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: THE LUXE HOTEL
11461 SUNSET BOULEVARD
LOS ANGELES, CALIFORNIA

DATE: MONDAY, JANUARY 30, 2006
TUESDAY, JANUARY 31, 2006

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

BRS FILE NO.: 74002 & 74003

I N D E X

ITEM	DESCRIPTION	PAGE NO.
	CALL TO ORDER AND OPENING REMARKS	3
	ROLL CALL	10, 296
	APPROVAL OF MINUTES FROM OCTOBER 24, 2006 DECEMBER 1, 2005	11
	CIRM STAFF PROGRESS REPORT:	
	GEOFF LOMAX	12
	ZACH HALL	20
	JEFF SHEEHY	23
	REVIEW OF DRAFT CIRM REGULATIONS:	
	SECTION 100000	49
	SECTION 100001	56
	SECTION 100002	80
	SECTION 100003	109
	SECTION 100004	123
	SECTIOB 100005	378
	SECTION 100006	424
	SECTION 100007	141, 352
	SECTION 100008	252
	SECTION 100009	349
	SECTION 100010	361
	SECTION 100011	377
	CONSIDERATION OF THE DRAFT CIRM REGULATONS FOR SUBMISSION TO THE ICOC	424
	ADJOURNMENT	287, 431

LOS ANGELES, CALIFORNIA; TUESDAY, JANUARY 31, 2006

CO-CHAIR LO: CAN WE CONVENE. WE ARE NOT QUITE AT A QUORUM, BUT I THOUGHT I'D LIKE TO TRY AND GET STARTED AND DO SOME INFORMATIONAL THINGS FIRST.

FIRST, I WANT TO SAY GOOD MORNING AND THANK EVERYBODY FOR WHAT I THINK WAS A VERY PRODUCTIVE DAY YESTERDAY. I THINK WE COVERED A LOT OF ISSUES. I THINK WE HEARD A LOT OF OPINIONS, GOT A LOT OF GOOD FEEDBACK FROM PUBLIC MEMBERS OF THE AUDIENCE. AND I THOUGHT WE REACHED SOME CLOSURE ON SOME IMPORTANT ISSUES.

I JUST WANT TO MAKE SURE THAT -- AS I WENT OVER MY NOTES LAST NIGHT, THERE'S A COUPLE OF THINGS I WASN'T QUITE SURE OF, AND I WANT TO MAKE SURE WE HAVE A CLEAR UNDERSTANDING OF WHAT WE DETERMINED YESTERDAY.

THE FIRST HAD TO DO WITH COMPLICATIONS OF OOCYTE RETRIEVAL AND OUR DESIRE -- AND I THOUGHT OUR DESIRE WAS TO HAVE INSTITUTIONS ENSURE THAT WOMEN WHO SUFFER IMMEDIATE AND SHORT-TERM COMPLICATIONS OF OOCYTE RETRIEVAL DIDN'T HAVE TO PAY FOR THEIR TREATMENT, AND IT WASN'T JUST AN ACCESS TO CARE ISSUE. THEY CAN ALWAYS SAY GO THE EMERGENCY ROOM AND SEE DOCTOR SO-AND-SO. IT WAS REALLY THAT WE DIDN'T WANT THE WOMAN TO HAVE TO PAY FOR THAT TREATMENT, AND WE SAID THE

INSTITUTIONS WERE THE PROPER PEOPLE TO SORT OF PROVIDE THAT FINANCIAL ASSURANCE, PARTICULARLY FOR WOMEN WHO DIDN'T HAVE INSURANCE. I JUST WANT TO MAKE SURE THAT WE'RE FOCUSING ON THE COST OF CARE, NOT JUST ACCESS.

SO DID I UNDERSTAND THAT?

CO-CHAIR LANSING: BUT IT WAS JUST IMMEDIATE AND SPECIFIC TO AVOID ANY MISREPRESENTATIONS.

CO-CHAIR LO: I THINK AS OUR CLINICIANS HAVE SAID, THERE ARE A NUMBER OF COMPLICATIONS THAT ARE WELL DESCRIBED, CLEARLY ARE RELATED TO THE RETRIEVAL PROCESS, INFECTION, BLEEDING, HYPEROVULATION SYNDROME, THE RISKS OF THE ANESTHETIC. SO THERE'S NO QUESTION IF ONE OF THOSE DEVELOP, IT'S GOT TO BE RELATED TO THE OOCYTE RETRIEVAL. THE FURTHER OUT YOU GO AND THE MORE POSSIBILITIES FOR OTHER THINGS CAUSING AN UNTOWARD MEDICAL CONDITION, THE MORE UNCERTAINTY THERE IS IT WAS OOCYTE RETRIEVAL OR SOME OTHER FACTOR.

SECOND, WITH REGARD TO WHAT I WOULD CALL COMPLIANCE, WE HEARD SOME CONCERNS THAT WE NEEDED TO MAKE SURE THAT OUR COMPLIANCE WAS STRICT. AND I THINK THIS IS ONE OF THOSE SITUATIONS WHERE THE GRANTS WORKING GROUP IS PUTTING TOGETHER A VERY THOROUGH AND RIGOROUS SET OF REQUIREMENTS AS A CONDITION OF FUNDING THAT WOULD INCLUDE THE RIGHT TO AUDIT, INSPECT, MONITOR, AND SO FORTH. AND I DON'T THINK WE SHOULD TRY

AND WRITE THOSE SPECIFICS, BUT WE SHOULD MAYBE JUST INDICATE, SO THERE'S NO MISUNDERSTANDING, THAT WE SUPPORT STRICT MEASURES TO MAKE SURE PEOPLE DO WHAT WE REQUIRE THEM TO DO, AND THAT INCLUDES AUDIT, INSPECTION, MONITORING, AND WE EXPECT THEM TO COMPLY FULLY WITH WHAT THE GRANTS WORKING GROUP REQUIRES.

WE KNOW THAT THAT IS TOO VAGUE TO PASS THE OFFICE OF ADMINISTRATIVE LAW. I'M JUST CONCERNED IF WE DON'T PUT SOMETHING, PEOPLE WILL SAY, WELL, YOU'RE NOT REALLY SERIOUS ABOUT COMPLIANCE. IS THAT SOMETHING THAT IS SORT OF IN THE SPIRIT OF WHAT WE SAID? I THINK THERE WAS ONE, I THOUGHT, VERY HELPFUL PUBLIC COMMENT YESTERDAY THAT SAID WE REALLY HAVE TO HAVE TEETH IN THIS, AND I THINK THAT'S TRUE. WE DON'T WANT THE PERCEPTION.

CO-CHAIR LANSING: HOW ABOUT SOMETHING THAT SAYS THAT THE GRANTS -- THE OFFICIAL GRANTS GOVERNANCE COMMITTEE, WE BELIEVE IN STRICT COMPLIANCE, AND ALL THE RULES OF THE GRANTS GOVERNANCE COMMITTEE, I KNOW IT'S REDUNDANT AND I KNOW IT'S UNDERSTOOD, BUT SOMETHING LIKE ALL THE RULES OF THE GRANT GOVERNANCE COMMITTEE APPLY OR SOMETHING LIKE THAT. JUST MAKE AN ACKNOWLEDGEMENT THAT THEY HAVE RULES, THAT WE ADHERE TO THOSE RULES AND AGREE WITH THOSE RULES. I KNOW IT'S REDUNDANT.

CO-CHAIR LO: AND THEN FINALLY ON PAGE 6, NO. 4 AT THE TOP, THIS IS THE SITUATION OF OOCYTE RETRIEVAL FOR RESEARCH PURPOSES. AND I THINK OUR GOAL HERE IS TO SEPARATE INSOFAR AS POSSIBLE TO MAKE SURE THAT DECISIONS MADE FOR THE OOCYTE DONOR REGARDING MANIPULATION OF HORMONAL INTERVENTIONS AND SO FORTH, THOSE DECISIONS ARE MADE WITH THE BEST INTEREST, THE HEALTH, SAFETY, AND WELL-BEING OF THE DONOR FOREMOST, AND THAT OTHER CONSIDERATIONS, THE NUMBER OF OOCYTES RETRIEVED, SORT OF THE HOPES FOR FAME AND SCIENTIFIC PROGRESS ON THE PART OF THE RESEARCH TEAM TAKES SECOND PLACE TO THE WELL-BEING OF THE DONOR.

NOW, I'M NOT QUITE SURE WHAT LANGUAGE. I THINK THAT'S THE SENTIMENT. I'M NOT SURE QUITE SURE WHAT THE LANGUAGE IS. ALTA, YOU HAD SOME IDEAS.

MS. CHARO: WE WERE TALKING ABOUT FOCUSING ON THE GOALS AND TALKING ABOUT THE DESIRE TO ENSURE THAT THE RECRUITMENT, THE COUNSELING FOR THE INFORMED CONSENT, AND THE ACTUAL PERFORMANCE OF THE PROCEDURE IN NO WAY WOULD BE INFLUENCED BY FINANCIAL OR OTHER GAIN. OTHER GAIN MEANING ACADEMIC YA-YAS, BUT WE HAVEN'T FIGURED OUT EXACTLY HOW TO PHRASE IT, BUT WE THOUGHT THOSE ARE THE KEY MOMENTS THAT WE WANTED TO HAVE THE DONOR'S INTERESTS PLACED FIRST IN THE PROFESSIONAL'S MIND AND NOT THE NEEDS OF THE RESEARCH.

CO-CHAIR LO: WHAT ALTA SUGGESTED, WHICH I THINK IS USEFUL, IS THAT WE FOCUS ON THE GOALS OF WHAT WE'RE TRYING TO DO AND THE SORT OF PERFORMANCE STANDARD OF WHAT WE WANT THE RESEARCHERS TO DO AND NOT BE TOO PRESCRIPTIVE AS TO SORT OF HOW THAT'S ENFORCED. NOW, WE NEED TO BE SPECIFIC ENOUGH SO THAT THE PEOPLE WHO HAVE TO LIVE WITH THESE REGULATIONS KNOW WHAT THEY HAVE TO DO. BUT I THINK IF WE'RE CLEAR ON KIND OF THIS IDEA OF SORT OF KEEPING THE INTERESTS AND WELL-BEING WITH DONORS FOREMOST, THAT'S PROBABLY THE MOST IMPORTANT THING. AND ONE MEANS TO THAT IS SEPARATING, HAVING DIFFERENT PEOPLE -- HAVING THE PERSON DOING THE OOCYTE RETRIEVAL NOT BE A PRINCIPAL INVESTIGATOR OF A GRANT AND PROBABLY NOT EVEN BE A CO-AUTHOR, JUST BE SORT OF THE PERSON WHO PROCURES THE MATERIALS THAT THE RESEARCHERS USE. I DON'T KNOW HOW PRESCRIPTIVE WE WANT TO BE ABOUT HOW THAT SEPARATION OR THE POTENTIAL CONFLICTS OF INTEREST COMES ABOUT, HOW WE WANT THAT ENFORCED.

ALTA, WHAT ARE YOUR THOUGHTS ON HOW WE SHOULD DRAFT THIS OR HOW WE SHOULD MODIFY NO. 4? NO. 4 IS WRITTEN AS IT SHALL NOT BE THE SAME PERSON EXCEPT THERE'S AN EXCEPTION, AND THAT MAY BE TOO SPECIFIC AND NOT REALLY GET TO THE POINT.

MS. CHARO: FOR ONE THING, IT MAY NEED TO

COME OUT OF THIS SECTION. THIS SECTION TALKS ABOUT ACCEPTABLE RESEARCH MATERIALS, WHAT MAKES A RESEARCH MATERIAL USABLE BY A CIRM-FUNDED RESEARCHER. AND I THINK WE'RE GETTING AWAY FROM A FOCUS ON THE GAMETES, WHICH MAKES SENSE. WHAT ARE THE LINES THAT ARE ACCEPTABLE, WHETHER THEY'RE LINES THAT COME FROM GAMETES THAT HAVE THESE CHARACTERISTICS, ETC. I THINK WE MAY JUST WANT TO PULL THIS OUT SEPARATELY AND MAYBE PUT IT INTO THE SECTION THAT FOCUSES ON INFORMED CONSENT AND THINK OF THAT SECTION AS RECRUITMENT AND INFORMED CONSENT WITH GUIDELINES FOR HOW WE RECRUIT.

AND THEN ONCE RECRUITED, HOW WE INFORM. WHAT'S THE CONTENT OF THE INFORMATION? AND REPHRASE IT IN TERMS OF THE RECRUITMENT PROCESS, AS WELL AS THE CONSENT PROCESS BY SAYING THAT THE PROFESSIONAL MOST DIRECTLY INTERACTING WITH POTENTIAL DONORS SHOULD BE FREE OF ALL FINANCIAL AND OTHER CONFLICTS OF INTEREST THAT MIGHT INFLUENCE THE PROFESSIONAL'S JUDGMENT. I'M NOT SURE. I'M TRYING TO DO THIS ON THE FLY, AND IT'S NOT QUITE WORKING.

CO-CHAIR LO: SHALL NOT COMPROMISE THE PROFESSIONAL'S COMMITMENT TO THE WELL-BEING AND INTEREST OF THE DONOR.

MS. CHARO: OH, I LIKE THAT. THAT'S NICE.

CO-CHAIR LO: SHALL NOT COMPROMISE THE

PROFESSIONAL'S COMMITMENT TO THE WELL-BEING OF THE DONOR.

DR. TAYLOR: I ACTUALLY THINK THAT MOVING IT FROM THIS SECTION WHERE IT'S KIND OF COMMODIFIED IN SOME WAYS AS GAMETES TO THE INFORMED CONSENT IS REALLY THE SPIRIT OF WHAT WE'RE TRYING TO ACHIEVE. SO I THINK THAT'S A WONDERFUL SUGGESTION.

CO-CHAIR LO: ACTUALLY DOESN'T IT GO BEYOND CONSENT TO THE ACTUAL OOCYTE RETRIEVAL PROCESS, THAT WE WANT THOSE DECISIONS ABOUT TIMING AND DOSAGE TO BE MADE WITH THE INTEREST OF THE DONOR?

MS. CHARO: SO YOU'RE SUGGESTING IN A SENSE IT MIGHT NEED TO BE PULLED OUT COMPLETELY SEPARATELY AS JUST BASICALLY THE INTERACTION BETWEEN THE PROFESSIONAL AND THE DONOR.

CO-CHAIR LO: ACTUALLY I REALIZE THAT WE DIDN'T OFFICIALLY CALL THE ROLL. KATE, SHOULD WE DO THAT?

MS. SHREVE: ALTA CHARO.

MS. CHARO: HERE.

MS. SHREVE: KEVIN EGGAN.

DR. EGGAN: HERE.

MS. SHREVE: MARCY FEIT.

MS. FEIT: HERE.

MS. SHREVE: ANN KIESSLING.

DR. KIESSLING: HERE.

MS. SHREVE: PATRICIA KING. ROBERT KLEIN. JEFFREY KORDOWER. SHERRY LANSING.

CO-CHAIR LANSING: HERE.

MS. SHREVE: BERNARD LO.

CO-CHAIR LO: HERE.

MS. SHREVE: KENNETH OLDEN. TED PETERS. 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: JOHN WAGNER.

DR. WAGNER: HERE.

MS. SHREVE: JAMES WILLERSON.

DR. WILLERSON: HERE.

CO-CHAIR LO: LET US SORT OF THEN TRY AND CONTINUE OUR MERRY MARCH THROUGH THE DRAFT REGULATIONS. WE HAD NOT QUITE FINISHED, AS I REMEMBER, WITH THE INFORMED CONSENT SECTION. AND WE WERE, AS I RECALL, ON PAGE 9 AT THE VERY TOP OF THE PAGE. WE FINISHED WITH THE -- WE HAD A GOOD DISCUSSION OF PAGE 8, AND THEN I

THINK OUR NEXT STEP WOULD BE TO GO TO PAGE 9 (H). RESEARCHERS OBTAINING CONSENT FOR GAMETE DONATION FOR DERIVATION OF HSC LINES NEED TO TAKE STEPS TO ENHANCE THE INFORMED CONSENT PROCESS. MEASURES TO DO SO SHALL INCLUDE, BUT ARE NOT LIMITED TO, AN ADEQUATE PERIOD OF TIME TO DELIBERATE ABOUT THE DECISION TO DONATE. AFTER SUCH DELIBERATION, POTENTIAL DONORS SHALL INITIATE RECONTACT WITH THE RESEARCHERS TO CONTINUE THE CONSENT AND DONATION PROCESS.

THESE WERE TAKEN FROM ANN KIESSLING'S VERY HELPFUL PRESENTATION AT ONE OF OUR EARLIEST MEETINGS WHERE SHE OUTLINED WHAT HER GROUP DOES IN THE OOCYTE RETRIEVAL PROCESS. AND THIS SORT OF TIME FOR DELIBERATION AND HAVING THE DONOR REINITIATE THE CONTACT, WE THOUGHT, WERE POTENTIAL WAYS TO ENHANCE THE AUTONOMY OF THE DONOR AND TO SORT OF CUT DOWN ANY UNDUE INFLUENCE.

ANN, DO YOU WANT TO SAY ANYTHING? THIS IS SOMETHING YOUR GROUP HAS HAD A LOT OF EXPERIENCE WITH.

DR. KIESSLING: WELL, WE'VE ACTUALLY FOUND THIS TO BE VERY HELPFUL BECAUSE THE DONORS AT THEIR INITIAL INTAKE, WHERE YOU SPEND ABOUT AN HOUR AND A HALF TALKING ABOUT THE RISKS AND THE SCIENCE, IT'S EMPHASIZED TO THEM THAT THEY HAVE TO KEEP THE PROCESS GOING. THEY'RE PROVIDED A LIST OF STEPS THEY HAVE TO

GO THROUGH, AND THEY MUST KEEP THOSE. AFTER THEY COMPLETE STEP 2, THEY MUST THEN REINITIATE STEP 3. NO ONE FROM THE PROGRAM CONTACTS THEM. THEY HAVE TO KEEP IT GOING THEMSELVES.

AND THIS WE HAVE FOUND TO BE NOT ONLY REALLY HELPFUL TO MAKE SURE THAT THIS IS SOMETHING THEY'RE REALLY GOING TO DO, BUT THAT IT ALSO PREDICTS WHO CAN HANDLE THE TWO WEEKS RATHER INTENSE CARE THAT THEY NEED DURING THE EGG COLLECTION PROCESS ITSELF. SO NOT ONLY DOES IT -- AND THEY FREQUENTLY CALL UP WITH A QUESTION THAT THEY THOUGHT OF BEFORE THEY INITIATE THE NEXT STEP. SO IT SEEMS TO BE VERY HELPFUL.

CO-CHAIR LO: THOUGHTS, COMMENTS? ALTA.

MS. CHARO: THE SUBSTANCE OF IT SOUNDS EXCELLENT. I'M HOPING THAT THERE'LL BE A COMFORT LEVEL AROUND THE TABLE WITH SOME SLIGHT REDRAFTING BECAUSE IN TERMS OF HOW YOU WOULD WRITE A REGULATION, THE FIRST PART ABOUT HOW THEY NEED TO TAKE STEPS TO ENHANCE MIGHT BE A LITTLE VAGUE FROM A REGULATORY STANDPOINT. AND THEN AT THE END, THAT POTENTIAL DONORS SHALL INITIATE CONTACT, WE CAN'T ORDER DONORS TO DO ANYTHING IN A REGULATION. WE HAVE TO, RATHER, PHRASE IT MORE LIKE INVESTIGATORS MAY NOT INITIATE FURTHER CONTACT UNTIL DONORS HAVE FIRST GOTTEN IN TOUCH WITH THEM. IT'S MORE A MATTER OF HOW TO RECAST IT.

CO-CHAIR LO: SHALL HAS TO GO IN THE RIGHT PLACE FOR THE RIGHT PERSON.

MS. CHARO: SO THE QUESTION WOULD BE WHETHER THERE'S ANY DISCOMFORT WITH JUST KIND OF REPHRASING, BUT NOT CHANGING THE SUBSTANTIVE GOAL OF THE SECTION.

MR. TOCHER: IF I COULD ALSO ADD ONE MORE POINT. THE SECOND SENTENCE IS A BIT TOO SUBJECTIVE IN THE TERM "ADEQUATE PERIOD OF TIME." THAT WOULD BE SOMETHING THAT WE WOULD WANT TO SPELL OUT MORE SPECIFICALLY. WHETHER THAT'S 14 DAYS OR SEVEN, WHATEVER THE COMMON PRACTICE IS, GO AHEAD AND PUT THAT IN. THAT WAY PEOPLE WILL KNOW WHEN THEY'RE IN COMPLIANCE AND WHEN THEY'RE NOT.

CO-CHAIR LO: ANN, WHAT WOULD YOU SUGGEST FOR A MINIMUM PERIOD?

DR. KIESSLING: THE PERIOD OF TIME THAT YOU WANT THE MOST REFLECTION IS THE TIME THAT THEY HAVE TO DIGEST THE CONSENT FORM. SO THEY'RE GIVEN THE CONSENT FORM, THEY'RE TOLD TO -- IT'S BEEN GONE THROUGH WITH THEM. IT'S 12 OR 13 PAGES LONG. THEY'RE ASKED TO SHARE IT WITH SOMEONE IN THEIR WORLD, GENERALLY THEIR SPOUSE, BUT FREQUENTLY, AND SOMEONE ELSE. AND THEN THAT'S THE TIME THAT YOU REALLY WANT THEM TO REFLECT AND ASK QUESTIONS.

AFTER THAT, ONCE THEY HAVE SIGNED THE CONSENT

FORM AND RESUBMITTED IT, THE TIME LAG IS KIND OF BUILT INTO THE PROCESS. IT TAKES AWHILE TO GET THE MMPI SCORED. ONCE THAT'S SCORED, IT TAKES AWHILE TO GET AN APPOINTMENT WITH THE PSYCHOLOGIST. SO EVERYTHING ELSE IS SORT OF BUILT IN. IT'S THAT INITIAL TIME THAT YOU WANT HER TO NOT JUST GO HOME AND SIGN THE CONSENT FORM THAT DAY. TWO WEEKS, THREE WEEKS FOR DELIBERATION OF THE CONSENT FORM ITSELF, THAT WOULD BE, I THINK, A REASONABLE TIME. YOU CAN'T MAKE IT TWO OR THREE MONTHS. SOME OF THESE PEOPLE ARE TRYING TO DO THIS PROCESS DURING SUMMER VACATION BECAUSE THEY'RE TEACHERS OR SOME OTHER COMMITMENT IN THEIR LIVES THAT ARE COMING UP IN THE NEXT SIX MONTHS.

SO THAT'S THE TIME THAT YOU REALLY WANT TO BUILD IN A TIME FOR REFLECTION IS DURING THE TIME THEY'RE DIGESTING THE CONSENT FORM.

CO-CHAIR LO: TWO WEEKS WOULD BE A MINIMUM.

DR. KIESSLING: YEAH. I DON'T THINK YOU WANT TO MAKE IT GREATER THAN A MONTH. THAT'S GOING TO REALLY CRAMP PEOPLE'S SCHEDULES.

CO-CHAIR LO: I THINK WHAT YOU'RE SAYING IS AT A MINIMUM AT LEAST --

MR. TOCHER: NOT LESS THAN 14 DAYS.

MR. SHEEHY: WHERE DOES THE COMPREHENSION ASSESSMENT TAKE PLACE, BEFORE OR AFTER THIS? I THINK

WE SHOULD --

CO-CHAIR LO: IT SHOULD TAKE PLACE BEFORE THEY SIGN THE CONSENT FORM, DECIDE THAT THEY WANT TO DONATE.

MR. SHEEHY: DOES IT TAKE PLACE BEFORE -- IN OTHER WORDS, WHEN ARE YOU GOING TO DO THAT BECAUSE THAT CAN BE CRITICAL? ARE YOU GOING TO DO IT BEFORE YOU HAVE THE DELIBERATIVE PERIOD OR AFTER THE DELIBERATIVE PERIOD?

CO-CHAIR LO: WHAT DO YOU ALL THINK?

