUIRED IRB REVIEW OF PURE LAB RESEARCH OR ANIMAL RESEARCH, NEITHER OF WHICH IS WITHIN IRB PURVIEW, WOULD SIMPLY CREATE AN AD HOC COMMITTEE. IN THIS CASE THEY WOULD JUST DEFER TO THE ESCRO. THEY'D SAY, FINE, WE'VE GOT AN ESCRO. LET THEM REVIEW IT, DO THEIR THING, AND THEN ADVISE US ON THE NONHUMAN SUBJECTS ASPECTS, AND WE WILL RUBBER STAMP

BECAUSE UNDER CALIFORNIA LAW WE ARE REQUIRED TO BE THE DECIDING BODY, BUT IT DOESN'T MAKE ANY SENSE THAT WE'RE THE DECIDING BODY.

THAT WAS ONE WAY THAT THEY COULD COMPLY WITH CALIFORNIA LAW AND GET THE EXPERTISE THEY NEEDED, AND IT WAS COMPLETELY CONSISTENT WITH HAVING THE ESCRO COMMITTEE. YOU'RE ABSOLUTELY RIGHT. THE ESCRO COMMITTEE REPLICATES SOME OF THE WORK OF THE IACUC, SOME OF THE WORK OF THE IBC, AND IT WAS THERE REALLY AS A KIND OF CATCHALL, AS A SUPERVISOR SOME PEOPLE HATED BECAUSE IT SEEMS LIKE AN UNNECESSARY MIDDLE ADDED LAYER OF BUREAUCRACY. OTHER PEOPLE LOVED IT BECAUSE THEY FELT LIKE IT WAS THE ONE PLACE WHERE YOU COULD GET EVERYTHING COMING TO ONE BODY OF PEOPLE. AND SO THERE'S A REAL DEBATE ABOUT ITS USEFULNESS, BUT IT'S VERY DIFFERENT FROM AN IRB.

MR. SHEEHY: MY ONLY POINT IS THE PROCESS YOU JUST DESCRIBED WAS A SUBCOMMITTEE OF AN IRB. WE'RE SAYING YOU CAN'T DO THAT.

MS. CHARO: WHY MAKE IT INTO -- WHERE IT'S NOT REQUIRED.

DR. EGGAN: HERE'S ANOTHER LOOPHOLE TO GO THROUGH, AND THIS IS THE SITUATION AT HARVARD. I WOULD VERY MUCH LIKE TO READ THE LEGISLATION IN CALIFORNIA BECAUSE WHAT HARVARD HAS DECIDED IS THAT INDEED THE IRB

MUST REVIEW ALL STEM CELL RESEARCH, BUT ONLY TO SAY WHETHER OR NOT, INDEED, THERE IS A HUMAN SUBJECT TO PROTECT IN THAT RESEARCH. SO ALL HUMAN ES CELL RESEARCH HAS A CHANCE OF INVOLVING SOME HUMAN SUBJECT, AND THEY WANT TO SAY YES OR NO, WHETHER OR NOT THERE IS A HUMAN SUBJECT. SO, THEREFORE, THEY MUST REVIEW IT IF ONLY TO SAY WE DON'T NEED TO REVIEW IT. SO IT COULD BE THAT THE LANGUAGE IN CALIFORNIA CAN FIT SUCH A DEFINITION.

MS. CHARO: IT'S DECIDING THAT IT'S EXEMPTED ESSENTIALLY.

MR. KLEIN: ONE OF THE POSSIBILITIES HERE IS THAT THIS LANGUAGE IS HERE BECAUSE PEOPLE RECOGNIZE THAT IRB'S HAVE A LOT OF POLITICAL POWER; AND THAT UNLESS YOU SAY THEY CAN'T BE THE SUBCOMMITTEE, THAT THE IRB'S WILL FORCE JURISDICTION INTO THAT IRB. THAT'S A POSSIBILITY.

MR. SHEEHY: ALL I'M TRYING TO DO IS I JUST HEARD, LIKE, A DESCRIPTION OF A PROCESS. OKAY. SO THE IRB RECOGNIZES IT DOESN'T HAVE THE EXPERTISE TO COMPLY WITH CALIFORNIA STATE LAW. WE HAVE ASKED THEM TO SET UP AN ESCRO. SO THEY SAY, FINE, WE'LL JUST HAVE THE ESCRO DO THAT FOR US; BUT IN THE SAME THING WE SAY, HOWEVER, ESCRO CAN'T BE A SUBCOMMITTEE OF THE IRB, SO HOW CAN IT FULFILL AN IRB FUNCTION IF WE COMPLETELY

SEVERED THAT RELATIONSHIP?

MS. CHARO: BECAUSE IF IT'S AN AD HOC COMMITTEE, IT IS NOT A SUBCOMMITTEE OF THE IRB. IT IS NOT SUBJECT TO THE COMPLICATED 45 CFR 46 RULES ABOUT QUORUMS, ABOUT MEETINGS, ABOUT DOCUMENTATION. THERE'S A WHOLE HOST OF REGULATORY STUFF THAT GOES ALONG WITH BEING AN IRB. YOU GET AUDITED AND YOU HAVE YOUR PAPER TRAILS. IF YOU ARE A SUBCOMMITTEE, YOU'RE SUBJECT TO ALL OF THAT BECAUSE YOU'RE PART OF THE IRB. IF YOU'RE JUST AN AD HOC ADVISORY GROUP, YOU'RE NOT. ALL YOU'RE DOING AT THE END IS YOU'RE DELIVERING YOUR ADVICE TO THE IRB.

MR. SHEEHY: I'M STILL CONFUSED. WELL --

CO-CHAIR LO: LET ME TRY AND SEE IF I CAN HELP US SORT THIS OUT. THIS IS A COMPLICATED ISSUE, AND IT'S ONE WE CLEARLY HAVE TO ADDRESS IN THE FINAL DRAFT GUIDELINES.

STEVE PECKMAN FROM UCLA HAS THOUGHT A LOT ABOUT THIS AND ACTUALLY HAD A LITTLE PRESENTATION FOR US WHICH WE WERE GOING TO INCLUDE AS PART OF THE -- TO LEAD INTO THE WORKING GROUP. WE CAN CERTAINLY ASK HIM FOR HIS INPUT NOW WITH THE VIEW TO MAKING A DECISION AS TO WHETHER WE WANT TO CHANGE WHAT WE NOW HAVE, WHICH WAS DRAFTED BY OUR STAFF CONSISTENT WITH OUR DIRECTIVE TO TRANSLATE THE NAS RECOMMENDATIONS INTO REGULATORY

LANGUAGE. THE ISSUE WE'RE DISCUSSING REALLY HERE IS WHETHER FOR THE INTERIM GUIDELINES WE WISH TO CHANGE THOSE BY, FOR INSTANCE, DELETING THESE TWO SENTENCES IN SUBPART B, AND WE'VE HAD SOME DISCUSSION BACK AND FORTH ABOUT WHETHER THAT WOULD BE DESIRABLE RIGHT NOW TO DEVIATE FROM THE NAS GUIDELINES WITHOUT SORT OF GIVING THE DECISION, SORT OF THE DETAILED ANALYSIS THAT WE WOULD GIVE IT IN THE FINAL.

I GUESS ONE ISSUE IS HOW MUCH WE WANT TO GET INTO THIS TODAY GIVEN OUR DESIRE TO TRY AND PASS INTERIM -- RECOMMENDATIONS FOR INTERIM GUIDELINES.

CO-CHAIR LANSING: I'D LIKE TO MAKE A RECOMMENDATION. THIS ALL STARTED WHEN ALTA GAVE US THIS WONDERFUL PAPER AND REMINDED ALL OF US THAT WE ONLY FUND, WE'RE NOT APPROVING THE RESEARCH. AND FRANCISCO SAID, WELL, LET'S TAKE ADVANTAGE OF WHAT WE'VE GOTTEN. IT SEEMS LIKE IT'S OPENING UP A WHOLE KEG OF PEAS. MAYBE WE SHOULD JUST LEAVE IT THE WAY IT IS FOR THE INTERIM GUIDELINES AND ADDRESS THIS ISSUE AS TO DO WE WANT OUR GUIDELINES TO BE THE STANDARD GUIDELINES FOR ALL THE STATE OF CALIFORNIA OR JUST FOR THE WORK THAT WE FUND BECAUSE I THINK WE HAVE TO GET INTO THE WORK THAT WE'RE REALLY SUPPOSED TO DO AS A COMMITTEE.

DR. KIESSLING: WHAT IS THE PURPOSE OF THESE

LAST TWO SENTENCES? IT SEEMS TO ME LIKE IF WE DIDN'T HAVE THOSE, WE WOULDN'T HAVE A PROBLEM.

MR. SHEEHY: I DON'T SEE WHY -- WE CAN PUT THEM BACK IN IF WE FEEL LIKE WE NEED THEM.

DR. HALL: WELL, I THINK THERE IS A REAL DESIRE OF SOME -- IN SOME PLACES TO SET UP THE ESCRO AS A PART OF THE IRB COMMITTEE. AND I THINK ALTA HAS MADE THE POINT THAT THIS HAS VERY POWERFUL IMPLICATIONS.

DR. KIESSLING: THIS IS A NEGATIVE REGULATORY.

DR. HALL: YES. LET'S DON'T DO THIS. IF AFTER A LONG DISCUSSION WE DECIDE IT'S OKAY, WE CAN, BUT IT'S A VERY SERIOUS STEP TO TAKE.

MR. SHEEHY: I THINK THAT THERE'S A RELATIONSHIP BETWEEN IRB'S AND STEM CELL RESEARCH IN CALIFORNIA. AND WHY DECIDE WHAT THAT RELATIONSHIP IS WITH ESCRO'S AND WE START PUTTING CATEGORIES ON IT? WE HAVEN'T HEARD FROM ANY INSTITUTION YET WHO IS ACTUALLY DOING STEM CELL RESEARCH, HAS IRB APPROVAL OF THEIR HUMAN EMBRYONIC STEM CELL RESEARCH, AND UNDERSTAND HOW THEY THINK THAT THEY'RE GOING TO BRING IN ESCRO'S.

DR. HALL: I'M HAPPY TO HEAR THAT LATER, JEFF, BUT I THINK FOR RIGHT NOW THE DEFAULT CASE OUGHT TO BE TO FOLLOW THE NATIONAL STANDARD.

MR. SHEEHY: THEN WE'RE SAYING THAT EVERYBODY

WHO GETS FUNDING HAS TO SET UP AN ESCRO THAT'S COMPLETELY SEPARATE FROM THEIR IRB AND CANNOT HAVE ANY RELATIONSHIP WITH THE IRB WHICH HAS TO APPROVE ALL OF THEIR OTHER HUMAN EMBRYONIC STEM CELL RESEARCH THAT'S GOING ON ACCORDING TO STATE LAW.

DR. HALL: I JUST THINK THE DEFAULT CASE OUGHT TO BE THE NATIONAL STANDARD RATHER THAN TO TRY TO SET A NEW STATE STANDARD.

MR. SHEEHY: YOU HAVE A DIFFERENT STATE STANDARD. THAT'S THE PROBLEM.

MR. KLEIN: SINCE THERE ARE DIFFERENT OPINIONS, MR. CHAIRMAN, MAYBE WE COULD JUST HAVE A VOICE -- AN INDIVIDUAL ROLL CALL VOTE AND DECIDE WHICH WAY WE WANT TO GO RIGHT AT THE MOMENT BECAUSE THERE'S LEGITIMATE POINTS OF VIEW ON BOTH SIDES, AND WE'LL FIGURE OUT WHETHER WE'RE GOING TO ADDRESS IT AS AN INTERIM OR AS THE FINAL.

SO I THINK IT WOULD TAKE A MOTION. AND THE MOTION WOULD BE FOR US TO FOLLOW THE NATIONAL ACADEMY FOR THE INTERIM, NOT ADDRESSING THE FINAL, BUT JUST FOR THE INTERIM GUIDELINES. THAT WOULD BE THE MOTION TO TAKE A ROLL CALL. I'M HAPPY WITH EITHER OUTCOME.

WE'RE JUST GOING TO VOTE ON WHETHER OR NOT WE'RE GOING TO INCLUDE -- WHETHER WE'RE GOING TO STAY WITH THE NATIONAL ACADEMY STANDARDS FOR THE INTERIM

REGULATIONS OR NOT, AND IT'S JUST AN INDIVIDUAL ROLL CALL VOTE SINCE --

MR. SHESTACK: I'M SORRY. FOR THE ENTIRE INTERIM GUIDELINES OR FOR SIMPLY THE SECTION THAT JEFF HAD A QUESTION ABOUT?

MR. KLEIN: JUST FOR THAT SECTION. JUST THE QUESTION OF WHETHER IT CAN BE A SUBCOMMITTEE OF THE IRB.

DR. PRIETO: FOR SECTION 6(B).

MR. SHEEHY: COULD WE ACTUALLY MAKE THE MOTION MORE SUBSTANTIVE AND JUST MAKE THE MOTION WHETHER OR NOT TO REMOVE THOSE TWO SENTENCES?

MR. KLEIN: THAT'S FINE. I WOULD ACCEPT THAT AS AN AMENDMENT, JEFF. SO THE MOTION WILL BE WHETHER OR NOT TO REMOVE THOSE TWO SENTENCES.

MR. SHEEHY: YES MEANS?

MR. KLEIN: YES MEANS WE'LL REMOVE THEM; NO MEANS WE WON'T AT THIS TIME, BUT IT DOES NOT FORECLOSE THE ISSUE LATER. IS THERE A SECOND?

DR. KIESSLING: BEFORE WE --

DR. ROWLEY: THIS IS JANET. WHAT ARE THE CONSEQUENCES? I'M HAVING A HARD TIME FOLLOWING SOME OF THIS. SO IF YOU VOTE IN FAVOR OF THE MOTION, ARE YOU FOR MAINTAINING THE STATEMENT MORE OR LESS AS THE NATIONAL ACADEMY HAD IT OR MODIFYING IT?

MR. KLEIN: IF YOU VOTE IN FAVOR OF THE MOTION -- IF YOU VOTE -- THE WAY THAT THE MOTION HAS BEEN REPHRASED IS THAT IF YOU VOTE FOR THE MOTION, YOU'RE GOING TO REMOVE THE TWO SENTENCES, SO YOU ARE DEPARTING FROM THE NATIONAL ACADEMY STANDARDS.

DR. KIESSLING: BEFORE WE VOTE --

MR. KLEIN: THE WAY THAT JEFF HAS REPHRASED THE QUESTION, THE QUESTION IS A MOTION TO REMOVE THE TWO SENTENCES.

MR. SHEEHY: FOR THE INTERIM STANDARDS.

MR. KLEIN: FOR THE INTERIM STANDARDS. AND SO IF YOU VOTE FOR THIS MOTION, THEN YOU WOULD BE DEPARTING FROM THE NATIONAL ACADEMY GUIDELINES.

DR. KIESSLING: BEFORE WE VOTE, CAN I, SINCE I'M THE ONE WHO SUGGESTED DOING THAT, CAN I SAY THAT I'VE BEEN CONVINCED THAT THAT'S AN IMPORTANT NEGATIVE REGULATORY AGAINST USING THE IRB?

MR. SHEEHY: YOU DON'T HAVE TO VOTE WITH ME. THAT'S OKAY.

DR. KIESSLING: I THINK I'M CONVINCED NOW THAT IF WE REMOVE THOSE SENTENCES, INSTITUTIONS MIGHT GIVE THIS COMMITTEE WORK TO AN IRB, AND THAT THAT COULD BE A PROBLEM.

CO-CHAIR LO: IS THERE A SECOND TO THAT?

DR. EGGAN: I SECOND IT.

CO-CHAIR LO: LET ME ASK FOR PUBLIC COMMENT. AGAIN, THIS IS ON THE ISSUE ON WHETHER FOR THE INTERIM GUIDELINES WE SHOULD REMOVE THESE TWO SENTENCES. LATER TODAY AND SUBSEQUENTLY WE WILL DISCUSS THE ISSUE OF THE RELATIONSHIP BETWEEN ESCRO'S AND IRB'S IN MUCH MORE DETAIL.

MR. PECKMAN: STEVE PECKMAN, UCLA. I APPRECIATE THE DISCUSSION THAT'S GOING ON REGARDING THE INTERIM GUIDELINES, AND I ALSO APPRECIATE THE IMPORTANCE OF FINALIZING INTERIM GUIDELINES FOR THE NEXT NINE MONTHS OF WORK THAT YOU HAVE TO DO. HOWEVER, I THINK THAT YOU ALSO SHOULD APPRECIATE WHAT IT TAKES FOR AN INSTITUTION TO IMPLEMENT GUIDELINES. AND FOR AN INSTITUTION TO IMPLEMENT GUIDELINES NOW THAT MAY BE CHANGED LATER IN NINE MONTHS IS LIKE GETTING A VERY BIG SHIP TO CHANGE DIRECTION IN THE MIDDLE OF THE OCEAN. AND THE AMOUNT OF WORK THAT IT'S GOING TO TAKE TO IMPLEMENT THESE GUIDELINES NOW AND THEY MAY BE FUNCTIONALLY AND VERY FUNDAMENTALLY ALTERED LATER CAN BE A VERY BIG ISSUE FOR INSTITUTIONS THAT ARE GOING TO DO THIS RESEARCH IN ORDER FOR THEM TO MAINTAIN COMPLIANCE WITH THE INTENT OF THE GUIDELINES.

THAT BEING SAID, I WOULD STRONGLY ENCOURAGE YOU TO WAIT ON THIS SECTION OF THE GUIDELINES UNTIL AFTER I CAN GIVE MY PRESENTATION BECAUSE I THINK THAT

YOU MAY HEAR SOME THINGS DIFFERENT THAN WHAT YOU'VE DISCUSSED SO FAR. AND THIS IS FROM A VERY GROUND FLOOR PERSPECTIVE IN IMPLEMENTING GUIDELINES AND HELPING RESEARCHERS CONDUCT THEIR RESEARCH AND DEALS WITH THE ISSUES OF NOT ONLY IRB REVIEW AND WHAT IRB'S ARE REQUIRED TO DO, BUT IACUC'S AND ALSO ESCRO COMMITTEES AS WELL. AS INSTITUTIONS HAVE TO IMPLEMENT ALL THESE THINGS THAT YOU ARE GOING TO CARRY OUT, THE IMPORTANCE OF GETTING SOMETHING SOLID THAT WE CAN USE AND THAT ULTIMATELY WE CAN USE OVER A LONG PERIOD OF TIME IS GOING TO BE CRUCIAL TO THE EFFECTIVE AND RESPONSIBLE SPENDING OF RESEARCH DOLLARS IN THE FUTURE.

MS. FOGEL: HI. I'M SUSAN FOGEL OF THE PRO CHOICE ALLIANCE FOR RESPONSIBLE RESEARCH. AND I JUST CAN'T STATE STRONGLY ENOUGH HOW IMPORTANT IT IS TO MAKE SURE THAT NOTHING YOU DO HERE UNDERMINES REPRODUCTIVE RIGHTS IN CALIFORNIA. THAT CERTAINLY WOULD BE BEYOND YOUR PURVIEW, WHETHER OR NOT YOU CAN DECIDE WHAT RESEARCH STANDARDS ARE FOR OTHER KINDS OF RESEARCH. BUT ANYTHING IN YOUR REGULATIONS THAT RECOGNIZES AN EMBRYO AS A HUMAN SUBJECT WILL GO MUCH FARTHER THAN JUST WHAT YOUR WORK IS. AND I APPRECIATE THE IMPORTANCE OF SIMPLIFYING GUIDELINES AND NOT MAKING TOO MANY LAYERS OF ADMINISTRATION, BUT YOU MAY BE AWARE THERE IS AN INITIATIVE ON OUR NOVEMBER BALLOT, PROP 73,

WHICH WILL REDEFINE WHEN LIFE BEGINS. AND IT'S SOMETHING ELSE YOU ALL OUGHT TO BE PAYING ATTENTION TO IN TERMS OF HOW THAT COULD IMPACT YOUR WORK OR OUR WORK. BUT TO THE EXTENT THAT CREATING TOO CLOSE A LINKAGE BETWEEN AN IRB FOR HUMAN SUBJECTS AND EMBRYOS AND ELEVATES THEIR STATUS WOULD BE REALLY DISASTROUS. THANK YOU.

MR. KLEIN: MR. CHAIRMAN, I PERSONALLY WOULD APPRECIATE GETTING THE MATERIALS ON PROPOSITION 73 AND THAT SPECIFIC ISSUE BEING ADDRESSED.

CO-CHAIR LO: SO WE CAN DISTRIBUTE TO THE REST OF THE WORKING GROUP.

MR. REED: I DON'T REALLY UNDERSTAND MUCH OF WHAT I'VE JUST HEARD, BUT I AM FRIGHTENED AT ANYTHING THAT COULD ALLOW FEDERAL GOVERNMENT TO TOUCH OUR RESEARCH IN ANY WAY. I THOUGHT NAS WAS REASONABLE, IT SEEMS GOOD TO ME, BUT I AM ALSO AFRAID OF WHAT'S HAPPENING AT NIH. IT SEEMS TO ME THAT THEY'RE BEING, QUOTE, UNQUOTE, STREAMLINED AND THAT MEANS UNDER MORE CENTRAL CONTROL. AND WHAT I'M HEARING ABOUT IRB'S, I HOPE THAT'S NOT IN ANY WAY TOUCHED BY THE NATIONAL GOVERNMENT.

LIKE I SAY, I DON'T UNDERSTAND THE ISSUE THAT YOU ARE WORKING WITH, BUT IT SEEMS TO ME IT WOULD BE A LOT EASIER TO TIGHTEN LATER, IF NEED BE, THAN TO

TIGHTEN DOWN TOO HARD NOW AND THEN TRY TO LOOSEN UP LATER.

CO-CHAIR LO: THERE WAS A SUGGESTION THAT STEVE PECKMAN MADE TO SORT OF DEFER THE MOTION BEFORE US TILL AFTER HE'S GIVEN A PRESENTATION THAT WE HAD ASKED HIM TO PREPARE WITH REGARD TO THE WORKING GROUP IN THE CONTEXT OF THE WORKING GROUP ISSUE. SO THAT'S ANOTHER OPTION.

ANY FURTHER DISCUSSION BY THE COMMITTEE IN LIGHT OF THE PUBLIC COMMENTS?

MR. SHESTACK: JEFF, ARE YOU FINE TO DEFER THIS MOTION? I, FOR ONE, WOULD LIKE TO HEAR MORE INFORMATION.

MR. SHEEHY: THAT ACTUALLY WOULD BE A GREAT OUTCOME. THAT WOULD BE A GREAT OUTCOME IF WE COULD GET MORE INFORMATION ABOUT THIS ISSUE BECAUSE MY FEAR IS NOT -- THERE'S NO POLITICAL ISSUE. I MEAN I INVITED STEVE TO COME TODAY. THERE ARE CONCERNS FROM INSTITUTIONS THAT ARE GOING TO IMPLEMENT THESE GUIDELINES ON THIS SPECIFIC ISSUE, AND WE'RE PUTTING IN INTERIM GUIDELINES AND WE'RE GOING TO BE GIVING THEM MONEY. AND THEY'RE SAYING THAT THESE GUIDELINES ARE GOING TO BE DIFFICULT FOR THEM TO IMPLEMENT, SO I WOULD LIKE TO HEAR WHY IT'S GOING TO BE DIFFICULT FOR THEM TO IMPLEMENT.

MR. SHESTACK: COULD I MAKE A SUGGESTION? I DON'T KNOW HOW YOU'RE PLANNING TO RUN THE MEETING, BUT AS WE RUN THROUGH THE SECTIONS, OBVIOUSLY PEOPLE BRING UP THEIR MAIN SPECIFIC POINTS AS IN THIS SECTION JEFF BROUGHT UP THIS. CAN WE JUST RUN THROUGH THE REST OF THE SECTIONS, SEE IF THERE'S ANYTHING REALLY SALIENT, AND THEN HEAR STEVE'S REPORT. IS THAT A WAY TO GET THROUGH THE MATERIAL? I'M JUST TRYING TO FIGURE OUT HOW WE CAN GET THROUGH THE MATERIAL.

DR. PRIETO: IF WE HAVE A MOTION ON THE TABLE, DO WE NEED A MOTION TO TABLE THIS?

MR. KLEIN: I'M PREPARED TO FOLLOW THAT SUGGESTION AND DEFER THE VOTE ON THAT MOTION UNTIL AFTER WE RUN THROUGH THE OTHER MATERIALS.

MR. SHESTACK: ONLY BECAUSE THERE ARE NINE OTHER SECTIONS, AND THERE MAY BE SOME REAL SALIENT COMMENTS FROM OTHER MEMBERS OF THE COMMITTEE. I DON'T KNOW.

CO-CHAIR LO: SOMEONE WANTS TO MOVE TO TABLE?

CO-CHAIR LANSING: THE THING THAT'S BOTHERING ME -- I JUST -- I LIVE IN FEAR BECAUSE WE HAVE A MEETING THAT'S COMING UP. I JUST WANT TO SAY THIS, AND I WANT TO HEAR STEVE'S REPORT AND HEARD SOME OF IT IN PREPARATION FOR THIS MEETING. BUT I JUST WONDER IF THIS ISSUE IS SUCH A BIG ISSUE BECAUSE IT'S

REQUIRING -- WE'RE GOING TO HAVE STEVE'S REPORT THAT'S GOING TO REQUIRE A LOT OF CONVERSATION, THAT WE'RE GOING TO KEEP TALKING, AND WE CAN'T LEAVE THIS MEETING WITHOUT HAVING SOME INTERIM GUIDELINES OR WE CAN'T GIVE OUT OUR FIRST GRANTS. AND I THINK THAT WOULD BE A TERRIBLE THING.

I'M JUST SAYING THAT I WANT TO SAY AGAIN THAT THESE ARE INTERIM GUIDELINES, AND THEY ARE GOING TO BE, I HOPE, OR OUR COMMITTEE IS NOT GOING TO BE DOING ANY WORK, CHANGED. AND IT'S A QUARTER OF THREE, TEN OF THREE. I'M JUST TRYING TO BE PRACTICAL.

I WANT TO ASK THE SERIOUS QUESTION, WHICH I ASKED ONCE BEFORE. AND, JEFF, I WANT YOU TO POSSIBLY THINK ABOUT WHETHER WE SHOULD JUST LEAVE THIS WHOLE THING ALONE TILL, AND ALTA AND FRANCISCO, IF WE SHOULD JUST LEAVE THIS WHOLE THING ALONE, STAY WITH THE LANGUAGE THE WAY IT IS, NOT ADD ANY LANGUAGE, SO WE'RE NOT GETTING INTO THE WHOLE ISSUE, AND THEN DO OUR WORK, AND THEN DECIDE WHETHER OR NOT TO ADD ANY LANGUAGE OR NOT TO ADD ANY LANGUAGE.

THIS HAS BEEN -- AND PUBLIC INPUT AND EVERYTHING. I JUST LIVE IN FEAR THAT YOUR REPORT IS GOING TO BE TERRIFIC. IT'S GOING TO STIMULATE TWO HOURS OF CONVERSATION, AND WE'RE GOING TO LEAVE HERE WITHOUT HAVING ANY INTERIM GUIDELINES, AND THEN WE

CANNOT GIVE OUT THE GRANTS THAT WE ALL WANT TO GIVE OUT.

I JUST ASK US TO THINK ABOUT DEFERRING THIS WHOLE BIG ISSUE INTO OUR STUDY GROUPS AND REALLY NOT LISTENING TO YOUR REPORT AND REALLY DELVING INTO IT AS WE SHOULD. WE HAVE THREE HOURS LEFT.

DR. KIESSLING: WE CAN JUST TABLE THAT MOTION, RIGHT?

MR. SHESTACK: ALL WE'RE ASKING TO TABLE -- TO POSTPONE THE MOTION AND SEE AT THE END WHEN WE'VE GONE THROUGH THE INTERIM -- WE ARE GOING GO THROUGH -- WE'RE GOING TO GO THE REST OF THE MAIN SECTIONS, RIGHT?

DR. PRIETO: AND THEN WE CAN BRING THIS UP AGAIN OR NOT.

(OVERLAPPING DISCUSSION AMONG THE MEMBERS.)

CO-CHAIR LO: I THINK WHAT WE WANT TO DO IS MAKE SURE THAT WE HAVE COVERED ANY IMPORTANT ISSUES THAT ANYONE WANTS TO RAISE IN TERMS OF THE INTERIM GUIDELINES.

DR. PRIETO: I MOVE THAT WE DEFER THIS QUESTION.

MR. KLEIN: SECOND.

CO-CHAIR LO: THOSE IN FAVOR OF TABLING. THOSE OPPOSED? LET'S TABLE THAT AND TRY AND COME BACK

TO IT.

ARE THERE OTHER ISSUES WITH REGARD TO THE INTERIM GUIDELINES THAT PEOPLE FEEL WE MUST DISCUSS BECAUSE THEY'RE UNCOMFORTABLE THEY'RE BEING IN PLACE AS JUST INTERIM GUIDELINES? SO WE'RE TRYING TO DISTINGUISH THOSE ISSUES FROM ISSUES THAT WE WILL CERTAINLY WANT TO DISCUSS IN WORKING GROUPS AND WITH THE PUBLIC FOR FINAL DRAFT GUIDELINES.

DR. HALL: SO WHAT'S THE -- YOU WANT TO HOLD THIS, THEN, AND GO ON TO THE STUDY GROUPS?

CO-CHAIR LO: NO. NO. WE'RE TRYING TO SEE IF THERE ANY OTHER BIG ISSUES ON THE INTERIM GUIDELINES, THEN COME BACK TO THIS ONE AFTER WE'VE GOT EVERYTHING ELSE OUT OF THE WAY.

MR. SHESTACK: WELL, THE STUDY GROUPS PERTAIN ULTIMATELY TO SOME OF THE THINGS IN HERE.

DR. HALL: BUT THE STUDY GROUPS HAVE A LONG-TERM AIM. WE TRIED TO DISTINGUISH THAT, THAT WE HAVE AN ITEM TO GET DONE -- IT'S A COMPLICATED THING. WE'RE DISCUSSING ISSUES WITH SORT OF DOUBLE VISION. ONE IS TO GET TO THIS END POINT OF APPROVING, AND THE OTHER IS A LONG DELIBERATIVE PROCESS IN WHICH WE HEAR A VARIETY OF POINTS OF VIEW, HEAR FROM THE PUBLIC, DISCUSS AMONG OURSELVES, AND THEN ARRIVE AT SOME CONSIDERED DECISION BY NOVEMBER 1ST.

CO-CHAIR LANSING: I WANT TO BE CLEAR. I'M ACTUALLY SUGGESTING THAT JEFF, YOUR ISSUE IS SUCH A BIG ISSUE, THAT IT REALLY SHOULD GO INTO THAT KIND OF LONG THING. I DON'T THINK WE'RE GOING TO HAVE THE ANSWER TODAY. WE'VE BEEN -- I GUESS I'VE SAID IT ALREADY. THE INTERIM GUIDELINES ARE ONLY INTERIM GUIDELINES TO GET US TO BE ABLE TO APPROVE THE GRANTS. THE GOAL WAS TO SEE IF THERE WAS ANY MAJOR THING THAT WE NEEDED TO CHANGE.

DR. KIESSLING: WE DON'T HAVE TO ADOPT THEM UNTIL 5:30 OR SOMETHING?

CO-CHAIR LANSING: THAT'S CORRECT.

MR. KLEIN: I HAD A TECHNICAL QUESTION ON 100008. EARLIER ON WAS THERE A CHANGE TO SUBPART E, SO IT NOW READS NO LONGER THAN 12 DAYS?

MR. HARRISON: WE MADE A CHANGE DURING THE LUNCH BREAK TO CONFORM THE LANGUAGE TO THE LANGUAGE THAT'S USED IN AN EARLIER SECTION.

DR. PRIETO: WHICH IS?

MR. KLEIN: IT SAYS NO LONGER THAN 12 DAYS; IS THAT RIGHT?

MR. HARRISON: IT'S AFTER THE APPEARANCE OF THE PRIMITIVE STREAK OR AFTER 12 DAYS, WHICHEVER IS EARLIER. I THINK THE LANGUAGE IS UP ON THE SCREEN NOW.

CO-CHAIR LO: ANY OTHER BURNING ISSUES?

MR. SHESTACK: FOR INSTANCE, IT SAYS INSTITUTIONS ENGAGED IN HUMAN STEM CELL RESEARCH SHALL MAINTAIN AT MINIMUM A REGISTRY. NOW, I'M ASSUMING -- I JUST DON'T UNDERSTAND THE LANGUAGE. I WAS ASSUMING THAT WE WILL MAINTAIN A REGISTRY, BUT -- THAT CIRM WILL MAINTAIN A REGISTRY, BUT THIS MEANS THAT ANY INSTITUTION, SAY, UCLA, WILL MAINTAIN A REGISTRY OF STEM CELL LINES? REGISTRY MEANS ALL AVAILABLE LINES. DOESN'T MEAN LINES THAT THEY ARE WORKING WITH. SO WHAT DOES IT MEAN?

DR. PRIETO: CAN I RESPOND TO THAT?

MR. SHESTACK: ALTA, CAN YOU TELL ME WHAT THE WORD "REGISTRY" MEANS HERE?

MS. CHARO: IN THE NATIONAL ACADEMIES' REPORT, IT REFERRED ONLY TO INSTITUTIONS KEEPING TRACK OF LINES BEING USED AT THAT INSTITUTION.

DR. PRIETO: CAN I RESPOND TO THAT? THE BANKING STUDY GROUP ADDRESSED THIS, AND THIS IS GOING TO BE IN OUR REPORT.

MR. SHESTACK: DOESN'T ACTUALLY MEAN -- SO IT'S NOT REALLY A REGISTRY. IT'S A LIST OF THE CELL LINES THEY ARE WORKING WITH AND THEIR DERIVATIONS?

MS. CHARO: RIGHT. BASICALLY IT WAS IF SOMEBODY CALLS UCSF AND SAYS WHAT DO YOU GOT, THEY SHOULD BE ABLE TO ANSWER. CURRENTLY LARGE INSTITUTIONS

COULDN'T.

MR. SHESTACK: AS OPPOSED TO SOMEONE ELSE WHO MIGHT AS A SERVICE FOR THE RESEARCH COMMUNITY HAVE A REGISTRY OF ALL AVAILABLE CELL LINES.

MS. CHARO: NO. NO. NO.

DR. HALL: THIS IS FOR THEIR OWN REGULATORY PURPOSES AS MUCH AS ANYTHING ELSE.

CO-CHAIR LO: OTHER ISSUES?

DR. PRIETO: I THINK WE TOUCHED ON THIS THIS MORNING, BUT WHETHER THESE ADDRESS SPECIFIC OTHER CATEGORIES OF STEM CELL LINES SUCH AS ADULT STEM CELLS THAT ARE ALLOWED FOR UNDER THE INITIATIVE. I DON'T KNOW WHETHER WE NEED TO INSERT LANGUAGE TO ACCOMMODATE THAT.

DR. HALL: OKAY. SO THIS IS AN IMPORTANT ISSUE BECAUSE -- FOR BOTH ADULT AND FETAL STEM CELL LINES. THAT'S NOT COVERED HERE. WE WILL NEED REGULATIONS FOR THOSE, AND WHAT WE PROPOSE TO DO, IT'S A LESS ELABORATE KIND OF THING, BUT WE PROPOSE TO LOOK AT EXISTING REGULATIONS IN OTHER PLACES, NIH AMONG OTHERS, AND THEN TO BRING TO YOU AT THE NEXT MEETING, THE NOVEMBER MEETING, A POLICY.

DR. PRIETO: SO WE'LL HAVE A SEPARATE SET OF GUIDELINES.

DR. HALL: AN INTERIM POLICY WITH RESPECT TO

THOSE LINES. WE HOPE THAT THE LONG-TERM POLICY WILL INCLUDE MATERIAL ON THAT SO THAT THAT CAN BE COVERED BECAUSE IT IS CERTAINLY WORK THAT WE WILL BE FUNDING, AND WE WILL NEED TO STATE WHAT OUR STANDARDS ARE. FOR EXAMPLE, IN THE GRANTS POLICY STATEMENT WE NEED TO REFER TO SOMETHING. SO WE WOULD LIKE TO HAVE THAT OUTLINED, BUT THAT'S NOT THE IMMEDIATE JOB AT HAND. SO WE'LL DEFER THAT. NOT DEFER DISCUSSION ON IT, AGAIN THIS DOUBLE VISION. WE'LL DEFER IT AS AN INTERIM STANDARD, BUT WE HOPE THAT AS THE NEXT TWO MONTHS GO ON, IN YOUR DISCUSSIONS YOU WILL THINK ABOUT IT.

CO-CHAIR LO: OTHER ISSUES?

DR. WILLERSON: I'D RECOMMEND YOU CONSIDER THE PLACENTAL AND CORD BLOOD. I'D RECOMMEND YOU CONSIDER THE PLACENTAL AND CORD BLOOD CELLS IN THAT CATEGORY.

DR. HALL: ABSOLUTELY. THANK YOU.

DR. TAYLOR: I GUESS I'M INTERPRETING THIS AS WHAT ARE THE OTHER AREAS AND DO WE WANT TO BRING THOSE UP NOW?

CO-CHAIR LO: WHAT ARE THE OTHER ISSUES WE WANT TO CHANGE IN THE INTERIM GUIDELINES.

DR. TAYLOR: SO, AGAIN, SORT OF IN RESPONSE TO STEVE'S COMMENTS, BUT AS A MEMBER OF THE DONOR RECRUITMENT AND PROTECTION SUBCOMMITTEE, JUST TELL ME

THAT WE CAN'T GO THERE, BUT I THINK THE COMPENSATION ISSUE IS GOING TO BE A VERY IMPORTANT, PRACTICAL ONE THAT I KNOW WE DON'T HAVE TIME TO PROBABLY DEAL WITH THAT AT THIS POINT, BUT I THINK THAT'S AN ISSUE.

CO-CHAIR LANSING: THAT'S AN ISSUE FOR OUR SUBCOMMITTEE, AND THAT IS A BIG ISSUE AND WE HAVE TO HAVE TIME TO DEAL WITH IT.

MR. SHESTACK: I THINK THIS IS TOO LIMITED.

MR. KLEIN: WE CANNOT.

CO-CHAIR LANSING: SAYS WE CAN'T COMPENSATE. I UNDERSTAND THAT, BUT WE CAN DEAL WITH --

CO-CHAIR LO: AS AN INTERIM GUIDELINE, WE'RE SAYING MAY NOT COMPENSATE.

MR. KLEIN: WE ACTUALLY CAN'T COMPENSATE AS A FINAL GUIDELINE EITHER. WE CAN'T DO IT EITHER AS INTERIM OR FINAL.

NOW, THERE'S A SEPARATE ISSUE, WHICH IS THAT IF CELL LINES ARE DERIVED FROM INSTITUTIONS NOT USING OUR FUNDS. FOR EXAMPLE, THEY COULD HAVE A COMPENSATION POLICY AND AS LONG AS IT MEETS CERTAIN ETHICAL STANDARDS. AND OUR RESEARCHERS COULD USE THOSE LINES, BUT OUR RESEARCHERS CANNOT DERIVE A LINE WHERE WE HAVE COMPENSATION FOR THE OOCYTE DONATIONS.

CO-CHAIR LANSING: THERE IS WHERE I GET CONFUSED.

MR. SHESTACK: PER THE LEGISLATION, NOT THE GUIDELINES.

MR. KLEIN: PER THE INITIATIVE.

CO-CHAIR LANSING: IF WE ADAPTED -- GOING BACK TO THE BIG ISSUE, IF WE ADAPTED THAT WE CAN ONLY FUND PEOPLE -- RESEARCH INSTITUTIONS THAT ADHERE TO OUR GUIDELINES, THE FAMOUS SENTENCE THAT WE'RE TALKING ABOUT, YOU WOULD NOT BE ABLE TO DO THAT THEN.

MR. KLEIN: TECHNICALLY IT WOULD CREATE A PROBLEM.

CO-CHAIR LANSING: THAT'S SUCH A BIG ISSUE. I'M NOT SAYING YOU'RE FOR IT. THAT'S WHY I WOULD LEAVE THE GUIDELINES ALONE.

CO-CHAIR LO: IF YOU WANTED TO CHANGE THE POLICY ON COMPENSATION, IT WILL REQUIRE GOING TO THE LEGISLATURE, GETTING TWO-THIRDS MAJORITY, AND NOT BEING ABLE --

MR. KLEIN: TWO MORE YEARS.

CO-CHAIR LO: IT'S NOT SOMETHING WE CAN DO TODAY.

CO-CHAIR LANSING: WE PAY FOR EXPENSES IF YOU MISS WORK.

MR. KLEIN: WE PAY FOR EXPENSES, BUT NOT LOST WAGES.

CO-CHAIR LANSING: NOT LOST WAGES. EXPENSES

TO GET TO --

MR. KLEIN: EXPENSES.

DR. EGGAN: REIMBURSEMENT.

MR. SHESTACK: SO I UNDERSTAND THESE GUIDELINES. OBVIOUSLY, ACCORDING TO THE INITIATIVE AND THE GUIDELINES, THERE'S NO COMPENSATION, NO IN-KIND COMPENSATION, JUST DIRECT EXPENSE REIMBURSEMENT. BUT ARE CIRM-FUNDED SCIENTISTS DOING CIRM-FUNDED MOLECULAR BIOLOGY ALLOWED TO USE OTHERWISE DERIVED CELL LINES FOR WHICH PEOPLE MAY HAVE RECEIVED COMPENSATION?

MR. KLEIN: YES.

CO-CHAIR LANSING: UNLESS WE CHANGE THE SENTENCE IN THE BEGINNING.

MR. SHESTACK: CURRENTLY ACCORDING TO THESE INTERIM GUIDELINES, IF I WORK AT UCLA AND I GET SOME CELL LINES FROM ISRAEL WHERE THEY PAID SOMEBODY TO DONATE THE EGGS, TOTALLY FINE. I'M ALLOWED TO DO IT.

CO-CHAIR LANSING: UNLESS YOU CHANGE THAT SENTENCE. THAT'S THE KIND OF ISSUE THAT COMES UP WITH THAT SENTENCE.

MR. KLEIN: AS LONG AS YOU MET INTERNATIONALLY ACCEPTED ETHICAL STANDARDS WITH THE CONSENT AND OTHER ISSUES.

MR. SHESTACK: FOR INSTANCE, THE BRITISH STEM CELL --

MR. KLEIN: THE BRITISH STEM CELL BANK MAY HAVE A NUMBER OF LINES WHERE UNDER ETHICAL PROCEDURES THEY DID COMPENSATE PEOPLE FOR LOST WORK TIME, FOR EXAMPLE, AND THOSE LINES ARE PERFECTLY ACCEPTABLE. BUT IT'S JUST THAT OUR MONEY CANNOT BE USED ON DERIVING A LINE WHERE THE OOCYTE DONOR IS PAID FOR TIME OR OPPORTUNITY COSTS.

CO-CHAIR LO: OTHER ISSUES FOR THE INTERIM GUIDELINES?

DR. KIESSLING: I HAVE A QUESTION ON SECTION 9, SUBSECTION B. IT SAYS INSTITUTIONS ENGAGED IN HES RESEARCH SHALL CREATE MECHANISMS FOR ESTABLISHING CENTRAL REPOSITORIES FOR HES CELL LINES. WHAT IF YOU'RE NOT DERIVING ANY CELL LINES?

MR. SHESTACK: RIGHT. THAT DOESN'T MAKE -- I HAD A SIMILAR QUESTION. THAT DOESN'T APPLY TO GRANTEES AS MUCH AS --

MS. CHARO: JUST TO -- I'M GOING TO APOLOGIZE IN ADVANCE. I REALLY DID NOT MEAN TO BE THE TROUBLEMAKER, BUT THIS IS EXACTLY THE KIND OF THING THAT ARISES WHEN THIS IS WRITTEN NOT TO FOCUS ON BEING A FUNDING AGENCY, BUT IT WAS A TRANSFORMATION OF SUBSTANTIVE RULES INTO REGULATORY LANGUAGE AS OPPOSED TO FUNDING CRITERIA. SO THIS ENTIRE SECTION ON BANKING IS ONE THAT READS BETTER IF YOU ARE DIRECTLY REGULATING

INSTITUTIONS IN YOUR STATE AND YOU WANT TO MAKE THIS A REQUIREMENT. IT DOES NOT READ VERY SENSIBLY IF YOU'RE A FUNDING AGENCY DECIDING WHETHER OR NOT TO GIVE MONEY TO DR. ROBERT TAYLOR.

MR. SHESTACK: BUT IT MIGHT MAKE SENSE AS A POLICY FOR YOUR FUNDING. THE FUNDING INSTITUTION MIGHT DECIDE THAT THEY WANT TO PROMOTE BANKING AND DO IT.

MS. CHARO: SO AT GREAT RISK AND WITH GREAT TREPIDATION, I WOULD LIKE TO AT LEAST FLOAT THE IDEA THAT THIS ENTIRE SECTION ON BANKING AND DISTRIBUTION, WHICH IS THE MOST PROBLEMATIC OF ALL --

MR. SHESTACK: IN TERMS OF THE ACTUAL LANGUAGE.

MS. CHARO: IN TERMS OF THE INTERIM GUIDELINES AND SUBSTANTIVE REQUIREMENTS BEING PLACED ON INSTITUTIONS, THAT THIS ONE SECTION BE DELETED FROM THE INTERIM GUIDELINES AND THEN REVISITED AS WE MOVE TO FINAL. JUST DELETE IT IN TOTO. PUT NO REQUIREMENTS ON INSTITUTIONS THAT THEY CREATE STEM CELL BANKS BECAUSE THIS WAS AIMED AT IF YOU'RE GOING TO CREATE A STEM CELL BANK, HERE'S HOW TO DO IT. THAT WAS REALLY WHERE IT WAS GOING.

DR. HALL: SO WHAT DO YOU WANT TO DELETE?

MS. CHARO: ALL OF SECTION 10.

DR. HALL: NO REGISTRY?

MS. CHARO: THIS IS NOT -- IT'S ALL SO MIXED UP.

DR. HALL: YOU KNOW --

DR. KIESSLING: SECTION B IS REALLY A PROBLEM.

DR. HALL: LET ME JUST SAY THAT IT SEEMS TO ME THAT IF YOU CREATE MECHANISMS FOR ESTABLISHING, INCLUDING PARTICIPANTS OR AUGMENTATIONS OF EXISTING QUALITY RESEARCH LINE REPOSITORIES, THAT SIMPLY MEANS THAT, IT SEEMS TO ME, YOU, FOR EXAMPLE, IN THE CASE OF HARVARD INVESTIGATORS WHO HAVE SUBMITTED THEIR LINES TO THE UK STEM CELL BANK, THIS IS A PERFECT EXAMPLE OF THAT. I THINK IT'S ENCOURAGING PEOPLE TO PUT LINES IN BANKS. THEY DON'T HAVE TO BE ESTABLISHED BY THAT INSTITUTION.

DR. KIESSLING: THIS ONLY APPLIES TO RESEARCH WHERE YOU ARE DERIVING LINES. SO WHAT IF YOU ENGAGE IN A LOT OF HES RESEARCH, BUT YOU DON'T DERIVE ANY OF THE CELL LINES?

DR. EGGAN: I DON'T READ IT THAT WAY.

DR. PRIETO: THIS IS GOING TO COME UP IN THE BANKING STUDY GROUP REPORT; BUT PERHAPS IF WE JUST ACCEPT THIS AS AN AMENDMENT BECAUSE THERE WILL BE MORE DISCUSSION HERE. ADDED THE WORDING "SHALL CREATE OR PARTICIPATE IN MECHANISMS FOR ESTABLISHING CENTRAL

REPOSITORIES," ETC., BECAUSE WE ARE GOING TO WANT TO ENCOURAGE INSTITUTIONS TO PARTICIPATE, NOT NECESSARILY ESTABLISH EACH THEIR OWN.

DR. HALL: THAT'S A VERY GOOD SUGGESTION.

DR. PRIETO: WOULD YOU ACCEPT THAT AS A FRIENDLY AMENDMENT?

MR. SHESTACK: WE DO WANT TO PRESCRIBE A METHODOLOGY THAT ULTIMATELY MAKES BANKING EASIER, MORE EFFICIENT, EVERYBODY WHO'S FUNDED BY CIRM IS OBSERVING CERTAIN STANDARDS THAT WILL ALLOW US --

DR. PRIETO: I THINK THIS IS AN AREA WHERE WE DO WANT TO HAVE STANDARDS AND BE THE AGENCY THAT SETS THAT STANDARD AND ENCOURAGE BANKING AND ENCOURAGE THE DISSEMINATION OF INFORMATION.

DR. HALL: THE GUIDELINES, I AGREE, FOR ANY FACILITY, ALTA, I THINK THESE ARE IN A CERTAIN SENSE SUPERFLUOUS IN A DOCUMENT LIKE THIS. BUT IF YOU DON'T -- IF UCLA IS NOT GOING TO ESTABLISH A STEM CELL BANK ON ITS OWN, IT DOESN'T HAVE TO PAY ANY ATTENTION TO THIS FOR THE MOMENT. I THINK OTHERWISE IT'S NOT UNREASONABLE GUIDELINES.

MS. CHARO: SO (B) DOESN'T COMMIT THEM TO CREATING MECHANISMS?

DR. PRIETO: I'M SUGGESTING --

DR. HALL: SHALL CREATE OR PARTICIPATE IN.

DR. PRIETO: I'M SUGGESTING A FRIENDLY AMENDMENT, WHICH I REALIZE COMPLETELY CHANGES THE MEANING OF YOUR MOTION, BUT THAT WE ENCOURAGE -- THAT THEY SHALL CREATE OR PARTICIPATE IN.

MR. KLEIN: I THINK THIS IS HELPFUL LANGUAGE TOO BECAUSE WHAT IF WE FUND A GMP FACILITY TO CREATE FDA-APPROVED BIOLOGICALS AND WE'RE PARTICIPATING IN A STEM CELL BANK IN PROVIDING THEM FDA-APPROVED BIOLOGICALS THROUGH ONE OF OUR FACILITY FUNDINGS? WE NEED SOME GUIDANCE HERE, AND I THINK THIS IS CONSTRUCTIVE CONCEPTUAL GUIDANCE.

MS. CHARO: IT'S CONSTRUCTIVE, BUT I'M HOPING ZACH IS RIGHT AND THAT IT'S JUST SUPERFLUOUS BECAUSE WE HAVE ABSOLUTELY NO BUSINESS TELLING INSTITUTIONS WHAT THEY SHOULD BE DOING. OUR ONLY BUSINESS IS TELLING INVESTIGATORS WHAT THEY CAN AND CANNOT DO WITH OUR MONEY.

DR. PRIETO: BUT I THINK WE DO HAVE A RIGHT TO TELL THEM WHAT WILL HAPPEN WITH THE BIOLOGICALS THAT THEY CREATE OR THAT THEY DERIVE WITH CIRM MONEY.

CO-CHAIR LO: FRANCISCO, COULD I ACTUALLY ASK YOU TO MAKE A FORMAL MOTION?

DR. PRIETO: I'M JUST A LITTLE WORRIED ABOUT THE WHOLE PARLIAMENTARY THING. IS THERE A MOTION ON THE FLOOR ALREADY?

DR. KIESSLING: WE TABLED IT.

DR. PRIETO: MY MOTION WOULD JUST BE THAT WE CHANGE THE LANGUAGE OF SECTION 100009(B) TO ADD THE WORDS "OR PARTICIPATE" AFTER CREATE, SO IT WILL READ "INSTITUTIONS ENGAGED IN HUMAN EMBRYONIC STEM CELL RESEARCH SHALL CREATE OR PARTICIPATE IN MECHANISMS FOR ESTABLISHING CENTRAL REPOSITORIES," ETC.

MR. KLEIN: I SECOND.

DR. KORDOWER: CAN I JUST GET A CLARIFICATION ON ONE POINT HERE? SO AN INVESTIGATOR IS NOT DERIVING STEM CELLS, BUT IT'S JUST TAKING STEM CELLS AND USING THEM IN AN EXPERIMENT, SO DID THEY HAVE TO THEN CREATE A BANK OR PARTICIPATE IN A BANK? THAT'S HOW I'M READING THIS.

DR. PRIETO: NO. NO. NO. THAT'S WHY I ADDED THAT WORD. THEY DO NOT -- EACH INSTITUTION DOES NOT NEED TO CREATE A BANK OR CREATE A REGISTRY, AND WE'RE GOING TO TALK ABOUT THAT A LITTLE LATER.

MR. SHESTACK: THEN MAYBE WHAT WE SHOULD SAY IS INSTITUTIONS ENGAGED IN HES DERIVATION.

DR. KIESSLING: RIGHT. STEM CELL DERIVATION.

DR. PRIETO: EXCEPT THAT EVEN IF THEY DON'T DERIVE THE LINES, I THINK IT'S PART OF SORT OF MAINTAINING THE OVERALL INTEGRITY OF THE RESEARCH WE'RE FUNDING THAT ALL THESE INSTITUTIONS SHARE INFORMATION

WITH THE REGISTRY. THERE ARE TWO SEPARATE ISSUES. ONE IS REGISTRY, ONE IS BANKING. AND THE BANK, WHATEVER STEM CELL BANK EXISTS, WILL BE EXPECTED TO MAINTAIN CELL LINES, BUT I THINK WE WILL ALSO WANT TO HAVE A REGISTRY.

DR. HALL: REGISTRY IS SEPARATE, AND I THINK IT'S COVERED.

MR. SHESTACK: THIS IS REPOSITORY. ALTA, COULD I JUST ASK YOU ONE OTHER QUESTION? THE REST OF THE NEXT TWO PAGES 7 AND 8 OF THIS BECAUSE THERE'S A SORT OF -- I DON'T UNDERSTAND THE NAME. THERE'S LIKE WE HAVE A, B, C, D, THEN WE GET TO ONE, WHICH I'M NOT SURE IF THAT'S A SUBCATEGORY OF D OR B. DOES THIS ALL PERTAIN TO --

MS. CHARO: I HAVE NO IDEA WHAT YOU'RE LOOKING AT.

MR. SHESTACK: LOOKING AT PAGE 7, ALL OF IT, AND PAGE 8. THESE PERTAIN TO WHAT, NOT HOW YOU DO A CONSENT FORM? HOW YOU DO WHAT EXACTLY?

MS. CHARO: I WANT TO GO BACK TO THE ORIGINAL POINT, RIGHT, BECAUSE IMAGINE THAT JDRF IS FUNDING, IMAGINE THAT MICHAEL J. FOX IS FUNDING, IMAGINE THAT CHRISTOPHER REEVE FOUNDATION IS FUNDING, AND IMAGINE THAT CIRM IS FUNDING, AND EVERYBODY IS FUNDING RESEARCH GOING ON IN THE SAME INSTITUTION. IF EVERY ONE OF

THESE FUNDERS DID WHAT WE'RE DOING, WHICH IS TO SAY, WELL, WE'D LIKE TO GUIDE THE FIELD, AND WE'D LIKE TO TELL THEM ALL HOW THEY NEED TO CREATE REGISTRIES AND HOW THEY NEED TO CREATE BANKS, THEY'RE GOING TO BE GETTING FOUR DIFFERENT SETS OF RULES, MANY OF WHICH WILL NOT BE CONSISTENT WITH ONE OTHER. AND THE INSTITUTIONS ARE GOING TO BE IN A TERRIBLE PICKLE.

THESE KINDS OF THINGS THAT CAME OUT OF THE NAS WERE REALLY AIMED AT THE ESCRO'S AND AT THE INSTITUTIONS SO THAT FUNDERS COULD DEFER. FUNDERS COULD SAY WE'RE GOING TO FUND SOMEBODY AT AN INSTITUTION THAT'S FOLLOWING ESCRO'S AND NAS GUIDELINES. AND THE ESCRO'S AND THE NAS GUIDELINES WITHIN THE INSTITUTION SET UP A SINGLE SET OF RULES FOR THEIR BANKS, FOR THEIR REGISTRIES. IN OTHER WORDS, THERE WAS A NOTION OF DEFERENCE. I'M JUST GETTING REALLY WORRIED THAT ALTHOUGH WITH ALL THE BEST INTENTIONS IN THE WORLD, WE MAY BE SETTING OURSELVES UP NOT TO GUIDE THE REST OF THE WORLD TOWARD ETHICAL BEHAVIOR, BUT TO, IN FACT, LEAD INSTITUTIONS INTO SITUATIONS OF INHERENT AND IMPOSSIBLE CONFLICT BECAUSE WE'RE GOING BEYOND WHAT IS REALLY AT THE CORE OF THE MANDATE HERE, WHICH IS WHAT MEETS OUR ETHICAL STANDARDS FOR WORK WITH OUR STEM CELL LINES OR WITH THE MATERIALS YOU USE TO CREATE NEW STEM CELL LINES.

MR. SHESTACK: I JUST DON'T KNOW HOW TO READ THIS.

MS. CHARO: FORGET ABOUT READING IT. I'M TRULY MEANING GO BACK TO DELETING THE WHOLE THING, INCLUDING THE REGISTRY THING.

MR. SHESTACK: YOU MEAN ALL OF PAGE --

MS. CHARO: I WOULD DELETE THE ENTIRE SECTION ONE AND ALL THE ZEROS AND NINE.

MR. SHESTACK: ALL OF SECTION 9.

MS. CHARO: INCLUDING THE REGISTRY. THAT'S UP TO THE INSTITUTION. THAT'S AN INTERNAL MATTER.

CO-CHAIR LANSING: CAN I JUST SAY SOMETHING? I'M, AGAIN, A LAYPERSON. I WANT TO HEAR WHAT THE BANKING COMMITTEE HAS TO SAY ON THIS. I JUST FEEL -- I DON'T HAVE YOUR KNOWLEDGE. DO YOU KNOW WHAT I MEAN? SO I DON'T KNOW HOW TO VOTE. I'D HAVE TO ABSTAIN. I FEEL THAT -- I KEEP REPEATING MYSELF, BUT I FEEL LIKE WE'RE DOING THE WORK OF THE COMMITTEE, AND WE NEED TO GET INTO THE COMMITTEE WORK. I NEED TO HEAR THE COMMITTEES' REPORTS. THE COMMITTEES NEED TO GO BACK. AND VERY WELL IT MAY BE THAT WE DELETE THE WHOLE THING. BUT I DON'T THINK IT'S INTERFERING WITH OUR WORK FOR THE NEXT MINE MONTHS IF IT STAYS, AND THEN WE CAN DELETE IT, WE CAN CHANGE IT, WE CAN MODIFY IT.

MR. SHESTACK: THE COMMITTEE MAY HAVE POINTS

OF VIEW, FOR INSTANCE, ON BANKING THAT HAVE NOTHING TO DO WITH FULL ICOC POLICY ON BANKING, FUNDING PRIORITIES, ALL THOSE THINGS THAT DON'T ACTUALLY HAVE -- THAT THIS LANGUAGE DOESN'T AFFECT OR NOT AFFECT. I WAS JUST TRYING TO UNDERSTAND THE LANGUAGE.

CO-CHAIR LANSING: BUT I DON'T KNOW THE ANSWER TO THAT TILL I HEAR THEIR REPORT, UNTIL THEY DO THEIR WORK.

MS. CHARO: SHERRY, WHAT STEVE PECKMAN SAID, INSTITUTIONS ARE GOING TO HAVE TO INVEST IN COMPLYING WITH THE INTERIM GUIDELINES. I THINK WHAT I WAS HEARING HIM SAY IS THAT ONCE THAT INVESTMENT IS MADE, THERE'S LITTLE BACKING DOWN. SO WE HAVE TO BE CAREFUL NOT ONLY WITH THE FINALS, BUT ALSO WITH THE INTERIMS, NOT PUT INTO PLACE SOMETHING THAT IN THE END IS SUPERFLUOUS.

CO-CHAIR LANSING: BUT THE INTERIMS -- AGAIN, I RESPECT WHAT STEVE'S SAYING, AND I RESPECTFULLY MAYBE DISAGREE. I DON'T KNOW YET. BUT WHAT I KNOW IS THAT THIS ALREADY EXISTS. SO THIS IS ALREADY THERE. DO YOU KNOW? SO WE'RE JUST DECIDING WHETHER TO ADOPT IT OR NOT FOR OUR INTERIM GUIDELINES. WE'RE NOT REINVENTING THE WHEEL. WE WILL EVENTUALLY PERHAPS BE REINVENTING THE WHEEL, AND THEN I THINK THAT OUR INSTITUTIONS, WHICH ARE JUST GOING TO START WORKING WHEN THEY GET

THIS, BECAUSE THAT'S WHEN WE'RE GOING TO START DOING OUR GRANTS, THEY WON'T HAVE A BACKLOG OF STUFF.

DR. HALL: LET ME JUST SAY THAT CIRM HAS SOME RESPONSIBILITY HERE. AND I THINK THAT ONE OF OUR RESPONSIBILITIES WILL BE VERY SHORTLY, AFTER THE INTERIM GUIDELINES ARE PASSED TODAY, THAT WE WILL MEET WITH REPRESENTATIVES FROM THE DIFFERENT UNIVERSITIES. AND WE NOW KNOW, SINCE WE'VE BEEN THROUGH A ROUND OF TRAINING GRANTS, WE KNOW WHO THEY ARE BY AND LARGE. AND WE WILL SAY TO THEM THESE ARE OUR INTERIM GUIDELINES. PLEASE UNDERSTAND THAT THE WORKING GROUP IS WORKING ON THE FOLLOWING POINTS. AND I THINK OUR DISCUSSIONS HERE TODAY ARE VERY HELPFUL, AND THEY WILL BE DISCUSSING AT GREAT LENGTH THE FOLLOWING ISSUES. WE WILL KEEP YOU APPRISED ON HOW THESE GO. IN FACT, BY NOVEMBER 1ST, YOU WILL KNOW WHAT THE DRAFT OF THE FINAL GUIDELINES IS.

AND SO I THINK WE WILL WORK WITH YOU TO BOTH TRY TO MAKE YOU ELIGIBLE FOR FUNDING; THAT IS, TO TELL YOU WHAT YOU NEED TO DO TO GET READY, AND ALSO TO KEEP YOU FROM DOING UNNECESSARY THINGS. I THINK THIS IS NOT -- THIS IS A SITUATION IN WHICH IT'S NOT -- THAT WE'RE GOING TO FROM SOME CENTRAL AUTHORITY SAY GO DO THIS AND THEN SEVERAL MONTHS LATER SUDDENLY ANNOUNCE NOW YOU GOT TO CHANGE EVERYTHING. WE WILL BE IN TOUCH

WITH PEOPLE. WE WILL ADVISE THEM. AND I THINK WE WILL SAY PLEASE UNDERSTAND THESE ARE IN TRANSITION.

I HAVE ALREADY MET WITH THE UC VICE CHANCELLORS OF RESEARCH, WHO ACTUALLY INVITED ME TO TALK WITH THEM. AND ONE OF THE ISSUES WE TALKED ABOUT WAS THE ESCRO COMMITTEES. AND I SAID YOU NEED TO BE THINKING ABOUT THESE AND HOW THESE MIGHT WORK AT YOUR INSTITUTIONS. AND I THINK WE WILL CONTINUE TO WORK WITH THEM THROUGHOUT THE WHOLE YEAR.

SO I DON'T SEE THE ISSUE OF INSTITUTIONAL INVESTMENT. THERE'S REALLY TWO MONTHS OF UNCERTAINTY. THERE WILL BE SOME UNCERTAINTY AFTER THAT IN THAT IT MAY CHANGE AS WE GO ALONG, BUT BY NOVEMBER 1ST, THIS COMMITTEE WILL HAVE COMPLETED ITS DRAFT OF THE FINAL GUIDELINES. I JUST DON'T SEE THIS AS A BIG ISSUE. I, AGAIN, MY VIEW IS THESE ARE ALL IMPORTANT POINTS. LET'S TRY TO TAKE WHAT WE HAVE HERE AND EVEN WITH ITS DEFECTS, UNLESS WE FEEL THEY'RE CRIPPLING, MOVE FORWARD AND THEN IMMEDIATELY BEGIN TO ADDRESS THESE ISSUES IN A DIFFERENT CONTEXT.

CO-CHAIR LANSING: AND WE NEED PUBLIC INPUT. I'M VERY NERVOUS TO THROW SOMETHING OUT BEFORE WE HAVE PUBLIC INPUT, UNTIL THE PUBLIC GETS A CHANCE TO WEIGH IN. YOU MAY BE A HUNDRED PERCENT RIGHT. I'M JUST SUGGESTING THAT FOR THE -- I'LL SHUT UP.