MR. SHEEHY: I'M JUST WONDERING -- BECAUSE THE PRIOR ELEMENT IN THIS REQUIRES SOME ASSESSMENT OF COMPREHENSION, AND WE LIST THEM ALL OUT, ALL THE THINGS THE PERSON HAS TO BE AWARE OF, I'M JUST CURIOUS AS TO WHETHER IT MAKES MORE SENSE, AND I'M PUTTING IT OUT THERE, TO HAVE THAT TAKE PLACE BEFORE YOU TAKE TWO WEEKS TO THINK ABOUT WHETHER YOU WANT TO DO THIS, OR IF THAT ASSESSMENT SHOULD TAKE PLACE WHEN YOU COME BACK AND YOU DECIDE TO SIGN. I KIND OF LEAN TOWARDS PROBABLY BEFORE BECAUSE YOU SHOULD KNOW WHAT YOU'RE DELIBERATING ABOUT, BUT I'M JUST THROWING THAT OUT THERE IN TERMS OF WHATEVER PEOPLE THINK MAKES MORE SENSE.

DR. KIESSLING: ONE OF THE PROBLEMS IN REQUIRING AN ASSESSMENT BEFORE THEY REALLY GET INTO THE

PROCESS IS THAT THEY CAN FORGET IT. THE PROCESS TAKES FOUR OR FIVE MONTHS. IT'S BEEN OUR EXPERIENCE THAT THE VERY BEST TIME TO MAKE SURE THEY KNOW EXACTLY WHAT THEY'RE DOING IS WHEN THEY'RE ALL THROUGH THE PROCESS. IT'S NOW BEEN THREE OR FOUR MONTHS SINCE ANYBODY EXPLAINED IT TO THEM AT THE BEGINNING, AND NOW YOU KNOW BEFORE THEY'RE ACTUALLY RECRUITED TO DONATE EGGS THAT THEY STILL REMEMBER AND THEY STILL KNOW IT. YOU NEED TO RETOUCH THAT BEFORE THEY ACTUALLY GO THROUGH.

THE WAY WE HAVE THIS SET UP, IT TAKES A LONG TIME TO GET THROUGH ALL THE PSYCHOLOGICAL TESTING AND THE PHYSICAL SCREENING. AND IT'S AT THE END OF THAT WHOLE PROCESS THAT I THINK YOU REALLY WANT TO MAKE SURE THEY STILL REMEMBER WHAT THEIR RISKS WERE, THEY STILL REMEMBER WHAT THE SCIENCE WAS, AND THEY STILL WANT TO DO IT.

MR. SHEEHY: I JUST MEANT JUST PURELY IN THE CONTEXT OF THIS.

DR. KIESSLING: OF UNDERSTANDING AT THE BEGINNING.

MR. SHEEHY: IN THE CONTEXT OF THIS DELIBERATION PERIOD. SHOULD IT TAKE PLACE BEFORE OR AFTER -- DO WE NEED TO STIPULATE THAT COMPREHENSION HAS BEEN ASSESSED BEFORE WE SEND THEM HOME TO THINK ABOUT WHAT THEY'RE GOING TO SIGN?

CO-CHAIR LANSING: THAT THEY UNDERSTAND BEFORE THEY GO HOME.

MR. SHEEHY: YEAH.

DR. TAYLOR: IDEALLY THE DELIBERATIVE PERIOD IS A TIME TO REFLECT AND TO FACT FIND. I GUESS I WOULD BE INCLINED TO POSTLOAD THAT RATHER THAN PRELOAD THE TEST.

CO-CHAIR LANSING: YOU CAN DO BOTH.

MR. SHEEHY: WE CAN BE SILENT ON IT.

DR. KIESSLING: ONCE YOU SET -- YOU COULD -- A TIME IN THE WAY OUR SCHEME WORKS IS A TIME TO ASSESS WHAT THEY REALLY UNDERSTAND IS WHEN THEY COME BACK TO TAKE THE MMPI. THEY DON'T SEE ANYBODY THEN. THEY JUST SCHEDULE THAT WITH THE OFFICE AND THEY GO INTO A QUIET ROOM, AND IT TAKES ABOUT TWO HOURS TO TAKE THAT TEST. AT THAT TIME -- AND WE'VE ACTUALLY BEGUN TO DRAFT SOME QUESTIONS THAT THE DONORS COULD BE ASKED AT THAT TIME. AND THEN EVERYBODY WOULD HAVE SOME IDEA THAT THEY'VE NOW SIGNED THE CONSENT FORM, THEY'VE NOW OPTED INTO THE PROGRAM, AND NOW DO THEY REALLY UNDERSTAND IT BEFORE THEY SEE THE PSYCHOLOGIST. THAT WOULD WORK.

THAT WOULD BE JUST SLIGHTLY AFTER THE TWO-WEEK DELIBERATION. THAT WOULD BE JUST AFTER THE TWO-WEEK DELIBERATION TIME AND JUST BEFORE THEY START THE PSYCHOLOGICAL ASSESSMENT.

CO-CHAIR LO: ONE QUESTION IS DO WE WANT TO SAY IN THE REGULATIONS THE TIMING OF THESE DIFFERENT STEPS OR LEAVE IT UP TO THE INVESTIGATOR AND THE IRB TO SORT IT OUT. AND THEY MAY FIGURE OUT SOMETHING THAT WORKS BETTER THAN WHAT WE CAN THINK ABOUT.

DR. KIESSLING: IT REALLY DEPENDS ON GEOGRAPHY SOMEWHAT HOW YOU DO THIS.

CO-CHAIR LANSING: I THINK YOU'RE BETTER OFF BECAUSE SOME OF IT HAS TO BE INDIVIDUALLY TAILORED. IF YOU START TO SAY IT HAS TO BE DONE IN TEN DAYS AND THEN SOMEONE -- I CAN'T COME BACK IN TEN DAYS. I HAVE TO DO THIS FOR MY JOB OR I HAVE TO TAKE A TRAIN AND I CAN'T DO IT, AND THEN THEY'RE DISQUALIFIED FROM THE PROGRAM. I THINK SO MUCH OF IT IS LAYING OUT WHAT HAS TO HAPPEN, MAKE SURE THEY UNDERSTAND IT BEFORE THE DELIBERATION PROCESS, WHICH HAS TO BE NOT OVERNIGHT, OR SOMETHING THAT SAYS, YOU KNOW, AND THEN THEY HAVE TO MAKE SURE THEY UNDERSTAND IT WHEN THEY COME BACK. IF WE START MAKING RULES THAT ARE CONCRETE, WE'RE GOING NOT TO BE ABLE TO ADAPT TO INDIVIDUAL PEOPLE'S NEEDS, WHICH I THINK WOULD BE A MISTAKE.

MR. TOCHER: THE ONLY THING I WOULD ADD, THOUGH, IS THAT IF YOU'RE GOING TO PUT REQUIREMENTS ON THEM, THEY NEED SOME GUIDANCE AT LEAST AS TO WHEN THEY KNOW THAT THEY'RE DOING IT AT THE RIGHT TIME IF WE'RE

GOING TO COME BACK AND DING IN SOME RESPECT OR FIND THAT IT'S INSUFFICIENT, WHICH IS WHAT, I THINK, MR. SHEEHY'S REMARK WAS GETTING TO IS JUST DO WE CARE AT WHAT POINT IT HAPPENS. IF WE DON'T CARE, THEN WE CAN SAY AT SOME POINT THE IRB OR THE PHYSICIAN SHALL MAKE A DETERMINATION THAT --

CO-CHAIR LO: WITH REGARD TO THE TIMING, IT'S IMPLIED IN (G) THAT THE IRB OR ESCRO HAS TO APPROVE THEIR PLAN. SO WE'RE SAYING THAT AS LONG AS YOU HAVE A PLAN IN PLACE THAT COVERS THESE ELEMENTS, AT LEAST THESE ELEMENTS, AND THE IRB APPROVES IT, WE'VE SORT OF SAID THAT'S OKAY WITH US. IT SEEMS TO ME THAT WOULD INCLUDE --

MR. SHEEHY: I DON'T HAVE A POSITION ON THIS ISSUE. IT JUST OCCURRED TO ME, SO I THOUGHT WE SHOULD AT LEAST CONSIDER IT.

CO-CHAIR LO: THAT WAS REALLY MEANT FOR SCOTT IN TERMS OF -- I THINK THAT'S PRETTY SPECIFIC FOR THAT PROVISION WHAT THEY NEED TO DO.

CO-CHAIR LANSING: IS THAT SPECIFIC ENOUGH THOUGH? I DON'T KNOW.

DR. KIESSLING: IF YOU WANT TO PUT IN A MINIMUM JUST BECAUSE YOU WANT TO MAKE SURE SOMEBODY HAS HAD TIME TO REALLY UNDERSTAND IT, I WOULD THINK THAT YOU'D ERR ON THE SIDE OF MAYBE A WEEK RATHER THAN TWO

WEEKS. EVERYTHING TAKES LONGER THAN A WEEK ANYWAY.

CO-CHAIR LO: I DEFER TO THOSE OF YOU WHO HAVE MORE EXPERIENCE WITH THIS KIND OF PROCESS. DOES A WEEK -- RIGHT NOW WE WANT TO MAKE IT THAT IT SEEMS REASONABLE AND GIVE PEOPLE LEEWAY. CERTAINLY IF THEY WANT TO DO MORE AND SAY WE ACTUALLY THINK TWO WEEKS, THAT'S FINE. THE MINIMUM SHOULD BE SOMETHING --

MS. CHARO: THERE'S A PART OF ME THAT CONTINUALLY WANTS TO DROP DETAIL AND LEAVE IT UP TO THE IRB'S AND ALSO LEAVE IT UP TO SUBSEQUENT BEST PRACTICES GUIDELINES THAT CIRM CAN BE DEVELOPING, THAT OTHER IRB'S CAN BE DEVELOPING BECAUSE REGULATIONS, ONCE WRITTEN, THEY DON'T GET CHANGED EASILY. AND WHEN THEY'RE MICROSCOPICALLY DETAILED, MORE OFTEN THAN NOT PEOPLE SUBSEQUENTLY START COMPLAINING THAT THEY'RE BEING FORCED INTO KIND OF A BUREAUCRATIC NIGHTMARE.

IS IT POSSIBLE FOR US TO STILL HAVE PUBLIC CREDIBILITY WITHOUT FEELING LIKE WE NEED TO BE A SUPRA IRB IN THE REGS THEMSELVES?

CO-CHAIR LO: WELL, WE COULD ALWAYS SAY THAT ADEQUATE TIME FOR DELIBERATION AS DETERMINED, AS APPROVED BY THE IRB OR ESCRO.

CO-CHAIR LANSING: YES. AGAIN, A WEEK MIGHT BE TOO SHORT, IT MIGHT BE TOO LONG DEPENDING ON THE PERSON. SOMEONE CAN SAY I'M COMING IN, I UNDERSTAND,

I'VE RESEARCHED IT. DEPENDS ON WHO THE PERSON IS. THIS IS SOMETHING I WANT TO DO. I NEED -- 48 HOURS, YOU COME BACK, THE PERSON CAN SAY I COMPLETELY UNDERSTAND IT. I KNOW WHAT I'M DOING. COULD BE A SCIENTIST -- DO YOU KNOW WHAT I'M SAYING? -- WHO UNDERSTANDS EVERYTHING. SEE THE COMPLIMENT, WHO UNDERSTANDS EVERYTHING.

WHAT I'M SAYING IS I DON'T KNOW WHAT IT IS. TO ME IT'S SO MUCH ABOUT THE INDIVIDUAL PERSON, AND SOMEONE MAY NEED A MONTH. SOMEONE ELSE MAY NEED A MONTH. I JUST THINK IT'S A MISTAKE. I'D LIKE TO LEAVE IT UP TO THE --

DR. PRIETO: I'D CERTAINLY BE COMFORTABLE LEAVING THAT TO THE IRB'S.

CO-CHAIR LANSING: MAYBE WE PUT AND TAILORED TO THE INDIVIDUAL PERSON.

DR. WAGNER: JUST TO ECHO THAT, I THINK THAT THERE'S DIFFERENT PROCESSES THAT COULD TAKE PLACE. SO THE WAY IT'S DONE IN BOSTON IS AN EXAMPLE THAT'S VERY GOOD, AND IT'S SOMETHING THAT PEOPLE SHOULD BE AWARE OF. ON THE OTHER HAND, JUST IN THE CONTEXT OF BONE MARROW TRANSPLANTATION WHERE 30 PERCENT WILL DIE WITHIN THE FIRST THREE MONTHS OF THE PROCEDURE, YOU CAN LOOK AT THAT AND SAY WE ONLY GIVE THEM FIVE DAYS TO MAKE A CONSENT. IT'S A VERY DIFFERENT RISK, RELATIVELY

SPEAKING.

ON THE OTHER HAND, WHAT WE DO IS THEY GET INFORMATION WELL IN ADVANCE OF EVEN ARRIVING. SO IT'S JUST THE PROCESS ITSELF MAY BE VERY DIFFERENT. SO WHEN THE TIME CLOCK BEGINS, IT'S NOT GOING TO BE AT THE MOMENT THEY COME TO YOUR CLINIC NECESSARILY. IT COULD BE WELL IN ADVANCE OF THAT WHEN THE PROCESS BEGINS. REALLY ALL WE WANT TO DO IS BE ABLE TO ASSESS THAT THEY UNDERSTAND WHAT THEY'RE DOING, HOWEVER THEY DO THAT. THE IRB'S WILL PROBABLY BE MUCH MORE STRICT THAN WHAT WE'RE EVEN SUGGESTING, BUT WE SHOULD LEAVE IT TO THEM.

CO-CHAIR LO: ACTUALLY AT THIS POINT -- ANY OTHER COMMENTS? AT THIS POINT ANY COMMENTS FROM THE PUBLIC ON THIS ISSUE ABOUT TIME TO DELIBERATE AND LEAVING IT TO THE LOCAL IRB?

MR. REED: I WOULD JUST HOPE THAT WHILE WE ESTABLISH MINIMUMS TO ALLOW, THAT IT WOULD NOT BECOME SO COMPLICATED THAT PEOPLE MIGHT LOSE INTEREST AND BACK AWAY.

CO-CHAIR LANSING: I ACTUALLY THINK THAT'S A GOOD POINT. I HAVE TO SAY THAT. IF IT'S SO OVERREGULATED, SOMEONE IS GOING TO SAY I CAME DOWN HERE FOR THE DAY. NOW I HAVE TO COME BACK EXACTLY TWO WEEKS LATER, AND I CAN'T DO IT ON THAT DAY. I JUST THINK IT'S SUCH AN INDIVIDUAL DECISION, THAT WE HAVE TO HAVE

RESPECT FOR EACH PERSON'S COMPREHENSION AND NEEDS.

CO-CHAIR LO: LET'S MOVE ON, THEN, TO 100009, FAIRNESS AND DIVERSITY IN RESEARCH. AGAIN, THIS IS A NEW INSERTION FROM THE PREVIOUS DRAFT.

DR. WAGNER: CAN I MAKE A CASE WHERE YOU DON'T COME BACK TO IT? MAYBE YOU'RE PLANNING ON COMING BACK. WHEN WE FIRST STARTED THIS SESSION THIS MORNING, WE WERE TALKING ABOUT THIS AREA OF THE CONSENT PROCESS, AND IN EACH OF THOSE IT SAYS THE RESEARCHER. I'M STILL CONCERNED ABOUT THE SEPARATION OF THE PERSON WHO IS ACTUALLY COLLECTING THE OOCYTES VERSUS THE REAL RESEARCHER.

AND WE NEED TO MAKE SURE THAT IF WE WANT THOSE TWO TO BE SEPARATE, THEN WE HAVE TO MAKE THE WORDING SUCH THAT WE CAN'T HAVE RESEARCHER IN HERE AT THE SAME TIME, OR DOES IT REALLY HAVE TO BE A SEPARATE INDIVIDUAL? I'M STILL NOT CLEAR WHETHER WE'VE FINALIZED THAT OR WHETHER IT'S STILL GOING TO BE DEBATED, OR WHETHER YOU'RE GOING TO PLAN ON COMING BACK TO THAT LATER THIS MORNING.

CO-CHAIR LO: LET'S TRY AND TACKLE THAT RIGHT NOW. IT'S AN IMPORTANT ISSUE, AND WE WANT TO MAKE SURE WE'RE CLEAR ON THAT.

SO I GUESS THERE IS A CIRM SORT OF PRINCIPAL INVESTIGATOR AND THERE'S A CIRM SORT OF RESEARCH TEAM

THAT'S GOING TO BE ACTUALLY DOING THE SCIENTIFIC WORK. AND THEN TO ME THERE'S A PHYSICIAN WHO'S ACTUALLY SUPERVISING, CARING FOR THE PATIENT -- OOCYTE DONOR DURING THE OOCYTE RETRIEVAL PROCESS. I GUESS THE CONCERN IS THAT ALL THOSE DECISIONS ABOUT TIMING AND DOSAGE AND THINGS SHOULD BE MADE WITH THE INTEREST -- THE SAFETY AND WELL-BEING OF THE DONOR FOREMOST.

NOW, ONE WAY TO DO IT IS TO SAY YOU SHOULD HAVE DIFFERENT PEOPLE DOING IT. SO YOU SHOULDN'T HAVE THE PI OF THE GRANT OR THE SECOND AUTHOR ON THE GRANT DOING THE OOCYTE RETRIEVAL. IT'S PROBABLY GOING TO BE LIKELY, ALTA POINTED OUT, THAT THE CIRM GRANT WILL PAY FOR THE OOCYTE RETRIEVAL PROCESS IN SOME SENSE THAT DOCTORS AND THE OOCYTE RETRIEVAL TEAM ARE GETTING REIMBURSED FOR IT.

NOW, IN A WAY IS THAT ANY DIFFERENT FROM BEING REIMBURSED BY AN INSURANCE COMPANY? BUT YOU WOULDN'T WANT THERE TO BE ANY PRESSURE ON THEM TO ARE WE GOING TO GET AT LEAST EIGHT OOCYTES THIS CYCLE. IT REALLY SHOULD BE WHATEVER. SO HOW CAN WE ENSURE PROTECTION OF THE OOCYTE DONOR, AND IS THERE A WAY OF SAYING THE PRINCIPAL INVESTIGATOR SHOULDN'T BE DOING THAT? I GUESS I'M STRUGGLING WITH SORT OF HOW TO OPERATIONALIZE THE CONCEPT.

DR. WAGNER: FROM MY POINT OF VIEW, FIRST

OFF, I WASN'T HERE WHEN ANN PREVIOUSLY WALKED THROUGH THE PROCESS. AND SO I MAY BE NOT UNDERSTANDING THE FULL PROCESS SINCE I'M NOT REALLY INVOLVED IN OOCYTE COLLECTIONS IN ANY WAY, SHAPE, OR FORM. BUT IN MY WAY OF THINKING, YOU KNOW, OBVIOUSLY THERE HAS TO BE SOME INCENTIVE FOR THE PHYSICIAN TAKING CARE OF THE WOMAN FOR DOING THIS. MAYBE IT'S PERSONAL. MAYBE IT'S FINANCIAL. MAYBE IT'S SOMETHING, BUT I CAN'T IMAGINE THAT JUST FOR NO REASON AT ALL THEY WILL SPEND THEIR TIME COLLECTING OOCYTES FOR AN INVESTIGATOR THEY KNOW NOTHING ABOUT OR FOR A RESEARCH PROJECT THEY KNOW NOTHING ABOUT.

SO I GUESS WE HAVE TO HAVE SOME GUIDELINES AS TO WHAT IS ACCEPTABLE, WHAT IS NOT ACCEPTABLE, WHAT'S THE POTENTIAL CONFLICT BECAUSE IF I WERE THE -- EVEN IF I WERE ON THE SCRO COMMITTEE, I WOULD NEED SOME GUIDELINES TO FIGURE OUT WHEN YOU HAVE CROSSED A BOUNDARY BEYOND WHICH IT'S NO LONGER ACCEPTABLE BECAUSE ALSO WHAT'S AN INVESTIGATOR. BECAUSE, FOR EXAMPLE, IF I WERE DOING WORK ON AN EMBRYO, AN ES CELL LINE, AND I MIGHT INCLUDE SOMEONE FROM THE IVF TEAM WHO HAS SPENT TIME WORKING ON IT, I COULD INCLUDE SOMEONE WHO IS DOING THE GENETIC TESTING OR WHATEVER IT WAS.

ARE WE PROHIBITING THAT FROM OCCURRING BECAUSE YOU DID MAKE A COMMENT EARLIER THIS MORNING

ABOUT MAYBE THEY SHOULDN'T BE ON THE PAPER OR WHATEVER IT IS. HOW PRESCRIPTIVE DO WE WANT TO BE BECAUSE IT COULD BE VERY LIMITING POTENTIALLY.

DR. KIESSLING: CAN I SPEAK TO THAT A LITTLE BIT? OUR PROGRAM HAS TWO -- WE HAVE A COUPLE OF MEDICAL TEAMS. AND THE CHARGE TO THOSE MEDICAL TEAMS IS ZERO TOLERANCE FOR RISK TO THE DONOR, PERIOD, BECAUSE THIS IS A RESEARCH PROJECT. SO UNDER CIRCUMSTANCES WHERE, FOR INSTANCE, IF SHE'S GOT A COLD, THEY MIGHT GO AHEAD AND GIVE HER ANESTHESIA IF SHE NEEDED HER EGGS COLLECTED OR HER TEETH PULLED OR SOMETHING. YOU DON'T DO THAT FOR A RESEARCH PROJECT. THAT'S ACTUALLY NOT BEEN -- THE TEAM SORT OF UNDERSTANDS THAT THEIR CHARGE -- THESE ARE ALL GOOD PHYSICIANS. THEIR CHARGE IS THE CARE OF THIS DONOR. THEY'RE INTERESTED IN THE RESEARCH AND GET APPRISED OF THAT AND WOULD BE ON PUBLICATIONS. I THINK IT'S A MATTER OF THE WHOLE PROJECT COMING TO GRIPS WITH THE FACT THAT ZERO TOLERANCE FOR RISK TO THE DONOR IS WHAT'S IMPORTANT.

MS. CHARO: I'M NOT SURE I UNDERSTAND THIS EMPHASIS ON ZERO TOLERANCE. FOR ONE THING, IT SEEMS IMPOSSIBLE TO ACHIEVE BY DEFINITION. WE CAN NEVER GET DOWN TO ZERO RISK.

DR. KIESSLING: NO, NOT ZERO RISK. THERE IS

SOME RISK. THERE'S OBVIOUSLY SOME RISK. BUT UNDER CIRCUMSTANCES, THE ONE I JUST GAVE IS AN EXAMPLE OF SOMEBODY SHOWS UP FOR AN EGG COLLECTION AND THEY'VE GOT A BAD COLD. THEY'VE GOT A BAD COLD. UNDER THOSE CIRCUMSTANCES, THIS IS A RESEARCH PROJECT, HER CHANCES OF COMPLICATIONS FROM ANESTHESIA ARE ONLY SLIGHTLY HIGHER THAN IF SHE DIDN'T HAVE A COLD, BUT SHE WOULD NOT GO THROUGH IT. AND THAT WOULD BE REALLY CONSERVATIVE MEDICAL JUDGMENT.

MS. CHARO: FAIR ENOUGH. YOU WERE SAYING SOMETHING ABOUT ZERO TOLERANCE FOR SOMETHING BEFORE.

DR. KIESSLING: HOWEVER YOU WANT TO SAY IT. VERY CONSERVATIVE MEDICAL.

DR. PRIETO: ZERO TOLERANCE FOR ANY INCREASED RISK.

CO-CHAIR LO: MINIMIZE THE RISK.

MS. CHARO: IT'S NOT GOING TO BE MINIMAL BY THE FEDERAL DEFINITION.

DR. KIESSLING: THE ONLY THING YOU HAVE TO EMPHASIZE IS THAT THIS IS NOT A PATIENT. THIS IS NOT SOMEBODY WHO'S DONATING A KIDNEY OR DONATING EGGS FOR ANYBODY TO HAVE A BABY. THIS IS PURE RESEARCH, AND SHE SHOULD NOT IN ANY WAY BE PUT IN ANY KIND OF BEYOND WHAT YOU CAN POSSIBLY CONTROL KIND OF RISK.