DR. CIBELLI: WE HAD A CONFERENCE CALL, I WAS PART OF THE BANKING GROUP, AND WE SHOULD STOP TALKING ABOUT BANKING FOR A WHILE UNTIL WE HEAR WHAT WE HAVE TO SAY.

AND THE OTHER THING IS IF YOU READ CAREFULLY THE SECTION, IT'S AWFUL THE WAY IT READS. IT'S USELESS. YOU WILL CONFUSE PEOPLE WHEN THEY START READING. THEY DON'T UNDERSTAND WHAT WE MEAN BY THIS. I JUST WANT TO SAY THAT I AGREE WITH ALTA. IF SHE WANTS TO PUT A MOTION, I'LL SECOND THAT.

MS. CHARO: I'VE WITHDRAWN THE MOTION.

DR. CIBELLI: I THINK WE MAY HAVE A DIFFERENT ROLE THAN THE NATIONAL ACADEMY OF SCIENCE. I HONESTLY HAVE TO SAY THIS, ZACH, THAT I SENSE FROM YOU TOO MUCH PRESSURE TO TAKE THE NATIONAL ACADEMY OF SCIENCE GUIDELINES AT FACE VALUE.

DR. HALL: AS INTERIM STANDARDS ONLY.

DR. CIBELLI: THAT'S THE WAY I SEE IT TODAY. THAT'S THE WAY I SEE IT TODAY. SO I FEEL LIKE WHETHER I CAME TO THIS MEETING OR NOT, IT DIDN'T MATTER. I FEEL THAT I'VE BEEN RUSHED.

DR. HALL: LET ME JUST SAY I'M SORRY YOU FEEL THAT WAY. ONE OF THE DANGERS, AND I THINK WE HAVE NOT SKIRTED IT, ONE OF THE THINGS I WAS WORRIED ABOUT IS WE WOULD SPEND ALL DAY TALKING ABOUT THE INTERIM STANDARDS

AND NOT GET ON TO OUR WORKING GROUPS AND TALK ABOUT THE REAL ISSUES. AND I FEEL TO SOME EXTENT THAT'S HAPPENED.

NOW THE ISSUE HAS BECOME -- I HAD HOPED THAT WE COULD DEAL WITH THE INTERIM STANDARDS IN A FAIRLY PERFUNCTORY WAY AND SAY THEY'RE NOT COMPLETE, BUT THAT'S WHAT THE ICOC HAS DONE AND ALL THE REST. LET'S JUST SAY, OKAY, THIS WILL HOLD US NOW TO LET US GET GOING, AND NOW LET'S START OUR REALLY SERIOUS DISCUSSIONS. IN A WAY, WHAT'S HAPPENED, I FEEL, YOU SEE WHAT I'M SAYING, THAT THE TIME IS BEING SPENT ON THE INTERIM ONES WHERE I THINK THE STAKES ARE VERY SMALL. AND WHAT WE REALLY NEED TO DO IS TO MOVE ON TO THOSE MORE IN-DEPTH DISCUSSIONS AND JUST PUT THIS BEHIND US AND SAY IT'S DONE. I DON'T THINK THERE'S ANY HARM DONE IN THIS.

CO-CHAIR LO: THE VERY ISSUES YOU'VE HIGHLIGHTED IN TERMS OF THE PROBLEMS WITH THIS ENTIRE BANKING SECTION, IT MAY VERY WELL BE THAT THE SUBCOMMITTEE WILL HELP US ARRIVE AT FINAL, DRAFT FINAL GUIDELINES THAT ARE ACTUALLY MORE THOUGHTFUL AND BETTER. THE QUESTION IS IS THAT SOMETHING THAT NEEDS TO BE DONE OVER THE LONG HAUL.

CO-CHAIR LANSING: AGAIN, I WANT TO REEMPHASIZE WHAT ZACH IS SAYING BECAUSE I THINK, AND

THIS COMES FROM A LAY PERSPECTIVE, I ALWAYS THOUGHT THAT THESE INTERIM GUIDELINES WERE JUST TEMPORARY, AND THEY WERE JUST TO GET US THROUGH. AND UNLESS THERE WAS SOMETHING ABSOLUTELY HORRENDOUS, DO YOU KNOW, THAT VIOLATED EVERYTHING, WE WERE JUST GOING TO APPROVE THESE LIKE LITERALLY IN A VERY PERFUNCTORY WAY, AS ZACH SAID, BUT THEN THE WHOLE POINT OF TODAY AND THE NEXT 200 DAYS OR WHATEVER IT IS, WE HAVE TILL NOVEMBER WHATEVER, WAS TO REALLY DIG IN AND THROW OUT THE WHOLE BANKING THING, IF YOU'RE TELLING ME IT'S NOT WELL WRITTEN, AND THEN TO CHALLENGE WHETHER WE'RE THE WATCHDOG FOR EVERYBODY, BUT REALLY TO DO THE WORK.

AND I THINK THAT'S WHAT WE'RE SAYING. THESE ARE BY NO MEANS ANYTHING THAT WE SHOULD ACCEPT OR WHAT'S THE PURPOSE OF OUR COMMITTEE?

DR. KIESSLING: THIS IS A SECTION IN WHICH ADOPTING THIS IS GOING TO CAUSE MORE PROBLEMS THAN IT'S GOING TO ALLEVIATE. THIS SECTION SHOULD BE TABLED. IT SHOULD BE TAKEN OUT OF HERE AS PART OF THE INTERIM. IT SHOULD BE NOT PART OF THE INTERIM GUIDELINES AT ALL. AND IT SHOULD BE ONE OF THOSE THINGS THAT IS TO BE DEVELOPED.

MR. SHESTACK: WHY?

DR. KIESSLING: BECAUSE IT'S VERY -- IF YOU WERE SIMPLY AN INVESTIGATOR AND WHAT YOU WANT TO GIVE

OUT IN THE FALL ARE TRAINING GRANTS, IF YOU WERE AN INVESTIGATOR AND YOU SIMPLY WANTED TO GET A CELL LINE FROM SOMEPLACE AND YOU WANTED TO GET STARTED, THIS WOULD KEEP YOU FROM DOING IT.

CO-CHAIR LANSING: SEE, HERE'S MY PROBLEM.

DR. KIESSLING: EVEN AS AN INTERIM, IT WOULD KEEP YOU FROM DOING IT.

CO-CHAIR LANSING: I SO RESPECT BOTH OF YOU, AND I'M SURE YOU'RE RIGHT. I DON'T HAVE ANY INFORMATION. I'M NOT PART OF THE COMMITTEE. HONESTLY, I CAN ABSTAIN.

DR. EGGAN: AS A SCIENTIST, I CAN TELL YOU THAT THAT'S THE CASE. I WOULD LOOK AT THIS, AND THEN I WOULD HAVE TO GO AND I WOULD HAVE TO CALL THE ASSISTANT TO THE PROVOST, AND THE ASSISTANT PROVOST WOULD HAVE TO GO TO THE PROVOST AND SAY AS A UNIVERSITY, WE HAVE TO DO THIS THING. AND THEN THERE'D BE A MEETING ABOUT THAT AND A MEETING ABOUT THAT, AND THEN NOTHING WOULD HAPPEN IN A YEAR.

DR. KIESSLING: TO NOT HAVE THIS INCLUDED IN THE GUIDELINES RIGHT NOW IS NOT GOING TO INHIBIT RESEARCH, IT'S NOT GOING TO ALLOW FAULTY RESEARCH TO GO FORWARD. IF YOU TAKE THIS OUT NOW AND SAY WE'RE DEVELOPING THIS, WE'RE GOING TO WORK ON BANKING AND DISTRIBUTION, AND PART OF OUR INTERIM GUIDELINES, IT'S

NOT INCLUDED, BUT IT'S COMING, YOU WILL DO EVERYONE A SERVICE.

CO-CHAIR LANSING: I HAVE A QUESTION. THIS IS SO OUT OF MY LEAGUE. I JUST WANT TO VOTE WITH MY CONSCIENCE. CAN THEY THEN DO THE WORK WITHOUT ANYTHING THERE THAT TELLS THEM WHAT TO DO?

DR. KIESSLING: YES. YES. THE ONLY THING THEY NEED IS IF YOU WANT EVERYBODY WHO'S DOING ES CELL WORK TO KEEP A REGISTRY, THAT'S FINE. THAT CAN BE DONE AT THE LABORATORY LEVEL.

MR. SHESTACK: TRAINING GRANTS WILL PRODUCE STEM CELLS, FOR INSTANCE?

DR. HALL: LET ME MAKE A SUGGESTION. I UNDERSTAND EXACTLY WHAT YOU'RE SAYING, AND I SHARE MANY OF YOUR POINTS OF VIEW. I SUGGEST YOU DECIDE IT ONE WAY OR THE OTHER RIGHT NOW, AND THEN LET'S GO ON AND HAVE DISCUSSION OF THE WORKING GROUPS. I JUST THINK THAT IT DOESN'T MATTER THAT MUCH EITHER WAY. WE WILL TELL PEOPLE WHO CALL, IF WE PASS THEM AS THEY ARE, LOOK, THIS MATTER IS BEING DISCUSSED. THIS SECTION IS LIKELY TO BE COMPLETELY REVISED. DON'T WORRY ABOUT IT.

DR. CIBELLI: BUT THERE ARE MEMBERS HERE WHO DON'T UNDERSTAND WHAT WE'RE TALKING ABOUT AND WHY WE'RE GOING TO DROP THIS OFF.

DR. HALL: WHATEVER YOU WANT TO DO, I DON'T

MIND. SAY YOU'RE GOING TO KEEP IT OR DROP IT, BUT I SUGGEST YOU MAKE THE DECISION AND LET'S MOVE ON AND HAVE THE REAL DISCUSSION.

CO-CHAIR LANSING: CAN I MAKE A SUGGESTION THEN? WHY DON'T WE HAVE THE REPORTS FROM THE STUDY GROUP, COME BACK TO THIS ISSUE, AND JEFF'S ISSUE, AND DECIDE WHETHER OR NOT WE WANT TO LEAVE IT AS IS OR WHETHER WE WANT TO REFER IT TO MORE DETAIL. I'M COMPLETELY --

DR. WILLERSON: I HAVE ANOTHER SUGGESTION. THAT IS, INDICATE THAT A LIBRARY RECORD OF CELLS MUST BE MAINTAINED AND INDICATE IN THIS SECTION THAT THIS SECTION IS UNDER DEVELOPMENT, UNDER CONSIDERATION AND DEVELOPMENT. THERE WILL BE GUIDELINES LATER.

MR. KLEIN: IS THAT A MOTION?

DR. KIESSLING: TO KEEP SECTION 9(A)?

DR. WILLERSON: NO. THERE'S A LOT OF DIFFERENCE OF OPINION IN HERE. I'M TALKING ABOUT THIS SECTION THAT SEVERAL OF YOU WANT TO DELETE. I THINK WHAT YOU COULD PUT IS A SENTENCE HERE THAT SAYS A LIBRARY OF RECORD OF CELLS THAT ARE USED MUST BE MAINTAINED AT EACH INSTITUTION. THAT ONLY MAKES SENSE. AND SAY WHAT THAT WOULD INCLUDE. THEN THE REST OF IT ABOUT STEM CELL BANKING SPECIFICALLY, THIS IS UNDER CONSIDERATION BY THE COMMITTEE, AND THERE WILL BE

GUIDELINES LATER SO THAT PEOPLE KNOW THEY'RE COMING, BUT IT DOESN'T REQUIRE SOMEBODY TO GO OUT AND BUILD SOMETHING RIGHT NOW.

TWO OTHER POINTS. THERE ARE ALREADY SOME FEDERAL STEM CELL CENTERS. THERE ARE PEOPLE AROUND THE COUNTRY -- MY DAUGHTER IS IN LABOR RIGHT NOW, AND SHE AND HER MOTHER HAVE ARRANGED FOR CELLS TO BE KEPT THAT ARE SENT TO SOME FEDERAL CENTER. MOST OF THE PEOPLE THAT ARE DOING THAT WANT TO USE THEM PERSONALLY. THEY WANT TO USE THEM FOR THEIR CHILDREN, THEY WANT TO USE THEM FOR THEIR FAMILIES. THERE WILL BE REASONS TO HAVE STEM CELL BANKING FOR OTHER PURPOSES, OF COURSE, BUT WE SHOULD KEEP IN MIND THAT A LOT OF THE PEOPLE ARE DOING THAT RIGHT NOW. INDIVIDUALS HAVE VERY PERSONAL INTEREST IN THEM. THEY'RE NOT INTERESTED IN HUMANITY. THEY'RE INTERESTED IN THEIR FAMILIES.

MR. SHESTACK: STEM CELL BANKING, IT'S NOT THE SAME KIND OF BANKING WE'RE TALKING ABOUT HERE.

MR. KLEIN: BUT STAYING ON HIS POINT, DR. WILLERSON, IS THAT A MOTION TO --

DR. WILLERSON: I'M TRYING TO BRING US --

MR. KLEIN: I WOULD SECOND THAT MOTION IF YOU'RE MAKING A MOTION.

DR. WILLERSON: I'M TRYING TO BRING US TOGETHER AND NOT SPEND A WHOLE LOT OF TIME ON THIS WHEN

WE'RE NOT READY TO APPROVE IT OR FINALIZE IT.

MR. KLEIN: I THINK IT'S AN EXCELLENT SUGGESTION. I'D LIKE TO SECOND THAT AS A MOTION. MY UNDERSTANDING IS THAT SECTION 9, WE WOULD STATE THAT THE INSTITUTIONS WILL MAINTAIN A LIBRARY OF --

DR. WILLERSON: MAINTAIN A REGISTRY.

MR. KLEIN: -- A REGISTRY OF THE CELLS.

DR. EGGAN: THAT'S 9(A).

DR. KIESSLING: 9(A) IS FINE.

MR. SHESTACK: IF YOU WANT TO MAKE THIS NOT HAVE TEETH --

MR. KLEIN: CAN I FINISH MY POSITION, PLEASE? SO 9(A), DOES 9(A) STATE YOUR FIRST POINT?

DR. WILLERSON: I THINK IT'S OKAY.

MR. KLEIN: SO THEN 9(B) WOULD SAY THE BALANCE OF THIS SECTION IS UNDER DEVELOPMENT. IT WILL ADDRESS THE STEM CELL BANK. INFORMATIONALLY, SOME OF THE THINGS UNDER CONSIDERATION, YOU COULD SHOW THE MATERIAL --

DR. WILLERSON: IN A LATER DOCUMENT.

MR. KLEIN: SHOW THE MATERIAL, BUT WE WOULD NOT ADOPT THE BALANCE OF SECTION 9.

DR. KIESSLING: RIGHT.

MR. KLEIN: I WOULD SECOND THAT AS A MOTION.

DR. WILLERSON: I WOULD MAKE IT AS A MOTION.

CO-CHAIR LO: WE HAVE A MOTION. IT'S BEEN SECONDED. BASICALLY WE'RE --

MR. SHESTACK: I'M SORRY.

CO-CHAIR LO: DISCUSSION ON THIS. LET ME JUST SAY THE OTHER OPTION IS WE CAN DO WITH THIS WHAT WE DID WITH THE ESCRO/IRB RELATIONSHIP. WE CAN SAY WE'VE GOT TO DECIDE THIS AT THE END OF THE DAY. WE COULD INVITE THE COMMITTEE REPORT FROM THE BANKING SUBCOMMITTEE TO ADDRESS US. IF YOU FEEL THAT WE'D MAKE A BETTER DECISION, SAY, AT 5 O'CLOCK OR 5:30 AFTER HEARING THAT REPORT, WE CAN ALSO DEFER THIS. DR. WILLERSON HAS MADE A MOTION THAT, I THINK, FOLLOWS IN THE SPIRIT OF ALTA'S ORIGINAL MOTION, WHICH SHE SUBSEQUENTLY WITHDREW, WHICH IS TO SORT OF REMOVE AS INTERIM GUIDELINE LANGUAGE ALL OF SECTION B, C, AND D, AS I UNDERSTAND IT, PERTAINING TO THE STORAGE.

DR. KIESSLING: ALL OF PAGE 7 AND 8.

MR. KLEIN: THAT'S RIGHT. AND INDICATE THAT THEY'RE UNDER DEVELOPMENT.

CO-CHAIR LANSING: BUT YOU WOULD SEE IT. IT WOULD STILL THERE BE THERE AS WE READ. WOULDN'T BE DELETED.

MR. KLEIN: INFORMATIONALLY YOU DELETE IT.

DR. KIESSLING: I WOULD DELETE IT.

CO-CHAIR LO: ARE YOU PROPOSING THAT WE LEAVE

IT OR DELETE IT? I WASN'T SURE.

MR. SHESTACK: I'M SORRY. I WOULD LIKE TO HEAR THE COMMITTEE'S REPORT. I WAS ACTUALLY ON THIS COMMITTEE, AND I WOULD LIKE TO HEAR STEVE'S REPORT. I WOULD BE -- I COULDN'T BE MORE AGAINST, UNTIL I HAVE THAT INFORMATION, DELETING THIS WHOLE SECTION ALTHOUGH IT MAY BE THAT THERE'S SOME SIMPLE WORDSMITHING THAT MAKES THIS -- WITHOUT IT IT MAKES IT RIDICULOUS AND IMPRACTICAL AND PUTS A RIDICULOUS BURDEN ON INSTITUTIONS, BUT I THINK IT IS SO MUCH IN THE OVERALL ZEITGIEST PHILOSOPHY OF WHAT CIRM IS ABOUT. IT IS 100 PERCENT WHAT I AM HERE AS AN ADVOCATE TO BE ABOUT, TO STRESS THE IMPORTANCE OF BANKING, TO STRESS THE IMPORTANCE OF ULTIMATELY A DISTRIBUTION OF STEM CELL LINES FUNDED BY THE CITIZENS OF CALIFORNIA TO THE SCIENTISTS OF THE ENTIRE WORLD AT A HEAVILY SUBSIDIZED COST AS WELL IS THE ONLY REASON I'M HERE AS AN ADVOCATE OF THE MENTAL HEALTH COMMUNITY TO DO THAT.

SO UNTIL I KNOW THAT SOMEHOW STRIKING THIS FROM THE RECORD FOR CONVENIENCE WON'T HAVE A DELETERIOUS EFFECT ON PUTTING THAT POLICY IN LATER, I'M NOT WILLING TO DO IT. I UNDERSTAND THAT IT MAY VERY WELL BE THAT WE MAY HAVE TO DO THAT. I DON'T WANT TO SEND ANY OTHER SIGNALS OUT RIGHT NOW UNTIL I HAVE MORE INFORMATION.

DR. WILLERSON: MY INTENTION WAS NOT TO OMIT IT PERMANENTLY, BUT TO DEFER IT, TO GIVE US A CHANCE TO ADDRESS IT IN THE DETAIL AND WITH THE TIME THAT WE NEED.

MR. SHESTACK: RIGHT. WE HAVE TO FIND A WAY TO DEFER IT AND STATE STRONGLY THAT IT IS AN OBJECTIVE.

DR. WILLERSON: THAT CAN BE MADE CLEAR.

CO-CHAIR LO: COULD I, AS A CHAIRMAN, LET ME OFFER A SET OF PROCEDURES HERE. I WOULD SUGGEST THAT WE TABLE DR. WILLERSON'S MOTION SO THAT IT'S THE SAME AS THE MOTION WITH THE ESCRO/IRB RELATIONSHIP. WE SPEND SOME TIME HEARING FROM OUR SUBCOMMITTEE ON BANKING, FROM STEVE PECKMAN ON THE IRB/ESCRO RELATIONSHIP, AND THAT WE AGREE TO COME BACK AT WHATEVER TIME WE WANT, 5:15, FOR EXAMPLE, AND SAY WE WILL RESOLVE THOSE TWO ISSUES, BUT TO DEFER THE DECISION TILL WE'VE HAD A LITTLE MORE INFORMATION. A DECISION AT 5:15 WILL BE EITHER TO ADOPT THESE RESOLUTIONS, TO ACCEPT OTHER AMENDMENTS, OR TO DO ANYTHING ELSE, BUT IT WOULD GIVE US A CHANCE TO GET A LITTLE MORE INFORMATION BEFORE VOTING ON THE DRAFT OR THE INTERIM GUIDELINES.

CO-CHAIR LANSING: I WOULD LIKE TO SUPPORT WHAT YOU ARE SAYING, BUT I WOULD ALSO LIKE TO JUST ADD ONE THING, THAT EVERYTHING THAT IS IN THIS GUIDELINE IS

UNDER DEVELOPMENT. THAT'S WHAT WE'RE HERE FOR. DO YOU KNOW? I KEEP COMING BACK TO THIS. EVERYTHING THAT WE HAVE -- I THINK WE SHOULD DO EXACTLY WHAT YOU'RE SAYING. I THINK WE SHOULD MOVE FORWARD, BUT IT IS EASY FOR US TO EXPLAIN TO ALL THE INSTITUTIONS AND IN PUBLIC SESSION TOMORROW THAT'S WHAT WE'RE DOING HERE. WE WANT TO HEAR WHAT YOU THINK ABOUT THIS AND CHANGE IT.

DR. EGGAN: I JUST DON'T THINK YOU CAN DO THAT BECAUSE YOU CAN'T GIVE SOMEONE INTERIM GUIDELINES AND THEN TELL THEM THEY DON'T HAVE TO FOLLOW THEM. YOU'VE GOT TO GIVE THEM GUIDELINES THEY CAN FOLLOW. SO I HAVE A FUNDAMENTAL DISAGREEMENT WITH WHAT YOU JUST SAID.

CO-CHAIR LANSING: I'M NOT SAYING THAT. I AM SAYING TO YOU -- I AM SAYING THAT.

DR. EGGAN: WE'VE GOT TO GET THINGS THAT THEY CAN WORK WITH IN THE MEANTIME. IF WE'RE GOING TO MAKE SUBSTANTIVE CHANGES, THEN I THINK WE SHOULD OMIT THEM. OTHERWISE WE'RE GOING TO MAKE THEM SPEND -- A LOT OF PEOPLE AT A LOT OF INSTITUTIONS ARE GOING TO SPEND A LOT OF TIME WORRYING ABOUT HOW TO MAKE THIS WORK IN THE INTERIM. AND ALL THAT IS GOING TO BE FOR NAUGHT. THAT'S WHAT I WORRY ABOUT.

DR. KORDOWER: IF WE JUST SAID --

DR. HALL: I DON'T AGREE WITH THAT, BUT I

TAKE YOUR POINT. I THINK IF YOU WANT TO GET RID OF THE BANKING SECTION, THAT IS FAIR. THE ESCRO THING, I THINK, IS A MUCH MORE SERIOUS ISSUE, BUT THE BANKING THING --

CO-CHAIR LO: WE CAN VOTE THAT AT 5:15.

DR. KORDOWER: IF WE JUST SAID INSTITUTIONS ENGAGED IN HUMAN EMBRYONIC STEM RESEARCH SHALL BE ENCOURAGED AT PRESENT AND POSSIBLY MANDATED IN THE FUTURE, AND THEN LET EVERYTHING ELSE FOLLOW, DOESN'T THAT SOLVE THE PROBLEM? THEY GET STARTED ON THE TRAINING GRANTS. IT TELLS THEM WHAT OUR DIRECTION IS GOING AND WE'RE DONE AND WE CAN MOVE FORWARD.

DR. PRIETO: MR. CHAIRMAN, I'D LIKE TO MAKE A MOTION THAT WE ACCEPT YOUR SUGGESTION TO DEFER THIS DECISION UNTIL AFTER WE'VE HEARD THE REPORTS --

MR. KLEIN: SECOND.

DR. PRIETO: -- OF THE STUDY GROUPS AND COME BACK TO IT AT 5 O'CLOCK.

CO-CHAIR LO: AT 5 O'CLOCK. ALL THOSE IN FAVOR.

DR. PETERS: MAY I ASK A QUESTION? WHAT IS YOUR INTENTION OR WHAT DO YOU WANT TO ACCOMPLISH? WILL YOU GIVE EACH OF THE STUDY GROUPS AN EQUAL AMOUNT OF TIME, OR WILL YOU EMPHASIZE ONLY THE BANKING STUDY?

CO-CHAIR LO: I THINK RIGHT NOW -- MY GOAL IS

TO TRY AND HAVE US REACH CLOSURE ON INTERIM GUIDELINES. IT SEEMS LIKE THE TWO ISSUES ON WHICH MORE INFORMATION FROM INDIVIDUALS AND GROUPS WHO HAVE THOUGHT THEM THROUGH IN MORE DETAIL ARE THE IRB/ESCRO RELATIONSHIP AND THE BANKING. SO I WAS THINKING OF EMPHASIZING THOSE, TRYING TO THEN VOTE AT FIVE ON OUR INTERIM GUIDELINES. AND THEN THE OTHER WORKING GROUPS WILL HAVE A MUCH, MUCH SHORTER PERIOD OF TIME. IF BEFORE FIVE WE FEEL THAT WE HAVE -- THE SENSE IS THAT WE'RE READY TO MAKE DECISIONS ON EITHER OF THOSE TWO ISSUES I'VE IDENTIFIED, I'M GLAD HAVE A VOTE THEN, BUT THERE ARE SEVERAL DIFFERENT PROPOSALS HERE WITH REGARD TO THE BANKING. ONE IS TO ADOPT AS IS. ONE IS TO DELETE PAGES 7 AND 8. AND THE OTHER IS TO MODIFY EITHER DR. WILLERSON'S OR JEFF KORDOWER'S PROPOSAL TO CHANGE, BUT THEY'RE ALL SOMEWHAT DIFFERENT. MY ONLY THOUGHT WAS THAT IF WE HEARD A LITTLE MORE FROM THE BANKING GROUP THAT THOUGHT ABOUT THIS, WE MAY FEEL WE'RE MAKING A BETTER DECISION. SO THAT'S ALL. I'M JUST POSTPONING A VOTE TILL FIVE, AND IN THE MEANTIME, RATHER THAN TALKING ABOUT PROCEDURE, TALK ABOUT SUBSTANCE.

SO THAT HAVING BEEN SAID, WE HAD ASKED STEVE PECKMAN FROM UCLA TO GIVE US A PRESENTATION.

THE REPORTER: BEFORE THAT, COULD WE TAKE A VERY SHORT BREAK?

MR. KLEIN: I THINK IT'S A COMFORT BREAK THAT'S BEING REQUESTED BY THE TRANSCRIPTIONIST.

CO-CHAIR LO: I THINK THAT'S ABSOLUTELY FINE, A TEN-MINUTE COMFORT BREAK. AND THEN WE WILL COME BACK TO HEAR FIRST STEVE AND THEN --

(A RECESS WAS TAKEN.)

CO-CHAIR LO: COULD I INVITE THE WORKING GROUP TO RECONVENE. OKAY. IN OUR EFFORT TO TRY AND BOTH ALLOW FOR SOME THOUGHTFUL DELIBERATION, BUT ALSO TO MAKE A DECISION ON OUR INTERIM GUIDELINES BY THE CLOSE OF THE MEETING, I'D LIKE TO KIND OF RECONVENE US HERE.

AT THE BREAK WE HAD TWO MAJOR ISSUES THAT WE WANTED TO HEAR A LITTLE MORE INFORMATION ON BEFORE WE VOTED ON THE INTERIM GUIDELINES. FIRST WAS THE FUNCTION AND STRUCTURE OF ESCRO'S VIS-A-VIS IRB'S. AND WHAT I WOULD LIKE TO DO IS SORT OF REALLY KEEP A CLOSE EYE ON THE CLOCK HERE. I HAVE 3:52. I WOULD LIKE TO SPEND THE NEXT 30 MINUTES DEALING WITH THE ESCRO/IRB ISSUE, AND THEN EXACTLY AT 4:20 SWITCH OVER TO THE REGISTRY BANKING ISSUE AND TURN TO OUR SUBCOMMITTEE THAT ACTUALLY THOUGHT ABOUT THIS AND HAD A CONFERENCE CALL, AND THEN AT FIVE, HOPEFULLY A LITTLE BEFORE FIVE, ACTUALLY COME BACK TO THE TABLED MOTIONS WE HAVE ON WHAT TO DO ABOUT OUR DRAFT INTERIM GUIDELINES ON THOSE

TWO ISSUES.

MY UNDERSTANDING IS THAT THERE ARE NO OTHER OUTSTANDING ISSUES WITH REGARD TO THE INTERIM GUIDELINES, SO THAT DEPENDING HOW WE DECIDE ON THOSE TWO ISSUES, WE WILL HAVE A SET OF INTERIM GUIDELINES TO RECOMMEND TO THE OVERSIGHT COMMITTEE. WITH THAT, I'D LIKE TO ASK STEVE PECKMAN FROM UCLA TO GIVE US AN OVERVIEW OF WHAT IT'S LIKE FROM AN INSTITUTION DOING STEM CELL RESEARCH TO DEAL WITH THE GUIDELINES THAT WE MAY BE PROPOSING. AND, AGAIN, THE UNDERSTANDING IS THAT I'VE ASKED STEVE TO SEPARATE OUT IN THIS PRESENTATION ISSUES THAT WE NEED TO HAVE IN MIND AS WE VOTE ON INTERIM GUIDELINES AND OTHER ISSUES THAT WE ALSO HAVE TO CONSIDER IN DRAFTING DRAFT FINAL GUIDELINES. AND WE MAY WELL, FOR EXAMPLE, WANT HIM TO HELP US THINK THROUGH THOSE AT A LATER DATE. IF WE COULD ASK YOU TO KEEP UNDER 15 MINUTES.

MR. PECKMAN: I'LL GIVE IT MY BEST SHOT. I'D LIKE TO THANK YOU FOR INVITING ME TODAY AND TO THANK PERSONALLY SHERRY AND BERNIE AND JEFF SHEEHY FOR DISCUSSING THESE ISSUES WITH ME, FOR KATE SHREVE AND GEOFF LOMAX FOR SETTING IT UP.

I'M GOING TO BEGIN BY STATING THAT I ACTUALLY READ THROUGH THE TRANSCRIPT OF YOUR LAST MEETING, SO I'M THANKFUL THAT THOSE TRANSCRIPTS EXIST BECAUSE

WITHOUT THEM, I WOULDN'T HAVE KNOWN WHAT WAS GOING ON AND I WOULDN'T BE HERE TODAY TALKING ABOUT THIS. IT'S OUR HOPE THAT WE CAN THINK ABOUT THE NAS GUIDELINES WITH A GOAL TOWARDS FLEXIBILITY, AND THAT WE COULD DISCUSS SOME OF THE IMPORTANT CONCEPTUAL AND IMPLEMENTATION DETAILS THAT WILL ENSURE THE HIGHEST ETHICAL AND SCIENTIFIC STANDARDS IN STEM CELL RESEARCH AND WILL PROMOTE PUBLIC CONFIDENCE IN OUR WORK.

SO AS FAR AS ESCRO'S AND IRB'S, IT APPEARS TO ME THE GOALS FOR REVIEW OF HUMAN EMBRYONIC STEM CELL RESEARCH ARE, OF COURSE, THE HIGHEST ETHICAL AND SCIENTIFIC STANDARDS IN THE RESEARCH. HIGH STANDARDS WILL PROMOTE PUBLIC CONFIDENCE, AND HOPEFULLY THERE WILL BE THOROUGH, EFFICIENT REVIEW THAT WILL AVOID DUPLICATION OF EFFORT. SO THERE SHOULD BE SOME METHODS, AND THE METHODS ARE THAT THERE'S POTENTIAL CONFLICTING CALIFORNIA STEM CELL LAW, WHICH JEFF SHEEHY ALLUDED TO EARLIER, AND THAT HOPEFULLY WE CAN FOCUS ON FLEXIBILITY IN AVOIDING LOCKING THE CIRM OR FUNDED INSTITUTIONS INTO A STRICT CONSTRUCTIONIST NAS MODEL WHEN THERE MAY BE MULTIPLE APPROPRIATE MODELS TO ACHIEVE THE SAME GOALS, AND REVIEW THIS AS A UNIQUE OPPORTUNITY TO CREATE A UNIFIED SYSTEM OF PROTECTIONS IN CALIFORNIA, ONE FOR BOTH CIRM-FUNDED RESEARCH AND FOR NON-CIRM FUNDED RESEARCH.

THIS IS A VERY UNIQUE OPPORTUNITY WE HAVE BECAUSE THE DEPARTMENT OF HEALTH SERVICES HAS NOT YET CREATED THEIR OWN GUIDELINES, SO THEY'RE ABOUT NINE MONTHS LATER ON THEIRS.