MS. CHARO: JUST FOR THE RECORD MORE THAN

ANYTHING ELSE, IT MIGHT BE WORTH NOTING WE HAVE OTHER SITUATIONS LIKE THIS. I'M BEGINNING TO SOUND LIKE YOU, ANN. WE HAVE OTHER SITUATIONS IN THE RESEARCH CONTEXT LIKE THIS. PHASE I TRIALS OFFER NO PROSPECT OF MEDICAL BENEFIT TO THE SUBJECTS. THEY'RE ENTIRELY ABOUT LEARNING SOMETHING AND NO PROSPECT, OUTSIDE OF THE CANCER TRIALS, BUT IN THE MORE COMMON PHASE I TRIALS, PURE METABOLIC STUDIES TRIAL. AND I FIND IT INTRIGUING THAT IN THIS AREA WE ARE GETTING MORE ATTENTIVE AND CONSERVATIVE THAN WE DO IN THE MORE COMMON AND PROBABLY SOMEWHAT RISKIER BECAUSE THE UNCERTAINTIES ARE GREATER, SOMEWHAT RISKIER AREAS OF PHASE I TRIALS. THAT SAID, I UNDERSTAND THE REALITIES.

DR. WAGNER: IT'S AN INTERESTING ISSUE. THERE ARE THINGS LIKE INSULIN CLAMPS ON NORMAL SUBJECTS, WHICH HAVE CONSIDERABLY GREATER RISK, AND WE NEVER HAD THIS DEGREE OF CONVERSATION.

DR. PRIETO: IN 100007 IT DOES SAY REGARDING WHETHER THIS PERSON -- WHETHER THE OOCYTE COLLECTOR SHOULD BE A SEPARATE PHYSICIAN. IT SAYS THE PHYSICIAN ATTENDING TO ANY DONOR INVOLVED IN OOCYTE RETRIEVAL PROCEDURES AND THE FUNDED RESEARCHER SHALL NOT BE THE SAME PERSON UNLESS AN IRB HAS APPROVED AN EXEMPTION. WE LEFT AN OUT THERE IF THERE IS A UNIQUE SITUATION WHERE THAT CANNOT BE AVOIDED. AGAIN, WE LEAVE IT TO

THE IRB.

CO-CHAIR LO: WELL, I GUESS ONE CONCERN NOW IN HINDSIGHT IS THE FUNDED RESEARCHER MAY BE AMBIGUOUS. JOHN RAISED THE QUESTION OF WHO'S AN INVESTIGATOR.

DR. PRIETO: A PRINCIPAL RESEARCHER.

CO-CHAIR LO: ONE OF THE AUDIENCE MEMBERS YESTERDAY SAID, WELL, WHAT ARE THESE EXCEPTIONS YOU'RE THINKING ABOUT JUST TO SORT OF GET A SENSE OF WHAT A CASE MIGHT BE.

DR. PRIETO: I THINK A SITUATION IN WHICH THERE'S A VERY SMALL RESEARCH TEAM AND THE PRINCIPAL INVESTIGATOR IS ONE OF THE ONLY PEOPLE IN THAT TEAM WITH THE TECHNICAL EXPERTISE TO DO THE OOCYTE RETRIEVAL.

CO-CHAIR LO: ANN'S POINT WAS THAT YOU CONTRACT WITH ANOTHER IVF CLINIC WHO DOES A LOT OF OOCYTE RETRIEVAL.

DR. KIESSLING: ONLY PART OF OUR MEDICAL TEAM IS PART OF AN IVF CLINIC. ONLY PART OF OUR MEDICAL TEAM IS PART OF AN IVF CLINIC.

CO-CHAIR LO: FRANCISCO RAISED SUPPOSE IT'S A SMALL TEAM AND THERE'S ONLY ONE MEMBER ON THE TEAM WHO KNOWS HOW TO DO OOCYTE RETRIEVAL. THERE ARE OTHER PEOPLE PRESUMABLY IN THE COMMUNITY WHO KNOW HOW TO DO THE OOCYTE RETRIEVAL.

DR. PRIETO: ARE THERE ALWAYS GOING TO BE? I DON'T KNOW HOW WIDESPREAD THAT EXPERTISE IS.

CO-CHAIR LO: THAT WOULD BE WHERE SORT OF THE PI WERE THE ONE DOING THE OOCYTE RETRIEVAL. THAT STRIKES ME THERE IT'S VERY HARD TO SEPARATE OUT TAKING GOOD CARE OF THE PATIENT FROM, GEE, I REALLY WOULD LIKE TO HAVE OOCYTES.

DR. WAGNER: MOST PEOPLE WOULDN'T DISAGREE WITH THAT. I THINK IT'S THAT GRAY AREA, HOW FAR DOWN FROM THE PI DOWN THE PIKE OF YOUR PEOPLE INVOLVED IN THE TRIAL. AND ALSO, AGAIN, IT'S THE PERCEIVED CONFLICT OF INTEREST. I WOULD IMAGINE THAT IF I WAS GOING TO CONTRACT WITH THE IVF CENTER THAT WAS A FEW BUILDINGS AWAY, THAT THE IVF DOCTOR IS NOT LIKELY JUST TO DO IT JUST FOR THE HECK OF IT. CONSIDERING THEIR BUSY CLINIC SCHEDULE, THEY'D BE FITTING THIS IN. AND SO SINCE I DON'T KNOW HOW TO DO IT MYSELF, I WOULD HAVE TO DEVELOP SOME TYPE OF COMPENSATION OR SOMETHING, MAYBE A PART OF THE PAPER OR SOMETHING LIKE THAT. AND, AGAIN, WHAT IS ACCEPTABLE VERSUS WHAT'S NOT ACCEPTABLE.

CO-CHAIR LO: ROB, YOU'RE ON THE OTHER END OF THINGS AS AN IVF. I WOULD HAVE IMAGINED THAT YOU COMPENSATE THE IVF DOCTOR FOR TIME AND EFFORT AS YOU WOULD FOR ANYTHING ELSE. I DON'T THINK THEY SHOULD BE DOING THIS GRATIS, BUT I THINK WE BELIEVE THAT DOCTORS

CAN BE COMPENSATED FOR THEIR TIME AND EFFORT WITHOUT HAVING THEIR JUDGMENT TO THE PATIENT COMPROMISED.

MR. TOCHER: MAYBE I CAN PROPOSE SOMETHING IF I UNDERSTAND. THE PRIMARY CONCERN IS THAT THE ATTENDING PHYSICIAN ON THE OOCYTE RETRIEVAL DOESN'T HAVE A FINANCIAL INTEREST IN THE RESEARCH. THEY CAN BE COMPENSATED OBVIOUSLY FOR THEIR PROFESSIONAL WORK IN THE OOCYTE RETRIEVAL AND THE TREATMENT OF THE PATIENT. AND THAT FUNDING, AS I UNDERSTAND IT, MAY ACTUALLY COME INITIALLY FROM THE POOL OF MONEY THAT CONSTITUTES THE GRANT. AND WE DON'T CARE ABOUT THAT. WE DON'T WANT TO RULE THAT OUT. SO IT'S REALLY JUST YOU WANT TO MAKE SURE THAT THAT PHYSICIAN DOESN'T HAVE A FINANCIAL INTEREST IN THE OUTCOME OF THE RESEARCH; ISN'T THAT CORRECT, IF I'M FOLLOWING THIS, OR IS THERE AN ADDITIONAL CONCERN BEYOND THAT?

CO-CHAIR LO: I THINK THERE IS THAT, AND THEN THE QUESTION IS ARE THERE ADDITIONAL CONCERNS IF THEY'RE ACTUALLY AN INTEGRAL PART OF THE RESEARCH TEAM AND THEY HOPE TO GET FAME AND GLORY.

DR. PRIETO: IT MAY NOT JUST BE FINANCIAL INTEREST.

DR. WAGNER: MAYBE YOU CAN TELL ME THEN. WHO IS THE ONE THAT'S GOING TO ACTUALLY GET THE CONSENT, AT LEAST THAT PART OF THE CONSENT THAT DESCRIBED WHAT THE

RESEARCH IS BECAUSE THAT WOULD BE SEPARATE FROM THE DOCTOR WHO IS ACTUALLY CARING FOR THE PATIENT. DOCTOR CARING FOR THE PATIENT IS THE ONE WHO KNOWS EVERYTHING ABOUT IVF. THAT'S OBVIOUSLY THE PRINCIPAL ASPECT OF IT, BUT THERE'S GOT TO BE A REASON WHY WE'RE COLLECTING THE EGGS. AND THAT DOCTOR MAY BE DELINKED OR MAY BE FAR ENOUGH AWAY THAT HE DOESN'T REALLY UNDERSTAND WHAT WE'RE GOING TO DO WITH IT.

DR. KIESSLING: I DON'T KNOW HOW MANY IN THIS ROOM REMEMBER THE CIRCUMSTANCES IN NORFOLK. WHEN WAS THAT, ROB, ABOUT FIVE YEARS AGO?

DR. TAYLOR: YEAH.

DR. KIESSLING: THIS IS A SITUATION THAT WE REALLY WANT TO AVOID, I THINK, BECAUSE ALTHOUGH I THINK THEY WERE VERY WELL-MEANING, IT CAUSED AN ENORMOUS AMOUNT OF CONCERN ABOUT CONFLICT OF INTEREST. IT WAS A RESEARCH TEAM WHERE THE IVF DOCTOR WAS ACTUALLY THE PI, AND THEY VERY MUCH WANTED TO DEVELOP THE EXPERTISE TO DERIVE STEM CELLS. AND THEY SET UP A PROGRAM WHERE EGGS DONORS WHO CAME FOR FERTILITY, IF THEY WERE NOT OKAY, IF THEY WERE NOT CHOSEN BY A COUPLE OR SOMEHOW HAD A HISTORY THAT RULED THEM OUT OF DONATING EGGS FOR FERTILITY, THEY ASKED THEM IF THEY'D LIKE TO DONATE EGGS FOR THIS RESEARCH PROGRAM. SO IT WAS SORT OF A BAIT AND SWITCH, FIRST OF ALL, THAT WAS A PROBLEM.

SECONDLY, IT WAS THE IVF DOCTOR HIMSELF WHO WAS THE PI ON THAT WORK.

KNOWING THAT TEAM, I'M SURE THERE WAS NOTHING AMISS, BUT IT CERTAINLY SET UP A CIRCUMSTANCE THAT WAS, WHAT WOULD YOU SAY, ROB, NOT DESIRABLE?

DR. TAYLOR: THEY HAD GONE THROUGH THEIR IRB, AND THEY HAD APPROVAL FOR DOING THIS, BUT IT WAS QUITE CONTROVERSIAL. AND THEY WERE THE FIRST PROGRAM TO REALLY DO IN VITRO FERTILIZATION FOR THE PURPOSE OF CREATING EMBRYOS THAT WERE ONLY GOING TO BE STUDIED IN THE LABORATORY. AND THAT, I THINK, WAS A BIT SHOCKING TO THE REST OF THE COMMUNITY.

DR. KIESSLING: THEY WOULD HAVE BEEN MUCH BETTER OFF IF THE PI HAD BEEN A DIFFERENT PERSON FROM THE PERSON COLLECTING EGGS, DON'T YOU THINK?

DR. TAYLOR: I THINK I REALLY APPRECIATE WHAT JOHN IS SAYING. I THINK THAT THE EXCEPTION, FRANKLY, IS GOING TO BE THE COMPLETELY DISSOCIATED IVF TECHNICIAN, ENTIRELY DISSOCIATED FROM THE PROJECT WITH THE SOLE EXCEPTION OF GETTING SOME SORT OF A STIPEND FOR DOING THE RETRIEVAL.

I THINK THAT THE MUCH MORE COMMON SITUATION IS GOING TO BE CLINICIANS WHO ARE INTERESTED IN SEEING THE SCIENCE MOVE FORWARD AND HAVE A COLLABORATIVE RELATIONSHIP AT SOME LEVEL, AT LEAST INTELLECTUALLY

STIMULATED RELATIONSHIP WITH THE GROUP OF PEOPLE THAT ARE DOING THE SCIENCE.

I THINK THAT SCOTT RAISES THE POINT ABOUT I DON'T THINK IT'S GOING TO BE A FINANCIAL IN THE DIRECT SENSE CONFLICT, BUT MORE OF THIS ISSUE ABOUT FAME AND GLORY AND CONTRIBUTION TO A SCIENTIFIC INQUIRY. SO THAT'S, I THINK, THE DICIER PART OF THIS.

DR. WILLERSON: I JUST WANT TO SECOND WHAT ROB SAID. WE DON'T WANT TO INTERFERE WITH THAT KIND OF TEAM BUILDING AND RELATIONSHIP. IT WILL BE REAL IMPORTANT TO MOVING THIS AHEAD.

DR. TAYLOR: IT MAKES FOR THE BEST SCIENCE.

MS. CHARO: IN MANY WAYS THIS STRIKES ME AS A CLASSIC DILEMMA IN RESEARCH BECAUSE IF WE THINK ABOUT IT, IN MOST CLINICAL RESEARCH, THE RECRUITMENT OF SUBJECTS IS GOING TO COME IN THE CONTEXT OF CLINICAL CARE AND A PATIENT POPULATION THAT'S BEING APPROACHED BY SOMEBODY, WHETHER IT'S THE TREATING PHYSICIAN OR SOMEBODY AFFILIATED WITH HIM OR HER, WHO APPROACHES THE PATIENT AND ASKS WOULD YOU PREFER TO BE ENROLLED IN A RESEARCH TRIAL. AND I'M NOT SUGGESTING THAT IRB'S HAVE DONE A PERFECT JOB ON THIS, BUT I AM SUGGESTING THAT IF THERE'S A PLACE WHERE IT SHOULD BE HANDLED, THAT'S MORE LIKELY THE RIGHT PLACE.

AND THE CHALLENGE WE HAVE, I THINK, IS TO

VERY CLEARLY DECIDE ARE THEY IN SUCH A DIFFICULT POSITION THAT WE NEED IN REGULATORY LANGUAGE TO SET DOWN SOME VERY HARD AND FAST RULES, OR ARE WE, RATHER, IN A SITUATION WHERE IRB'S COLLECTIVELY WOULD BENEFIT FROM MORE GUIDANCE AND BEST PRACTICES EFFORTS WHICH ARE NOT EMBODIED IN REGULATORY LANGUAGE WITH HARD AND FAST RULES, BUT, ONCE AGAIN, I THINK, WOULD FORCE US TO MAKE A REAL STRONG COMMITMENT FOR THIS WORKING GROUP AND FOR CIRM TO DEVELOP A PLAN FOR HOW TO MOVE ON TO THE NEXT STEP, WHICH IS THE DEVELOPMENT OF BEST PRACTICES DOCUMENTS AND MODEL PROTOCOLS, ETC., SO THAT WE'RE COMFORTABLE DEFERRING SOME OF THESE TO THE NEXT STAGE OF DELIBERATION.

MY INSTINCT IS THAT THE SECOND WOULD BE A BETTER WAY TO GO ABOUT IT. THAT'S, AGAIN, MY INSTINCT, THAT REGULATORY LANGUAGE SHOULD BE USED SPARINGLY AND THAT LESS IS MORE SO THAT WE CAN REACT TO EVOLVING SITUATIONS. BUT IF THERE'S A FEELING THAT THIS IS ONE WHERE THE IRB'S HAVE BEEN SO INCAPABLE ACROSS ALL RESEARCH AREAS OF MANAGING THIS INTRINSIC CONFLICT, WE COULD PUT IN SOMETHING HARD AND FAST. I JUST HAVEN'T HEARD ANYBODY REALLY KIND OF MAKE THE CASE FOR IT YET.

MS. FEIT: WHY DOES A PRINCIPAL INVESTIGATOR NEED TO BE THE ONE TO RETRIEVE THE DONATION? WHY CAN'T THAT BE -- SINCE IT'S A POTENTIAL AREA OF CONFLICT, WHY

WOULDN'T AN INVESTIGATOR WANT TO SEND IT OUT TO SOMEONE ELSE TO DO, KNOWING THAT HE/SHE HAS THEN ELIMINATED THE CONFLICT? WHAT DRIVES THAT THAT MAKES HIM/HER WANT TO STAY IN CONTROL OF THAT? THAT, TO ME, SEEMS TO BE THE ESSENCE OF WHAT WE'RE TALKING ABOUT.

DR. EGGAN: IF THEY THEMSELVES ARE A CLINICAL INVESTIGATOR WHICH HAS SKILL IN THIS PROCEDURE, THEY MAY FEEL THAT IT IS THE SAFEST THING TO DO. I THINK SOME MAY FEEL THAT WAY. THAT'S A SPECIAL PROCEDURE WHICH THEY PERFORM THEMSELVES AND OTHER PEOPLE DO IT. I THINK THAT'S ONE CLEAR EXAMPLE. BUT I THINK THERE'S OTHER EXAMPLES WHERE THERE ARE BASIC SCIENTISTS WHO WANT TO DO SOMATIC CELL NUCLEAR TRANSPLANTATION EXPERIMENTS WHO WON'T HAVE THE EXPERTISE AND WILL NEED TO EITHER COLLABORATE OR TO FEE-FOR-SERVICE OBTAIN MEDICAL ASSISTANCE.

I THINK IT'S IMPORTANT, THOUGH, IN THAT TYPE OF SITUATION THAT IT ALSO BE AS CLOSE TO A ZERO-SUM GAME OR AT THE LEVEL OF COMPENSATION THAT IS COMMENSURATE WITH THAT WHICH IS PERFORMED WITH RESPECT TO THAT MEDICAL SERVICE. I THINK WE ALL WANT TO MAKE SURE THAT IN THE PROCESS OF THESE THINGS, THAT NO ONE REALLY MAKES MORE MONEY THAN THEY WOULD NORMALLY MAKE, IF THEY'RE A PRIVATE ENTITY. THAT IS, IT SHOULD BE WHATEVER THE STANDARD FEE OR LESS FOR THAT SERVICE

WHICH IS OFFERED, OR AS CONSERVATIVE AS IT COULD BE. I THINK WE WANT TO MAKE SURE THAT THEY'RE AS CLOSE TO ZERO BALANCE OR IN THE RED FOR PARTICIPATING IN THE RESEARCH RATHER THAN BEING STRONGLY IN THE BLACK.

DR. TAYLOR: I ACTUALLY THINK THAT THERE ARE SOME PRETTY -- FAIRLY STRINGENT GUIDELINES, RVS CODES FOR VARIOUS ASPECTS OF THE PROCEDURE THAT WOULD BE QUITE EASILY QUANTIFIABLE.

MARCY, IN RESPONSE TO YOUR QUESTION, I THINK IT'S GOING TO ACTUALLY BE VERY, VERY UNUSUAL IN THE WAY IT'S WRITTEN, MAYBE WITH AN IRB EXCEPTION, THAT THE PI IS GOING TO BE THE PRIMARY IVF SORT OF PHYSICIAN, BUT I THINK IT'S -- SO THAT, I THINK, IS GOING TO BE EXTREMELY RARE. AND I AGREE WITH YOU, THAT IF YOU CAN CREATE THAT SORT OF FIREWALL BETWEEN CONFLICT, I THINK EVERYBODY IS GOING TO WANT TO DO THAT. BUT I ALSO THINK IT'S GOING TO BE VERY RARE FOR THERE NOT TO BE SOME TYPE OF A CLOSE COLLABORATION BETWEEN THE SIDES OF THIS. AND I THINK THAT WE MIGHT, AS JIM HAS KIND OF POINTED OUT, WE MIGHT ACTUALLY HURT OURSELVES MORE IN TERMS OF THE DEVELOPMENT OF THE SCIENCE IF WE TRY TO CREATE TOO THICK A FIREWALL ON THAT ONE.

DR. KIESSLING: ROB, SAY THAT YOU HAVE A BRAINSTORM TONIGHT AND YOU HAVE AN EXPERIMENT THAT YOU WANT TO DO, STEM CELL EXPERIMENT. HOW MUCH OF AN

IMPEDIMENT WOULD IT BE FOR YOU TO GET A COLLEAGUE TO DO THE ACTUAL EGG COLLECTION RATHER THAN YOU YOURSELF DO THE ACTUAL EGG COLLECTION? WOULD THAT BE AN IMPEDIMENT TO THE WORK?

DR. TAYLOR: NO, I DON'T THINK SO. CERTAINLY, AGAIN, UNLESS YOU WERE RUNNING A SOLO IVF PRACTICE IN FRESNO.

DR. KIESSLING: THAT WOULDN'T PLACE A BURDEN ON THE RESEARCH, WOULD IT?

DR. TAYLOR: NO, I DON'T THINK IT WOULD BE A BURDEN AT ALL.

CO-CHAIR LO: LET ME TRY AND SUMMARIZE A COUPLE OF STRANDS HERE THAT I'VE HEARD AND SEE IF THIS MAKES SENSE. SUGGESTION WOULD BE THAT THE IRB MUST ENSURE THAT IN THE OOCYTE RETRIEVAL PROCESS, THE RISKS TO THE OOCYTE DONOR ARE MINIMIZED -- THAT COMES STRAIGHT OUT OF THE COMMON RULE -- AND THAT THE WELL-BEING OF THE OOCYTE DONOR IS FOREMOST. AND THE PHYSICIAN DOING THE OOCYTE RETRIEVAL SHOULD NOT HAVE A FINANCIAL STAKE IN THE OUTCOME OF THE RESEARCH, BUT MAY RECEIVE REASONABLE COMPENSATION FOR SERVICES, BUT THERE SHOULDN'T BE ANY INCENTIVES FOR RETRIEVAL OF MORE RATHER THAN FEWER OOCYTES.

I'M NOT QUITE SURE -- I HEARD SOMEWHAT DIFFERENT THINGS ABOUT WHETHER WE WANTED TO EXCLUDE THE

PRINCIPAL INVESTIGATOR ON THE GRANT FROM BEING THE PERSON DOING THE OOCYTE RETRIEVAL. I'VE HEARD SOME PEOPLE SAY, WELL, THERE MAY BE SITUATIONS WHERE THE PI REALLY IS THE MOST SKILLED PERSON AT DOING OOCYTE RETRIEVAL. I GUESS MY SENSE IS THERE'S A LOT OF COMPETITION TO DO OOCYTE RETRIEVAL IN THE CLINICAL WORLD. THERE SHOULD BE GOOD PEOPLE.

I HEARD A LOT OF ARGUMENTS ABOUT NOT WANTING TO INTERFERE WITH TEAM BUILDING, WHERE TO DRAW THE LINE. ONE SUGGESTION MIGHT BE WHAT THE NIH DOES WHICH IS KEY PERSONNEL ON THE GRANT. SO I THINK IT'S FINE TO HAVE A COLLABORATIVE RELATIONSHIP, BUT I'M NOT SURE I WANT TO HAVE THE OOCYTE DONOR'S PHYSICIAN BE THE PI OR A KEY INVESTIGATOR.

I THINK ANOTHER SAFEGUARD FOR THOSE WHO ARE CONCERNED ABOUT THE IRB, AND WOULD ALSO ENHANCE THE DEVELOPMENT OF BEST PRACTICES, IS TO SAY THE IRB IN THESE KINDS OF PROTOCOL OF OOCYTE RETRIEVAL NEEDS TO DOCUMENT OR EXPLAIN TO THE -- OR THE INVESTIGATOR NEEDS TO SEND TO THE CIRM AS PART OF THE GRANT APPLICATION PROCESS HOW THE INTEREST OF THE OOCYTE DONOR WILL BE PROTECTED IN THE OOCYTE RETRIEVAL PROCESS. THE RATIONALE FOR WHAT THE -- WHAT THE IRB PERMITTED AND THE RATIONALE FOR IT AND THAT BE FORWARDED TO CIRM. AND THAT COULD SERVE BOTH AS A CHECK IN SOME WAYS FOR

SOMEONE ELSE TO REVIEW, BUT ALSO IT'S A STIMULUS TO BEST PRACTICES.

THAT PACKAGE SORT OF GETS AT WHAT WE'RE DOING WITHOUT EITHER BEING TOO BURDENSOME OR BEING TOO LAX. THE ONE AREA I'M NOT SURE WE REACHED AGREEMENT ON IS ARE THERE PEOPLE THAT WE REALLY -- ARE THERE MEMBERS OF THE INVESTIGATIVE TEAM WE REALLY DON'T WANT TO BE DOING THE OOCYTE RETRIEVAL, PI AND PEOPLE WHO ARE REALLY SENIOR PARTS OF THAT TEAM, WHILE STILL ALLOWING THE OOCYTE DOCTOR TO HAVE AN INTELLECTUAL ONGOING COLLABORATION WITH THE RESEARCHERS.

DR. WAGNER: THE ONLY WORRY ABOUT ALL THAT IS YOUR STATEMENT ABOUT NOT BEING A KEY INVESTIGATOR BECAUSE OF THE FACT THAT I THINK THAT THAT'S EXCLUSIONARY. I JUST COULD ENVISION THAT THERE WOULD BE -- FIRST OFF, IN PRACTICE WHAT HAPPENS WITH THE STUFF THAT I DO IS FREQUENTLY THE IVF TEAM OR ONE PERSON ON THE IVF TEAM WILL CALL OUR GROUP AND ASK IF WE WANT TO DEVELOP A COLLABORATION. THEY'RE MOTIVATED, FOR WHATEVER REASON, TO DEVELOP A PROGRAM.

I GUESS THE QUESTION IS THAT DO WE WANT TO BE SO RESTRICTIVE AND SAY YOU CAN'T BE A KEY INVESTIGATOR. RATHER, I WOULD FEEL MORE COMFORTABLE SAYING THERE IS THE POTENTIAL FOR CONFLICT, AND AS YOU SAID BEFORE, YOU GIVE US A PLAN OF HOW YOU ARE GOING TO MINIMIZE RISK

RATHER THAN US SAYING YOU CAN'T BE A KEY INVESTIGATOR.

CO-CHAIR LO: OTHERS?

DR. ROWLEY: I WOULD JUST SUPPORT THAT POSITION OF JOHN'S BECAUSE YOUR STATEMENT OF NOT BEING A KEY INVESTIGATOR, IT RINGS SOME BELLS WITH ME. I THINK PARTICULARLY AS ONE LOOKS FORWARD TO GRANT PROPOSALS, YOU ARE GOING TO HAVE TO DEMONSTRATE THAT YOU DO HAVE A RELATIONSHIP, AN ONGOING RELATIONSHIP WITH A CLINIC OR AN INDIVIDUAL TO BE ABLE TO RETRIEVE OOCYTES. AND YOU DON'T JUST GET ONE FROM THIS PERSON OR ONE FROM SOMEBODY ELSE AND ONE FROM A THIRD. YOU DEVELOP A RELATIONSHIP. AND THE REASON FOR THE CLINICIAN TO BE IN THIS RELATIONSHIP, AS HAS BEEN SAID BY OTHERS, IS BECAUSE THIS GIVES AN ADDED INTELLECTUAL CHALLENGE AND A REWARD AND EXCITEMENT TO WHAT CAN OTHERWISE BE, I WON'T SAY ROUTINE PROCEDURE, BUT LACKING THAT KIND OF INTELLECTUAL EXCITEMENT.

CO-CHAIR LO: SO I'M HEARING PEOPLE NOT WANTING TO EXCLUDE KEY INVESTIGATORS. HOW ABOUT THE PRINCIPAL INVESTIGATOR OF THE GRANT? SHOULD THAT PERSON DO OOCYTE RETRIEVAL?

DR. PRIETO: I THINK GENERALLY NOT. WE ALLOW -- OUR CURRENT LANGUAGE ALLOWS SPECIAL EXEMPTIONS. THOSE NEED TO BE LOOKED AT CAREFULLY, BUT PERHAPS WE DON'T NEED TO ADDRESS ALL THE POSSIBLE WAYS

THAT THAT EXEMPTION MIGHT HAVE TO COME UP OR MIGHT COME UP IN THE REGULATORY LANGUAGE. I LIKE ALTA'S IDEA OF KEEPING THE LANGUAGE SPARE AND COMMITTING TO DEVELOPING BEST PRACTICE GUIDELINES BECAUSE THOSE ARE MORE LIKELY TO BE ABLE TO EVOLVE AND CHANGE AS THE SCIENCE EVOLVES.

CO-CHAIR LO: I WANT AT THIS POINT TO ASK THE PUBLIC TO COMMENT ON THIS BECAUSE I THINK THIS IS A VERY IMPORTANT ISSUE, AND I WANT TO MAKE SURE WE HEAR CONCERNS, SUGGESTIONS FROM THE PUBLIC.

MR. REYNOLDS: GOOD MORNING. JESSE REYNOLDS. I'D ACTUALLY LIKE TO USE THIS OPPORTUNITY TO BRING UP ANOTHER ASPECT THAT YOU MAY WANT TO CONSIDER AND I ENCOURAGE YOU TO INCORPORATE INTO THIS PROVISION. I COMMENTED ABOUT THE ISSUE ABOUT THE PRINCIPAL INVESTIGATOR AND SO FORTH YESTERDAY.

BUT WHAT'S ON MY MIND ARE SOME OF THE IMPORTANT AND IN MANY WAYS NOVEL ISSUES THAT ARE BROUGHT UP BY THE SCNT ASPECT OF EMBRYONIC STEM CELL RESEARCH. AND A LOT OF OUR TALK IN THE LAST TWO DAYS HAS FOCUSED ON THE EGG RETRIEVAL PROCESS. I'D ALSO LIKE TO START THINKING ABOUT ISSUES REGARDING THE PRODUCT OF SCNT, CLONAL BLASTOCYST MIGHT BE APPROPRIATE LANGUAGE.

AND IN THIS REGARD, THERE ARE, I THINK, A COUPLE OF EFFECTIVE AND FAIRLY SIMPLE WAYS TO PREVENT

POTENTIAL MISUSES OF CLONAL BLASTOCYSTS, THE LOGICAL MISUSE BEING REPRODUCTIVE CLONING AND THERE ARE OTHERS. ONE THAT I ENCOURAGE YOU TO CONSIDER IN THIS SECTION MIGHT BE A GEOGRAPHIC SEPARATION IN SOME WAY OF THE EGG RETRIEVAL PROCESS AND THE LAB BENCH WORK OF SCNT. THE MOVEMENT OF PRODUCTS FROM THE EGG RETRIEVAL AREA TO THE BENCH SHOULD IDEALLY BE A ONE-WAY PATH, AND THAT THE SCNT BLASTOCYST SHOULD NOT BE RETURNED TO AN IVF CLINICAL SETTING FOR POTENTIAL ABUSE IN REPRODUCTIVE CLONING.

SO SOMETHING YOU MAY WANT TO CONSIDER ADDING WOULD BE SOME PHYSICAL SEPARATION OF THESE FACILITIES. THANK YOU.

CO-CHAIR LO: JUST TO REMIND US, YOUR CONCERNS, WHICH YOU STATED YESTERDAY, ABOUT HAVING A PRINCIPAL INVESTIGATOR BE INVOLVED IN THE OOCYTE RETRIEVAL PROCESS AND WHETHER YOU THINK WHAT WE JUST TALKED ABOUT ADDRESSES THOSE CONCERNS OR NOT.

MR. REYNOLDS: AS I SAID YESTERDAY, I'D ENCOURAGE YOU TO STRENGTHEN THAT PROVISION. IT SEEMS THAT THE SENSE OF THE BOARD IS NOT. TO MY PERSONAL OPINION, THAT SHOULD BE STRENGTHENED. SOME OF THE LANGUAGE THAT WAS CONSIDERED IN THE LAST FEW MINUTES ABOUT PERHAPS HAVING A PROVISION WHERE THE CLINICIAN RESPONSIBLE FOR EGG RETRIEVAL NOT HAVE A FINANCIAL

STAKE IN THE OUTCOME OF THE RESEARCH IS ONE APPROACH, AND I THINK I'D ENCOURAGE YOU TO ADOPT THAT.

CO-CHAIR LO: OTHER PUBLIC COMMENTS ON THIS ISSUE? OKAY.

DO WE HAVE A QUORUM? WE DO.

CO-CHAIR LANSING: WHO ARE WE WAITING FOR?

CO-CHAIR LO: JON SHESTACK.

CO-CHAIR LANSING: WE HAVE A QUORUM WITHOUT HIM.

CO-CHAIR LO: WE DO HAVE TWELVE. WE'RE IN BUSINESS.

DR. EGGAN: THIS PROCEDURE OF RETRIEVING OOCYTES IS A NOW HIGHLY REGIMENTED, WIDELY PERFORMED CLINICAL ACTIVITY. AND IT SEEMS TO ME THAT, OF COURSE, PARENTHETICALLY, THAT THE GREATEST CONCERN OVER, AT LEAST, MONETARY GAIN -- TO MAKE A LONGER STORY SHORT WITH RESPECT TO MONETARY GAIN, IT'S HARD FOR ME TO IMAGINE HOW THE PERSON DOING THE EGG RETRIEVAL COULD BE CONSIDERED AS AN INVENTOR, SAY, ON A PATENT, WHICH MIGHT RESULT FROM SOMATIC CELL NUCLEAR TRANSPLANTATION. OF COURSE, THAT WOULD BE, I WOULD THINK, THE GREATEST CONCERN OVER MONETARY GAIN.

SO I THINK THAT, IN FACT, IT'S REALLY NOT A PROBLEM THAT EXISTS WITH RESPECT TO THAT ONE ISSUE. AND SO REALLY I THINK THE WAY TO LIMIT THIS IS TO SAY

THAT THIS PERSON SHOULDN'T BE PAID EXORBITANT SUMS OF MONEY IN ORDER TO DO THAT RETRIEVAL. I DON'T KNOW IF THERE'S SOME WAY TO WORK THAT INTO THE LANGUAGE, THE SORT OF THINGS THAT WE TALKED ABOUT BEFORE. I DON'T KNOW HOW DIFFICULT IT IS TO CODIFY LANGUAGE LIKE THAT. THAT'S PROBABLY NOT TRIVIAL. THAT IT SEEMS TO ME SHOULD BE THE FOCUS BECAUSE I THINK THE OTHER CONCERN IS A LEGITIMATE ONE.

MS. FEIT: WHAT WAS THE OUTCOME OF THE GROUP IN VIRGINIA THAT HAD A POTENTIAL CONFLICT IN THEIR PROCESS?

DR. TAYLOR: THE ULTIMATE OUTCOME WAS THAT THE IRB ACTUALLY SHUT DOWN THE STUDY IN LIGHT OF THE SORT OF CONTROVERSY.

CO-CHAIR LO: PUBLIC CRITICISM. THE DIRECTOR OF THE IVF CLINIC WAS RETRIEVING OOCYTES SOLELY FOR RESEARCH PURPOSES AND ALSO WAS THE PRINCIPAL INVESTIGATOR FOR THE RESEARCH ITSELF. IT'S THE SAME PERSON FOR BOTH.

DR. KIESSLING: THIS IS A REALLY GOOD PERSON. THIS IS NOT -- THERE WAS NOTHING NEFARIOUS HERE. THIS IS GOOD TEAM, BUT IT WAS PERCEIVED -- THERE WERE LOTS OF ISSUES WITH IT, BUT IT WAS PERCEIVED A REAL CONFLICT.

DR. TAYLOR: I THINK IT'S FAIR TO SAY THAT

THE SUBJECTS THAT WERE INVOLVED WERE ALSO SATISFIED AND HAD AN OPPORTUNITY TO MAKE A CONTRIBUTION THAT THEY HAD PREVIOUSLY BEEN A LITTLE BIT FRUSTRATED BY BECAUSE THEY WEREN'T COMPLETELY CLEARED FOR CLINICAL OOCYTE DONATION.

NOW, I THINK THAT THERE MIGHT BE SOME LESSONS TO BE LEARNED THERE BECAUSE I BELIEVE THAT THERE MIGHT HAVE BEEN SOME CIRCUMSTANCES WHERE THERE WERE PSYCHOLOGICAL REASONS THAT THEY DIDN'T ACQUIRE THAT FINAL CLEARANCE. AND THAT WOULD NOT BE NECESSARILY THE IDEAL SOURCE OF SUBJECTS FOR THIS TYPE OF PURE STUDY.

DR. KIESSLING: ROB, I WOULD REALLY LIKE TO HEAR FROM YOU ON THIS. HOW DO YOU THINK THIS SHOULD BE? THIS IS YOUR WORLD. WHAT'S THE BEST WAY TO ALLOW EVERYBODY TO FEEL COMFORTABLE THAT THIS DONOR IS GOING TO BE NOT SUBJECT TO MORE THAN SHE SHOULD BE FOR THE RESEARCH?

DR. TAYLOR: MY PERSONAL FEELING IS THAT A CLINICIAN INVOLVED IN THE TEAM AND CARE OF A SUBJECT HAS A HIPPOCRATIC REASON FOR SEEING THAT THE VERY BEST OUTCOME OF THAT SUBJECT IS THE PRIMARY THING IN MIND. I THINK THAT THERE'S A RISK OF DISSOCIATING IT TOO MUCH TO SORT OF SENDING A PATIENT SUBJECT TO ANOTHER PLANET TO HAVE THE EGG RETRIEVAL DONE IN A VERY SORT OF STERILE, TECHNICAL FASHION WHERE THERE'S NOT A SENSE OF

RESPONSIBILITY. I THINK THAT MAY BE AS RISKY AS THE CONCERNS ABOUT UNDUE CONFLICT.

AGAIN, I BELIEVE AND I AGREE WITH KEVIN THAT I THINK THAT THE LIKELIHOOD THAT THERE'S GOING TO BE PATENT-DRIVEN, HUGE FINANCIAL GAIN FOR THE CLINICAL PERSON IS REALLY MINIMAL. BUT I DO THINK THAT IF YOU WERE TO TAKE AWAY ALL OF THE ACADEMIC OPPORTUNITIES TO CONTRIBUTE TO THE DEVELOPMENT OF THE SCIENCE, THEN YOU ARE GOING TO DISSOCIATE THAT PERSON SO MUCH, THAT WE POSSIBLY MIGHT NOT HAVE THE SUBJECT'S BEST INTEREST IN MIND.

DR. WILLERSON: I SEEM TO BE JUST FOLLOWING AND SUPPORTING YOU, BUT THIS IS REAL IMPORTANT. WE'RE TRYING TO BUILD TEAMS LIKE THIS IN MEDICINE WHERE BASIC SCIENTISTS AND CLINICAL SCIENTISTS WORK TOGETHER. IF YOU HAVE THE RIGHT PEOPLE INVOLVED AND INFORMED CONSENT IS ADHERED TO TO THE LETTER, THEN THIS SHOULD WORK VERY WELL. IN FACT, YOU HAVE PEOPLE WITH GREAT EMPATHY ABOUT IT, GREAT PASSION ABOUT IT. THEY'RE GOING TO MAKE SURE THIS IS DONE WELL. I DON'T THINK THEY'LL BE OUT ON THE STREET TRYING TO COAX PEOPLE INTO THE HOSPITAL FOR THIS KIND OF THING, BUT IT WILL HELP MOVE IT FORWARD, FOR SURE. AND I WOULDN'T FIDDLE WITH THIS VERY MUCH. I WOULD TRUST IRB'S. I WOULD INSIST ON THE INFORMED CONSENT. WE SHOULD HAVE SOME -- WE TALKED

YESTERDAY ABOUT SOME REVIEW OF THE GROUP THAT IS GOING TO REVIEW THESE PROPOSALS, SOME AUDITING CAPABILITY. THIS OUGHT TO BE PART OF THAT PROCESS, BUT I REALLY WOULD ENCOURAGE THIS, NOT DISCOURAGE IT.

CO-CHAIR LO: LET ME ASK A QUESTION, I GUESS, AGAIN, DIRECTED TO YOU, ROB. IT STRIKES ME THAT IN A NORMAL CLINICAL IVF, THERE'S A LOT OF DISCRETION FOR THE PHYSICIAN AND THE PATIENT TO MAKE DECISIONS ABOUT PARTICULARLY HORMONAL MANIPULATION. OFTEN A WOMAN WHO'S REALLY ANXIOUS TO GET PREGNANT MAY WANT TO MAXIMIZE THE NUMBER OF OOCYTES RETRIEVED EVEN IF THERE ARE SOMEWHAT INCREASED RISKS. IF WE'RE FOLLOWING THE PRINCIPLE OF RISKS TO THE RESEARCH DONOR MUST BE MINIMIZED, THEN YOU WANT THESE PEOPLE TO USE A DOSE THAT, IF ANYTHING, IS LOWER THAN THE RANGE OF DOSES THAT ARE NORMALLY USED IN CLINICAL PRACTICE.

I GUESS ONE QUESTION IS DO WE FEEL COMFORTABLE LEAVING IT TO THE IRB TO CARRY OUT THIS MANDATE OF MINIMIZING RISKS TO RESEARCH PARTICIPANTS, WHICH IS PART OF THEIR GENERAL MANDATE UNDER THE FEDERAL REGULATIONS, TO MAKE SURE THOSE DETAILS ARE IN PLACE? OR DO WE JUST -- SOMEONE, I THINK, NEEDS TO BE FAIRLY DETAILED. MY QUESTION IS IS THE IRB CAPABLE OF DOING THAT WITH REGARD TO THOSE DETAILS OF HOW THEY'RE GOING TO MANAGE THEM?

DR. WILLERSON: LET ME SUGGEST ONE OTHER POSSIBILITY. I DON'T WANT TO MAKE THIS TOO REGULATED, AS YOU CAN TELL. BUT ONE POSSIBILITY WOULD BE THAT THERE BE A TRAINING SESSION FOR THE PHYSICIAN SCIENTISTS, THOSE THAT ARE GOING TO BE INVOLVED IN DEALING WITH THESE WOMEN SO THAT THERE IS SOME COUNSELING ABOUT IT TO START WITH, AND THAT COULD BE THE RESPONSIBILITY OF THE IRB OR IT COULD BE THE RESPONSIBILITY OF THIS OTHER GROUP THAT WE FORM WHO HAVE SPECIALIZED KNOWLEDGE ABOUT IT.

WE'RE FORCED TO TAKE THOSE KINDS, I AM, THOSE KINDS OF TRAINING, EXAMINATIONS. I'VE BEEN INVOLVED IN CLINICAL RESEARCH FOR 35 YEARS, BUT EVERY YEAR, AND I THINK PROBABLY EVERYBODY ELSE IN HERE WHO'S DOING CLINICAL SCIENCE, HAS TO TAKE A REVIEW COURSE, AN EXAM, AND SO ON. THERE COULD BE -- THIS COULD BE FRAMED VERY CAREFULLY FOR THIS KIND OF WORK.

DR. TAYLOR: I THINK THERE ARE ACTUALLY SOME BEST PRACTICES THAT MIGHT BE HERE IN THE U.S. THAT WE HAVE THE BEST OPPORTUNITY TO LEARN THIS, BUT COUNTRIES LIKE GERMANY AND SWITZERLAND WHERE THEY'VE REALLY LIMITED THE NUMBER OF EMBRYOS THAT CAN BE TRANSFERRED HAS REALLY CHANGED THE MANAGEMENT OF THOSE PATIENTS IN TERMS OF OVARIAN STIMULATION. SO WE COULD, I BELIEVE, ADOPT BEST PRACTICES FROM CLINICAL REGULATIONS IN OTHER

COUNTRIES WHERE THAT'S BEEN LIMITED. AND I WOULD AGREE TO INCORPORATE THEM INTO PERHAPS A CIRM-SPONSORED INVESTIGATOR'S CONFERENCE OR EDUCATIONAL ACTIVITY THAT WOULD SORT OF GET ACROSS THOSE POINTS. I THINK THAT'S A WONDERFUL SUGGESTION.

DR. WAGNER: PART OF THIS DISCUSSION ABOUT HAVING THIS OVERSIGHT BY THE IRB AND HOW THAT'S ACTUALLY DONE, IT REMINDS ME TO ASK THE QUESTION, AND MAYBE THIS HAS BEEN ADDRESSED ELSEWHERE, AND THAT IS THAT SOMETIMES THE IVF CLINIC ITSELF WILL HAVE AN IRB SEPARATE FROM THE INSTITUTION THAT IS ACTUALLY DOING THE RESEARCH. AND IN MY OWN EXPERIENCE, IT'S BEEN THE NORM RATHER THAN THE EXCEPTION. SO WHEN WE TALK ABOUT HOW THIS IS GOING TO ACTUALLY FUNCTIONALLY BE DONE, WE HAVE TO KEEP IN MIND THAT THERE'S GOING TO BE A HIGH LIKELIHOOD THAT THE IRB MAY BE HUNDREDS OF MILES APART POSSIBLY.

SO HOW WOULD THE IRB ACTUALLY BE ABLE TO MONITOR WHAT IS ACTUALLY GOING ON IN AN IVF CLINIC WHEN THEY'RE SO DELINKED FROM EACH OTHER? THAT'S ONE ISSUE.

THE OTHER ISSUE THAT WE NEED TO KEEP IN MIND, AND A PART OF THIS DISCUSSION HAS BEEN BECAUSE SOMETIMES IVF CLINICS HAVE BEEN UNRULY, OFTENTIMES DRIVEN BECAUSE OF THE FACT THAT THEY WANT TO DO WHAT THE CLIENT WANTS. AND SO WE HAVE TO BE CAREFUL ABOUT

THE DESIRE TO DO THE RIGHT THING AND, IN FACT, TO BE MISGUIDED. AND I CAN GIVE YOU EXAMPLES OF THAT. YOU PROBABLY ALREADY KNOW THOSE THINGS. I THINK THAT'S PART OF THE REASON WHY THIS HAS BEEN SUCH AN AREA OF CONCERN IS BECAUSE WE NEED TO MAKE SURE THAT WHAT WE DESIRE IS ACTUALLY BEING IMPLEMENTED AND HOW DO WE MAKE SURE THAT THAT'S HAPPENING.

CO-CHAIR LO: I THINK I'M HEARING AGREEMENT. I'LL TRY AND SUMMARIZE IN A MINUTE. ONE POINT I WANT TO COME BACK TO. I THINK I'M HEARING AGREEMENT, AND I'LL TRY AND SUMMARIZE IT IN A MINUTE. THE ONE POINT I'M NOT SURE I UNDERSTAND THE WILL OF THE COMMITTEE IS WHETHER THE PI ON THE CIRM GRANT MAY BE A PRINCIPAL -- MAY BE THE PERSON DOING THE OOCYTE RETRIEVAL. CURRENTLY WE HAVE THAT THAT SHOULD NOT BE THE SAME PERSON UNLESS AN IRB HAS APPROVED AN EXEMPTION SO THAT WE SAY GENERALLY NOT, BUT THERE MAY BE SOME POSSIBILITY.

ARE WE COMFORTABLE WITH THAT? AND KEEPING IN MIND WHAT WE HEARD ABOUT THE NORFOLK IVF CLINIC SITUATION, ARE WE COMFORTABLE WITH THAT GENERAL RULE WITH POSSIBLY THE EXCEPTION BY THE IRB? IT'S ONE THING I'M NOT SURE I HEARD AGREEMENT.

DR. TAYLOR: I'D PERSONALLY BE UNCOMFORTABLE WITH ANYTHING LESS. I THINK THAT THAT -- I THINK WE

HAVE TO HAVE AT LEAST THAT LEVEL.

DR. PRIETO: DO YOU THINK IT SHOULD BE ABSOLUTELY PROSCRIBED?

DR. TAYLOR: I SUSPECT THAT THERE MIGHT BE OCCASIONAL CIRCUMSTANCES IN WHICH IT SHOULDN'T BE PROSCRIBED, BUT I THINK THAT IT SHOULD BE DISCOURAGED.

DR. WAGNER: CAN WE SAY DISCOURAGED? WE'RE LEANING TOWARD THE SAME WAY, I BELIEVE, THAT WE'RE SAYING THAT MAYBE THERE IS SOME REASON THAT WE CAN'T IMMEDIATELY COME UP WITH, AND SO WE DON'T WANT TO ELIMINATE IT, BUT AT THE SAME TIME MAKE IT CLEAR THAT IT'S DISCOURAGED.

CO-CHAIR LO: IT'S MORE THAN JUST A LITTLE PRESUMPTION. THIS IS A STRONG EXPECTATION.