SO REVIEW REQUIREMENTS, I'M GOING TO TOUCH ON THREE PARTS: CALIFORNIA LAW AND CIRM RESPONSIBILITIES, FEDERAL REGULATIONS, AND THE NAS GUIDELINES. SO WHAT DOES THE CALIFORNIA LAW SAY? JEFF SHEEHY ALLUDED TO THE LAW. IT'S 125119. ALL RESEARCH PROJECTS INVOLVING THE DERIVATION OR USE OF HUMAN EMBRYONIC STEM CELLS SHALL BE REVIEWED AND APPROVED BY AN IRB AS ESTABLISHED IN ACCORDANCE WITH FEDERAL REGULATIONS, INCLUDING 45 CFR 46, PRIOR TO BEING UNDERTAKEN. THIS IS FOR ALL HUMAN EMBRYONIC STEM CELL RESEARCH. OF COURSE, CIRM HAS THE ABILITY, AND I'LL GET TO THIS LATER, TO WRITE DIFFERENT LAWS FOR YOUR FUNDED RESEARCH.

THE CALIFORNIA STATE LAW HAVE TO APPLY THE GUIDELINES DEVELOPED, AND THE DHS, DEPARTMENT OF HEALTH SERVICES, WHICH IS A CALIFORNIA ENTITY, NOT TO BE CONFUSED WITH THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AT THE FEDERAL LEVEL, WERE REQUIRED TO SUBMIT GUIDELINES BY JANUARY 1ST OF THIS YEAR. IRB REVIEW MUST BE AT LEAST ONCE PER YEAR, AND IRB'S THAT CONDUCT SUCH REVIEW MUST REPORT ANNUALLY INFORMATION TO DHS.

CIRM, AS I SAID, HAS THE AUTHORITY, AND AS

YOU UNDERSTAND, TO CREATE DIFFERENT REVIEW REQUIREMENTS FOR YOUR RESEARCH. POTENTIALLY THIS CREATES TWO CLASSES OF HUMAN EMBRYONIC STEM CELL RESEARCH LAW, ONE FOR YOUR SPONSORED RESEARCH AND ONE FOR OTHER CONDUCTED RESEARCH. AND THIS PLACES RESEARCH INSTITUTIONS WHO CONDUCT STEM CELL RESEARCH WITH AND WITHOUT CIRM FUNDS IN A VERY CHALLENGING POSITION IN TERMS OF UPHOLDING THE HIGHEST ETHICAL AND LEGAL STANDARDS, ENSURING HIGH SCIENTIFIC PROPOSALS, AND COMPLIANCE WITH ALL THE APPLICABLE LAWS.

SO WHAT I ASK YOU TO ENGAGE IN TODAY IS A DISCUSSION ON AN OPPORTUNITY TO CREATE FLEXIBILITY THAT WILL HARMONIZE REQUIREMENTS AND ENSURE CONSISTENT STANDARDS AND NOT BE SO CONCERNED ABOUT THE ACTUAL STRUCTURE OF HOW THOSE STANDARDS ARE CARRIED OUT. AS I'M GOING TO PRESENT, I BELIEVE THAT THERE ARE MULTIPLE PROCESSES FOR ACHIEVING THE SAME STANDARD GOALS.

SO WHAT DO IRB'S DO? THERE SEEM TO BE, IN READING THE TRANSCRIPT FROM YOUR LAST MEETING, SOME MISCONCEPTION ABOUT WHAT IRB'S DO. IRB'S ARE CREATED TO PROTECT THE RIGHTS AND WELFARE OF HUMAN SUBJECTS AS DEFINED BY FEDERAL REGULATIONS AND LOCAL LAWS. THEY'RE GOVERNED BY HHS AND FDA REGULATIONS, OTHER FEDERAL AGENCIES, STATE LAWS, AND INSTITUTIONAL POLICIES. MOST OF THEM HAVE HHS ASSURANCES, IF THEY'RE GOING TO GET

HHS FUNDING, AND THEY COMMONLY AGREE TO APPLY THE SAME STANDARDS OF REVIEW TO ALL HUMAN RESEARCH. MEMBERSHIP OF IRB'S HAVE TO HAVE A MINIMUM OF FIVE MEMBERS, SUFFICIENT SCIENTIFIC EXPERTISE AMONGST THOSE MEMBERS TO REVIEW THE PROTOCOLS THAT COME BEFORE THEM, DIVERSITY OF RACE, GENDER, AND CULTURAL BACKGROUND, SENSITIVITY TO COMMUNITY ISSUES, AND THEY HAVE TO HAVE AT LEAST ONE SCIENTIST AND ONE NONAFFILIATED MEMBER, WHICH IN THE MAJORITY OF IRB'S ARE CONSIDERED COMMUNITY MEMBERS BECAUSE THEY USUALLY DEVOLVE TO ONE OR SEVERAL PEOPLE WHO FULFILL BOTH ROLES.

SO WHAT DOES AN IRB DO? IT REVIEWS PROPOSALS. IT APPLIES ETHICAL STANDARDS. AND THE THREE ETHICAL STANDARDS WRITTEN INTO THE REGULATIONS ARE BENEFICENCE OR RISK BENEFIT ANALYSIS OF THE RESEARCH. JUSTICE, EQUITABLE SELECTION OF SUBJECTS AND DISTRIBUTION OF THE RISKS AND BENEFITS, AND RESPECT FOR PERSONS, WHICH ASSURES THE DIGNITY AND AUTONOMY OF THE SUBJECTS THROUGH A PROCESS WE COMMONLY REFER TO AS INFORMED CONSENT. I'M NOT GOING TO TALK ABOUT THE RESPECT FOR PERSON STANDARD TODAY BECAUSE I THINK WE'RE ALL VERY WELL FAMILIAR WITH IT, BUT INSTEAD I'M GOING TO FOCUS ON THE FIRST TWO ETHICAL PRINCIPLES, BENEFICENCE AND JUSTICE, AND THEY HAVE TO APPLY LEGAL STANDARDS.

SO WHAT IS BENEFICENCE? IT'S ENSURING THE RISKS TO SUBJECTS ARE MINIMIZED BY USING PROCEDURES WHICH ARE CONSISTENT WITH SOUND RESEARCH DESIGN AND WHICH DO NOT UNNECESSARILY EXPOSE SUBJECTS TO RISK AND, WHENEVER APPROPRIATE, BY USING PROCEDURES ALREADY PERFORMED ON THE SUBJECTS FOR DIAGNOSTIC TREATMENT PURPOSES. TWO, RISKS TO SUBJECTS ARE REASONABLE IN RELATION TO ANTICIPATED BENEFITS, IF ANY, TO SUBJECTS AND THE IMPORTANCE OF THE KNOWLEDGE THAT MAY REASONABLY BE EXPECTED TO RESULT.

WHY IS THIS IMPORTANT? BECAUSE IRB'S DO MORE THAN READ CONSENT FORMS. THEY DO MORE THAN MOVE SEMICOLONS INTO COMMAS. THEY'RE ACTUALLY RESPONSIBLE FOR REVIEWING THE SCIENCE OF RESEARCH AS IT IMPACTS THE RIGHTS AND WELFARE OF THE SUBJECTS THROUGH THIS ETHICAL PRINCIPLE OF BENEFICENCE. JUSTICE IS THE SELECTION OF SUBJECTS AS EQUITABLE, THAT YOU HAVE TO ASSESS THE PURPOSE AND SETTING OF THE RESEARCH IN ORDER TO ADDRESS SPECIAL ISSUES OF RESEARCH INVOLVING VULNERABLE POPULATIONS, SUCH AS CHILDREN, PRISONERS, PREGNANT WOMEN, MENTALLY DISABLED, ETC., ETC., ETC., AND THROUGH THIS PROCESS ENSURING THAT THE RISKS AND BENEFITS ARE EQUITABLY DISTRIBUTED AMONGST SOCIETY.

SO WHAT'S THE FEDERAL DEFINITION OF A HUMAN SUBJECT? AND ALTA CHARO REFERRED TO THIS EARLIER. A

LIVING INDIVIDUAL ABOUT WHOM AN INVESTIGATOR CONDUCTING RESEARCH OBTAINS DATA THROUGH INTERVENTION OR INTERACTION WITH THE INDIVIDUAL OR IDENTIFIABLE PRIVATE INFORMATION. SO YOU HAVE TO BE ALIVE TO BE A HUMAN SUBJECT. IS A BLASTOCYST ALIVE BY FEDERAL REGULATORY DEFINITION? NO. A FETUS, AS DESCRIBED AND PROTECTED BY THE REGULATIONS, IS THE PRODUCT OF CONCEPTION FROM IMPLANTATION UNTIL DELIVERY. SO IF THE MATERIAL IS NEVER IMPLANTED INTO A WOMAN, IT IS NOT A HUMAN SUBJECT BY FEDERAL REGULATION STANDARDS. DEFINITION OF HUMAN RESEARCH SUBJECT DOES NOT INCLUDE BLASTOCYSTS THAT ARE IMPLANTED OR BLASTOCYSTS OR GAMETES WITHOUT IDENTIFIERS THAT COULD BE LINKED BACK TO THE DONORS. THEREFORE, SUCH MATERIAL IS NOT SUBJECT TO FEDERAL IRB REGULATORY OVERSIGHT. AND THIS FEEDS IN PERFECTLY WITH THE CONVERSATION YOU HAD EARLIER.

LABORATORY RESEARCH. DO THE HHS REGULATIONS COVER LABORATORY RESEARCH ON EMBRYOS CREATED FOR RESEARCH OR DERIVED FROM IVF PRIOR TO IMPLANTATION? NO. HHS, IRB REGULATIONS DO NOT COVER SUCH RESEARCH SO LONG AS THE PRODUCT IS NOT GIVEN TO A LIVING INDIVIDUAL. SO YOU MAY CREATE A THERAPEUTIC LATER IN TIME WHICH WOULD BE COVERED BY HHS REGULATIONS, BUT NOT BEFORE THAT TIME OR IF THE MATERIAL CONTAINS IDENTIFYING INFORMATION OF A LIVING INDIVIDUAL DONOR.

THEREFORE, SUCH MATERIAL USED IN HUMAN EMBRYONIC STEM CELL RESEARCH DOES NOT FALL WITHIN IRB PURVIEW UNDER THE FEDERAL REGULATIONS, BUT YOU HAVE TO REMEMBER THERE IS ANOTHER CALIFORNIA LAW THAT INSTITUTIONS ARE GOING TO BE REQUIRED TO IMPLEMENT REGARDLESS OF WHETHER THEY RECEIVE YOUR FUNDING OR NOT, WHICH IS ALL THAT OTHER STUFF THAT STILL HAS TO BE REVIEWED BY AN IRB.

AND I WOULD MAKE A STATEMENT TODAY THAT JUST BECAUSE THE CALIFORNIA LAW STATES THAT IRB REVIEW IS REQUIRED OF HUMAN EMBRYONIC STEM CELL RESEARCH, IT DOESN'T MEAN THAT THE CALIFORNIA LAW HAS IDENTIFIED A BLASTOCYST AS A HUMAN BEING. IT IS MY UNDERSTANDING OF READING THE HISTORY OF THE LEGISLATION THAT WHAT THEY WERE LOOKING FOR IS A WAY TO OVERSEE HUMAN EMBRYONIC STEM CELL RESEARCH. AND THEY LOOKED AROUND FOR A GROUP OF PEOPLE WHO WERE ALREADY DOING OVERSIGHT, AND THEY IDENTIFIED IRB'S AS THOSE SUBJECTS. BUT IN NO WAY DOES THE LAW STATE THAT IT IDENTIFIES A HUMAN BLASTOCYST AS A HUMAN SUBJECT.

SO WHAT DO THE NAS GUIDELINES SAY THAT YOU'VE BEEN DISCUSSING SO THOROUGHLY TODAY? YOU HAVE TO CREATE A LOCAL ESCRO COMMITTEE THAT WILL REVIEW ALL HUMAN EMBRYONIC STEM CELL RESEARCH. HE INTENDED THE GUIDELINES FOR THE ENTIRE U.S.A. THE NAS DID NOT WRITE THE GUIDELINES FOR CALIFORNIA, NOR DID THEY CONSIDER

THAT CALIFORNIA MAY HAVE DIFFERENT LAWS AND BE SUBJECT TO DIFFERENT STANDARDS. THEY STRUCTURED THE ESCRO MEMBERSHIP SIMILAR TO IRB'S AND HIGHLIGHTED SIMILAR RESPONSIBILITIES, UNDERSTANDING THAT HUMAN EMBRYONIC STEM CELL RESEARCH, INCLUDING NONHUMAN SUBJECT LABORATORY RESEARCH, SHOULD HAVE ETHICAL AND SCIENTIFIC OVERSIGHT. AND THEY WANTED TO ENSURE AN IRB-TYPE REVIEW OCCURRED WHEN FEDERAL IRB HUMAN RESEARCH REGULATIONS BY IRB REVIEW DID NOT APPLY AND LOCAL LAWS DID NOT REQUIRE IRB REVIEW.

SO WHAT DID THE NAS SAY AN ESCRO COMMITTEE SHOULD CONSIST OF? DEVELOPMENTAL BIOLOGISTS, STEM CELL RESEARCHER, MOLECULAR BIOLOGIST, ASSISTED REPRODUCTION SPECIALIST, AND SOMEONE INVOLVED WITH ETHICAL AND LEGAL ISSUES, AND COMMUNITY MEMBERS. AND, GOSH, THAT STARTS TO LOOK A WHOLE LOT LIKE AN IRB THAT HAS EXPLICIT SCIENTIFIC EXPERTISE TO REVIEW THE RESEARCH THAT COMES BEFORE IT PLUS COMMUNITY MEMBERS AND PEOPLE WHO ARE INVOLVED WITH ETHICS.

SO WHAT ARE THE RESPONSIBILITIES OF AN ESCRO COMMITTEE? PROVIDE OVERSIGHT FOR ALL ISSUES RELATED TO DERIVATION AND USE OF STEM CELLS, REVIEW AND APPROVE THE SCIENTIFIC MERIT OF EMBRYONIC STEM CELL PROPOSALS, REVIEW COMPLIANCE OF ALL IN-HOUSE EMBRYONIC STEM CELL RESEARCH WITH APPLICABLE REGULATIONS AND GUIDELINES,

MAINTAIN REGISTRIES, AND ACCOUNT FOR ALL RESEARCH, AND PROVIDE EDUCATION.

THIS IS WHERE WE'RE RUNNING INTO TROUBLE THOUGH. AS AN INSTITUTION THAT'S HAD TO IMPLEMENT NOT ONLY THE CALIFORNIA LAW FOR NON-CIRM RESEARCH, BUT ALSO LOOK AT NAS GUIDELINES AS APPROPRIATELY THOUGHT OUT AND INTELLIGENT GUIDELINES FOR THE MAJORITY OF RESEARCH WE DO, BUT IT RESULTS IN A POSSIBLE DUPLICATION OF EFFORT. THERE ARE OVERLAPPING DUTIES AND POTENTIAL FOR LOCAL FLEXIBILITY THAT NEEDS TO BE ADDRESSED. NAS EXPLICITLY STATED A PREEXISTING COMMITTEE COULD SERVE THE FUNCTIONS OF THE ESCRO COMMITTEE PROVIDED THAT IT HAS THE RECOMMENDED EXPERTISE AND REPRESENTATION TO PERFORM THE VARIOUS ROLES DESCRIBED IN THIS REPORT.

TWO, AND THAT THE INSTITUTION SHOULD CARE AND SHOULD BE TAKEN THAT THE ESCRO COMMITTEE DOES NOT DUPLICATE OR INTERFERE WITH THE PROPER FUNCTIONS OF AN IRB. THE FUNCTIONS OF IRB'S AND ESCRO COMMITTEES ARE DISTINCT AND SHOULD NOT BE CONFUSED. AND THIS, OF COURSE, WOULD BE VERY APPROPRIATE FOR LABORATORY-BASED RESEARCH IN WHICH IRB REVIEW IS NOT REQUIRED BY LOCAL LAW.

SO A COMPARISON CHART. THIS MAY BE DIFFICULT FOR YOU TO READ BECAUSE IT HAD TO GO DOWN TO PRETTY SMALL TYPE. LET'S SEE IF I CAN POINT SOME AREAS OUT

HERE. SO MEMBERSHIP: ESCRO AND IRB, ACCORDING TO 45 CFR 46 AND NAS GUIDELINES. SCIENTIFIC EXPERTISE: ESCRO, YES; IRB, YES. MEDICAL EXPERTISE: ESCRO, YES; IRB, YES, FOR BIOMEDICAL RESEARCH, WHICH THIS RESEARCH IS. ETHICS EXPERTISE: ESCRO, YES; IRB, NOT SPECIFICALLY, BUT CERTAINLY IMPLIED. COMMUNITY MEMBERSHIP: ESCRO, YES; IRB, YES.

AND THEN DIVERSITY OF MEMBERSHIP: ESCRO, NO; IRB, YES. DUTIES, SCIENTIFIC EVALUATION: ESCRO, YES; IRB, YES, AS THE RESEARCH DESIGN IMPACTS THE RIGHTS AND WELFARE OF SUBJECTS. IF THERE ARE NO SUBJECTS, THERE'S NOT GOING TO BE A SCIENTIFIC EVALUATION BY THE IRB. ETHICS: YES AND YES. RISK BENEFIT: YES, BOTH COMMITTEES WILL HAVE TO DO THAT. INFORMED CONSENT: YES. ESCRO IS RESPONSIBLE FOR INFORMED CONSENT ACCORDING TO NAS GUIDELINES. COMPLIANCE: YES. EDUCATION: YES ON BOTH SIDES. DERIVATION OF CELLS: YES. ACCOUNTING FOR CELLS: YES, EXCEPT THE IRB TRADITIONALLY IS LIMITED IN THE EXTENT OF ITS ABILITY TO COUNT FOR CELLS AS IT'S NOT REQUIRED FOR NONHUMAN SUBJECTS RESEARCH, BUT THEY MUST ACCOUNT FOR ALL RESEARCH. REVIEW OF HUMAN EMBRYONIC STEM CELL RESEARCH: YES, BY IOM GUIDELINES, AND YES AND NO IN TERMS OF WHO'S SPONSORING IN CALIFORNIA.

SO THERE'S A LOT OF OVERLAP HERE IN TERMS OF

DUTIES OF BOTH COMMITTEES. AND WITH THAT OVERLAP IS A TREMENDOUS EXPENSE FOR INSTITUTIONS.

ARE THERE POSSIBLE ALTERNATIVE APPROACHES? I CAME UP WITH FOUR OFF THE TOP OF MY HEAD IN DISCUSSION WITH OTHER IRB SPECIALISTS AND OTHER PEOPLE INVOLVED IN THIS AREA. PLAN A: ESCRO AND IRB, THIS IS EXACTLY WHAT THE NAS REQUIRES. TWO LOCAL COMMITTEES WITH OVERLAPPING DUTIES AND RESPONSIBILITIES.

PLAN B, A STEM CELL SCIENTIFIC REVIEW COMMITTEE AND AN IRB. THE STEM CELL SCIENTIFIC REVIEW COMMITTEE AND THE IRB WORKING TOGETHER CREATE AN ESCRO COMMITTEE. TWO LOCAL COMMITTEES WITH SEPARATE DUTIES REQUIRING COOPERATION MODELED ON THE NCI COMPREHENSIVE CANCER CENTER MODEL, REQUIREMENT TO PERFORM SCIENTIFIC EVALUATION OF CANCER CENTER AFFILIATED RESEARCH.

PLAN C, AN IRB THAT INCLUDES AN ESCRO COMMITTEE. IT WOULDN'T BE A SUBCOMMITTEE. THEY'D BE ONE AND THE SAME THAT ACCOMPLISHED ALL THOSE SAME GOALS. ONE LOCAL COMMITTEE REQUIRES AUGMENTING IRB MEMBERSHIP FOR A LIMITED NUMBER OF PROTOCOLS, MAY PLAY WITH QUORUM AND OTHER KINDS OF OTHER PROBLEMS THERE.

PLAN D, AN INTERESTING PLAN. THIS IS ONE THAT SHERRY LANSING MENTIONED AT YOUR LAST MEETING, WHICH IS A CENTRAL ESCRO COMMITTEE IMPLEMENTED BY THE STATES SIMILAR TO THE NIH RAC, RECOMBINANT DNA ADVISORY

COMMITTEE. WHY IS THIS AN INTERESTING IDEA, AND SHERRY ARTICULATED THIS AT THE LAST MEETING, IS THAT YOU HAVE LOCAL ESCRO'S THAT MAY COME TO DIFFERENT DECISIONS. AND SO, THEREFORE, YOU MAY HAVE A PI WHO'S ALLOWED TO DO X RESEARCH PROTOCOL AT Y INSTITUTION, BUT NOT ALLOWED TO DO IT AT Z INSTITUTION BECAUSE THEIR ESCRO COMMITTEE DISAGREES WITH IT. SO THAT MAY BE A DECENT ARGUMENT FOR A CENTRAL ESCRO COMMITTEE INSTEAD OF LOCAL COMMITTEES.

SO POSSIBLE INSTITUTIONAL CIRM APPROACHES, PLAN A, REMEMBER, IS THE NAS APPROACH. YOU HAVE LOTS OF OVERLAP BETWEEN THE IRB AND THE ESCRO. PLAN B, WHAT YOU HAVE IS EFFORT DIVIDED BETWEEN TWO COMMITTEES SEPARATING OUT SO THE IRB SPENDS ITS TIME ON IRB FUNCTIONS, AND THE STEM CELL SCIENTIFIC REVIEW COMMITTEE DOES ALL THE OTHER THINGS THAT ESCRO IS REQUIRED TO DO. IT DOESN'T GET INVOLVED IN ETHICS. IT LEAVES THAT TO THE IRB. IT GETS INVOLVED IN SCIENCE, AND THE IRB THEN USES THAT SCIENTIFIC REVIEW FROM THE SCIENTIFIC REVIEW COMMITTEE.

RISK BENEFIT ANALYSIS IS LIMITED, MOSTLY DONE ON THE IRB. INFORMED CONSENT, THE SCIENTIFIC REVIEW COMMITTEE DOES NOT GET INVOLVED IN AT ALL. RECRUITMENT THEY DON'T GET INVOLVED IN. PAYMENT THEY DON'T GET INVOLVED IN. AND ACCOUNTING OF CELL PROJECTS THEY DO.

DERIVATION ISSUES THEY DO BECAUSE THAT'S ACTUALLY THEIR EXPERTISE. PROVENANCE AND PROCUREMENT OF CELLS, YES. AND THEN EDUCATION, BOTH SIDES WOULD HAVE TO, YES, FOR THEIR REQUIRED ELEMENTS. SO HERE YOU HAVE A SHARED RESPONSIBILITY BETWEEN TWO COMMITTEES, OF WHICH I COULD SAY AT SOME CENTERS THAT HAVE COMPREHENSIVE CANCER CENTERS, THIS WOULD BE A LOGICAL WAY TO GO ABOUT IMPLEMENTING THE CONCEPT AND THE STANDARDS OF NAS IN TERMS OF HUMAN EMBRYONIC STEM CELL OVERSIGHT.

PLAN C IS A HYBRID WHERE YOU ACCOMPLISH EVERYTHING IN ONE COMMITTEE, WHICH COULD ALSO BE A POSSIBILITY.

AND THEN PLAN D IS THE CALIFORNIA GENERAL STATE ESCRO COMMITTEE.

SOME QUESTIONS THAT WE DEVELOPED ABOUT THIS ISSUE. WILL SOME INSTITUTIONS WANT TO CREATE A SINGLE UNIFIED PROTECTION SYSTEM FOR ALL HUMAN EMBRYONIC STEM CELL RESEARCH AT THE INSTITUTION THAT WILL ADDRESS BOTH CIRM-FUNDED AND NON-CIRM-FUNDED RESEARCH SIMILAR TO CURRENT HHS HUMAN RESEARCH ASSURANCES? WHY WOULD YOU WANT TO DO THAT? BECAUSE YOU MIGHT WANT TO AVOID HAVING TWO CLASSES OF HUMAN EMBRYONIC STEM CELL RESEARCH REVIEW AND OVERSIGHT AT YOUR INSTITUTION.

WILL A STRICT CONSTRUCTIONIST INTERPRETATION OF THE NAS GUIDELINES BY CIRM UNDULY LIMIT

INSTITUTIONAL FLEXIBILITY IN THE CREATION OF A UNIFIED AND SINGLE SYSTEM OF PROTECTIONS? THIS IS A REALLY IMPORTANT QUESTION, AND IT COMES TO CERTAIN IDEAS ABOUT COST AND IMPLEMENTATION. SOME INSTITUTIONS, BEFORE YOU EVER DECIDED TO ADOPT THE NAS GUIDELINES, HAVE ALREADY DEVELOPED PROGRAMS TO DEAL WITH HUMAN EMBRYONIC STEM CELL RESEARCH. AND THEN WITH THE ADVENT OF THE NAS GUIDELINES, DEVELOPED PROGRAMS THEN TO ADDRESS THAT. SO IN SOME WAYS THE CIRM IS A LITTLE BIT BEHIND THE CURVE OF WHERE THE INSTITUTIONS ALREADY ARE. AND IT COSTS A LOT OF TIME AND RESOURCES TO CREATE THESE PROGRAMS IN ORDER TO ASSUME RESPONSIBILITY AND ENSURE THE HIGHEST ETHICAL AND SCIENTIFIC STANDARDS.

TO CREATE INTERIM GUIDELINES THAT INSTITUTIONS THEN HAVE TO MODIFY AGAIN WHAT THEY'RE DOING AND THEN MAYBE HAVE THOSE GUIDELINES THEN MODIFIED AGAIN NINE MONTHS DOWN THE ROAD OR HOWEVER LONG THAT TAKES, IT TAKES A LOT OF EFFORT ON THE PART OF ANY INSTITUTION, AND SEVERAL OF YOU COMMENTED ABOUT THIS EARLIER, TO GET THESE KINDS OF PROGRAMS GOING, TO IMPLEMENT THEM, TO EDUCATE THE RESEARCH COMMUNITY, WHICH IS THE MOST IMPORTANT OF THESE PROGRAMS. NOTHING OF WHAT WE TALK ABOUT HERE TODAY OR ANY OTHER DAY IS WORTH ANYTHING UNLESS THE RESEARCH COMMUNITY IS APPROPRIATELY EDUCATED, TRUST IN THE PROGRAM, AND ARE

ABLE TO IMPLEMENT THOSE PROGRAMS.

SINCE CIRM IS EXEMPT FROM THE CALIFORNIA HEALTH AND SAFETY CODE REQUIREMENT FOR IRB REVIEW OF ALL HUMAN EMBRYONIC STEM CELL RESEARCH, SHOULD CIRM CREATE REGULATIONS THAT AVOID THE POSSIBILITY OF A TWO-CLASS SYSTEM OF REVIEW AND OVERSIGHT? INSTITUTIONS THAT RECEIVE BOTH CIRM AND NON-CIRM FUNDS MAY HAVE TWO DISTINCT AND COMPETING SETS OF OVERSIGHT REQUIREMENTS THAT MAY ALSO OVERLAP IN DECISION-MAKING RESPONSIBILITIES.

A TWO-CLASS SYSTEM COULD RESULT IN DUPLICATIVE FUNCTION, WASTED RESOURCES, AND RESULT IN DISCORDANT DETERMINATIONS ON THE SAME ISSUES, ULTIMATELY UNDERMINING THE INTEGRITY OF THE SYSTEM AND RESULTING IN A BREAKDOWN IN TRUST OF THE RESEARCH COMMUNITY, WHICH ARE ELEMENTS THAT WE DEFINITELY WANT TO AVOID.

IS THERE ROOM FOR FLEXIBILITY IN CRAFTING REQUIREMENTS SO THAT REVIEW STANDARDS ENABLE INSTITUTIONS TO ACHIEVE THE IMPORTANT GOALS OF ONLY CONDUCTING RESEARCH THAT MEETS THE HIGHEST ETHICAL AND SCIENTIFIC STANDARDS AND BUILDS PUBLIC CONFIDENCE AND ALLOWS INSTITUTIONS TO MEET THE INTENT OF THE NAS GUIDELINES, THE CONCEPTUAL ELEMENTS OF THOSE GUIDELINES THROUGH VARIOUS LOCAL COMMITTEE STRUCTURES THAT

MAXIMIZE RESOURCES, MINIMIZE DUPLICATION OF EFFORT, WHILE ALLOWING INSTITUTIONS TO CREATE THE BEST LOCAL COMMITTEE METHODOLOGY TO ACHIEVE THOSE GOALS?

THANK YOU. I'M HAPPY TO ENTERTAIN ANY QUESTIONS. WAS THAT 15 MINUTES? MY APOLOGIES TO THE STENOGRAPHER.

CO-CHAIR LO: WE HAVE ABOUT TEN MINUTES OF EITHER QUESTIONS FOR STEVE OR COMMENTS FOR THE COMMITTEE, SO I'D ENCOURAGE DISCUSSION, BUT ASK YOU TO KEEP YOUR COMMENTS BRIEF.

DR. EGGAN: I RESPECTFULLY SUBMIT THAT, ONE, I CAN SEE YOUR POINT, BUT ONE CAN INVERSELY CREATE OR PREVENT THERE FROM BEING A TWO-CLASS SYSTEM BY SIMPLY SAYING THAT THE NAS POSITION IS QUITE REASONABLE AND THAT EVERY INSTITUTION SHOULD HAVE AN ESCRO REGARDLESS OF CALIFORNIA STATE LAW. AND THAT PERHAPS IT'S NOT SUCH A BAD THING IF EVERY APPLICATION FOR RESEARCH IS REVIEWED BOTH BY THE IRB AND THE ESCRO.

I MEAN I CERTAINLY AGREE WITH, ALTA THAT IT'S A DANGEROUS SITUATION TO CALL THESE THINGS HUMAN SUBJECTS (INTERRUPTION), BUT IF THAT'S A SITUATION ESSENTIALLY, STICKING WITH THE NAS GUIDELINES ACROSS THE BOARD, WHICH I WOULD HOPE ALL INSTITUTIONS ARE GOING TO DO BECAUSE I THINK THAT WOULD HELP CREATE A NATIONAL STANDARD, IS NOT PROBLEMATIC.

MR. PECKMAN: I'M NOT SAYING THAT ONE SHOULDN'T CREATE AN ESCRO COMMITTEE. WHAT I'M SAYING IS TO THINK ABOUT FLEXIBILITY IN THE REQUIREMENT FOR A VERY STRICT INTERPRETATION OF THE NAS GUIDELINES AND THAT ALLOW FOR A MULTITUDE OF FRAMEWORKS TO ACCOMPLISH THE SAME GOALS.

MS. CHARO: VERY BRIEFLY, FIRST, I THINK THE GOAL OF FLEXIBILITY IS SHARED. HOW TO GET THERE IS THE SOURCE OF THE DISCUSSION. I THINK ANOTHER ALTERNATIVE THAT WASN'T PRESENTED IS THE ONE THAT'S ACTUALLY IN THE INTERIM GUIDELINE DRAFT WE HAVE HERE, WHICH IS THAT THE ESCRO IS NOT A FORMAL SUBCOMMITTEE OF THE IRB, BUT YOU CAN ALSO, NONETHELESS, HAVE TREMENDOUS OVERLAP OF MEMBERSHIP, AND THERE'S NOTHING THAT PRECLUDES OVERLAP OF STAFF EITHER.

I WOULD ALSO JUST BRIEFLY SAY TWO OTHER THINGS VERY QUICKLY. I THINK THAT ONE OF YOUR SLIDES LISTS FUNCTIONS FOR THE ESCRO THAT AREN'T ACTUALLY IN THERE. IT HAS THE ESCRO REVIEWING DERIVATION, REVIEWING OTHER THINGS THAT, IN FACT, IN THE GUIDELINES IS DEFERRED TO THE IRB. THE ESCRO SIMPLY WANTS CONFIRMATION THAT THE IRB HAS DONE THIS. IT SETS CERTAIN SUBSTANTIVE STANDARDS THAT ACTUALLY ARE TRACKING IN MANY WAYS ALREADY FEDERAL STANDARDS WITH REGARD TO INFORMED CONSENT, ETC., BUT IT DOES NOT

UNDERTAKE A DE NOVO REVIEW OF CONSENT DOCUMENTS, ETC. IT'S IMPORTANT TO BE CAREFUL ABOUT THE STATEMENT ABOUT WHERE THE REDUNDANCIES MIGHT BE.