DR. PRIETO: STRENGTHENING THIS LANGUAGE.

MS. FEIT: I WOULD AGREE WITH US COMING OUT WITH A STRONG STATEMENT ABOUT IT; AND IF THERE ARE EXCEPTIONS, THEN THOSE EXCEPTIONS NEED TO WORK THEIR WAY THROUGH ALL THE PROCESSES, INCLUDING CIRM, TO EXPLAIN WHY THEY THINK THEY NEED AN EXCEPTION. BUT LIKE THE VIRGINIA PROJECT, GREAT INVESTIGATOR, GREAT PROCESS, IRB FELT COMFORTABLE, GOOD INTEGRITY THERE, BUT THE COMMUNITY OUTCRY. THE COMMUNITY RECOGNIZED THE CONFLICT AND WAS UNCOMFORTABLE, AND WE WANT TO AVOID THAT. THERE'S NO REASON FOR US NOT TO COME OUT WITH A

STRONG STATEMENT THAT SAYS WE DON'T SUPPORT THAT PROCESS.

DR. PRIETO: HOW ABOUT A STATEMENT THAT EXEMPTIONS SHOULD BE GRANTED ONLY UNDER EXTRAORDINARY CIRCUMSTANCES WHEN NO REASONABLE ALTERNATIVE EXISTS?

CO-CHAIR LO: THAT'S STRONG. LET ME TRY AND SEE IF WE HAVE AGREEMENT. AND, FIRST, THAT THE IRB MUST IN A PROTOCOL THAT INVOLVES OOCYTE RETRIEVAL FOR RESEARCH, THE IRB MUST ENSURE THAT THE RISKS TO THE WOMAN DONATING OOCYTES ARE MINIMAL. THAT, I THINK, WILL PASS REGULATORY MUSTER. IF WE CAN THROW IN SOME LANGUAGE IN THE PREAMBLE ABOUT WE WANT TO KEEP THE WELL-BEING AND INTEREST OF THE DONOR PARAMOUNT, I WOULD LIKE TO TRY AND DO THAT TO SHOW OUR COMMITMENT. I'M NOT SURE THE AOL WILL LET US DO THAT IN REGULATION.

SECOND, WE WANT TO EXCLUDE THE PERSON DOING THE OOCYTE RETRIEVAL FROM HAVING A FINANCIAL STAKE IN THE OUTCOME OF THE RESEARCH. THAT'S LANGUAGE THAT SCOTT SUGGESTED THAT I THINK WILL PASS REGULATORY MUSTER. BUT THAT PHYSICIAN MAY RECEIVE REASONABLE COMPENSATION FOR HER SERVICES, BUT THERE SHOULD BE NO INCENTIVE TO PROVIDE MORE RATHER THAN FEWER OOCYTES FOR RETRIEVAL.

THE PRINCIPAL INVESTIGATOR -- NOW, GEOFF POINTED OUT THAT THE LANGUAGE WE CURRENTLY HAVE IS

TAKEN WORD FOR WORD FROM THE NAS REPORT ABOUT THE PHYSICIAN AND THE FUNDED RESEARCHER NOT BE THE SAME PERSON WITH THE AMBIGUITY IN FUNDED RESEARCHER. BUT I HEARD US WANTING TO EXCLUDE -- THE PERSON DOING THE OOCYTE RETRIEVAL SHOULD NOT BE THE PRINCIPAL INVESTIGATOR ALTHOUGH THE IRB MAY ALLOW AN EXCEPTION TO THIS UNDER EXTRAORDINARY CIRCUMSTANCES FOR COMPELLING REASONS.

DR. PRIETO: I'D SUGGEST WE CHANGE THAT. IF WE JUST MAKE THAT ONE CHANGE, FUNDED RESEARCHER TO THE PRINCIPAL RESEARCHER OR PRINCIPAL INVESTIGATOR SHALL NOT BE THE SAME PERSON, THEN ADD THE SENTENCE THAT I JUST GAVE YOU.

CO-CHAIR LO: I THOUGHT THE LANGUAGE WAS WONDERFUL, AND I DIDN'T QUITE GET IT ALL.

DR. PRIETO: EXEMPTIONS SHOULD BE GRANTED ONLY UNDER EXTRAORDINARY CIRCUMSTANCES WHEN NO REASONABLE ALTERNATIVE EXISTS. ADD TO THAT, AND THIS IS ON PAGE 6 (A)(4), ADDING TO THAT PARAGRAPH, EXEMPTIONS SHOULD BE GRANTED ONLY UNDER EXTRAORDINARY CIRCUMSTANCES, WHEN NO REASONABLE ALTERNATIVE EXISTS.

CO-CHAIR LO: THAT'S PRETTY STRONG. AND I THOUGHT THAT WE SHOULD ALSO ASK THE INVESTIGATOR TO EXPLAIN TO THE CIRM IN THE GRANT APPLICATION HOW THE RISKS TO THE DONOR WOULD BE MINIMIZED DURING THE

RETRIEVAL PROCESS. I THINK IN THE STATEMENT OF REASONS, WE SHOULD CALL FOR ADHERENCE -- IDENTIFYING BEST PRACTICES AND TRYING TO ADHERE TO THEM. AND AMONG THE WAYS THIS MIGHT BE CARRIED OUT, I HEARD SOME GOOD SUGGESTIONS ABOUT TRAINING SESSIONS FOR THOSE DOING THE OOCYTE RETRIEVAL AND ALSO MAKING SURE WE LEARN FROM THE EUROPEAN SITUATION WHERE THE STANDARD OF CARE IS ACTUALLY TO IMPLANT FEWER EMBRYOS SO THEY ACTUALLY RETRIEVE FEWER OOCYTES.

I GUESS I'M LOOKING FOR AGREEMENT ON THOSE PRINCIPLES, AND THEN THERE'S SOME LANGUAGE WE NEED TO DRAFT. COMMENTS FROM THE --

MS. GREENFIELD: MY QUESTION IS IN REGARD TO THE PATENT APPLICATION. LET'S SAY YOU'RE FUNDED AND YOU'RE NOT -- YOU DON'T HAVE A FINANCIAL INTEREST GOING IN, BUT LATER WHEN YOU APPLY FOR A PATENT ON INVENTIONS, THERE'S NOTHING TO STOP THE PROVIDER FOR WANTING TO BE ADDED TO THAT CLAIM. I JUST WONDER ABOUT THAT POTENTIAL SITUATION.

DR. EGGAN: YES, THERE IS SOMETHING THAT WOULD PREVENT THEM FROM BEING ADDED TO THE CLAIM BECAUSE IT'S EXTREMELY UNLIKELY THAT A PATENT OFFICER WOULD FIND THAT THAT WAS ACTUALLY AN ENABLING PART OF THE INVENTION. SO IT IS ALMOST CERTAIN THAT BY ADDING SOMEONE LIKE THAT TO A CLAIM, IT WOULD NULLIFY THE

PATENT APPLICATION.

MS. GREENFIELD: I'M NOT SURE. I'D HAVE TO DO SOME RESEARCH, BUT I THINK THERE ARE SOME EXAMPLES WHERE JUST BIOLOGICAL MATERIAL HAS BEEN THE UNDERLYING BASIS.

CO-CHAIR LO: ONE THING WE COULD DO IS JUST SAY IF YOU RETRIEVE THE OOCYTES, YOU CAN'T BE ON ANY PATENTS RESULTING FROM.

DR. WAGNER: COULD I MAKE ONE COMMENT OR JUST ASK A QUESTION TO THE GROUP? THAT IS, YOU DON'T KNOW YOU HAVE A PATENT UP FRONT, SO AT THE TIME YOU'RE TAKING CARE OF THE WOMAN WHO'S DONATING THE EGGS, YOU DON'T KNOW THAT A PATENT WILL BE ISSUED; SO, THEREFORE, YOU WOULDN'T THINK THAT IT WOULD INFLUENCE -- THIS IS TALKING OUT LOUD, AND I DON'T MEAN -- I'M NOT MAKING AN OPINION ONE WAY OR THE OTHER.

BUT TYPICALLY WE DON'T PROSCRIBE WHETHER OR NOT YOU CAN BE A PART OF A PATENT. IF YOU'RE PART OF THE THOUGHT PROCESS THAT THEN LEADS TO THE INVENTION, THEN YOU'RE TYPICALLY ALLOWED TO BE ON THE PATENT.

ON THE OTHER HAND, IF WHAT WE ARE TRYING TO DO IS TRYING TO PREVENT ABUSE OF THE WOMAN WHO'S DONATING THE EGGS, AND YET, AT THE TIME THAT THAT'S ACTUALLY TAKING PLACE, THERE IS NO PATENT. SO BY SAYING THAT YOU CAN'T BE PART OF THE PATENT, IS THAT

REALLY HELPING?

MS. GREENFIELD: WELL, IN OTHER WORDS, IF THERE'S SOME GENETIC MATERIAL THAT CAN BE TRACED BACK TO A DONOR THAT IDENTIFIES A PARTICULAR GENE THAT IS THEN USED, I DON'T SEE WHY THERE'S GOING TO BE ANY SORT OF RESTRICTIONS ON THE CLINICIAN COMING FORWARD SAYING I PROVIDED THAT BIOLOGICAL MATERIAL, AND AT LEAST TRY TO SORT OF HAVE SOME CLAIM ON IT. I KNOW IT'S SORT OF OUTSIDE MAYBE WHAT THE NORMAL THING IS, BUT I THINK THERE'S A POTENTIAL FOR IT.

CO-CHAIR LO: YOUR CONCERN IS THAT IF THAT WERE TO TAKE PLACE IN THE FUTURE, IT WOULD CALL INTO QUESTION THE OBJECTIVITY OF THE DECISIONS MADE DURING THE RETRIEVAL PROCESS?

MS. GREENFIELD: I THINK IT'S IN CONTRADICTION TO YOUR IDEA OF NO FINANCIAL INTEREST BECAUSE IF THERE'S A FUTURE FINANCIAL INTEREST, THERE'S A FUTURE FINANCIAL INTEREST.

MR. SIMPSON: JOHN SIMPSON FROM THE FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. I WANT TO JUST CLARIFY ONE THING HERE. YOU'RE BREAKING (3) AND (4) OUT INTO A SEPARATE SECTION; IS THAT CORRECT ESSENTIALLY? ARE THEY STAYING -- THE TWO ITEMS THAT WE'RE DISCUSSING HERE, ARE THEY BECOMING A SEPARATE SECTION?

CO-CHAIR LO: THAT'S WHAT WE'RE THINKING.

MR. SIMPSON: I JUST WANT TO CLARIFY THAT. IT DID SOUND TO ME LIKE THAT WAS MOVING IN THE RIGHT DIRECTION. BUT IN THE DISCUSSION THERE WAS SOMETHING THAT CAME UP THAT I THOUGHT WAS IMPORTANT TO NOTE, AND THAT IS HOW IN DISCUSSING WHAT HAPPENED IN THE VIRGINIA CLINIC, APPARENTLY VERY WELL-INTENTIONED SCIENTISTS WERE ABLE TO DO SOMETHING THAT REALLY WAS PRETTY OBVIOUSLY A CONFLICT, WHICH I THINK SHOWS THE DANGER OF CONFLICTS OF INTEREST OCCURRING AMONG PEOPLE WHO ARE WELL-INTENTIONED AND OFTEN LIKE-MINDED BECAUSE THEY'RE INVOLVED IN DOING A CERTAIN SPECIFIC KIND OF THING.

YOU HAVE THAT SYNDROME SOMETIMES WITH JOURNALISTS WHO ALL THINK THE SAME WAY AND DON'T REALIZE THAT THEY CAUSE SOME KIND OF A CONFLICT IN WHAT THEY'RE DOING. MY POINT SIMPLY BEING THAT THAT, ONCE AGAIN, REITERATES THE NEED FOR CONSTANT PUBLIC INVOLVEMENT AND GENUINE INPUT IN THESE KINDS OF PROCEDURES. THANK YOU.

CO-CHAIR LO: LET ME GO BACK TO THIS QUESTION ABOUT FUTURE PATENTS. HOW IS THIS DEALT WITH IN OTHER CLINICAL SITUATIONS? ORDINARILY, AT LEAST, DON'T YOU AT LEAST HAVE TO DISCLOSE TO THE PERSON YOU ARE GETTING CONSENT FROM THAT THE PERSON GETTING THE CONSENT AND DOING THE RESEARCH MAY HAVE A FUTURE INTEREST IN

PATENTING THE MATERIALS? ISN'T THAT STANDARD FOR IRB'S?

WE CERTAINLY DON'T WANT TO BE WEAKER THAN CURRENT REGULATIONS.

MS. GREENFIELD: I THINK IT'S ONLY AN AMA REGULATION.

CO-CHAIR LO: SO IT'S NOT A REGULATION. IT'S A GUIDELINE.

MS. GREENFIELD: ALTHOUGH IT MIGHT HAVE BEEN -- STATE BY STATE IT MIGHT BE. I'M NOT SURE.

CO-CHAIR LO: LET'S PLAY IT BACK. LET'S FAST-FORWARD TO THE FUTURE. HOW WOULD THE PUBLIC REACT IF UNDER CIRM FUNDING OOCYTES WERE RETRIEVED, SUCCESS, RESEARCH IS A SUCCESS, THE PATENT IS GRANTED, AND A PERSON WHO OBTAINED THE OOCYTES -- RETRIEVED THE OOCYTES, DESPITE KEVIN'S READING OF THE PATENT LAW, ACTUALLY IS NAMED ON THE PATENT? IS THAT SO FARFETCHED, ALTA? IT IS. SO IT'S NOT AN ISSUE.

MR. LOMAX: COULD I OFFER A CLARIFICATION TO THE WORKING GROUP? IF YOU TURN TO THE WORKING NOTES NO. 3, IF YOU LOOK AT THE SPIRIT -- I'M REFERRING BACK TO THAT TABLE AGAIN THAT COMPARES THE CALIFORNIA HEALTH AND SAFETY CODE TO THE COMMON RULE, BOTH OF WHICH ARE CITED IN THE INFORMED CONSENT REQUIREMENTS. YOU WILL ACTUALLY NOTICE THAT A MAJOR THRUST OF CALIFORNIA

POLICY IN THIS AREA IS DISCLOSURE OF FINANCIAL AND ECONOMIC INTERESTS OF THE RESEARCHER. SO BY BRINGING THIS, THAT GETS BACK TO A PREVIOUS DISCUSSION WE HAD THAT WE WERE TRYING TO BRING IN EXISTING REGULATIONS THAT ADDRESSED THE ISSUE OF INFORMING THE PARTICIPANT ABOUT POSSIBLE FINANCIAL INTERESTS AND FINANCIAL STAKES BY THE RESEARCHER. AND EXISTING CALIFORNIA LAW DOES GO ABOVE AND BEYOND THE COMMON RULE, AND IT'S REFLECTED IN THAT TABLE. IF YOU'D LIKE TO LOOK AT THOSE PROVISIONS, THEY'RE OUTLINED IN THIS DOCUMENT.

CO-CHAIR LO: SO THAT'S TAKEN CARE OF. I GUESS I'M ASKING FOR WHETHER WE AGREE TO THE REFORMULATION OF BOTH 04 AS I LAID THEM OUT. LEAVING IT UP TO THE IRB, EXCLUDING THE OOCYTE RETRIEVER FROM HAVING A FINANCIAL STAKE, ALLOWING REASONABLE COMPENSATION, EXCLUDING THE PI EXCEPT FOR EXTRAORDINARY EXCEPTIONS AND EXTRAORDINARY CIRCUMSTANCES WITH NO REASONABLE ALTERNATIVE, AND HAVING TO EXPLAIN TO THE CIRM IN THE GRANT APPLICATION HOW THE RISKS TO THE OOCYTE DONOR WILL BE MINIMIZED. DOES THAT CAPTURE WHAT WE'RE TRYING TO DO? ANY OBJECTIONS TO THAT? WE'LL JUST RATIFY THIS. SOMEONE WANT TO MAKE A MOTION?

MS. CHARO: SO MOVED.

DR. EGGAN: SECOND.

CO-CHAIR LO: THOSE IN FAVOR PLEASE RAISE

YOUR HAND. WE GOT TO HAVE JEFF -- OH, JON. WELCOME. BUT JON DOESN'T KNOW WHAT WE'RE DOING.

MR. SHESTACK: YOU NEED ME FOR A QUORUM?

DR. PRIETO: WE HAVE A QUORUM. MAYBE WHEN JEFF GETS BACK IN THE ROOM, WE CAN RESTATE THE MOTION AND VOTE.

MS. CHARO: WE CAN VOTE NOW AND LET JON ABSTAIN.

CO-CHAIR LANSING: WE DON'T HAVE A QUORUM.

DR. EGGAN: WE SHOULD STILL RESTATE THE MOTION.

CO-CHAIR LO: LET'S WAIT A MINUTE TO SEE -- THE OTHER THING WE CAN DO IS TAKE OUR BLADDER BREAK NOW, AND THEN LOCK SHEEHY IN THIS ROOM WHEN WE COME BACK. LET'S TAKE A SEVEN-MINUTE BREAK.

(A RECESS WAS TAKEN.)

CO-CHAIR LO: CAN WE RECONVENE, PLEASE. WE ACTUALLY HAVE A LOT OF THINGS I'D LIKE TO TRY AND COVER IN THE TIME WE DO HAVE. WE NEED TO MAKE SURE WE HAVE EVERYBODY BACK. WHO ARE WE MISSING? SCOTT AND KATE, IF YOU COULD PATROL THE LADIES AND MEN'S ROOMS. FRANCISCO, KEVIN, JANET. WE'RE MISSING A BUNCH OF PEOPLE. WE'RE WAITING FOR JANET, JIM WILLERSON.

MAYBE IF WE DON'T OFFICIALLY HAVE A QUORUM, COULD WE SORT OF PUT WHAT WE JUST TALKED ABOUT ON HOLD

AND TALK ABOUT SOME OTHER ISSUES AND COME BACK TO THAT? BY THE WAY, WE NEED -- A LOT OF YOU HAVE TIGHT PLANE CONNECTIONS. AND HOW MANY OF YOU NEED TO LEAVE RIGHT AT THE CLOSE OF THE MEETING AT ONE TO GO TO LAX? 12:30 IS OUR DEADLINE.

LET'S GO AHEAD TO THE NEXT SECTION WHILE WE'RE WAITING FOR OUR QUORUM. ON PAGE 9, SECTION -- SO WHAT WE HAVE TO DO, JUST SO WE'RE CLEAR, ON THE LAST PAGE 100009 IS NEW, 100011, THE LANGUAGE IS NEW, BUT THE THOUGHT WE TALKED ABOUT EXTENSIVELY, AND THEN WE NEED TO GO BACK TO TWO PARTS WE SKIPPED YESTERDAY BEFORE WE ADJOURNED, WHICH ARE PAGE 3 AND 4, SCRO, MEMBERSHIP AND FUNCTION, REVIEW AND NOTIFICATION. THOSE WE DISCUSSED EXTENSIVELY AT PREVIOUS MEETINGS. THERE ARE ONLY JUST MINOR WORD CHANGES TO THAT.

SO JUST WANT TO SORT OF FOCUS ON WHAT WE NEED TO DO, WHAT I'D LIKE TO ACCOMPLISH BETWEEN NOW AND OUR ADJOURNMENT. FAIRNESS AND DIVERSITY OF RESEARCH ON PAGE 9, IT IS THE INTENT OF CIRM TO ENSURE THAT WOMEN AND MEMBERS OF MINORITY GROUPS ARE APPROPRIATELY INCLUDED AS SUBJECTS OF HEALTH RESEARCH PROJECTS CARRIED OUT BY CIRM-FUNDED INSTITUTIONS. I DON'T KNOW IF ACTUALLY WE WANT TO SAY IN CIRM-FUNDED RESEARCH PROJECTS.

CIRM ENDORSES THE OBJECTIVES OF THE

CALIFORNIA HEALTH RESEARCH FAIRNESS ACT, THE INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH ACT, A CALIFORNIA LAW, ALL CIRM-FUNDED RESEARCH SHALL CONFORM TO THE REPORTING REQUIREMENTS IN THE CIRM GRANTS ADMINISTRATION POLICY PURSUANT TO THE OBJECTIVES OF THESE POLICIES. I GUESS IT'S TRACKING NUMBER OF WOMEN AND MINORITIES ENROLLED IN THE STUDIES.

SO LET'S OPEN THAT SECTION UP FOR COMMENT AND DISCUSSION.

MS. CHARO: WELL, I HATE TO BE THE KIND OF LAWYER OVER AND OVER, BUT THIS DOESN'T SOUND LIKE THE KIND OF THING YOU PUT IN A REGULATION. TALKING ABOUT THE INTENT AND SPIRIT IS NOT FOR REGULATIONS. AND IF THERE ARE APPLICABLE CALIFORNIA LAWS, AT MOST IN THE REGULATION YOU WOULD SAY THAT ALL CIRM-FUNDED RESEARCH SHALL COMPLY WITH AND LIST THE APPLICABLE CALIFORNIA LAWS. IF YOU WANT TO TALK ABOUT INTENT AND SPIRIT, YOU PUT IT INTO PREAMBLES, OR YOU PUT IT INTO MISSION STATEMENTS FOR CIRM THAT APPEAR ON THE WEBSITE OR ADOPTED BY ICOC. BUT IT'S NOT -- I HAVE NO PROBLEM WITH THE CONTENT, BUT THE FORM, I THINK, IS NOT APPROPRIATE FOR REGULATORY LANGUAGE.

CO-CHAIR LO: LET'S HOLD THAT BECAUSE THAT MAY BE JUST A TECHNICAL THING WHETHER WE PUT IT IN THE REGS OR THE PREAMBLE.

IN TERMS OF THE SPIRIT OF WHAT WE'RE TRYING TO DO, WHICH PROBABLY IS THE MOST IMPORTANT THING, CONCERNS, OBJECTIONS, COMMENTS, SUGGESTIONS?

MR. LOMAX: JUST A REMINDER. IT'S UNDER AGENDA ITEM 7 (I), THE ACTUAL TEXT OF BOTH THE ACTS CITED ARE IN YOUR PACKETS. IF YOU WANTED MORE DETAIL IN TERMS OF WHAT WE ARE REFERRING TO, THAT BODY OF CALIFORNIA REGULATION IS IN YOUR PACKET.

CO-CHAIR LO: COMMENTS OTHER THAN THE REGULATORY APPROPRIATENESS?

DR. PRIETO: TO RESPOND TO ALTA'S COMMENTS, IF WE JUST DELETED THE FIRST SENTENCE AND REWORDED THE SECOND TO SAY THAT CIRM-FUNDED RESEARCH SHOULD ABIDE BY THE TERMS OF -- THAT'S NOT THE MOST ELOQUENT PHRASE -- CALIFORNIA HEALTH RESEARCH FAIRNESS ACT AND THE OTHER ACTS REFERENCED, AND JUST THE REST OF IT STAY AS IS. THAT SOUNDS LIKE MORE REGULATORY LANGUAGE.

CO-CHAIR LO: I THINK AT THIS POINT, IF WE AGREE WITH THE CONTENT, LET'S LEAVE IT UP TO SCOTT AND OUR LEGAL CONSULTANTS HOW TO CRAFT IT IN A WAY THAT WILL PASS ADMINISTRATIVE MUSTER. I'M NOT SURE IT'S THE BEST USE OF OUR TIME TO TRY AND DRAFT IT. ARE PEOPLE COMFORTABLE WITH WHAT WE'RE TRYING TO SAY, I GUESS, IS THE QUESTION AND WHETHER IT GOES HERE OR IN THE PREAMBLE OR HOW IT GETS WORDED? I'D LIKE TO NOT TO

SPEND OUR TIME HERE, IF THAT'S OKAY.

NO OBJECTIONS. ANY PUBLIC COMMENT ON THIS SECTION, FAIRNESS AND DIVERSITY? OKAY. I'M GOING TO HOLD VOTES UNTIL WE GET -- WE TECHNICALLY HAVE A QUORUM, BUT I'D LIKE TO HAVE DR. WILLERSON HERE.

MR. TOCHER: YOU HAVE A QUORUM NOW, JUST FOR THE RECORD.