LAST, IT IS WORTH NOTING THAT IRB'S ARE SUBJECT TO VERY SPECIFIC REGULATORY REQUIREMENTS, NOT ONLY IN TERMS OF THEIR MEMBERSHIP, BUT ALSO IN TERMS OF THEIR RECORDKEEPING, THAT THEY HAVE CERTAIN MEETING SCHEDULES, THAT BY INCORPORATING AN ESCRO INTO AN IRB, YOU ARE MAKING THE ESCRO SUBJECT TO ALL OF THOSE FEDERAL REGULATIONS AND THE IRB'S SCHEDULE FOR REVIEW. IN SOME WAYS IT TAKES AWAY FLEXIBILITY FROM AN ESCRO IF IT HAS TO SLOT ITSELF INTO THE ADMINISTRATIVE PATTERNS OF AN IRB.

SO IN THINKING ABOUT FLEXIBILITY, LET'S THINK VERY GLOBALLY ABOUT ALL THE EFFECTS OF BEING THAT TIGHTLY TIED TO AN EXISTING IRB.

MR. PECKMAN: I WOULD SUBMIT THAT THE NAS GUIDELINES ARE UNCLEAR AS TO THE EXACT RELATIONSHIP BETWEEN AN IRB AND AN ESCRO IN THAT, AT LEAST IN OUR READING, IT APPEARED PRETTY CLEAR THAT THE ESCRO SHARED MANY OF THE RESPONSIBILITIES.

REGARDING AN IRB/ESCRO RELATIONSHIP, THERE ARE MANY THINGS IRB'S ARE CURRENTLY REQUIRED TO DO UNDER FEDERAL LAW THAT DON'T INVOLVE HUMAN SUBJECT RESEARCH. FOR EXAMPLE, FDA LAW REQUIRES IRB REVIEW OF

CERTAIN KINDS OF DEVICES THAT ARE ALREADY APPROVED BY THE FDA. AND THEY'RE NOT HUMAN SUBJECTS. FDA DOES NOT CALL THEM HUMAN SUBJECTS RESEARCH, BUT THEY REQUIRE IRB REVIEW. THREE IS THAT THERE'S NO REASON WHY IN A COMBINATION -- AND THIS IS NOT ONE I PERSONALLY ENDORSE, BUT I KNOW OTHERS DO -- THERE'S NO REASON WHY AN IRB/ESCRO HYBRID HAS TO CONVENE ITSELF AS ONE RATHER THAN TWO. SO THEN YOU COULD APPLY ESCRO STANDARDS TO A MEETING OF THE ESCRO COMMITTEE PART OF THAT MEETING AND THEN TURN IT INTO AN IRB MEETING AND HAVE TOTALLY DIFFERENT STANDARDS THAT ARE DONE THERE AS WELL.

I THINK THERE'S A LOT OF DIFFERENT METHODOLOGIES, AGAIN, TO ATTAIN A CERTAIN GOAL THAT DON'T NECESSARILY BIND YOU TO CERTAIN IRB LAWS WITHIN THE 45 CFR 46 OR THE 21 CFR AND TO CALIFORNIA LAW EITHER. JUST MAKE SURE IT COVERS ALL THE BASES WITH THE RESOURCES AN INSTITUTION FEELS IT CAN AFFORD TO ALLOCATE TOWARDS THIS ROLE.

MR. SHESTACK: COULD YOU JUST CLARIFY, ALTA, WHY IS IT THAT THE LEGISLATION EXEMPTS CIRM RESEARCH FROM IRB REVIEW?

MR. KLEIN: ALTA, WHY DON'T YOU ADDRESS THAT FIRST?

MS. CHARO: BASICALLY CALIFORNIA PASSED A LAW THAT SAID IN VERY BROAD STROKES EMBRYONIC STEM CELL

RESEARCH ALWAYS HAS TO BE REVIEWED BY AN IRB. NOW, I SUSPECT IF THEY REALLY THOUGHT ABOUT IT, REALLY THOUGHT ABOUT IT, THEY MIGHT NOT HAVE WRITTEN IT THAT BROADLY AND THEY MIGHT HAVE ISOLATED IRB REVIEW TO ISSUES AROUND THE ACTUAL HUMAN BEINGS WHO ARE DONATING BIOLOGICAL MATERIALS, BUT THEY DIDN'T. SO IT COVERS PURELY LAB RESEARCH. OKAY.

AS I UNDERSTAND IT, WHEN THE INITIATIVE WAS PASSED, IT WAS PASSED WITH LANGUAGE THAT EXEMPTED RESEARCH FUNDED THROUGH THE INITIATIVE FROM THAT PARTICULAR CALIFORNIA STATE LAW. THAT MEANS THAT INITIATIVE-FUNDED RESEARCH THAT, IN FACT, HAS AN ELEMENT THAT INVOLVES A HUMAN SUBJECT, FOR EXAMPLE, A FRESH DERIVATION REQUIRING THAT YOU COLLECT NEW MATERIALS FROM PEOPLE, WILL STILL GO TO AN IRB BECAUSE THAT'S PART OF THE GENERAL JURISDICTION OF IRB'S HAS TO DO WITH HUMAN SUBJECTS. BY WHERE THERE'S INITIATIVE-FUNDED RESEARCH THAT DOESN'T INVOLVE A HUMAN SUBJECT, FOR EXAMPLE, YOU'RE WORKING JUST WITH THE CELL LINE, THEN YOU WOULD NO LONGER HAVE TO GO RUNNING OFF TO YOUR IRB FOR APPROVAL OF YOUR LABORATORY RESEARCH.

THE NOTION THAT IF I WANT TO DO RESEARCH THAT INVOLVES TESTING CULTURE MEDIA FOR GROWTH OF MY CELL LINES AND I'VE GOT TO GO TO MY IRB FOR PERMISSION TO DO THAT JUST SEEMS SILLY, BUT THAT'S WHAT THE LAW NOW

SAYS.

MR. KLEIN: MORE IMPORTANTLY, BESIDES BEING MAYBE EXTRANEOUS, THE IRB'S IN CALIFORNIA AT THE INSTITUTIONS WE'RE DEALING WITH HAVE VERY LONG SCHEDULES. VERY -- THEY HAVE EXTREMELY QUALIFIED PEOPLE WITH TREMENDOUS WORKLOADS. THEY HAVE HUGE BACKLOGS. AND YOU CAN SLOW DOWN RESEARCH SOMETIMES BY MONTHS JUST TRYING TO GET THROUGH AN IRB WHEN IT'S NOT RELEVANT TO THE DECISION BECAUSE THERE'S NOT A HUMAN SUBJECT INVOLVED. SO THE INTENT IN EXEMPTING IT FROM THAT PROVISION WAS TO KEEP IRB'S WHEN HUMAN SUBJECTS ARE NEEDED TO BE PROTECTED; BUT WHEN THEY'RE NOT NEEDED TO BE PROTECTED, TO MOVE IT THROUGH AN EXPERT BODY THAT CAN MOVE THE RESEARCH EXPEDITIOUSLY.

MR. SHESTACK: WHY MOVE IT THROUGH ANYBODY IF IT DOESN'T INVOLVE ACTUAL HUMAN SUBJECTS?

MR. KLEIN: IN TERMS OF MAKING SURE THAT THERE'S INFORMED CONSENT AND SOME OF THESE OTHER STANDARDS ARE MET.

MS. CHARO: THE INFORMED CONSENT WOULD BE HUMAN SUBJECTS, BOB.

MR. KLEIN: THAT'S TRUE. THAT'S A BAD EXAMPLE.

MS. CHARO: SOME OF IT DOES ALREADY GO THROUGH COMMITTEES, RIGHT? THIS IS WHY I THINK WE'VE

BEEN HEARING ANN REPEATEDLY TRYING TO RAISE THE QUESTION OF WHETHER THE ESCRO'S THEMSELVES ARE IN A SENSE SO REDUNDANT, THAT WE SHOULD BE RETHINKING THEM.

THE BASIC RESEARCH THAT DOESN'T INVOLVE HUMAN SUBJECTS MAY INVOLVE ANIMALS. THERE ARE ANIMAL CARE COMMITTEES. IT MAY INVOLVE GENETIC ENGINEERING. THERE ARE INSTITUTIONAL COMMITTEES THAT DEAL WITH RECOMBINANT DNA STUFF.

MR. SHESTACK: IN ADDITION, AS AN EXTRA LAYER ON TOP OF AN IRB.

MS. CHARO: EXACTLY. THE ESCRO'S WERE RECOMMENDED BY THE ACADEMIES, AND IT'S UP FOR GRABS WHETHER PEOPLE WANT TO ADOPT IT. THEY WERE RECOMMENDED BECAUSE THEY WOULD BE THE ONE PLACE WHERE, A, THERE'S A BODY THAT'S CHECKING OFF THAT EVERY ONE OF THESE AREAS OF RESEARCH IS, IN FACT, GOING TO ALL THE COMMITTEES IT'S SUPPOSED TO. IN THAT SENSE IT REPLICATES WHAT THE PROVOSTS'S OFFICE OR THE DEAN OF THE GRADUATE SCHOOL WOULD BE DOING AT AN INSTITUTION.

SECOND, IT SITS THERE TO ADD A LEVEL OF EXPERTISE THAT ISN'T CURRENTLY AVAILABLE. ANIMAL CARE COMMITTEES MAY GROW IN THIS AREA, BUT RIGHT NOW ARE NOT MADE UP OF PEOPLE PRIMARILY WHO ARE FAMILIAR WITH WHAT MIGHT BE GOING ON WITH STEM CELL RESEARCH. THE ESCRO'S COULD RAPIDLY DEVELOP THAT EXPERTISE BECAUSE THEY'RE

FOCUSING SPECIFICALLY ON THIS.

AND THIRD, POLITICAL; THAT IS, IT PROVIDES A VENUE IN WHICH THESE ISSUES ARE BEING DISCUSSED. IF THERE'S SOMETHING THAT'S FALLING THROUGH THE CRACKS OF THESE ALL COMMITTEES AND THE PUBLIC CAN HAVE SOME DEGREE OF CONFIDENCE THAT THERE IS A WAY TO FIND THINGS THAT ARE FALLING THROUGH THE CRACKS, BUT IT IS A DEBATABLE PROPOSITION WHETHER THAT'S A STRONG ENOUGH JUSTIFICATION FOR THIS EXTRA LEVEL.

DR. ROWLEY: THIS IS JANET ROWLEY, AND I'D LIKE TO WEIGH IN ON THIS BECAUSE I TOO WAS ON THE NAS WORKING COMMITTEE. I THINK THAT ONE OF THE IMPORTANT ISSUES IS THE ESCRO AS COMPRISED BY OTHER SCIENTISTS HAD APPROPRIATE SCIENTIFIC JUSTIFICATION FOR DEVELOPING A BRAND NEW CELL LINE THAT SOMEBODY ON THE ESCRO MIGHT KNOW IS DUPLICATING MORE OR LESS EXACTLY A CELL LINE THAT'S ALREADY AVAILABLE. WHY SHOULD THIS PERSON REINVENT THE WHEEL? AND IT ALSO WAS GOING TO BE VERY IMPORTANT IN JUDGING THE SCIENTIFIC MERITS OF WORK THAT WOULD PARTICULARLY INVOLVE ANIMALS AND CHIMERAS THAT A STANDARD IRB WOULD NOT BE CAPABLE OF DOING. AND THIS WAS -- THESE WERE IMPORTANT ISSUES THAT THE ESCRO'S SHOULD BE RESPONSIBLE FOR.

CO-CHAIR LO: IN THE INTEREST OF TIME, I WANT TO TRY AND MAKE SURE WE ALSO HAVE A CHANCE TO HEAR FROM

THE BANKING STUDY GROUP ON THAT OTHER SET OF ISSUES WE WANTED TO HEAR MORE ABOUT. SO I'M GOING TO SORT OF, WITH THE APPROVAL OF THE WORKING GROUP, CUT SHORT THIS DISCUSSION AND ASK FRANCISCO TO PRESENT THE THINKING OF THE BANKING STUDY GROUP TO HELP US THINK THROUGH WHAT WE NEED TO UNDERSTAND IN ORDER TO MAKE A JUDGMENT ABOUT THE INTERIM GUIDELINES ON THAT TOPIC.

DR. PRIETO: THE BANKING STUDY GROUP MET LAST WEEK BY TELECONFERENCE, AND WE WORKED OFF SEVERAL ISSUES THAT WERE BROUGHT UP BY STAFF, QUESTIONS THAT WE THOUGHT WE SHOULD TRY TO ANSWER. THE FIRST ONE BEING WHETHER THE CIRM SHOULD MAINTAIN A REGISTRY OF STEM CELL LINES. AND WE FELT THAT, YES, THIS SHOULD BE A FUNCTION OF THE CIRM, THAT ESSENTIALLY WE'RE MIMICKING THE NIH IN THIS SENSE THAT THERE HAS TO BE A PLACE WHERE SOME CENTRAL REPOSITORY OF INFORMATION EXISTS. WE ARE GOING TO BE THE LARGEST FUNDER OF STEM CELL RESEARCH, AND IT'S IMPORTANT THAT THERE BE A PLACE WHERE THIS INFORMATION IS KEPT.

SEPARATE FROM THAT, WE ADDRESSED THE ISSUE OF BANKING. BANKING WE FELT IS VERY IMPORTANT FOR PURPOSES OF SHARING INFORMATION AND MOVING THESE LINES OUT TO THE MAXIMUM NUMBER OF RESEARCHERS POSSIBLE, GETTING THE MOST BANG FOR OUR BUCK, SO TO SPEAK, ENSURING THAT WE HAVE RESULTS WITHIN A REASONABLE TIME

FRAME. WE DID NOT FEEL THAT THE CIRM NECESSARILY NEEDS TO BE THE PHYSICAL BANKER, BUT THAT THIS COULD BE SOMETHING THAT WOULD BE CONTRACTED OUT, THAT WE WOULD, YOU KNOW, CONTRACT MORE BY GRANT. THERE WAS SOME DISCUSSION ABOUT THAT ISSUE, WHICH WE MAY NOT WANT TO GET INTO TODAY. BUT THAT SPECIFICALLY FOR RESEARCHERS DOING CIRM-FUNDED RESEARCH, THAT THERE SHOULD BE A TIME LINE FROM THE TIME THAT THEY DERIVE CELL LINES WITH CIRM MONEY TO THE TIME THAT THEY SHARE THOSE LINES WITH THE BANK. WE HAD SOME DISCUSSION ABOUT WHAT THAT TIME SHOULD BE, AND CERTAINLY WE CAN TALK ABOUT THAT TODAY.

AND WE ALSO TALKED A LITTLE BIT ABOUT THERE'S A QUESTION ABOUT WHETHER EACH FACILITY SHOULD CREATE A SEPARATE COMMITTEE FOR POLICY AND OVERSIGHT PURPOSES. WE THOUGHT THIS SHOULD BE A ROLE OF THE ESCRO. SHOULD THERE BE SEPARATE COMMITTEES? WE THOUGHT THAT THAT SHOULD BE COMBINED, THAT THERE WAS NOT A NEED AT EACH INSTITUTION FOR A SEPARATE BANKING COMMITTEE IF WE HAD CREATED THIS CENTRAL STRUCTURE.

AND THEN OUR LAST POINT WAS REGARDING THE TRACKING OF IDENTIFIABLE CELLS OR CELL LINES. AND THIS, WE FELT, SHOULD BE THE RESPONSIBILITY OF THE INSTITUTIONS, THAT THOSE THAT ORIGINALLY DERIVED THE SOURCE SHOULD BE RESPONSIBLE FOR MAINTAINING THE PERSONALLY IDENTIFIABLE INFORMATION IN ACCORDANCE WITH

HIPAA STANDARDS AND WITH APPROPRIATE IRB REVIEW, THAT THE CELL LINES SHOULD BE CODED SO THAT DONORS COULD BE CONTACTED, IF THAT WERE NECESSARY, THROUGH THE INSTITUTION, AND THAT THE ESCRO WOULD OVERSEE THIS, AND THE INSTITUTION WOULD BE RESPONSIBLE FOR MAINTAINING THAT INFORMATION.

MR. SHESTACK: BASICALLY THAT THERE WOULD BE A STANDARDIZED SET OF GUIDELINES WE WOULD RECOMMEND FOR INSTITUTIONS DOING CIRM-FUNDED RESEARCH THAT WOULD BASICALLY ENABLE BANKING TO BE DONE EASILY AT A LATER DATE, THAT THERE WOULD BE CERTAIN COMMON PLATFORMS OF ASCERTAINMENT OF DATA MANAGEMENT THAT WOULD ALLOW FOR EASE OF BANKING WHICH WOULD ULTIMATELY, I ASSUME, BE MANDATED BY THE ICOC, THAT IT WOULD BECOME POLICY, THAT IF YOU CREATED CELL LINES WITH CIRM MONEY, THE EXPECTATION WAS THERE WOULD BE A REASONABLE HOLD-BACK PERIOD, IF IT WAS 6 MONTHS OR 12 MONTHS, KEYED TO PUBLICATION OR PROBABLY NOT, YOU KNEW THAT YOU WOULD -- THAT YOU WOULD HAVE TO DEPOSIT THEM INTO A CENTRAL REPOSITORY THAT WOULD THEN MAKE THEM AVAILABLE WITHIN AND WITHOUT CALIFORNIA.

IT WAS OUR RECOMMENDATION THAT THIS BE ULTIMATELY ICOC POLICY.

DR. CIBELLI: ONE MORE THING, SO THE PURPOSE OF THIS IS THAT RESEARCH CAN MOVE FORWARD AS FAST AS

POSSIBLE. LET'S SAY WE CREATED A CELL LINE IN THE LAB. IT DOESN'T HAVE TO BE FROM A BLASTOCYST. IT COULD BE AN NIH CELL LINE THAT ALL OF A SUDDEN WE INTRODUCE A GENE THAT IS A KEY FOR AUTISM, AND THEN THAT'S A NEW CELL LINE. AND SO WITHIN SIX MONTHS, IF YOU DID IT WITH INSTITUTE MONEY, YOU HAVE TO PUT IT INTO X BANK.

NOW, SO THAT'S WHAT WE ACTUALLY CAN ENFORCE THE DIFFERENT INSTITUTIONS OR GROUPS TO DO. AND THEN HOW THE BANK ITSELF IS GOING TO WORK, THAT'S SOMETHING THAT WE'RE GOING TO HAVE TO DEVELOP WHEN WE DEVELOP AN RFA OR WE JUST DO THE CONTRACT WORK. AND IF YOU READ CAREFULLY WHAT THE NATIONAL ACADEMY OF SCIENCES TRIED TO PUT IN THIS DOCUMENT, THAT'S EXACTLY THE RFA THAT YOU SHOULD WRITE.

DR. HALL: LET ME JUST SAY ALSO THAT I THINK ONE OF THE EFFORTS IS GOING TO BE TO HAVE THE VARIOUS BANKS THAT ARE BEING CREATED AROUND THE WORLD BE AS COMPARABLE AS POSSIBLE AND AS TRANSPARENT AS POSSIBLE SO THAT YOU HAVE THE SAME INFORMATION ABOUT ALL THE LINES AND THAT YOU CAN COMPARE THEM USEFULLY. AND THERE ARE EFFORTS UNDERWAY TO TRY TO ACHIEVE THAT. WE ARE VERY INTERESTED IN AND ARE IN CONTACT WITH THOSE.

DR. CIBELLI: I THINK IT'S FAIR TO SAY, FRANCISCO, THAT WE DIDN'T ACTUALLY DIG INTO THE ISSUE OF DATABASES, WHO IS GOING TO HANDLE THE DATABASE. I

THINK WE SUGGESTED THAT THE INSTITUTION SHOULD BE HANDLING THE DATABASE, BUT THAT IS STILL UP IN THE AIR.

MR. SHESTACK: THERE WAS ALSO SOME DISCUSSION OF WHETHER OR NOT -- THERE ARE PEOPLE WHO ARE ALREADY DOING HIGH QUALITY STEM CELL BANKING, NOT IN CALIFORNIA, I BELIEVE, RIGHT, AND ARE WE ALLOWED, FOR INSTANCE, TO CONTRACT WITH THEM EVEN THOUGH THEY'RE OUTSIDE THE STATE OF CALIFORNIA? ARE THEY ALLOWED TO OPEN AN AFFILIATE IN CALIFORNIA? ARE WE ALLOWED TO CAPITALIZE ON, IN THE INTEREST OF SAVING TIME AND MONEY, PEOPLE WHO ARE DOING THIS OUTSIDE OF CALIFORNIA FOR THE BENEFIT OF ALL OF US, OR MUST WE RECREATE THE WHEEL IN CALIFORNIA?

DR. PRIETO: THIS IS A QUESTION THAT CAME UP IN OUR CONFERENCE, AND I DON'T KNOW UNDER THE INITIATIVE WHETHER THAT'S SOMETHING THAT WOULD BE --

MR. SHESTACK: SERVE THE HIGHER GOAL. WE DON'T KNOW THE ANSWER TO THAT.

DR. HALL: WE EVEN KNOW OF SOME OUTSIDE ENTITIES WHO ARE INTERESTED IN CREATING A STEM CELL BANK IN CALIFORNIA.

MR. SHESTACK: YEAH. PEOPLE WHO ALREADY DO IT.

DR. PRIETO: WOULD IT HAVE TO BE PHYSICALLY LOCATED IN CALIFORNIA?

DR. HALL: OURS OR THEIRS?

DR. PRIETO: OURS OR THE --

DR. HALL: IT SHOULD BE. OH, YES. IT SHOULD BE LOCATED IN CALIFORNIA, I THINK.

DR. PRIETO: ONE OF THE THOUGHTS THAT WE HAD WAS THAT AN OUTSIDE INSTITUTION ALREADY DOING BANKING AND WITH BANKING EXPERTISE MIGHT CHOOSE TO ESTABLISH A BRANCH IN CALIFORNIA.

MR. KLEIN: IS THIS INTERSTATE BANKING? LET ME ASK, FRANCISCO. IF IN TERMS OF DR. WILLERSON'S PRIOR MOTION, IF WE RECOGNIZE THE REGISTRY AND IF WE STATE THAT THIS SECTION IS UNDER DEVELOPMENT, AND, IN FACT, IN TERMS OF JON'S POSITION, IT'S UNDER DEVELOPMENT AND CIRM HAS A STRONG INTEREST IN ACHIEVING THE BANKING OBJECTIVES AND ENCOURAGING THE BANKING -- STEM CELL BANKING OBJECTIVES, SO WE'RE CLEARLY SENDING A MESSAGE THAT THIS IS GOING TO BE IMPORTANT TO US IN THE FUTURE, DOES THAT ACCOMPLISH YOUR INTENT TO, A, PUT A MARKER DOWN, BUT ALLOW US THE TIME TO DEVELOP THOSE ITEMS; OR DO YOU BELIEVE WE NEED TO TRY AND INCORPORATE SOME OF THESE BANKING DIRECTIVES NOW?

DR. PRIETO: GOOD QUESTION. JON?

MR. SHESTACK: MY POINT OF VIEW ON THIS IS THAT WE HAVE TO MAKE -- I THINK WE NEED TO MAKE A STRONG SIGNAL TO THE PUBLIC AND TO THE ICOC THAT

BANKING IS AN ETHICAL ISSUE. THAT IF WE ARE WORKING WITH HUMAN SUBJECTS, PEOPLE ARE DONATING WITH SOME DISCOMFORT THEIR BIOMATERIALS, THAT CERTAINLY SOME OF THEIR TAX DOLLARS, THAT IT IS AN ETHICAL ISSUE THAT WE LEVERAGE THEIR CONTRIBUTION AS FAR AS IS HUMANLY POSSIBLE EVEN TO THE POINT OF IT BEING SOMEWHAT PAINFUL SOMETIMES, THAT YOU MUST GO TO EXTREME LENGTHS TO DO IT, THAT IT WILL PAY OFF FOR THE GENERAL POPULATION SOON AFTER. I DON'T KNOW HOW YOU DO IT. I KNOW THAT STRIKING IT FROM THE GUIDELINES DOESN'T SEEM TO DO IT.

AND BUT ON THE OTHER HAND, THESE GUIDELINES ARE AWKWARD. THEY DO -- IF YOU READ THEM CAREFULLY, THEY MAKE IT SOUND LIKE EVERY GRANTEE INSTITUTION HAS TO DO IT, WHICH IS EXACTLY NOT HOW YOU WOULD WANT TO DO IT. SO I DON'T KNOW WHAT THE IN BETWEEN IS.

DR. HALL: THERE WAS WORDING SUGGESTED, JON, AND I CAN'T REMEMBER, I THINK THIS WAS FRANCISCO'S ORIGINAL WORDING, THAT INSTITUTIONS ENGAGED IN HES -- WELL, HE CHANGED IT FROM RESEARCH TO DERIVATION OF LINES SHALL CREATE OR PARTICIPATE IN CENTRAL REPOSITORIES FOR HES CELL LINES. I THINK THAT IS REASONABLE, AND I THINK THAT CAPTURES, IF NOT THE FULL SPIRIT OF WHAT YOU ARE TRYING TO SAY, AT LEAST POINTS IN THE RIGHT DIRECTION. THAT IS, THAT WE WANT THESE IN CENTRAL REPOSITORIES WHERE THEY'LL BE AVAILABLE WITHOUT

SPECIFYING ALL THE RULES OF HOW LONG.

MR. SHESTACK: I GUESS THE POINT IS JUST TO TRY AND MAKE IT CLEAR UP FRONT THAT IT'S NOT GOING TO BE UP TO THE GRANTING INSTITUTION HOW LONG OUR HOLD-BACK IS. THAT WILL BE UP TO THE FUNDING INSTITUTION, WHICH IS CIRM.

DR. HALL: COMMIT ONE WAY OR THE OTHER.

DR. PRIETO: DR. CIBELLI MADE THE POINT THAT REALLY 9(B) ON PAGES 7 AND 8 COULD BE REWORDED WITHOUT TOO MUCH CHANGING IN WORDING INTO AN RFA THAT THE CIRM COULD GENERATE FOR A GRANT FOR BANKING.

MR. KLEIN: THAT WOULDN'T BELONG IN THE GUIDELINES, BUT WE COULD STATE UNDER (B) THAT THERE'S A STRONG ETHICAL OBJECTIVE, JON, A STRONG ETHICAL OBJECTIVE OF CIRM TO ENCOURAGE THE OBJECTIVES -- STRONG OBJECTIVE TO ENCOURAGE BANKING.

DR. CIBELLI: I'D CHANGE THE LANGUAGE. I THINK THE PURPOSE IS TO SHARE THE REAGENTS. AND TO ACCOMPLISH THAT, YOU WILL HAVE A BANK THAT'S GOING SUBSIDIZED, AND YOU DON'T HAVE TO WORRY ABOUT IT. YOU DEVELOP A CELL LINE, YOU GET YOUR PUBLICATION, AND YOU MOVE ON IN YOUR RESEARCH. THIS CELL LINE IS PUT IN THE BANK, AND EVERYBODY HAVE WILL HAVE ACCESS TO IT X AMOUNT OF TIME AFTER YOUR PUBLICATION, AND IT'S AVAILABLE FOR EVERYBODY. SO THE MAIN PURPOSE HERE IS

TO MAKE THIS REALLY DISSEMINATE THIS, GET AS MUCH AS POSSIBLE FROM WHATEVER RESEARCH YOU GET. THE MAIN THING IS NOT BANKING FOR THE BANKING SAKE. IT'S JUST TO HAVE A PLACE WHERE YOU STANDARDIZE THE CELLS, YOU GROW THEM UNDER SPECIFIC CONDITIONS, THEY'RE ALL THE SAME, AND THEN YOU SHARE. SO THAT'S THE ETHICAL, I THINK, POINT HERE.

MR. SHESTACK: THE SPECIFICS ARE ACTUALLY PART OF YOUR GRANTING GUIDELINES. TO ACCEPT MONEY, YOU HAVE TO PREPARE YOUR CELL LINES.

MR. KLEIN: AND THAT APPROACH, KEVIN, MAKES IT CLEAR THAT ALL THESE DIFFERENT INSTITUTIONS ARE NOT BEING REQUIRED TO PARTICIPATE IN BANKING -- IN SETTING UP A BANK; IS THAT RIGHT, KEVIN?

DR. EGGAN: SO WHAT I WAS GOING TO SAY WHY NOT CHANGE (B) TO SAY THAT A REQUIREMENT FOR CIRM FUNDING WILL BE THAT YOU MAINTAIN AND SHARE ALL THE LINES THAT YOU DERIVE? AND THEN LEAVE IT OPEN FOR LATER INTERPRETATION AS TO WHAT THAT MEANS. THERE WILL BE A REQUIREMENT.

MR. SHESTACK: SHARE. I DON'T THINK THE INDIVIDUAL RESEARCH INSTITUTION HAS TO MAINTAIN IT. THAT COST SHOULD BE BORNE BY CIRM.

DR. CIBELLI: THERE'S A VERY IMPORTANT POINT HERE. THERE IS THIS RULE, I DON'T KNOW IF IT'S WRITTEN

RULE, THAT WHEN YOU PUBLISH SOMETHING, EITHER YOU DEVELOP A NEW CELL LINE OR A NEW VECTOR, YOU'RE SUPPOSED TO SHARE WITH THE SCIENTIFIC COMMUNITY IF YOU DID IT WITH NIH MONEY. THAT NOT ALWAYS HAPPENS. THERE ARE MANY REASONS WHY RESEARCHERS, THEY DIDN'T GET THE E-MAIL. OH, I WAS TRAVELING. I DIDN'T HAVE TIME TO GET BACK TO YOU. SOMEHOW YOU HAVE TO MAKE SURE THAT IF YOU'RE GOING TO SPEND THE MONEY TO FUND THE RESEARCH, THAT THE PRODUCT OF THAT IS AVAILABLE FOR OTHER PEOPLE TO USE. THIS IS A TIME WHEN WE CAN CHANGE THAT. AM I CORRECT, NIH?

DR. KIESSLING: AND YOU'RE ABSOLUTELY CORRECT. IT DOESN'T ALWAYS HAPPEN. AND I THINK -- SO, JOSE, WHAT YOU'RE SAYING IS THAT YOU'D LIKE TO KEEP 9(A), AND YOU'D LIKE 9(B) JUST BE SOME KIND OF GUIDANCE TO THE INVESTIGATOR THAT THEY'RE OBLIGATED TO SHARE THEIR REAGENTS.

DR. CIBELLI: TO SHARE, AND IF THEY CHOOSE SO, THERE'S A BANK AVAILABLE FOR THEM TO MAKE THIS EASIER.

DR. HALL: LET ME JUST SAY I THINK THIS IS A TREMENDOUSLY IMPORTANT DISCUSSION, AND I THINK THE REQUIREMENT AND THE WAY IN WHICH WE PHRASE THIS AND HOW WE DO IT IS GOING TO BE VERY CRITICAL, VERY, VERY IMPORTANT. I THINK THE POINT WE MAKE IS THAT IT'S

IMPORTANT TO SHARE; THAT IN ORDER TO MAKE SURE THAT THAT SHARING HAPPENS OR TO FACILITATE IT, THAT WE THINK THERE SHOULD BE A BANK CREATED. IN FACT, WHAT WE'RE TALKING ABOUT IS ALMOST SOMETHING SEPARATE AS TO SAY YOU DON'T HAVE TO HAVE THE BANK, THAT IT WILL BE DONE FOR YOU.

BUT I THINK, AGAIN, THESE ARE -- WE HAVE A SCIENTIFIC MEETING COMING UP IN A MONTH, OCTOBER 1ST AND 2D, THAT IS CHARGED WITH SETTING A SCIENTIFIC AGENDA AND PRIORITIES FOR CIRM. WE EXPECT MANY OF THESE RECOMMENDATIONS REGARDING BANKING TO COME OUT OF THAT. AND OUR EXPECTATION IS THAT SUBSEQUENT TO THAT MEETING, WE WILL BEGIN PLANNING SOME SORT OF RESOURCES FOR MAKING, MAINTAINING CELL LINES THAT WOULD SORT OF BE BASED ON THOSE DISCUSSIONS.

AGAIN, WHAT I SUGGEST -- I THINK ALL THIS IS GOING TO BE HAPPENING VERY QUICKLY. I THINK IT'S GOING TO BE HARD TO PUT ANYTHING VERY DETAILED OR VERY --

MR. KLEIN: I THINK WHAT THEY'RE LOOKING FOR --

DR. HALL: I THINK EITHER WE JUST LEAVE IT OR ELSE WE PUT IN SOMETHING THAT IS VERY SHORT AND VERY CONCISE, AND THEN LET IT GO AT THAT.

MR. KLEIN: IN TERMS OF VERY SHORT, IF WE PUT SOMETHING IN AS SUGGESTED HERE, THAT UNDER (B) THAT THE

LINES SHALL BE SHARED, AND STILL AN ETHICAL OBJECTIVE IS TO DEVELOP GUIDELINES TO ENCOURAGE BANKING.

MR. SHESTACK: THEN EVERYTHING ELSE BECOMES A SUGGESTION ON HOW TO DO IT, WHICH IS OKAY BECAUSE YOU WILL HAVE TIME.

DR. HALL: WHAT WE HAVE -- IF WE CHANGE THIS, I THINK, ALMOST A LITTLE BIT, I'M PERFECTLY HAPPY JUST -- A FIRST SENTENCE THERE THAT SAYS THAT THE SHARING OF CELL LINES, SOMETHING DEVELOPED WITH CIRM FUNDING. I WOULD CHANGE IT FROM THE SECOND PERSON, BUT SIMPLY TO SAY THAT CIRM -- CELL LINES DERIVED WITH CIRM FUNDS, WE'RE EAGER THAT THESE CELL LINES, SOMETHING LIKE THAT, BE SHARED AS WIDELY AS POSSIBLE AND BE AVAILABLE AS QUICKLY AS POSSIBLE. AND WE ENCOURAGE OR WE REQUIRE --

DR. PRIETO: I WOULD PREFER TO KEEP LANGUAGE --

DR. HALL: WE WILL REQUIRE INVESTIGATORS TO SUBMIT LINES TO AN APPROPRIATE BANK OR REPOSITORY.

MR. SHESTACK: AND APPROPRIATELY PREPARED.

DR. PRIETO: IN A TIMELY MANNER.

DR. HALL: SOMETHING LIKE THAT. AND THEN I THINK THE POINT IS WE CAN FIGURE OUT WHAT THAT REPOSITORY IS LATER. MY SENSE IS THAT -- OKAY.

MR. SHESTACK: MY PRACTICAL CONSIDERATION,

AND IT ALL COMES, AND YOU HAVE TO TELL ME THAT IT DOESN'T APPLY AT ALL, COMES FROM EXPERIENCE IN GENETIC BANKING WHERE YOU HAVE A DISEASE WITH, LIKE, VERY TEDIOUS ASCERTAINMENT ISSUES AND NO BIOMARKERS WAS THAT I WOULD HAVE MANY INVESTIGATORS USING DIFFERENT METHODS, DIFFERENT DATA PLATFORMS, USE THAT AS AN EXCUSE FOR NOT SHARING DATA, AND THEN A TOTAL INABILITY TO GET A SIGNIFICANT DATA SET OF SIGNIFICANT SIZE. IT MAY BE NOT A PROBLEM AT ALL IN STEM CELL RESEARCH. I KNOW IT'S A PARTICULAR PROBLEM THAT I RAN THROUGH, AND I'M EAGER TO MAKE SURE THAT PEOPLE DON'T HAVE THAT SAME MISTAKE AGAIN.

DR. HALL: SHARING LINES IS A PROBLEM, AND STEM CELL RESEARCH ALREADY HAS A RICH HISTORY AND THE DIFFICULTIES OF MAKING LINES AVAILABLE. I DON'T THINK THERE'S ANY DOUBT ABOUT THAT, THAT'S IT BEEN VERY DIFFICULT TO HAVE AVAILABLE LINES BE WIDELY DISPERSED. ANYTHING WE CAN TO DO ADDRESS THAT.

MR. SHESTACK: MY CONCERN IS THAT CIRM SUBSIDIZE TO SOME EXTENT WHATEVER THE INFRASTRUCTURE IS, IF THAT'S DATA MANAGEMENT PLATFORMS, IF IT'S THE SAME SET OF REAGENTS, IF IT'S A GNP FACILITY, WHATEVER IT IS, IT ACTUALLY SUBSIDIZES THAT TO MAKE SHARING DOWN THE LINE BE EASIER.

DR. HALL: ABSOLUTELY, BUT THAT'S NOT AN ITEM

FOR THE GUIDELINES.

MR. SHESTACK: IT'S NOT AN ITEM FOR THE GUIDELINES. IT IS AN ETHICAL GOAL OF CIRM AND, THEREFORE, I THINK COMES UNDER A STANDARDS RUBRIC. I'M SORRY TO BE TEDIOUS ABOUT IT. IT'S JUST IF WE DON'T GET IT RIGHT FROM THE BEGINNING AND MAKE IT A PRIORITY, IT WON'T BE A PRIORITY. IT WILL BE VULCANIZED AND IT WILL BE DRAG. JUST KNOW IT.

DR. HALL: WE DON'T HAVE THAT YET. THROUGH A WHAT? A RECOGNIZED -- IT SHOULD BE A WELL ESTABLISHED, A WHAT?

MR. SHESTACK: I CAN'T SEE WHERE THE CURSOR IS.

DR. HALL: SHARED THROUGH A STEM CELL BANK.

MR. SHESTACK: THROUGH A CENTRAL REPOSITORY.

DR. EGGAN: I THINK THE REASON WHY THEY COULDN'T ENGAGE IN THE UK STEM CELL BANK, FOR EXAMPLE. THROUGH A WELL-RECOGNIZED STEM CELL BANK OR --

DR. KORDOWER: YOU WANT TO ESTABLISH A LIST OF CIRM APPROVED?

DR. HALL: NOT FOR NOW. A WELL-RECOGNIZED STEM CELL BANK.

MR. SHESTACK: WE MAY ULTIMATELY DECIDE TO FUND ONE, AND I HOPE WE DO.

DR. HALL: THAT WILL MAKE THE LINES WIDELY

AVAILABLE TO INVESTIGATORS.

DR. EGGAN: THAT'S A GOOD CAVEAT TO ADD.

DR. PRIETO: GOOD LANGUAGE THERE.

DR. HALL: I THINK THE TIMELY MANNER IS FINE. WE CAN WORRY ABOUT THAT LATER. I THINK THIS IS GOOD.

DR. EGGAN: SO IS ALL THE REST OF THIS SECTION --

MR. SHESTACK: THEN ALL THE REST OF IT IS COMMENTARY. YOU DON'T NEED TO CUT IT.

DR. HALL: IT'S HARMLESS.

MR. SHESTACK: I THINK IT'S HARMLESS, AND IT SERVES AS GUIDELINES FOR FURTHER DISCUSSION WHEN YOU GET INTO THE MORE PERMANENT STANDARDS.

DR. HALL: AND WE KNOW WHERE TO GO WHEN WE DO OUR RFA'S.

DR. CIBELLI: ON THAT COMMENT, I THINK IT'S CONFUSING IF WE LEAVE IT IN. THEN YOU HAVE TO GET RID OF IT. THEN YOU PUT AN RFA DESCRIBING HOW YOU WANT TO MAKE THE BANK. THAT'S NOT THE POINT.

WHAT I WANT TO SAY PERHAPS TO YOU THAT YOU ARE VERY FAMILIAR WITH NIH. WHAT'S THE REASON WHY NIH SOMETIMES, WELL, ALMOST ALL THE TIME, FAILS TO ENFORCE THIS SHARING OF MATERIALS? IS THERE ANYTHING WE CAN LEARN?

DR. HALL: I DEFER TO MY COLLEAGUE, DR.

KENNETH OLDEN, WHO'S HAD MUCH MORE EXPERIENCE IN THESE MATTERS THAN I HAVE.

DR. OLDEN: I DON'T KNOW WHAT TEETH IS IN THE GUIDELINES ANYWAY. I GUESS WE COULD DENY SUBSEQUENT RESEARCH FUNDING.

DR. CIBELLI: RENEWALS.

DR. OLDEN: RENEWALS. BUT I THINK WE -- THE OUTCRY FROM THE SCIENTIFIC COMMUNITY WOULD BE SO LOUD, THAT NIH HASN'T CHOSEN TO DO IT THAT WAY, BUT WE COULD. I DON'T KNOW WHY NOT.

DR. HALL: I THINK A BANK ACTUALLY IN SOME WAYS IT'S GOOD BECAUSE IT TAKES THE RESPONSIBILITY AWAY FROM THE INVESTIGATOR. THERE'S NO EXCUSE FOR NOT PUTTING SOMETHING IN A BANK. AND ALL OF US HAVE HAD THE EXPERIENCE OF REQUESTING A REAGENT OR A CELL LINE OR A VIRUS. THERE'S A FAMOUS STORY ABOUT THIS. AND SAY, WELL, THE FREEZER JUST BROKE DOWN. I'M SORRY. OR, GOSH, WE DON'T -- WE'LL HAVE GROW UP SOME MORE. PUT IT IN A BANK AND IT'S ALL TAKEN CARE OF.

DR. EGGAN: I COULD SAY IT'S BEEN LARGELY A FULL-TIME JOB FOR TWO PEOPLE IN DOUG MELTON'S LABORATORY TO DISTRIBUTE THE LINES TO THOSE PEOPLE THAT HAVE REQUESTED THEM. IT IS A SUBSTANTIAL BURDEN ON HIM THAT HE HAS TAKEN ON WITHOUT ANY RESPONSIBILITY TO DO SO. AND I THINK IT WOULD BE A LOT TO EXPECT OTHER

INVESTIGATORS TO DO THE SAME. A CENTRAL BANK WOULD SOLVE THAT PROBLEM.

MR. SHESTACK: THE REASON IS INVESTIGATORS HAVEN'T WANTED TO DO IT, AND PROGRAM OFFICERS DEVELOP CLOSE RELATIONSHIPS WITH INVESTIGATORS AND DON'T WANT TO FORCE THEM TO DO IT, AND THERE ISN'T REGULATORY LANGUAGE. THERE'S POLICY, AND IT ALSO TENDS TO VARY, MY RECOLLECTION, FROM INSTITUTE TO INSTITUTE. AND THERE ISN'T ACTUALLY FEDERALLY MANDATED LANGUAGE ABOUT BANKING OR DATA SHARING. SO I SORT OF THINK THAT THIS IS AN OPPORTUNITY TO GET IT RIGHT FROM THE BEGINNING. IT'S NOT SO ONEROUS TO A COUPLE OF INVESTIGATORS WHO WILL BE UPSET ABOUT IT, AND THERE WILL BE MANY MORE NEW INVESTIGATORS WHO WILL PROFIT FROM IT.

DR. HALL: THERE ARE MECHANISMS FOR DOING IT.

CO-CHAIR LO: I'M SENSING, MAYBE I'M JUST OVERLY OPTIMISTIC, THAT WE ARE REACHING SOME AGREEMENT HERE ON THIS SECTION. I JUST WANT TO MAKE SURE THAT WE UNDERSTAND WHAT THE TEXT IS WE'RE TALKING ABOUT. SO WE HAVE AN (A), AND ONE TO FOUR PRESENT DIFFERENT OPTIONS. IS THAT NO LONGER PART? THAT'S GOING TO BE DELETED.

AND THEN THE BALANCE OF THE SECTION, FROM DEVELOPMENT WE'RE GOING TO DELETE THAT BLUE SENTENCE.

MR. KLEIN: WELL, IN TERMS OF THE DISCUSSIONS OF WHETHER OR NOT TO DELETE THE SECTION, JON, I THINK

IT WAS -- THERE NEEDS TO BE AN INTRODUCTION TO THE BALANCE OF THE SECTION SO IT'S NOT CONFUSING. SO YOU SAY THE BALANCE OF THIS SECTION IS UNDER DEVELOPMENT. THE NATIONAL ACADEMY CONCEPTS UNDER CONSIDERATION ARE AS FOLLOWS, RIGHT?

DR. PRIETO: YES. THAT NEEDS TO BE MOVED DOWN UNDER SECTION B RATHER THAN BEFORE SECTION B. I THINK WE'VE AGREED ON LANGUAGE FOR SECTION B.

DR. HALL: MY SENSE IS IT SAYS ANY FACILITY ENGAGED IN, AND I THINK, AS SOMEBODY SAID, I THINK JEFF KORDOWER SAID SORT OF IF YOU'RE NOT GOING TO DO IT, YOU DON'T NEED TO FOLLOW THESE. IT'S THERE. IT DOESN'T MATTER. I THINK THAT'S --

DR. PRIETO: I'M NOT SURE I UNDERSTAND WHAT 1 THROUGH 4 REPRESENT, DIFFERENT OPTIONS.

MR. LOMAX: I WAS ASKED BY THE CHAIR, BECAUSE AT THE TIME WE HAD THREE OPTIONS THAT WERE ON THE TABLE, SO I WAS TRYING TO FIND SOME CLEVER WAY TO INDICATE EACH OF THOSE THREE, AND THEN WE ADDED FOUR. SO NOW WE'RE STARTING TO WORK BACKWARDS.

CO-CHAIR LO: THE PROPOSAL NOW IS TO DELETE THAT BLUE LINE. ARE WE GOING TO LEAVE IN THE HES DERIVATION? ENCOURAGE AT PRESENT AND POSSIBLY MANDATED.

DR. HALL: LEAVE IN DERIVATION AND TAKE OUT

RESEARCH.

MR. SHESTACK: NO. JOSE SAYS YOU MAY ACTUALLY NOT DERIVE -- YOU MAY DERIVE A NEW CELL, A NEW VARIANT ON A STEM CELL LINE.

DR. CIBELLI: SHOULD BE DERIVATION AND/OR RESEARCH.

MR. KLEIN: BUT YOU DON'T NEED BRACKETS AROUND DERIVATION.

DR. PRIETO: WE DON'T NEED THE NUMBERS. DO WE WANT TO SAY BE ENCOURAGED AND POSSIBLY MANDATED IN THE FUTURE?

DR. KORDOWER: THIS IS THE INTERIM.

DR. HALL: CAN I JUST SUGGEST --

CO-CHAIR LO: THIS IS SIMILAR TO WHAT --

DR. HALL: WHAT IF IT JUST SAYS INSTITUTIONS ENGAGED IN HES DERIVATION AND RESEARCH SHALL PARTICIPATE IN CENTRAL REPOSITORIES FOR HES CELL LINES?

DR. CIBELLI: JUST NO. 4.

DR. KORDOWER: THE ISSUE WE WERE DEALING WITH BEFORE IS DEALING WITH THE NINE MONTHS VERSUS THE PERMANENT GUIDELINES. SO I THOUGHT THAT THE LANGUAGE UP IN SHALL BE ENCOURAGED AT PRESENT AND MANDATED IN THE FUTURE COVERS BOTH THE TEMPORARY GUIDELINES AND WORKS TOWARDS THE FUTURE GUIDELINES.

MR. SHESTACK: I THINK ACTUALLY IF YOU JUST

USE 4, YOU COULD DELETE (B) AND YOU WOULD ACCOMPLISH YOUR SAME PURPOSE.

DR. HALL: DELETE THE FIRST PARAGRAPH?

DR. PRIETO: BUT THERE'S REALLY NOTHING WRONG WITH THAT LANGUAGE THAT WE JUST FLIPPED. I DON'T SEE ANY PROBLEM WITH LEAVING IT AS IT WAS. INSTITUTIONS ENGAGED IN HES DERIVATION OR RESEARCH SHALL BE ENCOURAGED AT THE PRESENT, POSSIBLY MANDATED IN THE FUTURE TO CREATE OR PARTICIPATE IN MECHANISMS FOR ESTABLISHING CENTRAL REPOSITORIES. AND THEN THE SECOND PARAGRAPH OR COULD BE PART OF THE SAME PARAGRAPH, THAT CELL LINES DERIVED ARE REQUIRED TO BE SHARED.

MR. KLEIN: MAKE IT C.

MR. SHESTACK: WE JUST WANT TO MAKE SURE THAT, LIKE, PEOPLE DON'T HAVE A PROBLEM, LIKE UCLA GETS MONEY AND THEY GO, OH, DO I GOT TO START MY OWN STEM CELL BANK? THEY DON'T. THEY JUST HAVE TO PARTICIPATE ON ONE WHEN THEY START.

DR. PRIETO: THAT'S WHY IT SAYS CREATE OR PARTICIPATE IN.

DR. HALL: JUST SAY PARTICIPATE IN CENTRAL REPOSITORIES. I DON'T KNOW THAT YOU HAVE TO PARTICIPATE IN MECHANISMS FOR ESTABLISHING. LEAVE THAT OUT. PARTICIPATE IN CENTRAL REPOSITORIES.

DR. CIBELLI: SO YOU'RE TRYING TO MAKE A

DISTINCTION BETWEEN RESEARCH BEING DONE WITH THE FUNDS THAT ARE NOT FROM THE INSTITUTE AND FROM MONIES THAT ARE COMING FROM THE INSTITUTE. ONE PARAGRAPH AND THE NEXT.

DR. HALL: WANT TO PUT ENGAGED IN CIRM-FUNDED HES?

DR. PRIETO: YES.

CO-CHAIR LO: SECOND PARAGRAPH IN BLUE, YOU WANT TO TALK ABOUT LINES DERIVED FROM CIRM FUNDS, AND SOMEONE RAISED THE POINT IF YOU DON'T ACTUALLY DERIVE, IF THEY'VE BEEN MODIFIED.

DR. EGGAN: MODIFIED IN ANY WAY. CELL LINE DERIVED OR MODIFIED.

DR. PRIETO: DERIVED OR MODIFIED IN ANY WAY WITH CIRM FUNDS.

(OVERLAPPING DISCUSSION AMONG MEMBERS.)

MR. KLEIN: THAT SHOULD BE A (C) SO IT'S CLEARLY -- SO IT'S NOT AN EXPLANATION OF (B).

CO-CHAIR LO: NEXT LINE, BALANCE OF THE SECTION UNDER DEVELOPMENT.

MR. KLEIN: THAT WOULD BE A (D).

SAY THE BALANCE OF THE SECTION IS UNDER DEVELOPMENT. THE FOLLOWING NATIONAL ACADEMY PROVISIONS ARE UNDER CONSIDERATION.

DR. HALL: LET ME JUST SAY I THINK THAT'S

AWKWARD IN THE SENSE OF THE WHOLE THING IS UNDER DEVELOPMENT, AS SOMEBODY COMMENTED BEFORE. AND I JUST -- WHAT LANGUAGE, I THINK WE CAN PUT IN SOMETHING THAT JUST SAYS THE FOLLOWING GUIDELINES -- YOU COULD EVEN SAY CIRM ENDORSES THE FOLLOWING GUIDELINES FOR THE ESTABLISHMENT OF STEM CELL REPOSITORIES. HOW IS THAT?

MR. SHESTACK: IF THEY DO, I DON'T KNOW. I MEAN THAT'S A LOT OF MATERIAL. MORE TO GO THROUGH THAN I WAS PREPARED FOR PERSONALLY. I'M QUITE SATISFIED WITH (C).

DR. HALL: IT DOESN'T MATTER. YOU CAN JUST GET RID OF IT.

CO-CHAIR LO: BEFORE WE GET RID OF IT, IT STRUCK ME ON PAGE 7, NO. 2, SOME OF THAT MIGHT BE REFRAMED AS WHAT RESEARCHERS, EITHER DERIVING OR MODIFYING STEM CELL LINES, NEED TO GATHER INFORMATION ABOUT, HOPEFULLY IN A STANDARDIZED WAY, THAT FED INTO THIS CIRM-FUNDED DATABANK.

MR. SHESTACK: I DON'T WANT US TO SEE THIS INFORMATION DISAPPEAR FROM THE DISCUSSION, RIGHT, BECAUSE THE POINT IS AVAILABLE CELL LINES SHOULD BE CHARACTERIZED TO -- CHARACTERIZATION, KARYOTYPING, GENETICS. THIS IS A GOOD IDEA. IT SHOULD BE IN YOUR SCIENTIFIC GUIDELINES.

DR. HALL: WHY DON'T WE JUST SAY THAT WE

ENDORSE THESE, AND THEN THIS IS AN INTERIM GUIDELINES. WE CAN REVISIT IT AND EDIT IT, AND THAT WAY I THINK WE CAN JUST DISPOSE OF IT QUICKLY AND MOVE ON.

MR. SHESTACK: I DON'T WANT TO SEE IT VANISH.

DR. HALL: IS THAT OKAY? I THINK TO SAY IT'S UNDER DEVELOPMENT. AS YOU SAY, THERE'S A POSITIVE THING TO SAY.

MR. KLEIN: SO YOUR INTRODUCTION UP HERE ON (D) IS YOU COULD SAY IT'S UNDER DEVELOPMENT WHEN YOU SAY THE BALANCE OF THIS SECTION IS ENDORSED BY.

DR. HALL: THE CIRM ENDORSES THE FOLLOWING GUIDELINES FOR THE ESTABLISHMENT OF STEM CELL BANKS.

(OVERLAPPING DISCUSSION AMONG THE MEMBERS.)

DR. HALL: DOESN'T SAY WHO HAS TO CREATE THEM OR ANYTHING LIKE THAT. I THINK IT HAS THE VALUE THAT --

DR. PRIETO: DO YOU WANT TO RESTATE THAT THEY'RE INTERIM? ENDORSES THE FOLLOWING INTERIM GUIDELINES.

DR. HALL: THERE'S VERY POSITIVE POINTS IN HERE.

DR. PRIETO: THERE ARE SOME VERY GOOD POINTS IN THERE.

CO-CHAIR LO: LET'S GET THE LANGUAGE RIGHT.

MR. KLEIN: JAMES IS A LITTLE TORMENTED HERE. THIS IS AN INFORMATIONAL SECTION OF THE GUIDELINES.

MR. HARRISON: RIGHT. SO YOU'RE NOT ADOPTING THESE AS REGULATIONS THAT WILL GOVERN RESEARCHERS OR INVESTIGATORS. THESE ARE ASPIRATIONAL AT THIS POINT IN TIME.

DR. HALL: I THINK THEY'RE IDENTIFIED INCORRECTLY. THAT IS ACTUALLY EXACTLY WHAT THEY ARE. AND I THINK THE PROBLEM WE'VE BEEN WRESTLING WITH IN A WAY IS THAT THEY APPEAR IN A REGULATORY DOCUMENT.

DR. EGGAN: ENDORSES, BUT NOT REQUIRES.

MR. HARRISON: ENCOURAGES, THEN, I THINK IS THE LANGUAGE. ENCOURAGES, BUT NOT DOES NOT REQUIRE THE FOLLOWING.

DR. KIESSLING: I'M CONCERNED ABOUT TWO THINGS. ONE, I'M CONCERNED ABOUT THEM BEING QUOTED OUT OF CONTEXT. SOMEBODY IS GOING TO LOOK AT THESE AND THEY'RE GOING TO FORGET THE FACT THAT THERE'S AN INTRODUCTORY HERE THAT SAYS THIS IS WHAT WE'RE THINKING ABOUT.

SECONDLY, I'M NOT SURE THESE ARE -- I'M NOT SURE THAT YOU WANT THIS KIND OF OUTLINE. I THINK THAT YOU MAY WANT THIS PRESENTED IN AN ENTIRELY DIFFERENT WAY IN THE FUTURE.

DR. HALL: IT'S PRESENTED IN AN ENTIRELY

DIFFERENT WAY IN THE FUTURE.

DR. KIESSLING: I DON'T SEE AN ADVANTAGE TO KEEPING THESE IN HERE IF WE HAVEN'T ADOPTED THEM AS REGULATIONS. WE'RE TRYING TO ADOPT INTERIM GUIDELINES. WE HAVEN'T ADOPTED THESE. YOU'RE WORRIED ABOUT THEM DISAPPEARING. I THINK THAT'S A DECENT WORRY, BUT TO LEAVE THEM IN WHAT WE'RE ADOPTING AS INTERIM GUIDELINES, I THINK, OPENS US UP TO HAVING TO DEAL WITH SOMETHING IN THE FUTURE.

MR. SHESTACK: FOR THE SAME REASON, I AM WORRIED ABOUT THE SCRUTINY THAT OUR INTERIM GUIDELINES WILL BE PUT UNDER, WHICH IS WHY I'M CONCERNED THAT THIS NOT DISAPPEAR FROM THEM. THAT'S ALSO WHY YOU'RE CONCERNED THAT IT BE THERE.

CO-CHAIR LO: THIS HAS GOT TO HAVE COME UP BEFORE WITH OTHER DRAFTERS OF REGULATIONS. IS THIS ENDORSES, BUT DOES NOT REQUIRE --

MR. KLEIN: ENCOURAGES.

MR. HARRISON: YEAH. CIRM ENCOURAGES, BUT DOES NOT REQUIRE. IT'S A LITTLE BIT ODD BECAUSE REGULATIONS TYPICALLY GOVERN CONDUCT. THEY'RE NOT ASPIRATIONAL, BUT THESE ARE INTERIM GUIDELINES. TO SOLVE THE VARIOUS GOALS THAT YOU ARE TRYING TO ACHIEVE, THIS IS A PLACEHOLDER.

DR. HALL: ANYBODY IN THE SCIENTIFIC

COMMUNITY WILL RECOGNIZE THESE AS COMING FROM THE -- CONCERNED WITH STEM CELL RESEARCH WILL RECOGNIZE THESE AS COMING FROM THE NATIONAL ACADEMY GUIDELINES, I THINK WILL UNDERSTAND. I SUGGEST WE TAKE THAT SOLUTION, MOVE ON.

CO-CHAIR LO: DO WE HAVE A PACKAGE HERE? CAN I HEAR A MOTION TO ADOPT?

DR. KORDOWER: I HAVE A MOTION.

MR. KLEIN: SECOND.

CO-CHAIR LO: ANY FURTHER DISCUSSION? ANY PUBLIC DISCUSSION?

MR. PECKMAN: IT'S BEEN A LONG DAY. IN TERMS OF SECTION 9(A), I WOULD SUBMIT THAT THE REGISTRY REQUIREMENT IS AN ESCRO REQUIREMENT. IT'S NOT A BANKING REQUIREMENT. IT SHOULD BE REMOVED FROM THIS SECTION COMPLETELY AND PUT UNDER ESCRO.

TWO, REGARDING THAT SECTION, I THINK YOU NEED TO SAY SOMETHING ABOUT THE EXEMPTION POLICY THAT YOU IMPLEMENTED THIS MORNING, WHICH IS ALL THE DOCUMENTATION IS REQUIRED UNLESS OTHERWISE EXEMPTED BY SECTION 2.

DR. EGGAN: I DISAGREE. I THINK THAT IF YOU HAVE ONE OF YOUR STEM CELL LINES IN ONE OF THOSE BANKS, YOU SHOULD SAY SO.

MR. PECKMAN: THAT'S RIGHT. BUT IF YOU LOOK

AT SECTION 9(A), IT REQUIRES ALL THE DOCUMENTATION REGARDING HOW THEY WERE ATTAINED ETHICALLY WITH INFORMED CONSENT IN A MANNER CONSISTENT WITH BLAH, BLAH, BLAH, WHICH YOU'VE ALREADY WAIVED IN SECTION 2 THIS MORNING. SO YOU NEED TO REITERATE THAT. THOSE ARE MY TWO SUGGESTIONS. THANK YOU.

CO-CHAIR LO: I'M SORRY. WE'RE NOT SURE WE UNDERSTOOD THE FIRST ONE.

MR. PECKMAN: THE FIRST ONE IS THAT WHAT YOU'RE TALKING ABOUT HERE IN SECTION 9 ARE TWO THINGS THAT ARE REALLY DIFFERENT THINGS. ONE IS A REGISTRY. THAT'S A RESPONSIBILITY OF THE ESCRO COMMITTEE AS OUTLINED EARLIER. IT'S NOT A BANKING FUNCTION. IT'S AN INSTITUTIONAL FUNCTION. SO THIS SECTION A SHOULD BE REMOVED AND PUT UNDER ESCRO AS AN ESCRO FUNCTION, TO MAINTAIN REGISTRIES FOR THE TYPE OF CELLS AND THE TYPES OF RESEARCH THAT ARE BEING DONE AT THE INSTITUTION.

TWO IS THAT THE EXEMPTION THAT YOU DID EARLIER TODAY HAS TO BE INCLUDED IN THIS SECTION, OTHERWISE IT WON'T BE EXEMPT. THEN YOU RESERVE THAT SECTION TOTALLY FOR BANKING AND NOT FOR REGISTRIES.

DR. EGGAN: I MOVE THAT SECTION 100009(A) BECOME SECTION 100006(C)(6).

MR. KLEIN: AND DO YOU HAVE A SECOND PART TO THAT?

DR. EGGAN: AND THAT WE ADOPT THIS GRANDFATHERING CLAUSE AS BROUGHT TO THE FLOOR.

MS. CHARO: ACTUALLY IT'S ALREADY THERE. IT'S (C)(4). ACTUALLY 9(A) IS REDUNDANT TO (C)(4) ON THE BOTTOM OF PAGE 3. IT'S THERE.

DR. PRIETO: EXCEPT FOR ADDING --

CO-CHAIR LO: I'M WILLING TO LEAVE THIS UP TO STAFF TO GO THROUGH THIS BECAUSE I DON'T THINK IT'S THAT SUBSTANTIVE. WE'D LIKE TO MAKE SURE THAT WHAT NOW IS 100009(A) IS THERE WITH THE EXEMPTION. I'D BE WILLING TO LEAVE THAT TO STAFF.

DR. HALL: LET'S JUST GET IT IN THE RIGHT PLACE AND MOVE IT, AND WE'LL SMOOTH OUT THE PROBLEMS WITH IT.

CO-CHAIR LO: WE HAVE ANOTHER PUBLIC COMMENT.

MR. REED: WE LEFT THE IRB WITHOUT A PUBLIC COMMENT ON THAT. I WANT TO GO BACK TO THAT FOR A SECOND. THE IRB --

CO-CHAIR LO: WE'RE GOING TO HAVE TO COME BACK TO THAT AS A COMMITTEE.

MR. REED: WE WILL COME BACK TO THE IRB?

CO-CHAIR LO: DEFINITELY. WE HAVE TO SAY SOMETHING ABOUT THAT, OR ELSE WE DON'T HAVE INTERIM GUIDELINES. I'M TRYING TO GET US THROUGH THIS ONE. I THINK WE DO HAVE AGREEMENT ON THIS LANGUAGE.

I'D LIKE TO CALL THE QUESTION. THE LANGUAGE IN BLUE ON THE SCREEN PLUS ASKING THE STAFF TO MOVE THAT PARAGRAPH A TO THE OTHER SECTION, IF NEEDED. ALL THOSE IN FAVOR. ANY OPPOSED? SO THAT'S UNANIMOUSLY PASSED. I THINK THAT'S A GOOD WAY OF DEALING WITH WHAT WAS A DIFFICULT AND COMPLICATED ISSUE. THANK YOU MUCH FOR LEADING US THROUGH THIS.

MR. KLEIN: WE SHOULD APPLAUD THE CHAIRMAN FOR LEADING US THROUGH THIS.

(APPLAUSE.)

CO-CHAIR LO: NOW I WANT TO GO BACK TO THE ESCRO/IRB ISSUE, WHICH WE AGREED TO DEFER, AND IT'S EXACTLY 5 O'CLOCK. SO LET'S GO BACK. AND WITH WHAT STEVE PECKMAN LED US THROUGH AND THE QUESTIONS AND DISCUSSIONS AFTERWARDS, LET'S GO BACK TO THE -- SOMEONE HELP ME -- IT'S SECTION 100006 ON PAGE 3, WHICH IS THE ESCRO OVERSIGHT COMMITTEE.

SOMEONE IS GOING TO HAVE TO REMIND ME. WE HAD TABLED A MOTION ABOUT THAT. IF SOMEONE ON THE STAFF COULD REFRESH US ON WHAT WE HAVE IN FRONT OF US.

MR. HARRISON: THE MOTION THAT WAS ON THE TABLE WAS TO DELETE THE LAST TWO SENTENCES IN, FOR EASE OF REFERENCE, SECTION 6(B).

CO-CHAIR LO: AN INSTITUTION MAY CONSTITUTE FROM AMONG EXISTING MEMBERS. IT SHALL NOT BE A

SUBCOMMITTEE. IN LIGHT OF WHAT WE HEARD FROM STEVE AND OUR DISCUSSION AFTERWARDS, IS THERE ANY ADDITIONAL DISCUSSION OF THAT PARTICULAR ISSUE FOR DELETING THOSE TWO SENTENCES? ANYONE CHANGE THEIR MINDS? CONVINCED ONE WAY OR THE OTHER OR NEW ISSUES RAISED?