CO-CHAIR LO: ON THIS SECTION 100009, DO I HEAR A MOTION TO ADOPT THIS WITH THE UNDERSTANDING THAT LEGAL COUNSEL WILL ADVISE US AS TO HOW TO WORD IT IN A WAY THAT'S ACCEPTABLE TO THE OFFICE OF ADMINISTRATIVE LAW AND, IF NECESSARY, MOVE IT TO THE STATEMENT OF REASONS?

DR. PRIETO: SO MOVED.

DR. KIESSLING: SECOND.

CO-CHAIR LO: ALL THOSE IN FAVOR. ANYBODY OPPOSED? IT'S UNANIMOUS.

LET'S NOW GO BACK TO WHAT WE WERE TALKING ABOUT BEFORE JON WAS ABLE TO JOIN US. I'M GOING TO TRY AND REVIEW THIS. SO THIS, JON, IS ON A REPLACEMENT ON PAGE 6, THE BULLET NO. 4, AT THE SORT OF TOP THIRD OF THE PAGE. OUR GOAL HERE IS TO MAKE SURE THAT WE'RE PROTECTING, IN THE CASE OF OOCYTE DONATION FOR RESEARCH, WE'RE PROTECTING THE INTERESTS AND WELL-BEING OF THE DONOR. AND, ONE, THE IRB MUST ENSURE THAT THE

RISKS TO THE OOCYTE DONORS ARE MINIMIZED. THAT'S A REQUIREMENT THAT'S CONSISTENT WITH THEIR OBLIGATIONS UNDER FEDERAL REGULATIONS.

SECONDLY, THE PHYSICIAN CARRYING OUT OOCYTE RETRIEVAL MAY NOT HAVE A FINANCIAL STAKE IN THE OUTCOME OF THE RESEARCH, BUT MAY RECEIVE REASONABLE COMPENSATION FOR HER SERVICES. THERE MAY BE NO FINANCIAL INCENTIVES TO INCREASE THE NUMBER OF OOCYTES RETRIEVED.

THIRD, THE PRINCIPAL INVESTIGATOR IN THE CIRM-FUNDED GRANT MAY NOT BE THE PHYSICIAN RETRIEVING OOCYTES; HOWEVER, AN IRB MAY GRANT AN EXCEPTION TO THIS CLAUSE ONLY UNDER EXTRAORDINARY CIRCUMSTANCES WHERE NO OTHER REASONABLE ALTERNATIVE EXISTS. THE REASON, WE WANTED TO SORT OF BALANCE PROTECTION OF THE WOMEN DONORS WITH TRYING TO BUILD A TEAM TO CARRY OUT THIS RESEARCH AND TO SORT OF ENCOURAGE CLINICIANS TO HAVE AN INTEREST IN THIS RESEARCH.

NO. 4, IN THE CIRM GRANT APPLICATION, IF THE PROJECT INVOLVES OOCYTE RETRIEVAL, THE INVESTIGATOR MUST EXPLAIN TO THE CIRM WHAT MEASURES ARE TAKEN TO MINIMIZE THE RISKS TO OOCYTE DONORS.

AND THEN IN THE STATEMENT OF REASONS, NOT IN THE REGS, BUT IN THE PREAMBLE, THAT WE ENCOURAGE THE DEVELOPMENT AND ADOPTION OF BEST PRACTICES, AND

MEASURES MIGHT INCLUDE A TRAINING SESSION FOR PHYSICIANS DOING OOCYTE RETRIEVAL FOR RESEARCH PURPOSES, AND TO LEARN ABOUT AND INCORPORATE BEST PRACTICES FROM EUROPEAN CENTERS THAT HAVE MINIMIZED THE NUMBER OF OOCYTES RETRIEVED AND EMBRYOS TRANSFERRED.

MR. SHESTACK: COULD YOU JUST WALK ME THROUGH THE MIDDLE PORTION? IF EGG RETRIEVAL IS REQUIRED, THE CIRM-FUNDED RESEARCHER MUST DO WHAT EXACTLY?

CO-CHAIR LO: MUST IN THE GRANT APPLICATION TO CIRM EXPLAIN THE STEPS THEY'RE GOING TO TAKE TO MINIMIZE RISKS TO THE DONOR.

MR. SHESTACK: WHICH MEANS THAT THEY WOULD REALLY ONLY KNOW THIS IF THEY HAD A REAL RELATIONSHIP WITH WHOMEVER WAS DOING THE EGG RETRIEVAL? THEY --

CO-CHAIR LO: THEY'D HAVE TO HAVE SOME UNDERSTANDING HOW THEY WERE GOING TO DO THAT.

MR. SHESTACK: SO THEY WOULD HAVE TO KNOW IN ADVANCE IN ORDER TO BE FUNDED WHERE THEY WERE GOING TO GET EGGS, THE AVAILABILITY OF EGGS, AND HAVE A RELATIONSHIP WITH THAT PERSON WHO WOULD PROBABLY BE IN THEIR SAME INSTITUTION. BUT YOU ASKED BEFOREHAND THAT THOSE RELATIONSHIPS BE SOMEWHAT AT ARM'S LENGTH.

CO-CHAIR LO: YOU PUT YOUR FINGER ON THE DILEMMA, RIGHT. WE WANT THEM TO HAVE SOME RELATIONSHIP SO THAT THE OOCYTE -- THERE'S SOME ASSURANCE THE OOCYTE

DONORS ARE EXPERIENCED, THEY'RE SKILLED; BUT ON THE OTHER HAND, YOU DON'T WANT THE PRINCIPAL INVESTIGATOR SO INVOLVED THAT THERE'S UNCONSCIOUS OR CONSCIOUS PRESSURE TO SORT OF RETRIEVE A NUMBER OF OOCYTES THAT MAY PLACE THE DONOR AT RISK. WE'RE TRYING TO HAVE THAT NOT TOO CLOSE, NOT TOO FAR.

MR. SHESTACK: SEEMS KIND OF CAMEL-ISH. SEEMS KIND OF LIKE A CAMEL. IS THIS REALLY THE -- FOR PEOPLE WHO WORK IN THIS FIELD, IS THIS -- AND INTERACT WITH ALL THE DIFFERENT PARTIES EVERY DAY, IS THIS REALLY THE BEST WE CAN DO? I'M SORRY TO COME IN LATE AND BE A DOPE ABOUT IT.

DR. PRIETO: MAYBE ROB CAN ANSWER THIS BETTER, BUT IS IT REALLY SO DIFFICULT TO DESCRIBE WHAT YOU ARE GOING TO DO TO ENSURE SAFETY FOR THE DONOR? AND IF YOU ARE FAMILIAR WITH THE PROCEDURES AND YOU'VE BEEN IN THE FIELD AND KNOW WHAT THEY ARE, DO YOU REALLY NEED TO KNOW THE SPECIFIC INDIVIDUALS WHO ARE GOING TO BE DOING IT TO DESCRIBE THIS?

DR. TAYLOR: ACTUALLY I THINK THAT THIS SORT OF PROVIDES AN OPPORTUNITY FOR A DISCUSSION BETWEEN THE SORT OF SCIENTIFIC SIDE AND CLINICAL SIDE TO COME TO SOME AGREEMENT. SO I ACTUALLY THINK THAT THIS REGULATION ACTUALLY ENFORCES PART OF THAT COLLABORATIVE DISCUSSION THAT I THINK THAT WOULD BE BENEFICIAL.

I GUESS AN INVESTIGATOR -- WHEN I LEAVE HERE TODAY, I GET TO GO TO BETHESDA TO REVIEW GRANTS, SO I READ A LOT OF GRANTS WHERE PEOPLE PROPOSE THINGS THAT THEY'RE GOING TO DO THAT IS FAIRLY CLEAR THAT ONLY OCCASIONALLY THEY ACTUALLY HAVE COMPLETELY CLEAR UNDERSTANDING OF WHAT'S GOING TO HAPPEN. I THINK IN A SITUATION LIKE THIS, YOU REALLY WANT TO HAVE THAT DISCUSSION. SO I THINK IT'S ACTUALLY SOMEWHAT INAPPROPRIATE FOR A PRINCIPAL INVESTIGATOR COMPLETELY LABORATORY BASED TO WRITE AN APPLICATION THAT'S GOING TO EXPLAIN IN A SORT OF FORMULAIC WAY HOW PATIENTS ARE GOING -- OR SUBJECTS ARE GOING TO BE PROTECTED.

MR. SHESTACK: TO BE KIND OF REALLY CONCRETE ABOUT IT, HOW DOES ANYBODY GET EGGS? THE INVESTIGATOR WHO IS AN ACADEMIC INVESTIGATOR PUTS OUT A CALL OR REQUEST TO WHOM? I'M JUST TRYING TO TRACK THE PROCESS BY WHICH SOMEONE ACTUALLY FINDS OUT, OH, THEY NEED AN EGG DONOR. I THINK I WILL DO IT. IT ACTUALLY STARTS WITH THE RELATIONSHIP BETWEEN THE DONOR AND ACADEMIC INVESTIGATOR, DOESN'T IT, UNLESS THERE ARE PEOPLE WHO ARE OUT THERE AS THEIR BUSINESS COLLECTING EGGS, WHICH THERE AREN'T, WE'RE SAYING; OR IF THERE ARE, WE DON'T WANT TO SPONSOR THAT.

DR. TAYLOR: I GUESS I WOULD SAY IF THERE'S A BUSINESS OF COLLECTING EGGS, IT'S THE CLINICAL IVF

PRACTICE. THOSE ARE THE FOLKS WHO HAVE THE EXPERIENCE DOING THAT. AND I WOULD SAY THAT A LABORATORY THAT'S SOMEWHAT ISOLATED FROM THAT GROUP INITIALLY WOULD NEED TO FORGE A RELATIONSHIP, I THINK, BEFORE THEY SUBMIT A PROPOSAL THAT WOULD INCLUDE SORT OF PRECISELY HOW THEY'RE GOING TO SORT OF MANAGE THE PATIENT FLOW AND WHO'S GOING TO BE RESPONSIBLE FOR WHAT ASPECT OF IT. CERTAINLY THERE ARE GOING TO BE SOME PROGRAMS THAT ARE INTRAINSTITUTIONAL, BUT I DON'T BELIEVE THAT -- AND IF THERE'S A BIOTECHNOLOGY COMPONENT, THEY WOULD NEED TO PARTNER WITH A CLINICAL FACILITY, BUT I THINK THOSE RELATIONSHIPS EXIST FOR PROCUREMENT OF HUMAN TISSUES AND CELLS IN OTHER WAYS THAT ARE SORT OF OUTSIDE THE OOCYTE, GAMETE.

DR. KIESSLING: YOUR CONCERN IS HAVING TO FORM A RELATIONSHIP BEFORE?

MR. SHESTACK: I'M JUST WORRIED THAT WE'RE ASKING -- WE'RE SAYING SOMETHING BOGUS. THAT'S ALL. I'M JUST TRYING TO ACTUALLY IMAGINE WHAT IS -- HOW DO PEOPLE -- FOR ALL MY TIME ON CIRM, THE ONE THING I NEVER QUITE UNDERSTOOD IS HOW SCIENTISTS GET EGGS, HOW THEY RECRUIT DONORS, WHAT THE DEMAND IS FOR OOCYTE DONORS OUTSIDE OF ALREADY DISCARDED FERTILIZED EGGS IN AN IVF CLINIC. I'M TRYING TO FIGURE OUT ARE WE SAYING SOMETHING THAT'S ACTUALLY SORT OF UNNECESSARY OR

PRACTICAL AND CAN BE FOLLOWED THAT WILL HELP BOTH RESEARCHERS GET OOCYTES AND PROTECT DONORS BECAUSE THERE'S BOTH THINGS YOU WANT TO DO?

CO-CHAIR LO: I THINK JON POSED IT -- THE WAY HE POSED IT AT THE VERY END, I THINK, IS VERY MUCH ON POINT. WE TALKED ABOUT IT AT SOME LENGTH. I THINK, ANN AND ROB, SINCE YOU ARE THE ONES WITH THE MOST EXPERIENCE IN THIS, IF YOU COULD JUST SAY TO JON, NO, THIS IS WORKABLE AND DOABLE AS OPPOSED TO OFF TARGET AND IMPRACTICAL AND -- WHAT WAS THE TERM JON USED? -- BOGUS. JON NEEDS TO HEAR FROM YOU WHO HAVE THE EXPERIENCE.

DR. KIESSLING: SO THE SPECIFIC QUESTION IS IS IT APPROPRIATE TO ASSUME THAT A SCIENTIST IS GOING TO BE ABLE TO PREESTABLISH A RELATIONSHIP?

CO-CHAIR LO: NO. NO. NO.

MR. SHESTACK: THAT'S PART OF IT. HOW DOES IT ACTUALLY WORK SO THAT THIS IS THEREFORE PRACTICAL?

DR. KIESSLING: THAT IS WORKABLE. FROM EVERYTHING THAT A SCIENTIST DOES WITH CLINICAL TISSUES, IT STARTS WITH ESTABLISHING A SOURCE. WE DO THAT EVERY DAY. IT'S WHAT WE DO AND HOW WE DO IT, AND THAT'S DEFINITELY WORKABLE. YOU HAVE TO FIND A CLINICAL SOURCE IF YOU ARE DOING CLINICAL RESEARCH.

CO-CHAIR LO: QUESTION ABOUT WHETHER THIS IS,

ON THE ONE HAND, FEASIBLE AND, ON THE OTHER HAND, REALLY BENEFICIAL AND PROTECTIVE.

MR. SHESTACK: RIGHT.

CO-CHAIR LO: CAN YOU ANSWER THAT QUESTION AS WELL?

DR. KIESSLING: I THINK THE WAY THAT ROB HAS OUTLINED THAT IT SHOULD WORK IS GOING TO PROTECT THE DONOR. AND ROB'S SUGGESTION IS THAT THERE BE STRONG LANGUAGE TO INDICATE THAT THERE'S A SEPARATION OF THE PERSON TAKING CARE OF THE DONOR AND THE PRINCIPAL INVESTIGATOR ON THE GRANT, IF AT ALL POSSIBLE.

DR. TAYLOR: I THINK ABSENT THAT, IT'S QUITE DIFFICULT. I THINK IT'S VERY HARD FOR SOMEBODY WHO DOESN'T HAVE A RELATIONSHIP WITH THE CLINICAL PROGRAM TO GO THROUGH THE YELLOW PAGES AND FIND EGG DONORS. SO YOU ACTUALLY -- I THINK A PRIORI THAT RELATIONSHIP ALMOST NEEDS TO BE ESTABLISHED TO FACILITATE THIS MOVING FORWARD.

CO-CHAIR LO: ROB, AGAIN, TO ANSWER JON'S LAST QUESTION, ARE THESE RECOMMENDATIONS IN YOUR VIEW FEASIBLE AND BENEFICIAL?

DR. TAYLOR: YEAH, DEFINITELY.

DR. PRIETO: IS THIS SOMETHING THAT SHOULD BE FLESHED OUT IN BEST PRACTICES GUIDELINES OF THE SORT THAT ALTA WAS TALKING ABOUT?

CO-CHAIR LO: SURE. AGAIN, THESE ARE REGULATIONS THAT CAN THEN BE EXPANDED UPON THROUGH OTHER MEANS, BUT IN TERMS OF REGULATIONS, I DON'T THINK WE WANT TO GET TOO...

IF SOMEONE WOULD LIKE TO -- I WOULD LIKE TO ENTERTAIN A MOTION THAT WE AGREE ON THOSE THREE PROVISIONS -- FOUR PROVISIONS PLUS THE RECOMMENDATION FOR BEST PRACTICES IN THE STATEMENT OF REASONS.

DR. TAYLOR: SO MOVED.

MS. CHARO: SECOND.

CO-CHAIR LO: ALL THOSE IN FAVOR SO SIGNIFY. THAT'S UNANIMOUS. THANK YOU.

OKAY. CAN WE BACK NOW TO 100009 ON PAGE 9.

MR. TOCHER: JUST FOR THE RECORD, IT WAS A UNANIMOUS VOTE.

CO-CHAIR LO: THE PROVISION ON PAGE 9 ON FAIRNESS AND DIVERSITY, WHICH WE WERE TALKING ABOUT THE QUORUM, AND I WANT TO SORT OF COME BACK TO THAT. ALTA HAD RAISED SOME CONCERNS ABOUT WHETHER THIS IS APPROPRIATE REGULATORY LANGUAGE, WHETHER IT NEEDS TO GO IN THE PREAMBLE, THINGS LIKE THAT. AND I THINK I WOULD LIKE TO DEFER -- MY SUGGESTION IS THAT WE DEFER THOSE DECISIONS TO THE LEGAL COUNSEL, BUT THAT I'D LIKE TO GET SOME SENSE OF WHETHER THIS EXPRESSES THE SENTIMENT OF THE WORKING GROUP. I'M SORRY. WE VOTED ON IT.

THAT'S GREAT.

CO-CHAIR LANSING: REMEMBER WE ALREADY DID THAT.

CO-CHAIR LO: 100010, RESEARCH TRACKING. AND THIS IS SOMETHING WE TALKED ABOUT BEFORE, AND THERE ARE NO CHANGES; IS THAT RIGHT, GEOFF, THAT I CAN SEE? JUST WANT TO LOOK AT THAT FOR A MINUTE AND MAKE SURE WE'RE COMFORTABLE WITH THAT.

DR. ROWLEY: I ASSUME THAT ITEM 1, CONDUCTED BY THE INSTITUTION, HAS BEEN CORRECTED.

CO-CHAIR LO: YEAH. THIS NEEDS A GOOD SPELL CHECK. THERE'S A LOT OF VERSIONS AND CUT AND PASTE. THANK YOU.

THESE ARE REALLY TRACKING CIRM-FUNDED RESEARCH SO THERE'S A RECORD OF WHAT'S DONE AND WHAT STEM CELL LINES WERE DERIVED. IF THERE ARE NO CONCERNS, QUESTIONS.

MS. FEIT: YESTERDAY THERE WAS SOME MENTION BY SOME OF THE MEMBERS PRESENT ABOUT THE POSSIBILITY OF AUDITS BEING PERFORMED. IS THAT SOMETHING THAT SHOULD BE PLACED IN HERE?

CO-CHAIR LO: THERE'S AN AUDIT SECTION.

MR. LOMAX: THE ISSUE OF WHAT ENABLES THE AUDIT IS THE INFORMATION SYSTEM WHICH IS BEING DEVELOPED THROUGH THE GRANTS ADMINISTRATION TEAM TO

COMPILE SPECIFIC RECORDS, THINGS. IN OUR CASE IT WOULD BE SPECIFIC TYPES OF ITEMS THAT THEY WOULD BE LOOKING FOR IS SORT OF INDICATION OF A REVIEW AND APPROVAL BY BOTH AN IRB AND OVERSIGHT COMMITTEE, FOR EXAMPLE.

SO WHAT WOULD ENABLE -- THE SYSTEM IS INTENDED OR BEING DESIGNED TO CAPTURE THOSE TYPES OF REVIEW AND APPROVAL. SO THEY'RE LOOKING THROUGH THIS DOCUMENT AND SAYING WHAT ARE CONCRETE ITEMS THAT WE COULD ASK TO RECEIVE FROM THE INSTITUTION TO DOCUMENT COMPLIANCE? SO IT'S THE INTERACTION OF REVIEWS AND APPROVALS THAT WE'VE STATED HERE IN THEIR INFORMATION SYSTEM THAT WOULD THEN BE TRACKING THOSE TYPES OF ACTIVITIES AND THOSE TYPES OF APPROVALS THAT WOULD ENABLE AN AUDIT.

AND THEY ARE IN THEIR REGULATIONS WRITING OUT ITEM BY ITEM THE TYPES OF THINGS THAT THEY WOULD REQUIRE A GRANTEE TO REPORT BACK TO CIRM IN THEIR REPORTS. AND THOSE REPORTS, WHETHER THEY BE ANNUAL, QUARTERLY, DEPENDING ON HOW THEY'RE GOING TO STAGE THOSE REPORTS. SO THAT'S WHERE THE AUDIT CAPACITY COMES FROM. IT'S FROM THAT TRACKING THAT'S DONE THROUGH THE GRANTS ADMINISTRATION POLICY.

CO-CHAIR LO: MARCY, THE QUESTION OF WHETHER WE MOVE WHAT WE DECIDED YESTERDAY IN TERMS OF SUPPORTING -- REQUIRING COMPLIANCE WITH ALL REGULATIONS

AND SUPPORTING -- INCLUDING THE COMPLIANCE WITH THE GRANTS WORKING GROUP PROVISIONS FOR AUDITING AND MONITORING, WHETHER THAT GOES WITH THIS SECTION OR IN A DIFFERENT SECTION, WE'LL HAVE TO SORT THAT OUT. YES, THAT ARE CONCEPTUALLY RELATED.

LET US THEN FORGE AHEAD, IF THERE'S NO CONCERN. I'M SORRY. MEMBERS OF THE PUBLIC, PLEASE.

MR. REYNOLDS: THANKS FOR THE OPPORTUNITY TO COMMENT. I'D LIKE TO ELABORATE ON SOMETHING THAT I BROUGHT UP A MINUTE AGO ABOUT THE PROVISIONS THAT CAN BE ADOPTED TO PREVENT MISUSE OF THE CLONAL BLASTOCYSTS THAT RESULT FROM SCNT. ONE THING I MENTIONED WAS THE GEOGRAPHIC SEPARATION OF THE EGG RETRIEVAL FACILITIES AND THE BENCH WORK.

ANOTHER THING THAT I THINK NEEDS TO BE ADOPTED IS UNDER THE RESEARCH REGISTRY COULD BE -- SHOULD BE AN INVENTORY OF THE CLONAL BLASTOCYSTS THAT ARE CREATED AND THEIR EVENTUAL FATE. AND I THINK THIS MIGHT HELP PREVENT ANY POTENTIAL MISUSE. AND I ALSO ENCOURAGE YOU, TO THE EXTENT POSSIBLE, WITH KEEPING INTELLECTUAL PROPERTY CONCERNS IN MIND, THAT THESE RESEARCH REGISTRIES BE PUBLIC INFORMATION.

MR. SHEEHY: I THINK THAT'S PART OF THE INTELLECTUAL PROPERTY.

CO-CHAIR LANSING: I THINK THE FILE SHARING

COVERS IT. MAYBE I'M WRONG.

MR. SHEEHY: THERE'S A WHOLE ANNUAL REPORT.

CO-CHAIR LO: SO IT IS PUBLIC.

CO-CHAIR LANSING: I THINK IT'S ALL PUBLIC IN HIS REPORT. IT'S SORT OF LIKE NONE OF US EXIST IN A VACUUM. I HAVE TO KEEP REFERRING BACK, AND I THINK THE INTELLECTUAL PROPERTY WENT REALLY TO WHAT YOU ARE TALKING ABOUT.

MR. REYNOLDS: RIGHT. I'M AWARE THAT THERE'S COMPONENTS OF THE INTELLECTUAL PROPERTY REPORT THAT WOULD BE PUBLIC. I'M REFERRING TO THE RESEARCH REGISTRY HERE THAT IS DESCRIBED. WOULD THAT BE COVERED BY THE --

CO-CHAIR LO: WHILE JEFF IS DOING THAT, DR. ROWLEY.

DR. ROWLEY: IN THE MEANTIME I WANTED TO POINT OUT THAT ANY LINES THAT WOULD ULTIMATELY BE USED FOR PATIENT TREATMENT, THIS IS ALL REQUIRED BY THE FDA, SO YOU HAVE TO HAVE THAT. NOT THAT IT'S NECESSARILY PUBLIC, BUT THE TRACEABILITY AND THE PROVENANCE OF ALL OF THIS HAS GOT TO BE CLEARED TO THE FDA IN THE EVENT THAT THEY'RE USED FOR TREATMENT.