MR. SHESTACK: I'M JUST TRYING TO UNDERSTAND WHAT HE SAID. WHAT STEVE SAID HE WAS GOING TO TELL US WAS THAT INTERIM GUIDELINES ARE VERY HARD TO CHANGE, AND IT'S LIKE MOVING A SHIP ONCE IT STARTS; BUT, IN FACT, HE DIDN'T ADDRESS THAT PARTICULARLY AT ALL. AND SO I DON'T UNDERSTAND WHETHER OR NOT -- YOU MENTIONED IT IN PASSING, BUT I DON'T KNOW HOW THAT POINT PERTAINS TO WHETHER OR NOT THIS GROUP SHOULD DECIDE TO STRIKE THESE SENTENCES OR NOT.

MR. PECKMAN: I'M HAPPY TO RESPOND TO THAT. FIRST OF ALL, I WASN'T AWARE THAT THE INTERIM GUIDELINES WERE GOING TO BE MADE GUIDELINES TODAY. SO WHEN I WAS ASKED TO GIVE THIS PRESENTATION, IT WAS ABOUT ONE THING, NOT THE OTHER. HOWEVER, I THINK I CAN ADDRESS THAT, WHICH IS THAT INSTITUTIONS HAVE ALREADY IMPLEMENTED GUIDELINES. INSTITUTIONS HAVE ALREADY IMPLEMENTED STRUCTURES TO BE IN COMPLIANCE WITH THE CURRENT LAW. AND THAT IF YOU ARE GOING TO LOCK IN NOW CERTAIN TYPES OF GUIDELINES THAT ARE INCONSISTENT WITH WHAT INSTITUTIONS HAVE ALREADY DONE, THEN THEY'RE GOING

TO HAVE TO CHANGE THOSE IN ORDER TO CONTINUE WITH THE RESEARCH THAT THEY'RE CURRENTLY REVIEWING.

MR. SHESTACK: THEN PERHAPS CHANGE THEM AGAIN.

MR. PECKMAN: THAT'S CORRECT.

MR. SHESTACK: AS THIS GROUP CHANGES.

MR. PECKMAN: THAT'S CORRECT.

CO-CHAIR LANSING: AREN'T THEY DOING THESE INTERIM GUIDELINES?

MR. PECKMAN: NO, THEY'RE NOT.

DR. HALL: LET ME JUST SAY THAT I THINK THIS PARTICULAR --

MR. PECKMAN: SOME ARE, SOME ARE NOT.

DR. HALL: THE TERM THAT ANN USED WAS A VERY GOOD ONE, AND THAT IS THAT IT'S A SORT OF NEGATIVE REGULATION. THAT IS, I THINK THE IMPLICATIONS OF THIS PARTICULAR, AMONG THE VARIATIONS THAT YOU PRESENTED IN YOUR VERY NICE DISCUSSION, BY THE WAY, I THINK THIS ONE HAS IMPLICATIONS THAT GO BEYOND SORT OF THE BUREAUCRATIC WHAT IS THE MOST EFFICIENT AND SO FORTH. AND SO I THINK THERE'S A REAL STATEMENT MADE HERE, AND I THINK FOR US TO TAKE THAT OUT HAS THE SIGNIFICANCE THAT I FEEL -- I HOPE WE WON'T FEEL NECESSARY TO TAKE AT THIS STAGE OF THE GAME.

MR. KLEIN: THERE'S ALSO A VERY STRONG --

THERE'S A VERY STRONG SENTIMENT, AT LEAST WHEN THIS INITIATIVE WAS BEING WRITTEN, I CAN TELL YOU THAT THERE'S A REAL PROBLEM IN ALL THIS RESEARCH BEING SHOVED THROUGH IRB'S. AND YET IRB'S ARE VERY POWERFUL AT DIFFERENT INSTITUTIONS AND CAN EFFECTIVELY FORCE POLITICALLY THINGS THROUGH THE IRB'S. AND THERE'S A VALUE TO HAVING A STATEMENT THAT THE ESCRO COMMITTEE SHALL NOT BE A SUBCOMMITTEE OF THE IRB BECAUSE IT GIVES PEOPLE A BASIS FOR ESTABLISHING A SEPARATE ESCRO AND GETS A LOT OF RESEARCH THAT IS NOT INVOLVED IN HUMAN SUBJECTS OUT FROM BEHIND THAT LOGJAM. THAT'S A REAL PROBLEM AT MANY INSTITUTIONS.

MR. SHESTACK: CAN I JUST ASK A COUPLE PRACTICAL QUESTIONS? EVERY INSTITUTION HAS AN IRB, BUT DOES EVERY FACILITY IN CALIFORNIA WHO WILL BE APPLYING FOR TRAINING GRANTS, FOR INSTANCE, ALREADY HAVE AN ESCRO COMMITTEE?

DR. HALL: NO. THERE HAS BEEN DISCUSSION ABOUT THIS. AND ONE OF THE THINGS THAT WE PUT IN THIS, SEVERAL OF THE SMALLER INSTITUTIONS WANT TO WORK OUT ARRANGEMENTS WHERE THEY CAN SHARE AN ESCRO, AND WE MADE AN ADAPTATION TO THE GUIDELINES FOR THAT. GEOFF SHOWED YOU THAT EARLIER, WHICH WE THINK THAT'S QUITE A REASONABLE SOLUTION. AND --

MR. SHESTACK: IF WE PASS THESE GUIDELINES,

FOR INSTANCE, TODAY, EVERYBODY WHO DOESN'T HAVE ONE WILL EITHER COLLABORATE OR FORM ONE, BUT WE'RE RESERVING THE RIGHT, FOR INSTANCE, SUBSEQUENTLY TO SAY, YOU KNOW WHAT, WHAT WOULD ACTUALLY BE THE MOST EXPEDITIOUS FOR RESEARCH IS IF THERE WAS ONE CENTRAL STATE ESCRO, SOMETHING THAT IS IN STEVE'S REPORT.

DR. HALL: IT'S UNAVOIDABLE. WHAT STEVE SAID IS WHATEVER WE DECIDE TODAY, IF IT'S NOT A FINAL DECISION, MAY BE CHANGED. AND THAT WILL HAVE IMPLICATIONS FOR THE INSTITUTIONS. WE WILL KEEP THEM IN TOUCH. AND I THINK, AGAIN, WE WILL KNOW VERY SOON WHAT'S GOING TO HAPPEN, BUT THE DISCUSSION HAS ALREADY STARTED, AND MANY INSTITUTIONS HAVE MOVED TO SET UP ESCRO'S IN ONE FORM OR ANOTHER. AND I THINK WHAT THIS DOES IS TO SIMPLY, FOR REASONS THAT WE'VE ALREADY DISCUSSED AT LENGTH, SAY THAT ONE FORM OF THIS IS NOT A GOOD IDEA.

MR. SHESTACK: RIGHT. THANK YOU.

MS. CHARO: YOU KNOW, THINKING ABOUT STEVE'S PRESENTATION, THINKING ABOUT ALL THE CONCERNS ABOUT THE SYMBOLISM AND POLITICS AROUND THIS, IT DOES SEEM THAT THE SENTENCES AS WRITTEN MIGHT BE AMENDED SLIGHTLY TO ACCOMMODATE A LOT OF PEOPLE'S INTEREST. IT NOW SAYS AN INSTITUTION MAY CONSTITUTE AN ESCRO COMMITTEE FROM AMONG THE MEMBERS OF AN EXISTING IRB. WE CAN AMEND

THAT TO SAY MAY CONSTITUTE AN ESCRO COMMITTEE FROM AMONG THE MEMBERS AND STAFF OF AN EXISTING IRB. THAT COVERS ALL THE PERSONNEL.

THE ESCRO COMMITTEE -- YOU CAN ALSO EVEN ADD THAT AN INSTITUTION MAY DELEGATE THE ESCRO FUNCTIONS THAT DIRECTLY CONCERN HUMAN SUBJECTS TO AN IRB. THAT'S ACTUALLY ALREADY PRESENT IN THE NAS GUIDELINES. AND THEN THE ESCRO COMMITTEE, HOWEVER, SHALL NOT BE A FORMAL SUBCOMMITTEE OF AN IRB CLEARLY SIGNALS THAT IT IS NOT DIRECTLY REPORTING TO. WHERE IT DOESN'T HAVE TO, IT'S NOT SUBJECT TO ALL OF THE MISCELLANEOUS 45 CFR REQUIREMENTS THAT YOU MIGHT NOT HAVE WANTED IT TO BE SUBJECT TO AND HAVE ITS OWN SCHEDULE, ETC. I THINK IT'S A WAY OF ALLOWING INSTITUTIONS TO LEVERAGE THEIR PERSONNEL AND THEIR RESOURCES TO THE MAX WHILE KEEPING SOME LEGALISTIC DISTINCTION THAT PRESERVES THE INDEPENDENCE OF THE ESCRO. I THINK THAT MIGHT BE A COMPROMISE THAT EVERYBODY CAN LIVE WITH FOR THE MOMENT WHILE WE FINALIZE THESE THINGS OVER TIME.

DR. HALL: YOU DON'T THINK THE WORD "FORMAL" IS A SLIPPERY SLOPE THERE?

MS. CHARO: SLIPPERY SLOPE, YOU JUST NEED SPEED BUMPS ON THE SLIPPERY SLOPE.

MR. SHESTACK: EXPEDITIOUS IF AN IRB COMES IN AND SAYS, OKAY, NOW, 3 O'CLOCK WE'RE THE ESCRO

COMMITTEE. LET'S GET IT ALL DONE. THAT'S WHAT YOU'RE PROPOSING THAT THEY'RE ABLE TO DO.

MS. CHARO: I WOULD LIKE TO MAKE SURE THAT THEY'RE NOT SUBJECT TO 45 CFR. THAT'S ONE OF MY GOALS.

MY SECOND GOAL HAD TO DO WITH POLITICAL SYMBOLISM, BUT I'M RECOGNIZING THE NERVOUSNESS IN CALIFORNIA BECAUSE OF THE INVESTMENT WITH CALIFORNIA LAW. SO I'M TRYING TO WORK ON TWO TRACKS HERE AT ONCE AND SEE IF THERE'S SOME STRUCTURES THAT SATISFY EVERYBODY.

MR. KLEIN: I THINK WE'RE GONG TO GET LITIGATION IF WE TRY THE WORD "FORMAL." IT'S JUST TOO CLOSE. YOU'RE JUST SETTING US UP. WE BETTER KEEP THE DISTINCTION.

DR. EGGAN: I'D LIKE TO EVEN GO ONE STEP FURTHER THAN THAT. I WOULD LIKE TO HOPE THAT INSTITUTIONS ARE GOING TO TAKE THIS REALLY SERIOUSLY AND UNDERSTAND THAT THE ISSUES ARE SO SIGNIFICANTLY DIFFERENT, THAT THEY REALLY WILL FIND NEW PERSONNEL, MAYBE NOT NEW STAFF, BUT THAT THEY WILL CHOOSE PEOPLE BASED ON THEIR ABILITY TO THINK ABOUT THESE ISSUES, NOT OUT OF CONVENIENCE SO THAT THERE WILL BE SERIOUS DISCOURSE ABOUT THESE THINGS BECAUSE IF THERE'S NOT, THERE'S GOING TO BE BIGGER PROBLEMS.

DR. OLDEN: I THINK THAT'S THE REASON THAT

THE NATIONAL ACADEMY OF SCIENCE COMMITTEE MADE THE RECOMMENDATION IN THE FIRST PLACE IS THAT THEY DID WANT THERE TO BE SERIOUS DIALOGUE ABOUT THIS IMPORTANT ISSUE. BECAUSE IF YOU THINK ABOUT THE IMAGE OF IRB'S, IT IS NOT SO GOOD. AND TO ASSURE THE AMERICAN PEOPLE THAT WE'RE TAKING THIS SERIOUSLY, I THINK WE NEED A NEW COMMITTEE WITH DIFFERENT KIND OF COMMITMENT TO PROTECTING HUMAN SUBJECTS. SO I THINK THIS IS A GOOD THING TO HAVE IN THERE. AS A CITIZEN, I FEEL MUCH MORE CONFIDENT HAVING ANOTHER CONSTITUTED COMMITTEE RESPONSIBLE FOR OVERSIGHT THAN HAVING THE IRB, THAT CERTAINLY THERE'S SOME HIGHLY PUBLICIZED DISASTERS, AND THOSE WERE REVIEWED IN MOST CASES BY IRB'S.

CO-CHAIR LO: I'M GOING TO HAVE ONE MORE ROUND OF COMMENTS. I HAVE ANN, FRANCISCO, KEVIN. ANYONE ELSE THAT I MISSED? ROB.

DR. KIESSLING: I'M THE ONE THAT ORIGINALLY MADE THE MOTION, I THINK, TO DELETE THESE TWO SENTENCES, OR MAYBE YOU MADE IT, JEFF. BUT I WAS THE ONE WHO WAS INITIALLY INTERESTED IN DELETING THOSE TWO SENTENCES UNTIL THIS DISCUSSION REMINDED ME OF HOW IMPORTANT IT IS THAT THESE ENTITIES NOT BE CONSIDERED HUMAN SUBJECTS. AND THAT'S ACTUALLY CRITICAL. SO SOMEHOW WHAT KEVIN IS PROPOSING -- MAYBE YOU WANT TO MAKE THIS LANGUAGE STRONGER, KEVIN. AND THAT ESCRO'S

MAY NOT BE COMPOSED ENTIRELY OF IRB MEMBERS. I DON'T KNOW IF YOU WANT TO GO TO THAT EXTENT.

DR. EGGAN: I'M HAPPY TO WAIT ON THAT. I'M HAPPY TO WAIT.

DR. KIESSLING: BUT IT IS REALLY CRITICALLY IMPORTANT THAT THERE BE SOME LANGUAGE IN HERE THAT MAKES IT REALLY CLEAR THAT THE EMBRYOS THEMSELVES THAT ARE USED FOR DERIVATION ARE NOT HUMAN SUBJECTS.

DR. OLDEN: ALSO, AT THE NIH WE CERTAINLY HAVE THE IMPRESSION, BECAUSE UNIVERSITIES HAVE TOLD US THAT, THAT IRB'S ARE OVERWORKED ALREADY. SO GIVING THEM ANOTHER RESPONSIBILITY SEEMS TO ME IT'S JUST PROVIDING AND CREATING AN OPPORTUNITY FOR MORE FAILURES OF THE IRB. SO...

DR. PRIETO: I WANTED TO ENDORSE THE CHANGES THAT ALTA PROPOSED BECAUSE I THINK THAT I DO FEEL MORE COMFORTABLE HAVING THIS IN THERE. AND I UNDERSTAND THE QUESTIONS THE GENTLEMAN FROM UCLA RAISED, BUT I THINK THERE ARE ALREADY SEVERAL CLASSES OF RECOMMENDATIONS. WE HAVE THE ISSUE OF NIH AND NON-NIH-FUNDED RESEARCH ALREADY THAT INSTITUTIONS ARE DEALING WITH. I THINK WE HAVE TO LOOK AT WHAT THE DOMINANT NATIONAL STANDARDS AND INTERNATIONAL STANDARDS ARE GOING TO BE AND TRYING TO BE CONGRUENT WITH THOSE AS MUCH AS POSSIBLE.

AND I THINK WITH THESE CHANGES, THE LANGUAGE

WE HAVE NOW IS SOMETHING WE CAN GO FORWARD WITH.

DR. EGGAN: I WAS JUST GOING TO ADD A STATEMENT SAYING, BELIEVE ME, AS A SCIENTIST, IT PAINS ME TO HEAR MYSELF ENDORSING MORE REGULATION. I FEEL SO STRONGLY THAT THIS IS IMPORTANT, THAT, YOU KNOW, I THINK THIS OTHER LEVEL OF OVERSIGHT WILL PREVENT PROBLEMS WITH PUBLIC CONFIDENCE, WHICH ARE THE THINGS THAT ARE GOING TO UNDERMINE US THE MOST.

DR. TAYLOR: I WAS JUST GOING TO MAKE A COMMENT THAT WAS ACTUALLY FROM STEVE'S PRESENTATION. I THINK THAT THE SEPARATION OF KIND OF CHURCH AND STATE AND IRB AND ESCRO'S IS REALLY IMPORTANT FROM EXACTLY THE POINT THAT ANN MADE. BUT ON HIS FIFTH OR SIXTH SLIDE, THERE WAS A STATEMENT THAT HUMAN SUBJECTS WERE DEFINED AS SORT OF HUMANS UNDERGOING SORT OF INVESTIGATION OR HUMAN SUBJECTS CONTAINING IDENTIFYING INFORMATION OF A LIVING INDIVIDUAL. I'M A LITTLE BIT CONCERNED ABOUT GOING FORWARD WHERE THIS IS GOING TO PUT OUR EMBRYONIC STEM CELL RESEARCH.

THIS MIGHT BE KIND OF A TECHNICALITY. MAYBE I'M OVERINTERPRETING IT, BUT I'M A LITTLE BIT CONCERNED THAT AS WE GATHER THE IDENTIFYING INFORMATION, GENETIC INFORMATION --

MS. CHARO: ROB, THERE'S A WAY AROUND IT. THERE'S A WAY AROUND IT BECAUSE BASICALLY ANY TIME YOU

WORK WITH MATERIAL THAT COULD BE LINKED BACK TO AN IDENTIFIABLE PERSON, THAT IDENTIFIABLE PERSON NOW IS POTENTIALLY A HUMAN SUBJECT. AND SO THE REGULATIONS NOW ALLOW YOU TO WORK WITH THE MATERIAL WITH THE INFORMATION THAT IDENTIFIES THOSE INDIVIDUALS IN A CODED FASHION. AND SO LONG AS THE INDIVIDUALS ARE NOT -- WHAT WAS THE EXACT PHRASE -- READILY ASCERTAINABLE.

CO-CHAIR LO: AS LONG AS THE --

MS. CHARO: AS LONG AS THE INDIVIDUALS FROM WHOM THE MATERIALS CAME ARE NOT READILY ASCERTAINABLE TO THE INVESTIGATOR, THOSE INDIVIDUALS WILL NOT BE CONSIDERED HUMAN SUBJECTS, AND YOU CAN WORK AWAY WITH THE BIOLOGICAL MATERIALS WITHOUT HAVING TO GO THROUGH HUMAN SUBJECTS REVIEW.

DR. TAYLOR: GREAT.

DR. PRIETO: DO WE WANT TO INCLUDE THE SENTENCE THAT ALTA ADDED ABOUT ALLOWING ESCRO'S TO DELEGATE SOME OF THEIR FUNCTIONS TO THE IRB?

MS. CHARO: THAT'S REALLY ALREADY THERE. WHAT HAPPENS IN THE WAY THE GUIDELINES WERE WRITTEN AND THE WAY THIS IS WRITTEN TOO IS THAT THERE ARE CERTAIN KINDS OF MINIMUM STANDARDS. THERE ARE NOTIONS ABOUT WHAT GOES INTO INFORMED CONSENT FOR DONATING BIOLOGICAL MATERIALS IN THIS CONTEXT THAT ARE LAID OUT IN THE

GUIDELINES. AFTER THAT, IT'S UP TO THE IRB TO REVIEW THE PROCUREMENT PROCESS. IT'S UP TO THE IRB TO REVIEW THE CONSENT DOCUMENTS. IT'S UP TO THE IRB TO SIGN OFF THAT IT WAS TRULY VOLUNTARY AND NONPAID. THE ESCRO DOES NOT DO A DE NOVO REVIEW OF THOSE ASPECTS OF THE HUMAN SUBJECTS WORK.

DR. PRIETO: YOU DON'T FEEL WE NEED TO STATE THAT EXPLICITLY?

MS. CHARO: WELL, IF IT'S CONFUSING, SURE STATE IT EXPLICITLY. WHY CONFUSE PEOPLE?

MR. KLEIN: ALTA, WAS IT ACCEPTABLE TO YOU TO REMOVE THE WORD "FORMAL"?

MS. CHARO: OH, YES, OF COURSE.

CO-CHAIR LO: LET ME NOW JUST ASK FOR PUBLIC COMMENTS. I THINK WE HAD A PUBLIC COMMENT. I THINK WE HAD A PUBLIC COMMENT FROM EARLIER WE DEFERRED.

MR. REED: IT WAS STATED THAT THE IRB MUST DEFEND THE HUMAN SUBJECT. AND SINCE WE KNOW THAT THERE IS BOTH A NATIONAL AND A STATE ATTEMPT TO REDEFINE THE BEGINNING OF LIFE AT CONCEPTION, IT SEEMS TO ME THAT THIS IS A REAL POISON PILL WE COULD BE TAKING IN TO CLOSE TO OURSELVES IF WE ALLOW THE IRB. I WOULD SUGGEST WE CALL IT A CALIFORNIA INTERNAL REVIEW BOARD AND MAKE OUR OWN DEFINITIONS OF WHAT A HUMAN SUBJECT IS BECAUSE IF WE ALLOW THE FEDERAL PEOPLE TO MAKE THAT

DECISION, THEN WE KNOW WHAT THEY WILL BE. THEY WANT TO STOP SCNT. I THINK THIS IS REALLY IMPORTANT, THAT THE IRB EITHER WE DON'T DO IT OR WE DEFINE IT OUR WAY, NOT THE WAY THE FEDERAL GOVERNMENT WOULD LIKE TO DO.

CO-CHAIR LO: SO WE HAVE --

MR. PECKMAN: ONE MORE COMMENT, WHICH IS I SEE WHERE THIS IS GOING, AND I THINK THAT YOU'VE HAD A VERY STUDIED DISCUSSION ON IT. I'D LIKE TO ENCOURAGE THE CIRM TO WORK CLOSELY WITH DHS TO TRY TO HARMONIZE REGULATIONS AND LAW REGARDING RESEARCH WITH HUMAN EMBRYONIC STEM CELLS. WITHOUT SOME KIND OF HARMONIZATION, INSTITUTIONS WILL RUN INTO PROBLEMS IN TERMS OF CARRYING OUT YOUR REQUIREMENTS AND STATE REQUIREMENTS. I THINK IT'S CRUCIAL FOR YOU TO TAKE THE LEAD ON THAT.

CO-CHAIR LO: AGAIN, THESE ARE JUST INTERIM GUIDELINES. WE HAVE A COUPLE OF THINGS HERE. WE HAVE A TABLED MOTION TO DELETE THESE TWO SENTENCES. WE HAVE SOME OTHER IDEAS FROM ALTA ABOUT ADDING SOME LANGUAGE, BOTH KEEP THOSE TWO SENTENCES, ADD OR STAFF. ALTA, DID YOU WANT TO ADD SOMETHING ABOUT DELEGATING -- IT'S PERMISSIBLE TO DELEGATE HUMAN SUBJECTS TO THE IRB?

MS. CHARO: OR SIMPLY TO SAY, IF YOU WANT TO SAY EXPLICITLY THAT THE ESCRO IS FREE TO DEFER ALL HUMAN SUBJECTS MATTERS TO THE IRB. WE'LL TAKE UNDER

ADVISEMENT THE SUGGESTION THAT HUMAN SUBJECTS AS A DEFINITION WE MIGHT WANT TO ADD INTO THE FINAL VERSION OF THE GUIDELINES.

MR. KLEIN: DIDN'T YOU ALSO SAY -- PER SE THE INITIATIVE ALREADY CALLS FOR HUMAN SUBJECTS TO BE REVIEWED BY IRB'S. THE INITIATIVE ITSELF DOES.

MS. CHARO: THAT'S TRUE. MAYBE JUST GET IT OUT.

CO-CHAIR LO: THERE'S A VIRTUE TO KEEPING THIS SIMPLER. SO DOES THE TABLED MOTION HAVE PRECEDENCE?

MR. KLEIN: WELL, I'D BE PREPARED TO WITHDRAW MY SECOND, I THINK, TO THE TABLED MOTION IN DEFERENCE TO ALTA'S MOTION.

MR. SHEEHY: I WOULD BE PREPARED TO WITHDRAW THE TABLED MOTION.

CO-CHAIR LO: THAT'S WITHDRAWN. NOW WE HAVE THIS -- BASICALLY WE'RE SAYING WE'RE GOING TO ACCEPT THE SECTION ON ESCRO'S AND IRB'S WITH THIS ADDITION OF MORE STAFF, AS ALTA SUGGESTED. IS THAT THE GIST? IF SOMEONE COULD FORMALLY MOVE THAT.

MR. KLEIN: IS THAT A MOTION?

MS. CHARO: I GUESS SO.

DR. PRIETO: QUESTION. WAS DR. WILLERSON'S MOTION DEALT WITH, OR DO WE NEED TO VOTE ON THAT?

MR. LOMAX: THAT WAS THE MOTION TO SIMPLY DELETE THE SECTION, AND WE'VE NOW REDRAFTED IT TO MAKE IT A STATEMENT OF LONG-TERM INTENT.

CO-CHAIR LO: THAT WAS THE OTHER SECTION.

CO-CHAIR LANSING: WE OVERRULED THAT WITH WHAT WE VOTED ON.

CO-CHAIR LO: THAT WAS FOR THE OTHER SECTION. THAT WAS FOR BANKING. ALTA HAS MADE A MOTION. SECOND?

MR. KLEIN: SECOND.

CO-CHAIR LO: ALL THOSE IN FAVOR. OPPOSED? NONE. OKAY.

SO NOW COULD I HAVE AN OMNIBUS MOTION TO RECOMMEND AS INTERIM GUIDELINES THE TEXT OF WHAT WE'VE APPROVED?

DR. PRIETO: SO MOVED.

CO-CHAIR LANSING: SO MOVED.

DR. OLDEN: SECOND.

CO-CHAIR LO: SECOND DR. OLDEN. ANY DISCUSSION?

MR. KLEIN: I'D JUST LIKE TO SAY THAT THERE ISN'T ANYTHING THAT'S PERFUNCTORY ABOUT THIS COMMITTEE OR CIRM. AND THERE IS -- THERE ARE TREMENDOUS QUALITY TO THE NATIONAL ACADEMIES' CONTRIBUTIONS. AND BOTH JANET AND ALTA SHOULD BE THANKED AMONG MANY OTHERS FOR THEIR CONTRIBUTIONS, BUT CERTAINLY WE HAVE A TREMENDOUS

QUALITY ON THE STANDARDS COMMITTEE. AND I CAN TELL YOU FROM THE CAMPAIGN HISTORY, ALL OF THOSE PEOPLE AND PATIENT GROUPS THAT PARTICIPATED, SPEAKING AS AN INDIVIDUAL, I GREATLY APPRECIATE THE THOUGHT THAT'S GOING JUST TO THE INTERIM REGULATIONS, WHICH WILL HAVE A REAL MODEL STANDARD FOR COUNTRY AND THE STATE, AS WELL AS WHAT'S CLEARLY GOING TO BE A VERY THOUGHT PROVOKING AND EXTENSIVE REVIEW FOR THE PERMANENT REGULATIONS.

CO-CHAIR LANSING: DITTO.

CO-CHAIR LO: ANN RAISES A QUESTION. I THOUGHT WE HAD EARLIER SAID THERE WERE NO BURNING ISSUES TO BE RAISED, AND THE INFERENCE WAS WE WERE HAPPY WITH WHAT WAS THERE AS INTERIM GUIDELINES. SO --

MR. SHESTACK: I THINK YOU BETTER ASK AGAIN. MAYBE ANN HAS ONE.

DR. KIESSLING: WE HAVEN'T DISCUSSED SECTION 10 AT ALL, AND THERE'S ONLY A COUPLE OF LITTLE THINGS IN THERE THAT ARE GOING TO CAUSE PROBLEMS. THIS IS PRETTY TINY.

MR. KLEIN: DID I INSPIRE THAT, ANN?

DR. KIESSLING: SECTION 10(B). YOU WANT TO ADD TO THAT LANGUAGE ABOUT THE CELL LINES THAT YOU GRANDFATHERED? OTHERWISE, THERE'S A LOT OF DOCUMENTATION REQUIRED THERE. SECTION 10(F). THIS HAS

TO DO WITH OUR STUDY GROUP IS WHY I'M BRINGING IT UP NOW. SECTION 10(F), THERE'S SOME AMBIGUITY HERE ABOUT TRANSPLANTATION, DIFFERENTIATED DERIVATIVES OF HES CELLS INTO ADULT DOES NOT REQUIRE EXTENSIVE ESCRO COMMITTEE REVIEW. WHAT DOES THAT MEAN?

CO-CHAIR LO: IT'S IN THE NAS REPORT.

MS. CHARO: THE LANGUAGE IS JUST AWKWARD HERE. WHAT WAS GOING ON IS THAT THERE WAS A FEAR THAT PEOPLE WERE GOING TO READ THESE THINGS AS REQUIRING IMMENSE AMOUNTS OF EXTRA REVIEW FOR EVERY SINGLE STEM CELL EXPERIMENT OUT THERE. AND THE IDEA WAS TO NOTE THAT THE VAST MAJORITY OF PURELY LAB STUDIES THAT DON'T INVOLVE IDENTIFIABLE TISSUE, THAT DON'T INVOLVE ANIMALS, AND THEY DON'T INVOLVE RECOMBINANT DNA COULD ESSENTIALLY BE WAIVED ON THROUGH WITH BASICALLY THE NOTICE TO THE ESCRO THAT YOU'RE WORKING WITH A LINE AND THAT YOU ARE WORKING -- AND THEY REQUIRE DOCUMENTATION THAT THE LINE IS AN ACCEPTABLE LINE FOR YOUR INSTITUTION. AND THAT SHOULD BE PRETTY MUCH IT. THE EXPERIMENTS SHOULD BE OTHERWISE UNPROBLEMATIC, AND THAT MOST OF THE BASIC RESEARCH TODAY STILL FALLS IN THAT CATEGORY. THAT WAS THE GOAL. THE PHRASING, NOT --

MR. SHESTACK: WHICH SUBSECTION, F? THAT IS -- I HAVE TO SAY THAT IS INCENDIARY PHRASING.

MS. CHARO: YES.

DR. KIESSLING: SO THAT'S GOT TO GET FIXED.

MR. SHESTACK: THAT'S HEADLINE PHRASING.

CO-CHAIR LO: WE HAVE A SUGGESTION FOR HOW TO FIX THAT. (B) CAN BE FIXED. I THINK WE CAN DEFER TO STAFF.

MS. CHARO: SO HERE --

DR. KIESSLING: IT'S EITHER GOT TO REQUIRE ESCRO COMMITTEE REVIEW OR NOT.

MR. SHESTACK: IF WE DELETED (F).

DR. TAYLOR: DELETE THE FIRST SENTENCE.

MR. KLEIN: WHAT ABOUT POSSIBLY SAYING SHALL ATTEMPT TO AVOID A REDUNDANT REVIEW OR SOMETHING.

DR. KIESSLING: THESE ARE EXPERIMENTS THAT JEFF DOES. LET HIM WEIGH INTO IT.

DR. KORDOWER: CAUGHT ME AT A TIRED TIME. 10(F), CORRECT? TRANSPLANTATION OF DIFFERENTIATED DERIVATIVES OF HUMAN EMBRYONIC STEM CELLS OR HUMAN EMBRYONIC STEM CELL THEMSELVES INTO ADULT ANIMALS DOES NOT REQUIRE EXTENSIVE ESCRO COMMITTEE REVIEW. ANY PROBLEM WITH THAT?

MS. CHARO: DOES NOT WHAT?

DR. KORDOWER: DOES NOT REQUIRE SIGNIFICANT ESCRO COMMITTEE REVIEW.

(OVERLAPPING DISCUSSION AMONG THE MEMBERS.)

MR. SHESTACK: THAT SOUNDS BAD.

DR. KORDOWER: THIS GOT INTO THE QUESTION ABOUT WHAT A CHIMERA IS. THIS IS GOING TO LAST US A LONG TIME.

DR. KIESSLING: IT'S NOT USED ANYWHERE. THE TERM IS NOT USED ANYWHERE.

DR. KORDOWER: I MEAN I DON'T REALLY UNDERSTAND THE SECOND PART OF THIS.

DR. EGGAN: YOU COULD SAY ROUTINE TRANSPLANTATION OF DIFFERENTIATED DERIVATIVES.

MS. CHARO: IF YOU'RE PUTTING HUMAN HEART MUSCLE INTO AN ADULT SHEEP HEART, NOBODY WORRIES VERY MUCH. YOU'RE PUTTING HUMAN BRAIN TISSUE INTO AN ADULT SHEEP BRAIN, UNLESS YOU EXPECT IT'S GOING TO DIFFERENTIATE IN AND INTEGRATE IN, YOU'RE NOT GOING TO WORRY TOO MUCH.

DR. KORDOWER: BUT YOU'RE USING WORDS THAT MAYBE HAVE DIFFERENT MEANINGS FOR DIFFERENT PEOPLE. IT'S GOING TO INTEGRATE IN AND IT'S GOING TO DIFFERENTIATE, BUT IT'S NOT GOING TO BECOME A HUMAN OR A HUMAN CHIMERA IN THE WAY A LOT OF PEOPLE USE THE WORD "CHIMERA."

DR. KIESSLING: ALL WE HAVE TO DECIDE --

DR. KORDOWER: JUST DON'T BREED THOSE ANIMALS.

DR. KIESSLING: WE HAVE TO DECIDE ON (F) WHETHER THIS EXPERIMENT REQUIRES ESCRO COMMITTEE REVIEW OR WHETHER IT JUST REQUIRES ANIMAL COMMITTEE REVIEW. I THINK WE DON'T HAVE TO DO ANYTHING BEYOND THAT. BUT TO LEAVE IT THE WAY IT IS NOW, I DON'T THINK ANYBODY IS GOING TO KNOW WHAT TO DO.

MS. CHARO: THE GUIDELINES CAN SAY DEFINITELY REQUIRES ESCRO REVIEW. IF THEY WANT THE ESCRO TO LOOK OVER ANYTHING THAT INVOLVES HUMAN, NONHUMAN COMBINATIONS, THE GOAL HERE IS TO GIVE GUIDANCE TO THE ESCRO'S OF EXACTLY HOW HYSTERICAL TO GET. IF YOU WANT TO DROP THAT OUT AND TRUST THEM TO NOT GET HYSTERICAL, THEN YOU CAN JUST ELIMINATE.

MR. SHESTACK: JEFF SAYS HE DOESN'T MIND ESCRO REVIEW FOR THIS. IT'S A PRO FORMA ESCRO REVIEW ANYWAY. WHY ARE YOU GOING TO HAVE THIS CLAUSE IN? IT JUST WILL BE MISINTERPRETED TO BE LIKE SCIENCE GONE MAD. SEEMS LIKE IT'S OPEN TO MISINTERPRETATION.

DR. KIESSLING: SO SHOULD (F) JUST GO AWAY? BECAUSE IF (F) GOES AWAY, THEN THE ASSUMPTION IS THAT EVERYTHING IS GOING TO BE REVIEWED BY AN ESCRO AND EVERYTHING INVOLVING ANIMALS IS GOING TO BE REVIEWED BY AN ANIMAL COMMITTEE. AND (F) RAISES ISSUES THAT ARE --

DR. KORDOWER: I MOVE TO DELETE (F) COMPLETELY, AND THEN WE'RE FINE.

DR. EGGAN: SECOND.

DR. KIESSLING: THIS STANDS NICELY WITHOUT (F).

CO-CHAIR LO: ALTA, CAN YOU GIVE US THE RATIONALE FOR THE NAS INCLUDING THIS? I THINK THE FIRST SENTENCE IN (F) WAS MEANT TO ALLOW FOR WHAT WOULD BE KNOWN IN THE IRB WORLD AS EXPEDITED REVIEW. SO THAT IT DOESN'T REQUIRE THE SAME LEVEL OF DEPTH AND TIME OF REVIEW, BUT IT DOES REQUIRE AN ESCRO SO LOOK AT IT.

THE SECOND SENTENCE, MY READING WAS, TO SAY THAT THERE'S CERTAIN TYPES OF RESEARCH WHERE YOU'VE GOT TO BE VERY CAREFUL ABOUT IT. AND WE WANT YOU TO REALLY MAKE SURE THAT THE EVIDENCE IS PERSUASIVE.

DR. KORDOWER: THAT'S AN IACUC ISSUE. IACUC SHOULD NOT ALLOW ANY SCIENCE TO GO FORWARD THAT DOESN'T HAVE A STRONG RATIONALE.

MS. CHARO: IF YOU LOOK AT (E) ABOVE, (E) SAYS ANY TIME YOU TAKE HUMAN ES CELLS AND COMBINE IT WITH A NONHUMAN ANIMAL AT ANY STAGE OF DEVELOPMENT, IT HAS TO GO TO THE ESCRO. THAT'S WHAT IT SAYS.

SO (F), YOU'RE RIGHT, YOU COULD DROP (F) OUT AND JUST TRUST THAT THE ESCRO'S ARE NOW GOING TO BE LOOKING AT THESE AND MAKE A SENSIBLE DISTINCTION BETWEEN HUMAN, NONHUMAN COMBINATIONS THAT POSE REAL DILEMMAS, LIKE WHERE THEY MIGHT RESULT IN ENOUGH MERGED

NEUROLOGICAL TISSUE THAT WE DON'T REALLY UNDERSTAND THE NATURE OF CONSCIOUSNESS VERSUS THOSE THAT ARE REALLY NOT PROBLEMATIC, SUCH AS TAKING HUMAN TISSUE AND PUTTING IT INTO A NONHUMAN ANIMAL IN ITS KIDNEY OR ITS LIVER WHERE IT'S REALLY JUST NOT --

DR. KORDOWER: OR ITS BRAIN.

MS. CHARO: THE POINT HAD BEEN THAT WE FELT LIKE THERE WAS ENOUGH UNCERTAINTY IN THE AREA OF NEUROLOGY ABOUT WHERE -- THERE'S GOING TO BE A LOT OF STUFF THAT'S TOTALLY UNPROBLEMATIC. THERE'S A SPECTRUM, AND WHERE THAT GRAY AREA BEGINS AND ENDS IS STILL BEING DISCUSSED, AND THAT WAS WHY THE NOTION WAS TO SIGNAL TO THE ESCRO'S TO TAKE A CLOSER LOOK AT THOSE. THAT'S ALL. I DON'T KNOW HOW TO CAPTURE IT IN LANGUAGE.

DR. KORDOWER: (E) TAKES CARE OF THE ESCRO ISSUE.

MS. CHARO: (E) TAKES CARE OF THE FORMAL PROCESS, YOU HAVE TO SUBMIT IT.

DR. HALL: I THOUGHT THE FUNNY THING WAS THAT ALMOST AS (F) IS A WAY OF EXPLAINING WHY ADULT ANIMALS IS IN (F).

MR. SHESTACK: (E), (F), AND (G) SEEM REALLY SIMILAR TO ME.

DR. HALL: OKAY. SO WE JUST SAID YOU HAVE TO

LOOK AT ADULT ANIMALS, BUT ACTUALLY YOU DON'T HAVE TO LOOK AT THEM VERY SERIOUSLY UNLESS -- THERE'S THIS ONE CASE, AND THAT'S WHY WE REALLY ARE CONCERNED ABOUT IT. IT'S SORT OF LIKE AN EXPLANATION OF INCLUDING ADULTS IN (E) IS MY THINKING ABOUT IT NOW.

DR. KIESSLING: BUT THEY'RE GOING TO LOOK AT THAT MORE SERIOUSLY.

MR. KLEIN: IN THE FIRST SENTENCE, COULD WE USE BERNIE'S LANGUAGE AND SAY ADULT ANIMALS SHOULD BE GIVEN AN EXPEDITED ESCRO COMMITTEE REVIEW?

DR. PRIETO: MAY BE GIVEN AN EXPEDITED REVIEW.

DR. HALL: I THINK THAT JUST DELETING IT IS FINE.

MS. CHARO: LET THE ESCRO'S HANDLE IT.

DR. KIESSLING: DELETE (F). I THINK IF WE DELETE (F), YOU'VE DELETED A LOT OF CONFUSION.

DR. HALL: IT DOES HAVE A CONFUSING MESSAGE.

MR. SHESTACK: YOU'RE DELETING CONFUSION.

CO-CHAIR LO: FORMAL MOTION.

DR. EGGAN: IT'S MOVED AND SECONDED ALREADY.

DR. KIESSLING: DO YOU AGREE WITH THAT, JEFF?

DR. KORDOWER: YEAH. I AGREE WITH THAT.

CO-CHAIR LO: DO WE HAVE A FORMAL MOTION?

DR. KIESSLING: I MOVE THAT WE DELETE SECTION

10, PARAGRAPH F.

DR. KORDOWER: SECOND.

CO-CHAIR LO: ANY PUBLIC COMMENT? ALL THOSE IN FAVOR OF DELETING (F). ALL OPPOSED? NONE.

SO NOW I'D LIKE TO GO BACK TO THIS SORT OF OMNIBUS MOTION TO RECOMMEND THE INTERIM GUIDELINES TO CIRM FOR CONSIDERATION. BOB HAS GRACIOUSLY MADE SUCH A MOTION.

DR. OLDEN: SECOND.

CO-CHAIR LO: ANY PUBLIC DISCUSSION OF THAT? ALL THOSE IN FAVOR. OPPOSED? UNANIMOUS. THANK YOU.

(APPLAUSE.)

CO-CHAIR LO: I WOULD ALSO LIKE TO PUT IN A WORD OF APPRECIATION TO THE STAFF HERE AT CIRM. I THINK WE MAY NOT APPRECIATE -- WE JUST SORT OF SAID TRANSLATE THIS INTO REGULATORY-ESE. I THINK ZACH AND GEOFF AND JAMES AND KATE HAVE REALLY DONE A LOT OF THE BEHIND-THE-SCENES WORK IN MAKING THIS HAPPEN. I JUST WANT TO SORT OF, FIRST OF ALL, THANK THEM AND TO SAY WE WILL BE RELYING ON YOU EVEN MORE AS WE START TO GET INTO THE SUBSTANTIVE ISSUES WITH THE DRAFT FINAL DOCUMENT.

DR. HALL: LET ME SAY I HAD VERY LITTLE TO DO THIS. IT WAS JAMES, GEOFF, AND KATE. I ALSO WANT TO SAY THAT -- SOMEBODY MENTIONED THE TRANSCRIPT. THERE'S

A BEAUTIFUL TRANSCRIPT OF THE LAST MEETING, FOR THOSE OF YOU WHO HAVE NOTICED, AND THAT WAS AN INCREDIBLE JOB THAT KATE SHREVE DID. I JUST WANT TO NOTE THAT AS WELL.

CO-CHAIR LO: I NOW HAVE 5:30, AND WE HAVE SOME UNFINISHED BUSINESS IN TERMS OF SEVERAL OF THE WORKING GROUPS HAVE NOT SORT OF MADE ANY FORMAL REPORT. AND I'M JUST WONDERING IF WE COULD JUST HAVE AN INFORMATIONAL QUICK GO-ROUND FOR THE OTHER WORKING GROUPS. WE HEARD VERY NICELY ABOUT REGISTRIES AND BANKING. I THINK THAT WAS EXTREMELY HELPFUL. I WOULD JUST LIKE TO ASK THE OTHER THREE WORKING GROUPS: INTERSTATE AND INTERNATIONAL COLLABORATION, PRECLINICAL RESEARCH STANDARDS, AND DONOR RECRUITMENT, JUST TO HIGHLIGHT THE ISSUES THAT THEY'RE GOING TO BE ADDRESSING AS WE START TO -- THE SUBSTANTIVE ISSUES THEY'RE GOING TO BE ADDRESSING AS WE SORT OF TRY TO FORMULATE THESE DRAFT FINAL GUIDELINES.

SO FOR THE INTERSTATE INTERNATIONAL COLLABORATION, THERE ARE SOME REALLY TOUGH ISSUES THAT THAT GROUP IS GOING TO HAVE TO DEAL WITH. CAN I ASK THAT GROUP TO JUST QUICKLY HIGHLIGHT FOR US THE ISSUES AND THE CONSIDERATIONS THAT YOU'RE DEALING WITH.

MS. CHARO: BASICALLY THE QUESTION IS HOW TO FACILITATE COLLABORATION. SO QUESTION: IF SOMEBODY

WANTS TO BE WORKING WITH MATERIALS THAT COME FROM OUTSIDE CALIFORNIA, OUTSIDE OF THE CIRM-DERIVED PROCESS, ARE THERE GOING TO BE RESTRICTIONS ON WHAT YOU CAN WORK WITH IN TERMS OF MATERIALS? AND IF SO, THE QUESTION IS GOING TO BE WHAT ARE THE MINIMUM ETHICAL STANDARDS WE WANT TO APPLY? SO THIS IS BACK TO THE EARLIER CONVERSATION ABOUT EQUIVALENCE, AND THE EQUIVALENCE HAS TWO PARTS.

ONE IS THE SUBSTANTIVE RULES. FOR EXAMPLE, WE MIGHT SAY THE MINIMUMS ARE GOING TO BE INFORMED CONSENT, BUT INFORMED CONCEPT FROM WHOM? THAT GETS YOU INTO YOUR LITTLE ANONYMOUS DONOR DO LOOP; NO COMPENSATION, AND THAT GETS YOU INTO WHETHER OR NOT OUR VERY STRICT RULES ABOUT NO COMPENSATION, WHICH INCLUDES NO LOST OPPORTUNITY COST REIMBURSEMENTS HAS TO BE MIMICKED IN THE OTHER JURISDICTION FOR YOU TO BE ALLOWED TO USE THEIR LINES. SO A SUBSTANTIVE QUESTION.

AND THEN A PROCEDURAL QUESTION, WHICH IS WHO, EVEN ASSUMING WE'RE THE ONES WHO DECIDE TO SAY WHAT THAT MINIMUM IS GOING TO BE, WHO THEN MEASURES OTHER INSTITUTIONS AND OTHER STATE OR NATIONAL LAWS TO DETERMINE WHETHER OR NOT THEY DO OR DO NOT MEET OUR MINIMUM STANDARDS?

AND WE HAVE A PROPOSAL OUTLINED ON THE VERY LAST PAGE OF THE BOOK FOR YOUR REVIEW. AND THAT IS

REALLY THE FOCUS ON THE REQUIREMENT THAT CIRM-FUNDED RESEARCHERS ALWAYS BE WORKING WITH MATERIALS THAT WE CALL ETHICALLY DERIVED. THAT WE HAVE A BEGINNING OF A DEFINITION OF ETHICALLY DERIVED, WHICH HAS TO DO WITH MEETING CIRM STANDARDS, MEETING STANDARDS FROM NIH, OR DERIVED IN ACCORDANCE WITH THE POLICIES OF -- AND WE'RE GOING TO BEGIN LISTING PLACES, LIKE WE DID TODAY WITH THE UK STEM CELL BANK.

AND FINALLY, ANYTHING THAT WAS DERIVED IN ACCORDANCE, AND THIS IS THE REAL RECOMMENDATION FOR DISCUSSION, ANYTHING DERIVED IN ACCORDANCE WITH THE EXTANT LAWS AND ETHICAL NORMS OF AN AREA BE PRESUMED TO BE ETHICALLY DERIVED UNLESS THE ESCRO HAS SOME REASON FOR DOUBTING THAT.

IN OTHER WORDS, WE WANTED TO GIVE THE BENEFIT OF DOUBT TO LINES THAT WERE DERIVED IN ACCORDANCE WITH LOCAL LAW AND REGULATION IN OTHER PLACES. INSTEAD OF ASSUMING THAT THE WHOLE WORLD IS UNETHICAL, WE WANTED TO ASSUME THAT THEY ARE UNLESS WE WANT TO STOP AND TAKE A CLOSER LOOK AND SAY THIS ONE MAY BE TOO DIFFERENT FROM US. SO THERE'S A QUESTION HERE ABOUT PRESUMPTIONS AND THE USE OF PRESUMPTIONS TO TRY AND BOTH PAY RESPECT TO OTHER PARTS OF THE WORLD AND ALSO MAKE THE WORK A LITTLE BIT EASIER.

THE SECOND QUESTION IS GOING TO BE A LITTLE

LESS IMPORTANT, BUT IT'S ONE WE WANT TO FOCUS ON JUST BRIEFLY; AND THAT IS, WHEN YOU'VE GOT CIRM-FUNDED RESEARCHERS WHO ARE NOT ACTUALLY WORKING WITH MATERIALS, THEY ARE DOING THE ANCILLARY WORK, THEY'RE DOING THE STATISTICAL ANALYSIS, FOR EXAMPLE, FOR OTHER PEOPLE IN OTHER PLACES, TO WHAT EXTENT DO WE WANT TO LIMIT THEIR ABILITY TO DO THESE COLLABORATIONS BASED ON OUR VIEW THAT THE OTHER PARTNERS ARE NOT MEETING ONE OF OUR MINIMUM STANDARDS, OR DO WE WANT TO LEAVE THEM TOTALLY FREE TO COLLABORATE AS CIRM-FUNDED RESEARCHERS PROVIDED THAT THE MATERIALS THAT THEY WORK WITH WERE ALL COLLECTED AND MANAGED IN ACCORDANCE WITH OUR RULES.

CO-CHAIR LO: THANK YOU. PRECLINICAL RESEARCH STANDARDS WORKING GROUP, A BRIEF REPORT.

DR. KIESSLING: THAT WAS MYSELF AND JEFF KORDOWER AND TED PETERS. WE HAD A COUPLE OF CONFERENCE CALLS ON THIS. AT FIRST WE THOUGHT -- WE WEREN'T TOO SURE EXACTLY WHAT OUR CHARGE WAS, BUT AS YOU CAN SEE ON THE REPORT THAT'S SUBMITTED, THERE'S A LOT THAT'S GOING TO HAVE TO BE DISCUSSED HERE. ALL WE SIMPLY DID WAS SORT OF OUTLINE WHAT WE THOUGHT OUR CHARGE WAS, WHAT THE PROBLEMS ARE GOING TO BE WITH THE SOURCES OF THE STEM CELLS, AND WE INCLUDED ADULT TISSUES, FETAL TISSUES, CORD BLOOD, AND PLACENTA AS WELL. MANY OF THESE HAVE GUIDELINES THAT ARE ALREADY COVERED. I

DON'T KNOW HOW MUCH DEBATE THIS COMMITTEE IS GOING TO HAVE.

WHAT I WOULD HOPE EVERYBODY WOULD DO BETWEEN NOW AND THE NEXT TIME WE MEET OR WHENEVER WE CONSIDER THIS AGAIN IS TO GO OVER EACH -- IN OUR OUTLINE WE LISTED WHAT WE THOUGHT THE CONSIDERATIONS WERE GOING TO BE FOR EACH OF THESE SOURCES. I DON'T KNOW HOW COMPREHENSIVE THIS IS. SO THAT WOULD BE VERY USEFUL IF THIS COMMITTEE WOULD LOOK AT EACH OF THOSE CONSIDERATIONS.

I THINK THE TOUGH ISSUES HERE HAVE TO DO WITH EGGS FERTILIZED FOR STEM CELL DERIVATION. THIS IS NOT ALLOWED IN CANADA. IT IS ALLOWED SO FAR IN CIRM. THERE MAY BE SOME GUIDELINES AROUND THIS. THERE MAY BE HAVE TO BE SOME JUSTIFICATION FOR CREATING EMBRYOS FOR RESEARCH PURPOSES BECAUSE THAT'S PRETTY CONTROVERSIAL.

AND I THINK OTHER AREA THAT'S CONTROVERSIAL -- WELL, WE KNOW THAT SOMATIC CELL NUCLEAR TRANSFER IS CONTROVERSIAL. AND ANOTHER AREA THAT'S CONTROVERSIAL HAS TO DO WITH INTRODUCING EMBRYONIC STEM CELLS INTO EMBRYOS OF OTHER ANIMALS. THERE MAY BE TIMES WHEN THOSE ARE REALLY IMPORTANT EXPERIMENTS TO DO, AND WE MAY HAVE TO SPEND SOME TIME TALKING ABOUT THOSE GUIDELINES.

I DON'T THINK -- WE NEED SOME BACKGROUND

INFORMATION ABOUT OTHER LAWS. FOUR STATES HAVE ADOPTED LAWS ABOUT THIS, NOT VERY MANY OTHER STATES HAVE. AND I THINK THAT'S IT. I THINK THAT'S WHERE OUR WORKING GROUP IS. IF THIS GROUP WOULD LOOK OVER THOSE THREE PAGES THAT WE GENERATED, PARTICULARLY WITH THE CONSIDERATIONS, SO THAT WHEN THIS COMES UP FOR OVERALL DISCUSSION, WE'VE ALL HAD A HEADS-UP ON THAT. I THINK THAT WOULD BE A BIG HELP.

CO-CHAIR LO: THANK YOU. AND THEN THE FINAL WORKING GROUP WAS ON DONOR RECRUITMENT PROTECTION. ACTUALLY SOME OF OUR DELIBERATIONS OVERLAP WITH ANN'S COMMITTEE, SO WE'RE GOING TO HAVE TO SORT OF WORK OUT AND SORT OF PROBABLY TURN OVER TO YOUR GROUP A LOT OF THOSE CONSIDERATIONS.

THERE ARE A COUPLE OF ISSUES THAT WE WANT TO RAISE. ONE, AGAIN, WITH RECRUITMENT, I KNOW THIS OVERLAPS A LOT WITH THE CONSENT PROCESS, IS TO LOOK SEPARATELY AT TWO GROUPS OF WOMEN WHO MIGHT DONATE OOCYTES FOR DERIVATION OF NEW STEM CELLS. ONE ARE WOMEN WHO ARE ALREADY UNDERGOING OOCYTE RETRIEVAL FOR INFERTILITY TREATMENT, AND COULD OOCYTES THAT WOULD NOT BE USED FOR THE FERTILITY TREATMENT BE DONATED TO RESEARCHERS. THERE ARE A NUMBER OF CONSIDERATIONS THERE ABOUT HOW EITHER THE WOMAN IN THE INFERTILITY TREATMENT BECAUSE SHE'S THE ONE UNDERGOING THE OOCYTE

RETRIEVAL, OR IF SHE IS RECEIVING OOCYTES FROM A DONOR, OOCYTE DONOR, THE CONSIDERATIONS FOR THAT HAVE TO GO INTO MAKING SURE SHE UNDERSTANDS THE POSSIBLE SETBACKS TO HER REPRODUCTIVE GOALS.

SECOND ISSUE REALLY HAD TO DO WITH COMPENSATION FOR INJURIES THAT WERE A DIRECT RESULT OF PARTICIPATING IN OOCYTE RETRIEVAL FOR RESEARCH PURPOSES. WE WANTED TO SEPARATE OUT THE LONG-TERM POSSIBLE ADVERSE EFFECTS, WHICH ARE NOT VERY WELL CHARACTERIZED AND A VERY LONG TAIL, FROM THE VERY IMMEDIATE SHORT-TERM ADVERSE CONSEQUENCES WHICH WOULD BASICALLY INCLUDE HYPEROVULATION SYNDROME.

AND AS YOU KNOW, CURRENTLY THE FEDERAL GUIDELINES ARE THAT YOU HAVE BEEN TOLD IN THE INFORMED CONSENT PROCESS WHAT THE COMPENSATION WOULD BE. YOU'RE USUALLY TOLD THAT THERE IS NONE. AND I THINK THE ISSUE IS IF WE'RE NOT COMPENSATING WOMEN WHO ARE DONATING OOCYTES SPECIFICALLY FOR RESEARCH FOR ANYTHING OTHER THAN THEIR OUT-OF-POCKET EXPENSES, SHOULD THEY BEAR, THEY OR THEIR INSURERS BEAR THE COST OF TREATMENT FOR COMPENSATION FOR RESEARCH-RELATED INJURIES. SO THAT'S A BIGGER ISSUE, BUT IT'S SOMETHING WE WANTED TO HIGHLIGHT AS BEING A POTENTIAL INEQUITY.

I THINK THE OTHER THING WE NEED TO DO, AND THE CHAIRS AND THE STAFF WILL WORK ON THIS, IS TO

SOMEHOW WORK IN THE POINTS THAT KEN OLDEN MADE ABOUT DIVERSITY OF DONORS AND ACCESS TO TREATMENT AND HOW THAT'S GOING TO BE MAYBE ASSIGNED TO ONE OF OUR WORKING GROUPS.

SO I THINK THAT -- LET ME JUST NOW SHIFT GEARS AND SORT OF ORIENT US TOWARDS THE FUTURE. IF YOU LOOK AT THAT VERY WONDERFUL COLOR CHART THAT STAFF MADE UP FOR US, YOU NOTED THAT THE BIG TAKE IS THE MIDDLE OF NOVEMBER WHEN THE APA RULEMAKING PROCESS STARTS. AND THAT BEFORE THEN, WE NEED TO PRESENT -- WE WOULD LIKE TO PRESENT TO THE ICOC OUR RECOMMENDATIONS FOR FINAL GUIDELINES. THAT MEANS BEFORE THEN, AFTER THESE PUBLIC INPUT MEETINGS THAT WE'RE GOING TO HAVE, WE'LL PROBABLY NEED TO HAVE, THE PROPOSAL IS, TWO MEETINGS, ONE AT THE END OF SEPTEMBER AND ONE TOWARDS THE END OF OCTOBER. THEY MAY WELL NEED TO BE TWO-DAY MEETINGS TO SORT OF MAKE SURE WE GET THIS JOB DONE WITH APPROPRIATE DELIBERATIONS SO THAT AS WE LOOK AT OUR TIME LINE IN TERMS OF THE DELIVERABLE BY NOVEMBER 2D, THERE'S GOING TO BE A LOT OF SUBCOMMITTEE WORK THAT NEEDS TO BE DONE, AND THEN SOME DELIBERATION AS THE COMMITTEE AS A WHOLE.

SO I GUESS, FIRST, I'D JUST SORT OF LIKE TO ALERT YOU TO WHAT WE'LL BE ASKING IN TERMS OF YOUR SCHEDULES. I KNOW SEPTEMBER AND OCTOBER ARE BUSY FOR ALL OF US. AND JUST SORT OF SAY THAT IT MAY WELL BE

NECESSARY TO SCHEDULE MORE THAN THE ONE-DAY MEETINGS THAT WE'VE HAD SO FAR, WHICH I THINK WERE FINE FOR GETTING THESE INTERIM GUIDELINES OUT, BUT THE FINAL GUIDELINES ARE GOING TO BE -- THAT'S WHERE THE REAL SUBSTANTIVE TOUGH ISSUES ARE GOING TO BE. NO ONE IS SMILING ABOUT THE EXTRA DAYS.

CO-CHAIR LANSING: WHEN YOU LOOK AT THE INCREDIBLY INTENSE AND HARD WORK THAT WENT INTO TODAY, AND YOU'RE TALKING ABOUT FINAL GUIDELINES THAT HAVE TO BE DONE BY NOVEMBER, NOT FINAL GUIDELINES, BUT RECOMMENDED GUIDELINES BY NOVEMBER 2D, YOU'RE TALKING ABOUT EIGHT WEEKS.

MR. SHESTACK: WHAT'S THE BLACK MAGIC ABOUT NOVEMBER 2D?

CO-CHAIR LANSING: WE HAVE -- BOB CAN EXPLAIN IT BETTER THAN I CAN, BUT WE HAVE TO GET OUR GUIDELINES DONE WITHIN 270 DAYS, AND WE HAVE TO ALLOW 45 DAYS FOR PUBLIC COMMENT, AND THAT'S WHEN IT ALL STARTS.

MR. KLEIN: NOVEMBER 2D DOES NOT MEAN THAT THOSE ARE FINAL. IT'S THE FINAL RECOMMENDATION, AND THEN YOU GO THROUGH THE PUBLIC -- THE ADMINISTRATIVE PROCEDURES ACT PROCESS WITH THE PUBLIC COMMENT PERIOD.

IF YOU LOOK AT THE CHART, AND THE OAL REVIEW PERIODS, AND THEN 30 DAYS FOR IT TO BECOME LAW. SO THERE WILL BE PUBLIC COMMENTS THAT MAY BE VERY MATERIAL

AND COME FROM SCIENTIFIC AND PATIENT GROUPS AND OTHERS AND THE GENERAL PUBLIC THAT WILL BE BROUGHT INTO THAT PROCESS DURING THE PUBLIC COMMENT PERIOD. SO IN NO WAY WILL THEY BE FINAL ON NOVEMBER 2D, BUT THEY WILL BE FINAL RECOMMENDATIONS SO THEY CAN GO THROUGH THE REST OF THE PROCESS.

DR. EGGAN: DO WE EXPECT THEN NEW GREEN DOTS ARE GOING TO APPEAR AT THE TAIL ENDS OF EACH ONE OF THOSE YELLOW BOXES TOO PROBABLY?

DR. HALL: YES.

CO-CHAIR LO: OUR JOB IS NOT DONE.

DR. EGGAN: THOSE ARE TIMES TO HOLD SPACE OUT ON OUR CALENDAR. THOSE ARE LIKELY BENCHMARKS.

CO-CHAIR LO: ANY OTHER QUESTIONS ABOUT --

MS. CHARO: ONCE THIS NOVEMBER 2D DRAFT IS DELIVERED FOR PUBLIC COMMENT, HOW MUCH ALTERATION OF THAT IS PERMITTED WHILE THE PUBLIC COMMENT IS GOING ON? IN OTHER WORDS, CAN WE BE WORKING IN PARALLEL WITH THE PUBLIC COMMENT TO CONTINUE TO REFINE THIS, OR ARE WE SOMEHOW RATHER STUCK AS OF THE NOVEMBER 2D VERSION, JUST TO GIVE US A SENSE OF EXACTLY HOW MUCH OF A TRUE DROP-DEAD DEADLINE NOVEMBER 2D IS.

MR. HARRISON: THE SHORT ANSWER IS THAT IF YOU MAKE TECHNICAL CHANGES, IT DOES NOT INTERFERE WITH THE APA CLOCK. IF YOU MAKE SUBSTANTIVE CHANGES, WHAT

THAT TRIGGERS IS AN ADDITIONAL 45-DAY PUBLIC COMMENT PERIOD. AND CONSISTENT WITH THAT 270-DAY PERIOD WE HAVE TO ADOPT FINAL REGULATIONS, SUBSTANTIVE CHANGES MAY PRESENT PROBLEMS IN MEETING THE ULTIMATE GOAL OF HAVING FINAL REGULATIONS IN PLACE BY THE FIRST WEEK OF JUNE.

MR. KLEIN: JAMES, LET ME ASK THIS QUESTION. DOES IT RESTART THE CLOCK FOR ALL THE ENTIRE TEXT OR JUST THE PORTION CHANGED?

MR. HARRISON: WELL, THEY'RE SUBMITTED AS A PACKAGE. I GUESS CONCEIVABLY IT'S POSSIBLE THAT A PARTICULAR SECTION OF THESE REGULATIONS COULD BE CARVED OUT, BUT --

MR. KLEIN: MY QUESTION TO YOU IS CAN WE, IN FACT, SUBMIT IT BY SECTION ALL AT ONCE UNDER VARIOUS SECTION NUMBERS; THEREFORE, IF WE MODIFY A SECTION, THAT SECTION CLOCK RESTARTS, BUT NOT THE CLOCK ON THE BALANCE?

MR. HARRISON: WE CAN WORK THROUGH THE OFFICE OF ADMINISTRATIVE LAW TO DETERMINE WHETHER WE CAN PRESENT THEM IN THAT MANNER.

MR. KLEIN: A MODULAR APPROACH COULD BE HELPFUL HERE BECAUSE THEN POTENTIALLY IF WE FIND A MAJOR SUBSTANTIVE ISSUE THAT COMES UP WITH ONE SECTION, WE COULD TAKE TIME TO DEAL WITH THAT SECTION WHILE

EVERYTHING ELSE MOVES FORWARD, AND SUBSTANTIVELY WE WILL HAVE PERFORMED WITHIN 270 DAYS, AND WE'LL HAVE A TRAILING SECTION. IF WE COULD INVESTIGATE THAT.

MR. HARRISON: WE'LL INVESTIGATE THAT.

CO-CHAIR LO: ANY OTHER QUESTIONS ABOUT THE PROCEDURES? HEARING NONE, I WILL BE DELIGHTED TO ENTERTAIN A MOTION FOR ADJOURNMENT.

DR. KORDOWER: SECOND. THANK YOU VERY MUCH.

MR. KLEIN: MR. CHAIRMAN, I'D ALSO LIKE TO, IN ADDITION TO THE STAFF WHO HAS BEEN THANKED FOR THEIR TREMENDOUS EFFORT, JAMES HARRISON DID A TREMENDOUS AMOUNT OF WORK ON THE BYLAWS.

(APPLAUSE.)

(THE MEETING WAS THEN CONCLUDED AT 05:46 P.M.)

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE PROCEEDINGS BEFORE THE SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS WORKING GROUP OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATON INDICATED BELOW

OMNI SHOREHAM HOTEL
251 S. OLIVE STREET
LOS ANGELES, CALIFORNIA
ON
AUGUST 30, 2005

WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

_____
BETH C. DRAIN, CSR 7152