CO-CHAIR LO: WHILE JEFF IS LOOKING IT UP, ANOTHER SPECIFIC SUGGESTION THAT WAS JUST MADE WAS THAT WE INCLUDE AN ARTICLE 7 HERE, DOCUMENTATION OF -- I'M

NOT SURE WHAT TERM WE WANT TO USE -- THE PRODUCTS OF ANY SCNT RESEARCH FUNDED BY CIRM, THAT THE -- I'M NOT SURE WHAT TERM TO USE -- THAT A TRACKING OF THOSE BE CARRIED OUT, SO YOU CAN ACCOUNT FOR EVERY ONE THAT WAS PRODUCED. AND THAT WOULD BE ANOTHER GUARANTEE THAT NONE OF THEM WENT BACKWARDS INTO THE REPRODUCTIVE. I THINK THAT IS A SUGGESTION THAT WE SHOULD ADOPT.

I DON'T KNOW HOW OTHER PEOPLE FEEL ABOUT IT.

MR. SHEEHY: THERE'S A WHOLE SECTION ON INVENTION REPORTING REQUIREMENTS IN HERE, LIKE A WHOLE PAGE.

CO-CHAIR LO: THAT'S ONLY FOR INVENTIONS.

MR. SHEEHY: THAT'S ONLY FOR INVENTIONS. THERE'S ALSO A REQUIREMENT FOR AN ANNUAL REPORT THAT WOULD ALSO -- WE DON'T HAVE ANYBODY. ZACH WOULD KNOW MORE ABOUT THIS FROM THE SPO POINT OF VIEW, BUT THERE'S GOING TO BE AN ANNUAL REPORT THAT'S GOING TO BE FILED BY GRANTEES THAT WILL BE TELLING THEIR PROGRESS ON THE GRANTS.

CO-CHAIR LANSING: EVERYTHING THAT HAPPENED.

MR. SHEEHY: EVERYTHING THAT HAPPENS IS PUBLIC.

CO-CHAIR LANSING: MAYBE WE NEED BOTH.

CO-CHAIR LO: IS THERE ANY PROBLEM WITH REQUIRING THIS TRACKING IN THIS SECTION TO BE AVAILABLE

TO THE PUBLIC? I DON'T KNOW IF THERE'S A PROBLEM WITH THAT. I THINK IN THE SPIRIT OF MAKING SURE THE PUBLIC UNDERSTANDS WHAT'S GOING ON, IT DOESN'T HURT TO MAKE SURE. IF IT'S REDUNDANT, THAT THEY ALREADY HAVE ACCESS TO INFORMATION OTHER WAYS, THEN WE'RE JUST SAYING THE SAME THING TWICE.

MR. REED: DAN PERRY OF CAMERA ONCE TALKED ABOUT OVERREGULATING RESEARCHERS AS PUTTING BOXING GLOVES ON PIANO PLAYERS. I THINK WE HAVE TO BE CAREFUL WE DON'T HAVE TOO MANY REGULATIONS. I CAN SEE WHERE TRYING TO TRACK EVERYTHING BACK AND BACK AND BACK AND FORWARD, IF WE'RE REQUIRED TO DO THAT, I THINK WE COULD BE HAVING SOMETHING THAT'S IMPOSSIBLE TO DO. I THINK THERE COMES A CERTAIN POINT WHEN YOU HAVE TO SAY, ALL RIGHT, HOWEVER SACRED THIS DERIVATION, THIS IS HUMAN TISSUE, AND WE CAN'T KEEP TRACK ABOUT WHERE A DROP OF BLOOD WHICH IS GIVEN BY A DONOR GOES. I THINK THERE HAS TO BE AN OPENNESS IN THE SOURCE, BUT NOT ENDLESS TRACKING.

CO-CHAIR LO: WELL, AGAIN, LET'S MAKE SURE WHAT SECTION 100010 SAYS. IT'S SIX AND NOW SEVEN SPECIFIC THINGS. AND AS DR. ROWLEY POINTED OUT, THESE ARE THINGS THAT NEED TO BE KEPT TRACK OF FOR FDA REQUIREMENTS IN THE EVENTUAL USE FOR TRANSPLANTATION. SO IT'S NOT AN INDEFINITE FORWARD TRACKING. IT'S

REALLY HOW THOSE STEM CELLS WERE DERIVED AND THE CONDITIONS UNDER WHICH THEY'VE BEEN MAINTAINED AND STORED SO THAT THERE'S SOME ASSURANCE THEY'RE USABLE FOR TRANSPLANTATION. A NEW RESEARCHER USING THEM HAS SOME ASSURANCE AS TO WHAT'S GOING ON.

SO I'VE HEARD NOW TWO SUGGESTIONS. I'M GOING TO ASK THE COMMITTEE TO -- ANY OTHER PUBLIC COMMENTS? I'M GOING TO ASK THE COMMITTEE TO, FIRST, ADDING TO THIS LIST 1 THROUGH 6 A SEVENTH PROVISIONS. WHAT'S OUR PREFERRED TERM NOW FOR THINGS RESULTING FROM SCNT RESEARCH FUNDED BY CIRM? TRACKING OF EGGS, BLASTOCYSTS, AND PRODUCTS OF SCNT. SO THAT'S 1 THROUGH 7.

AND THEN I GUESS THERE WOULD BE A PROVISION (B), THIS TRACKING INFORMATION SHALL BE MADE AVAILABLE TO THE PUBLIC CONSISTENT WITH PROTECTION OF TRADE SECRETS OR SOMETHING. THERE'S SOMETHING IN THERE ABOUT INTELLECTUAL PROPERTY. LET'S ASK THE COMMITTEE THEIR THOUGHTS ON THOSE TWO AMENDMENTS TO THE SECTION.

FIRST ON TRACKING OF PRODUCTS OF SCNT, BLASTOCYSTS AND EMBRYOS PRODUCED BY RESEARCH. ANY OBJECTION TO INCLUDING THAT? SOMEONE WANT TO MOVE WE INCLUDE THAT?

DR. PRIETO: SO MOVED.

DR. ROWLEY: I SECOND.

CO-CHAIR LO: ALL IN FAVOR. ANY OPPOSED? ANY ABSTENTION? UNANIMOUS.

AND THEN MAKING THIS TRACKING AVAILABLE TO THE PUBLIC.

MS. CHARO: I HAVE SOME CONCERNS HERE ABOUT OPERATIONALIZING THAT. FOR ONE THING, A LOT DEPENDS UPON EXACTLY WHAT INFORMATION IS INCLUDED BECAUSE WE HAVE HIPAA, WHICH HAS VERY PICKY, PICKY REQUIREMENTS ABOUT MEDICAL PRIVACY.

NOW, AGAIN, THINKING CONSTANTLY ABOUT WHAT'S APPROPRIATE FOR A REGULATION AS OPPOSED TO WHAT'S APPROPRIATE FOR WHAT HAPPENS AFTER REGULATIONS ARE ISSUED, WE HAVE ESCRO'S THAT ARE CHARGED WITH MAINTAINING REGISTRIES OF WHAT'S GOING ON ON THE INSTITUTION'S CAMPUS, RIGHT. AND IF IT IS SUMMARY INFORMATION THAT DOES NOT PROVIDE ANY DETAILS ABOUT THE INDIVIDUAL DONORS AND DOES NOT VIOLATE ANY TRADE SECRETS OR OTHER CONFIDENTIALITY PROVISIONS THAT ARE OPERATIONAL FOR THE BUSINESSES, THEN THE SUMMARY RECORDS COULD EASILY BE MADE AVAILABLE TO THE PUBLIC AS PART OF THE ESCRO'S FUNCTIONING.

CO-CHAIR LO: CONCERNS ABOUT MAKING PUBLIC THINGS THAT MAY EITHER VIOLATE EITHER THE PRIVACY OF DONORS OR TRADE SECRETS OR ACTUALLY ACADEMIC INTELLECTUAL PROPERTY. HOW DO WE WANT TO BALANCE

PUBLIC ACCESS WITH PUTTING IN PLACE ALL THESE PROTECTIONS, WHICH MAY BE MORE -- AGAIN, THIS IS NOW AT THE INSTITUTIONAL LEVEL, NOT AT CIRM ITSELF.

DR. EGGAN: I GUESS IF THE CONCERN IS SPECIFICALLY OVER MISAPPROPRIATION OF EMBRYOS CREATED BY SCNT, I DON'T NECESSARILY SEE HOW THAT'S EMBROILED WITH HIPAA. THERE WILL BE A CERTAIN NUMBER OF OOCYTES WHICH ARE TRANSFERRED FROM THE CLINIC TO THE LAB. THAT'S NOT IDENTIFYING INFORMATION. IT WILL BE RECORDED BY BOTH GROUPS. AS LONG AS THERE IS DOCUMENTED EVIDENCE FOR WHAT HAPPENED TO THOSE OOCYTES AND ANY RESULTING EMBRYOS THAT WERE MADE, I GUESS I DON'T SEE HOW THAT'S REALLY A PROBLEM.

CO-CHAIR LO: IT'S NOT DONE ON AN INDIVIDUAL PATIENT LEVEL. A SUMMARY, X NUMBER WERE PRODUCED.

DR. EGGAN: THERE WILL BE A REPORT BY THE CLINIC WHICH HAS X NUMBER WERE PRODUCED AND TRANSFERRED TO THE LAB. NOW -- YOU KNOW, IT'S GETTING INTO THE NITTY-GRITTY, BUT IT SHOULD BE POSSIBLE TO COUNT THAT NUMBER OF OOCYTES THAT ARE TRANSFERRED, AND A RECORD IS KEPT AT THE CLINIC, THERE WILL BE RECORDS KEPT AT THE LAB. AS LONG AS THERE'S BASICALLY SOME SORT OF GEOGRAPHIC EVIDENCE OF WHAT HAPPENED TO THAT THING, THEN I FEEL LIKE THAT SHOULD BE ENOUGH. CAREFULLY REPORTING.

AGAIN, I FEEL, AS ALTA DOES, THAT I'M A LITTLE BIT SENSITIVE ABOUT PRESCRIBING EXACTLY WHAT THAT IS AND WHEN THAT SHOULD BE, BUT I FEEL LIKE IT WOULD BE POSSIBLE AND SEEMS REASONABLE, MUCH MORE REASONABLE THAN, FOR INSTANCE, STATING THERE NEEDS TO BE A SEPARATION BETWEEN THE LAB AND THE CLINIC, WHICH MIGHT BE PROBLEMATIC.

CO-CHAIR LO: IN TERMS OF PHYSICAL SEPARATION. YEAH. GETTING YOUR SAMPLES.

DR. KIESSLING: THE AMERICAN ASSOCIATION OF FOR THE ADVANCEMENT OF SCIENCE HAD A PANEL ON THIS. I THINK THIS IS WHERE SOME OF THIS COMES FROM. ONE OF THEIR RECOMMENDATIONS WAS THAT THE STEM CELL RESEARCH LABORATORY AND THE CLINIC LOCATION FOR COLLECTING EGGS BE GEOGRAPHICALLY SEPARATED. AND I THINK THAT WAS BASICALLY DESIGNED TO SPEAK TO THE CONCERN ABOUT HUMAN CLONING, THAT IF THE RESEARCH WAS DONE AWAY FROM THE CLINIC, THERE WAS NO WAY THAT THE NUCLEAR TRANSPLANT UNITS COULD GET PUT BACK INTO THE WOMAN.

I DON'T KNOW IF THAT'S REALISTIC OR NOT, BUT I THINK IT'S THAT REPORT THAT HAS GENERATED SOME OF THIS SENTIMENT.

DR. EGGAN: I'M SORRY, BUT I HAVE TO INTERJECT THAT I FIND THIS ABSOLUTELY RIDICULOUS. AND THE REASON I FIND THIS ABSOLUTELY RIDICULOUS IS THE

FOLLOWING. AND THAT IS, IF A PERSON WANTS TO REPRODUCTIVELY CLONE, THEN THEY CAN DO THAT REGARDLESS OF WHETHER OR NOT THERE'S PHYSICAL SEPARATION BETWEEN THE LABORATORY AND THE CLINIC OR NOT. BECAUSE WE HAVE PORTABLE INCUBATORS THAT, FOR INSTANCE, WE USE TO TRANSFER --

DR. KIESSLING: SURE, KEVIN.

DR. EGGAN: ANN, LET ME FINISH. AND BECAUSE IT'S NOT LIKE A SUBTLE THING TO BRING A WOMAN IN FOR OOCYTE -- FOR EMBRYO TRANSFER. SO THERE IS PREPARATION REQUIRED TO DO EMBRYO TRANSFER. IT'S NOT AS IF, OH, YOU KNOW, WE'VE GOT A WOMAN HANGING AROUND WE COULD JUST SQUIRT SOME SOMATIC CELL NUCLEAR TRANSPLANTATION EMBRYOS INTO TO SEE IF WE CAN MAKE A CLONED CHILD. THIS WOULD BE A PREMEDITATED ATTEMPT, AND IT WOULD BREAK CALIFORNIA LAWS. AND THAT SORT OF PREMEDITATED ATTEMPT CAN OCCUR WHETHER OR NOT THERE'S SEPARATION BETWEEN THE LAB AND THE CLINIC.

DR. KIESSLING: I'M NOT SPEAKING TO WHETHER IT'S APPROPRIATE OR NOT. I'M JUST SPEAKING TO THE FACT THAT THERE'S A REPORT OUT THERE BY THE AAAS THAT THIS IS HOW IT SHOULD BE DONE. AND I THINK THAT REPORT IS WHAT'S GENERATED SOME OF THIS CONCERN.

I PERFECTLY AGREE WITH YOU, KEVIN. OBVIOUSLY IF YOU WANT TO DO THIS, YOU'RE GOING TO DO IT. AND IF

YOU DON'T WANT TO DO IT, YOU'RE NOT GOING TO DO IT. THERE'S THIS REPORT THAT EXISTS.

DR. PRIETO: I HAVE TO AGREE WITH KEVIN, THAT IF SOMEONE IS DETERMINED TO DO THIS IN VIOLATION OF CALIFORNIA LAW AND THE CALIFORNIA CONSTITUTION, THE PHYSICAL SEPARATION OF 25 OR 50 OR A HUNDRED MILES IS GOING TO MEAN NOTHING.

DR. ROWLEY: I'D LIKE TO BRING THIS BACK TO THE REAL WORLD ALSO IN THAT IT SEEMS TO ME THE THING THAT ONE REALLY WANTS TO KEEP CLOSE TRACK OF ARE THOSE EFFORTS IN THE RESEARCH LABORATORY THAT ACTUALLY APPEAR TO BE SUCCESSFUL IN DEVELOPING NOT ONLY A BLASTOCYST, BUT CELL LINES FROM THE BLASTCYST. WHEN WE TALK ABOUT SETTING UP A CELL BANK, IT'S THAT MATERIAL THAT WILL ULTIMATELY BE USEFUL.

WHAT'S CLEAR FROM THE KOREAN EXPERIENCE IS THAT YOU HAVE 2,000 EGGS AND NOTHING TO SHOW FOR IT. SO I THINK IT'S TRUE YOU WANT TO TRACK THAT YOU GOT TEN EGGS FROM HERE AND 12 FROM THERE AND SUCH-AND-SUCH A DAY AND YOU DID THUS AND SO, AND THESE ARE THE RESULTS. BUT AT THE END OF THE DAY, THE THINGS THAT SHOULD BE REGISTERED ARE THE SUCCESSES, IF YOU WILL; NAMELY, THE EMBRYONIC STEM CELL LINES, WHETHER FROM SCNT OR JUST EMBRYO CULTURE, THAT ARE AVAILABLE.

CO-CHAIR LO: ...SUPPORTS THE IDEA OF

GEOGRAPHICAL SEPARATION IN TERMS OF NOT ADDING PROTECTIONS BEYOND WHAT WE HAVE.

TO COME BACK TO THE OTHER SUGGESTION ABOUT MAKING THIS PUBLIC, MY SUGGESTION IS THAT WE GO AND -- I THINK IN PRINCIPLE WE AGREE THAT INFORMATION SHOULD BE MADE AVAILABLE TO THE PUBLIC REGARDING WHAT CIRM RESEARCH FUNDING HAS PRODUCED. AND I THINK WE NEED TO TALK WITH THE GRANTS MANAGEMENT WORKING GROUP AS TO WHAT THEY ARE REQUIRED TO REPORT BACK TO CIRM. I THINK CIRM CAN CERTAINLY TAKE THE INFORMATION THAT'S REPORTED BACK TO THEM AND MAKE THAT AVAILABLE TO THE PUBLIC IN TERMS OF SUMMARY STATISTICS, AS KEVIN SUGGESTED, TO REASSURE THE PUBLIC THAT ALL THE OOCYTES RETRIEVED WERE ACCOUNTED FOR IN A RESPONSIBLE MANNER WITHOUT COMPROMISING PATIENT IDENTITY AND PRIVACY.

WITHOUT KNOWING SPECIFICALLY WHAT PROVISIONS ARE IN PLACE FOR REPORTING UNDER THE GRANTS WORKING GROUP, IT'S HARD FOR US TO CRAFT SOMETHING THAT'S NOT CONSISTENT WITH THAT. THEY'VE PUT A LOT OF EFFORT AND TIME SORT OF FIGURING THAT OUT.

DR. TAYLOR: I THINK, JUST TO REITERATE WHAT JANET SAID, IT'S REALLY IMPORTANT THAT THAT REPORTING TO THE PUBLIC NOT COMPROMISE HIPAA PROTECTED INFORMATION. THAT'S GOING TO BE REALLY IMPORTANT. IN THOSE FEW CELLS THAT GO FORWARD, WE WANT TO TRACK THOSE

INDIVIDUALS. WE DON'T WANT TO LOSE TRACK OF THEM. I JUST WANT TO MAKE SURE THAT OUR PUBLIC REPORTING PROCESS DOESN'T COMPROMISE THE ABILITY TO FIND OUT FIVE YEARS DOWN THE LINE THAT SOMEBODY DEVELOPED PARKINSON'S DISEASE WHO ACTUALLY WAS A DONOR THAT MIGHT REALLY CHANGE THE WAY WE COULD THERAPEUTICALLY USE THOSE CELLS.

CO-CHAIR LO: MY UNDERSTANDING IS THAT THE, KEVIN'S SUGGESTION, THAT WOULD BE DEEMED AN AGGREGATE FORM THAT'S REALLY ACCOUNTING FOR A NUMBER OF OOCYTES AND SORT OF GIVING A SUMMARY REPORT HOW MANY FAILED TO HAVE ANYTHING HAPPEN AND WERE DISCARDED, HOW MANY WERE USED TO CREATE EMBRYONIC STEM CELL LINES THAT ARE NOW ONGOING, BUT NOT TO IDENTIFY THE DONORS AT ALL.

DR. EGGAN: THAT'S RIGHT.

CO-CHAIR LO: I THINK THAT WOULD BE A GRAVE VIOLATION OF PRIVACY.

DR. EGGAN: THERE MAY BE -- SO THE OOCYTE DONORS, THAT'S SORT OF IRRELEVANT BECAUSE THE GENETIC MATERIAL IS GOING TO BE REMOVED FROM THE EGG. THIS IS CERTAINLY A GREAT CONCERN AND THERE SHOULD BE SOME THINKING ABOUT SORT OF -- THESE CONCERNS ABOUT SOMATIC CELL DONORS ARE IMPORTANT, AND THERE CERTAINLY NEEDS TO BE SOME TRACKING OF THIS MATERIAL AS WELL. CERTAINLY NOT ON THE SAME LEVEL AS WE'RE CONSIDERING FOR THE

OOCYTE DONORS. AND, AGAIN, THIS SORT OF INFORMATION, I DON'T SEE HOW ANY HOW IDENTIFYING INFORMATION WOULD NEED TO BE INCLUDED HERE. IN FACT, IN GENERAL, IT'S HARD FOR ME TO IMAGINE, EXCEPT FOR UNDER VERY SPECIFIC CIRCUMSTANCES, WHY YOU NEED TO RECONTACT THESE WOMEN LATER.

DR. PRIETO: I THINK I CAN FORESEE HOW YOU MIGHT -- I MEAN THE IDENTITY --

CO-CHAIR LO: LET'S TRY AND FOCUS ON THIS PARTICULAR. I'M A LITTLE CONCERNED ABOUT SORT OF OUR GETTING INTO TOPICS THAT REALLY AREN'T DIRECTLY ON TARGET. I THINK JANET'S POINTED OUT THAT THERE ARE TRACKING REQUIREMENTS THAT THE FDA PUTS IN PLACE IF YOU'RE GOING TO USE THIS THERAPEUTICALLY. I THINK ANY RESEARCHER, SINCE THAT'S THE GOAL, IS GOING TO KEEP VERY METICULOUS RECORDS AS WILL THE INSTITUTION, AND IT WILL INCLUDE SOME SORT OF LOOK-BACK. THAT'S GOT TO BE DONE WITH THE UTMOST RESPECT FOR PRIVACY AND CONFIDENTIALITY.

WHAT WE NOW IMPOSE UNDER 100010 IS A REQUIREMENT THAT INSTITUTIONS, EACH INSTITUTION TRACK CIRM-FUNDED RESEARCH ACTIVITIES. AND THEN I THINK WHAT WE NEED TO WORK OUT IS WHAT THEY NEED TO REPORT UNDER THE GRANTS WORKING GROUP REGULATIONS BACK TO CIRM AND HOW THAT INFORMATION CAN BE MADE PUBLIC IN A WAY THAT

DOESN'T VIOLATE PRIVACY AND CONFIDENTIALITY OF THE DONORS AND DOESN'T VIOLATE TRADE SECRETS AND POTENTIAL INTELLECTUAL PROPERTY OF THE INVESTIGATORS. BUT CONSISTENT WITH THAT, I THOUGHT OUR SPIRIT WAS WE DO WANT TO MAKE THAT AGGREGATE INFORMATION PUBLIC TO MAKE SURE THE PUBLIC UNDERSTANDS WHAT HAPPENS TO ALL THESE MATERIALS THAT WERE DONATED FOR RESEARCH.

DR. ROWLEY: THIS WAS AN ISSUE THAT WE SPENT A LOT OF TIME ON IN THE NATIONAL ACADEMY WORKING GROUP. AND IT'S MY RECOLLECTION, AND ALTA CAN ADD TO THIS, THAT THIS WAS ONE OF THE IMPORTANT FUNCTIONS OF THE ESCRO COMMITTEE SO THAT THEY HAVE ONE BODY, AND THIS WAS MODELED ON THE UNITED KINGDOM, HFEA, THAT THERE IS ONE OFFICE THAT LOOKS AT ALL OF THE CONSENT FORMS AND SAYS, YES, EVERYTHING WAS DONE APPROPRIATELY, THE DONORS WERE INFORMED, ETC., AND THEN THAT THEY CERTIFIED TO THE INVESTIGATORS THAT THIS IS THE CASE. AND WHEN THE INVESTIGATOR COMES BACK AND SAYS OOCYTE NO. 120 ACTUALLY LED TO A CELL LINE, AND THEN THE CELL LINE IS IDENTIFIED. THAT CAN BE TRACKED TO OOCYTE 120, AND YOU HAVE ALL OF THE INFORMATION THAT WAS OBTAINED WITH PROPER INFORMED CONSENT.

YOU SEE, THE WHOLE UNDERPINNING OF SHARING OF CELL LINES IN CALIFORNIA AND ELSEWHERE IS THAT SOMEBODY IS MINDING THE STORE, AND YOU DON'T NEED TO KNOW ANY OF

THAT INFORMATION ABOUT THE DONOR, BUT YOU NEED TO KNOW THAT SOMEBODY DID DO DUE DILIGENCE.

CO-CHAIR LO: THIS IS WHY WE INCORPORATED THOSE NAS GUIDELINES, WHICH ARE THE GROUNDS FOR THIS SECTION. AS JANET SAID, THEY WERE WELL THOUGHT OUT.

I'M GOING TO MOVE AHEAD, THEN, TO 100011, MATERIALS SHARING, AGAIN, JUST TO REMIND US THAT THIS ATTEMPTS TO PUT INTO LANGUAGE WHAT WE AGREED ON, THAT STEM CELL LINES AND BIOMEDICAL MATERIALS DEVELOPED WITH CIRM FUNDING SHOULD BE BROADLY DISSEMINATED. AND CIRM-FUNDED RESEARCH INSTITUTIONS SHALL COMPLY WITH THE CIRM IP POLICY INTENDED TO ENSURE DATA AND MATERIALS EXCHANGE. IT'S WHAT JEFF SHEEHY PRESENTED TO US YESTERDAY. AND THEY'RE EXTENSIVE, DETAILED REGULATIONS, AND WE'RE NOT GOING TO REPEAT THOSE, BUT WE WANT TO JUST SIGNAL TO THE PUBLIC THAT THIS IS AN INTERLOCKING SET OF RECOMMENDATIONS, AND THEY ARE REALLY STATE-OF-THE-ART, OR BEYOND STATE-OF-THE-ART, JEFF -- WHAT'S THE PHRASE YOU USED? -- PUSHING THE ENVELOPE OF REALLY EXPANDING ACCESS TO OTHER RESEARCHERS AND ACCESS TO THE PUBLIC OF PUBLICATIONS AND RESULTS OF RESEARCH.

SO I JUST WANT TO SIGNAL HERE THAT THIS IS SOMETHING THAT IS A RESPONSIBILITY OF CIRM-FUNDED RESEARCHERS TO COMPLY WITH.

SO THE LANGUAGE, AGAIN, IS GOING TO NEED TO BE CRAFTED TO MAKE SURE THAT IT PASSES ADMINISTRATIVE LAW OFFICE MUSTER, AND THERE WILL BE CITATION TO THE PROVISIONS THAT JEFF'S IP WORKING GROUP IS GOING TO RECOMMEND TO THE ICOC.

PUBLIC COMMENTS ON THIS MATERIAL. STARTING AGAIN, I WANT TO REMIND US, WE HAD THE SUBSTANCE OF THIS PRESENTED YESTERDAY MORNING.

I WANT TO THEN GO BACK TO SOME THINGS WE SKIPPED YESTERDAY. AND THAT'S BACK TO PAGE 3, PAGES 3, 4, AND PART OF 5 ABOUT THE STRUCTURE OF SCRO'S, FORMERLY ESCRO'S. AND AT THE BOTTOM OF PAGE 3, 100005, MEMBERSHIP AND FUNCTION, TURNING OVER TO THE NEXT PAGE, AGAIN, THESE ARE THINGS WE TALKED ABOUT AT LENGTH IN PREVIOUS MEETINGS. THERE'S ONLY SOME MINOR EMENDATIONS.

THE FIRST SECTION HAS TO DO WITH THE COMMITTEE MEMBERSHIP AND FUNCTION. AND JUST TO REFRESH OURSELVES, WE ALLOW A LOT OF FLEXIBILITY TO SET UP, TO COOPERATE ON A SCRO. IF CIRM WANTS TO SET ONE UP, THAT'S EXPRESSLY PERMITTED.

SUBPART (A), MEMBERSHIP, WHAT WE'VE ADDED IS AT LEAST ONE REPRESENTATIVE OF THE PUBLIC ON THAT SCRO WHO IS NOT OTHERWISE AFFILIATED WITH THE RESEARCH INSTITUTION, AGAIN, KEEPING IN THE SPIRIT OF OUR

WANTING TO KEEP THE PUBLIC VERY MUCH INVOLVED WITH THIS ONGOING RESEARCH PROCESS.

AND THEN (B), WHICH HASN'T CHANGED AT ALL, IS ON THE FUNCTION OPERATION. SO WHAT'S ADDED HERE FROM BEFORE IS THE REPRESENTATIVE OF THE PUBLIC AS OPPOSED TO -- A MEMBER OF THE PUBLIC IS WHAT THE NAS GUIDELINES SAID. AND A COMMENTER SAID THAT PUBLIC IS VAGUE, AND SOMEONE ELSE SAID LAY MEMBER. WE THOUGHT WHAT WE REALLY WANT IS SOMEONE WHO'S NOT OTHERWISE PART OF THE RESEARCH INSTITUTION.

THOUGHTS ON THAT EMENDATION?

MR. SHEEHY: IT SEEMS VAGUE. I DON'T KNOW IF OTHER BODIES THAT HAVE PUBLIC REPRESENTATION MIGHT HAVE A BETTER DEFINITION. I'M NOT UNHAPPY WITH THE LANGUAGE.

CO-CHAIR LO: THIS IS TAKEN FROM THE COMMON RULE. 45 CFR 46 REQUIRES SOMEONE WHO'S NOT OTHERWISE AFFILIATED WITH THE RESEARCH INSTITUTION. THAT'S THEIR DEFINITION OF NONAFFILIATED.

ANY PUBLIC COMMENT ON THIS PARTICULAR POINT?

MR. SIMPSON: I THINK IT IS A LITTLE BIT VAGUE. THIS IS JOHN SIMPSON FROM THE FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. I GUESS WHAT WOULD CONCERN ME, I UNDERSTAND WHY YOU WOULDN'T WANT SOMEONE AFFILIATED WITH THE RESEARCH INSTITUTION, BUT SUPPOSE

YOU HAD SOMEONE WHO WAS THE PRESIDENT OF A BIOTECH FIRM. I THINK THAT RAISES POTENTIAL CONFLICTS. MY UNDERSTANDING OF REPRESENTATIVE OF THE PUBLIC WOULD BE A LAYPERSON WHO IS NOT INVOLVED IN -- HAS FINANCIAL INTEREST IN THE POSSIBLE RESULTS OF THE RESEARCH.

CO-CHAIR LO: SO THERE ARE TWO DIFFERENT SUGGESTIONS. LET ME JUST MAKE SURE WE HAVE THEM IN MIND. ONE IS THAT IT BE A NONSCIENTIST AND OTHERWISE THAT THERE BE NO FINANCIAL CONFLICT OF INTEREST THAT THIS REPRESENTATIVE HAS.

MR. SIMPSON: THAT WOULD BE IT, YEAH.

CO-CHAIR LO: JUST, AGAIN, TO REMIND OURSELVES, THERE ARE ALSO UNDER THE COMMON RULE PROVISIONS FOR LAY MEMBERS AS WELL AS SO-CALLED COMMUNITY MEMBERS THAT MAY, IN FACT, BE THE SAME PERSON ON IRB'S, SO THERE'S SOME PRECEDENT FOR THIS NOTION OF NOT BEING A SCIENTIST.

MR. REYNOLDS: I WOULD RECOMMEND THAT YOU CONSIDER A PROVISION REGARDING THE OVERALL COMPOSITION OF THE SCRO COMMITTEE REGARDING TOTAL NUMBER OF SCIENTISTS RELATIVE TO NONSCIENTISTS. I BELIEVE THE ANALOGOUS COMMITTEE IN THE UNITED KINGDOM REQUIRES THAT A MAJORITY OF THE BOARD ACTUALLY BE NONSCIENTISTS. I THINK THAT THAT COULD BE AN ADMIRABLE TARGET OR DIRECTION TO HEAD TOWARDS IN THE SENSE OF HAVING A

BALANCE OF PERSPECTIVES ON THE COMMITTEE.

CO-CHAIR LO: THANK YOU. SO COUPLE SUGGESTIONS MADE. COMMITTEE MEMBERS, THOUGHTS, COMMENTS, RESPONSES?

DR. PRIETO: I THINK THAT I HAVE SOME MIXED FEELINGS ABOUT WHETHER WE SHOULD SPECIFY THAT IT BE A LAYPERSON OR PERSONS. I'M JUST WONDERING ABOUT THE -- WHETHER A LAYPERSON WOULD HAVE SOME FAMILIARITY WITH THE CONCEPTS AND THE ISSUES. AND I WOULDN'T WANT TO SEE SOMEONE THERE WHO COULD BE SNOWED BY INFORMATION AND NOT REALLY HAVE SOME GRASP OF THE ISSUES. I DO THINK IT WOULD BE IMPORTANT, THOUGH, TO SPECIFY THAT THAT PERSON OR PERSONS SHOULD NOT HAVE ANY CONFLICTS, ANY EXISTING OR POTENTIAL FUTURE INTEREST IN THE OUTCOME OF THE RESEARCH.

MS. CHARO: I'M GOING TO CHECK ON THE UK BECAUSE I WAS NOT UNDER THE IMPRESSION THAT A MAJORITY IS MADE UP OF LAYPEOPLE, BUT THE PROBLEM ALSO THE COMPARABILITY OF THE KINDS OF COMMITTEES WE'RE TALKING ABOUT SINCE THEY'VE GOT A LICENSING SCHEME DIFFERENT FROM WHAT WE'RE TALKING ABOUT HERE. I JUST WANT TO MAKE SURE THAT WE STAY FOCUSED ON THE PURPOSE OF THE ESCRO COMMITTEE AND MATCH THE MEMBERSHIP TO THE PURPOSE.

THE PURPOSE IS NOT TO REDEBATE THE ETHICS OF

STEM CELL RESEARCH. THE PURPOSE IS NOT TO BE TAKING PRIMARY RESPONSIBILITY FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH OR OF PEOPLE WHO DONATE MATERIALS FOR RESEARCH WHICH IS IN THE PURVIEW OF THE IRB. IRB'S PARAMETERS BEING DETERMINED BY THIS GROUP'S REGULATORY DIRECTIONS.

THE REAL PRIMARY PURPOSES OF THE ESCRO ARE, FIRST, AS JANET WAS EMPHASIZING BEFORE, TO MAINTAIN AN OVERALL AWARENESS OF WHAT IS GOING ON IN TERMS OF MATERIALS IN USE AND FORMS OF RESEARCH BEING PERFORMED FOR THE SIMPLE PURPOSE OF EVERYBODY SIMPLY HAVING A WAY TO KNOW.

SECOND, AND VERY IMPORTANTLY, TO WORK ON VERY TECHNICAL ISSUES HAVING TO DO WITH, FOR EXAMPLE, SAFETY EVALUATIONS IN THE CONTEXT OF SPECIFIC EXPERIMENTS THAT ARE BEING PROPOSED. EXAMPLES BEING HUMAN, NONHUMAN CELLULAR COMBINATIONS AT VARIOUS STAGES OF NONHUMAN ANIMAL DEVELOPMENT WHERE IT IS VERY MUCH ABOUT KNOWING WHAT IS ABSOLUTELY THE MOST CURRENT INFORMATION IN THE LITERATURE ABOUT THE DEVELOPMENTAL BIOLOGY OF THESE ORGANISMS AND WHAT IS KNOWN ABOUT THE DIFFERENTIATION IN SITU OF STEM CELLS ONCE TRANSPLANTED OR TISSUES ONCE IN GRAFTING.

SO I DO WANT TO MAKE SURE THAT WE FOCUS ON MAKING SURE THAT THE ESCRO'S MEMBERSHIP IS CAPABLE OF

PERFORMING THOSE FUNCTIONS WHICH ARE THE CORE OF ITS RESPONSIBILITIES. TO ME THAT SPEAKS TO A NEED TO HAVE A VERY SUBSTANTIAL AMOUNT OF TECHNICAL EXPERTISE EITHER PERMANENTLY PART OF IT OR AVAILABLE ON A CONSULTING BASIS. I THINK THE LAY REPRESENTATION IS PART OF, I AGREE, A KIND OF PUBLIC REASSURANCE THAT THIS IS NOT GOING ON BEHIND CLOSED DOORS. BUT I DON'T BELIEVE THAT NONTECHNICALLY TRAINED PEOPLE ARE IN A GOOD POSITION TO EVALUATE THE SAFETY ISSUES ASSOCIATED WITH, FOR EXAMPLE, TRANSPLANTING STEM CELLS OR DERIVED TISSUES INTO NONHUMAN ANIMALS AT VARIOUS DEVELOPMENTAL STAGES. I JUST DON'T THINK THAT'S A KIND OF EVALUATION THAT SOMEBODY IS CAPABLE OF IF THEY DON'T HAVE ANY TRAINING.

DR. ROWLEY: I ALSO WANTED TO MAKE THE POINT THAT CAME OUT IN EARLIER SESSIONS SOME TIME AGO, THAT WE'RE ADDING ANOTHER LAYER OF REGULATION AND OVERSIGHT, BUT THIS HAS TO BE DONE IN THE CONTEXT OF TRYING NOT TO BE A MAJOR IMPEDIMENT IN THE SCIENCE THAT THIS WHOLE PROPOSAL IS SUPPOSED TO BE ENCOURAGING. THEREFORE, YOU MAY HAVE ESCRO'S MEETING MONTHLY ON SOME OF THESE ISSUES. AND SO THE MORE UNWIELDY YOU GET IT IN TERMS OF MANY, MANY MEMBERS NOT AFFILIATED WITH THE INSTITUTION, THE MORE DIFFICULT IT IS FOR THEM TO COME TO REGULAR MONTHLY MEETINGS OR SOMETHING OF THAT SORT.

DR. TAYLOR: I ABSOLUTELY AGREE WITH ALL OF

THIS. WE CAN'T UNDERESTIMATE THE IMPORTANCE. THE ESCRO IS REALLY GOING TO BE THE WHOLE CRUX OF THE WHOLE CIRM PROGRAM GOING FORWARD. THESE PEOPLE ARE GOING TO HAVE TO CONSISTENT. THEY'RE GOING TO HAVE TO BE REALLY COMMITTED. THERE'S, I THINK, GOING TO HAVE TO BE A LOT OF FUNDING, FRANKLY, TO SUPPORT THE ESCRO'S BECAUSE WHEN YOU THINK ABOUT THE OVERSIGHT AND THE TRACKING RESPONSIBILITIES THAT WE'VE LAID OUT FOR THEM, IT REALLY IS THE MOST ONEROUS PART OF THE REGULATION, I THINK, THAT'S GOING ON. SO WE DEFINITELY DON'T WANT TO UNDERESTIMATE THIS COMPONENT OF IT.

DR. EGGAN: I THINK WE SHOULDN'T LOSE SIGHT OF THE FACT THAT THERE ARE LARGE SUMS OF MONEY AT STAKE IN THESE INSTITUTIONS IN COMPLYING. SO THE FUNDING ASPECT IS EXPLICIT. AND IT SEEMS -- I DON'T KNOW THAT THERE'S SPECIAL FUNDS AVAILABLE FOR INSTITUTIONAL REVIEW BOARDS, BUT MEDICAL SCHOOLS AND UNIVERSITIES CERTAINLY HAVE THEM BECAUSE THEY MUST. I DON'T THINK THIS SHOULD BE AN EXCEPTION.

I'M GOING TO SAY THIS AGAIN. I THINK THAT THE REAL ONEROUS PORTION OF THIS IS GOING TO FALL TO THE INVESTIGATORS THEMSELVES. FOR THEM, I THINK THERE SHOULD BE A RECOGNITION THAT THERE NEEDS TO BE MONEY BECAUSE I THINK IT'S VERY DIFFICULT FOR THE SCIENTISTS TO GET THE SORT OF ADMINISTRATIVE SUPPORT THAT'S GOING

TO BE REQUIRED TO NAVIGATE THROUGH THESE THINGS.

MR. SHEEHY: WELL, FIRST, I THINK THERE SHOULD BE TWO MEMBERS OF THE PUBLIC. WE SHOULDN'T HAVE ONE PERSON HANGING OUT THERE BY THEMSELVES. I HAVE TO SAY, BASED ON MY EXPERIENCE WITH HIV RESEARCH WHERE IT IS ROUTINE TO HAVE COMMUNITY ADVISORY BOARDS, I DON'T THINK THAT THIS -- IT'S A LITTLE BIT DEMEANING TO SUGGEST THAT MEMBERS OF THE PUBLIC CANNOT MEANINGFULLY PARTICIPATE IN THIS DISCUSSION WHEN I'VE SEEN EXAMPLES IN HIV RESEARCH WHERE PEOPLE HAVE DRILLED DOWN FAIRLY DEEPLY ON THIS. I THINK BERNIE HAS EXPERIENCE WITH THIS.

THE STUPID PUBLIC ARGUMENT IS NOT A GOOD ONE. AND I THINK -- I DO THINK -- I THINK WE KIND OF DIMINISH THE VALUE OF HAVING A LAYPERSON IF WE DO MAKE THAT THE ONLY PERSON WHO FULFILLS THAT ROLE. IT GETS AWFULLY LONELY, I THINK IN, THOSE KINDS OF SCENARIOS.

DR. KIESSLING: I DON'T KNOW MANY HERE HAVE ACTUALLY PARTICIPATED IN AN ESCRO MEETING, AND I HAVE, EVEN THOUGH I'M OPPOSED TO THEM. AND ONE OF THE THINGS THAT WAS CLEAR IS THAT WHAT'S GOING TO BE REQUIRED OF THAT COMMITTEE MEMBER IS NOT NECESSARILY SOMEBODY WITH EXPERTISE IN ASSISTED REPRODUCTION, BUT SOMEBODY WITH EXPERTISE IN ANIMAL RESEARCH GUIDELINES BECAUSE MOST OF THE RESEARCH THAT'S GOING TO COME BEFORE ESCRO'S, AT

LEAST IN THE SHORT TERM, ARE GOING TO INVOLVE ANIMALS, STEM CELLS AND ANIMALS OF SOME KIND.

SO IF YOU ARE GOING TO REQUIRE CERTAIN EXPERTISE ON IT, I DON'T -- THERE WAS NO PARTICULAR ISSUES OF NEEDING EXPERTISE IN ASSISTED REPRODUCTION. THAT'S GOING TO BE HANDLED BY THE IRB.

CO-CHAIR LO: SO YOU'RE SUGGESTING ADDING EXPERTISE IN ANIMAL --

DR. KIESSLING: I DON'T THINK THAT THE SCRO COMMITTEE NEEDS EXPERTISE IN ASSISTED REPRODUCTION. THE DANGER YOU HAVE HERE IS DUPLICATING THE IRB.

DR. ROWLEY: IT WAS OUR ASSUMPTION AT THE ACADEMY THAT THE ANIMAL CARE COMMITTEE WOULD BE HANDLING ALL THE SPECIFIC THINGS RELATED TO ANIMAL CARE SO THAT THAT'S NOT AN ISSUE FOR ESCRO.

DR. KIESSLING: IT ISN'T SO MUCH ANIMAL CARE AS SORT OF ANIMAL RESEARCH, SORT OF CAN YOU REALLY JUSTIFY PUTTING HUMAN STEM CELLS INTO A MOUSE BRAIN. THERE NEEDS TO BE SOME KIND OF EXPERIENCE WITH THAT. THERE NEEDS TO BE ALMOST NO HUMAN EXPERIENCE.

DR. ROWLEY: IACUC DOESN'T NECESSARILY HAVE THAT KIND OF EXPERIENCE.

DR. KIESSLING: NO, THEY DON'T. THAT'S RIGHT. SO THE SCRO COMMITTEE NEEDS THAT. THESE PROGRAMS, LIKE THE PROJECT THAT I REVIEWED, IS GOING

TO -- HAS BEEN THROUGH IRB, AND IT'S BEEN THROUGH IACUC. AND NOW IT'S COMING TO SERVE THE FUNCTIONS THAT WE'VE TALKED ABOUT HERE, THAT YOU WANT TO HAVE AN OVERSIGHT, SOMEBODY WHO'S KEEPING TRACK OF WHAT'S GOING ON AND SOMEBODY WHO'S KEEPING TRACK OF THE STEM CELL LINES THAT ARE BEING USED. BUT IN ORDER TO JUDGE IF THIS IS AN EXTRAORDINARY EXPERIMENT OR AN ORDINARY EXPERIMENT, YOU DON'T REALLY NEED ANY KIND OF HUMAN EXPERIENCE. YOU NEED SOME KIND OF ANIMAL EXPERIMENTATION EXPERIENCE.

DR. WAGNER: I'M NOT EXACTLY SURE IF I COMPLETELY AGREE. I UNDERSTAND WHERE YOU'RE COMING FROM. I THINK WHAT WE SAID AT LEAST YESTERDAY IN PART OF OUR DISCUSSION WAS THAT IF YOU TAKE THE MODEL THAT WE HAVE WITH THE NCI AND HAVING A REPORT REVIEW COMMITTEE THAT IS SPECIFICALLY FOCUSED IN CANCER, PART OF THE ROLE OR PRIMARY ROLE IS ACTUALLY TO LOOK AT THE SCIENCE THAT'S UNIQUE TO THE FIELD THAT YOU ARE DEALING WITH BECAUSE A LOT OF THESE TECHNOLOGIES ARE NOT GENERALLY AVAILABLE IN AN IRB SETTING EVEN IF WE'RE DEALING WITH HUMAN ISSUES.

AND SO WHAT THE IRB'S TYPICALLY WILL DO IN TERMS OF THE CANCER CENTER MODEL, IF THAT'S USEFUL, IS THEY USE THAT INFORMATION AS A CHECKPOINT TO SAY, YES, THE SCIENCE IS INDEED ADEQUATE BECAUSE WE CAN'T ASSESS

THE SCIENCE. WE CAN ASSESS THE PROTECTION OF THE PATIENT. BUT THEY CAN ONLY ASSESS THAT IN THE CONTEXT OF THE SCIENCE AND WHETHER THE SCIENCE JUSTIFIES THE WORK THAT'S BEING DONE.

I THINK THE ESCRO IS GOING TO PROVIDE THAT ROLE, I THINK, OF OVERSEEING THE SCIENCE. AND EVEN FOR ANIMAL STUDIES, AS YOU KNOW, WHAT WILL HAPPEN IS THAT, FOR EXAMPLE, HOW MANY TIMES DO YOU DO AN EXPERIMENT BEYOND WHICH YOU SAY THAT IT'S NOT GOING TO WORK. FOR EXAMPLE, DO I KEEP ON TAKING OOCYTES OVER AND OVER AND OVER AGAIN WHEN I KNOW AT SOME POINT IT'S NOT GOING TO WORK? WHY PUT PEOPLE AT RISK WHEN THE STUDY HAS SUFFICIENTLY HAD A NEGATIVE RESULT SO THAT YOU DON'T CONTINUE THAT WORK. THAT WOULD BE A HUMAN SETTING.

SIMILARLY, WITH THE ANIMALS, THERE'S CERTAIN EXPERIMENTS YOU WOULD NOT CONTINUE DOING. YOU HAVE TO HAVE A FINITE NUMBER OF ANIMALS THAT YOU WOULD PRESCRIBE. PERHAPS THAT NEEDS TO BE IN THE CONTEXT OF A GROUP THAT IS FAMILIAR ENOUGH WITH THE STEM CELL RESEARCH TO SAY WHETHER OR NOT THAT'S INDEED TRUE OR NOT. HOPEFULLY THAT MAKES SENSE.

THE POINT IS THAT I THINK THAT IT PROVIDES, AS ALTA WAS SAYING, IS THAT IT PROVIDES A SCIENTIFIC REVIEW AT LEAST AS PART OF ITS FUNCTION, THAT THERE IS NOWHERE ELSE TO GO IN AN INSTITUTION BECAUSE THE WORK

IS SO UNIQUE.

CO-CHAIR LO: THIS IS BASED ON THE NAS RECOMMENDATION WHICH REALLY ACKNOWLEDGED THAT THE SCIENTIFIC EXPERTISE IS NOT NECESSARILY THERE IN THE IRB AND THAT THERE ARE ETHICAL ISSUES THAT ARE RAISED UNIQUE TO STEM CELL RESEARCH THAT GO BEYOND TRADITIONAL IRB HUMAN SUBJECTS CONCERNS, AND THAT YOU NEED A STRONG SCIENCE UNDERSTANDING TO MAKE THOSE KINDS OF JUDGMENTS. ALTA GAVE US THE EXAMPLE OF THE TRANSPLANTATION OF HUMAN STEM CELLS INTO ANIMALS.

THERE'S ONE ISSUE THAT I'M NOT SURE I'VE HEARD AGREEMENT, AND THAT'S THE REPRESENTATIVES OF THE PUBLIC. AGAIN, THIS WAS WRITTEN TO BE NONAFFILIATED. IT DOESN'T SAY LAY. IT JUST SAYS NONAFFILIATED. THERE ARE CONCERNS RAISED ABOUT WHETHER ONE REPRESENTATIVE ON A COMMITTEE IS GOING TO BE EFFECTIVE, AND SHOULD WE HAVE AT LEAST TWO. AND, AGAIN, THERE'S NOTHING TO PREVENT THAT PERSON FROM ACTUALLY HAVING EITHER BY TRAINING OR BY LEARNING ACQUIRING AN EXPERTISE.

I MUST SAY ON A PERSONAL LEVEL I CERTAINLY AGREE WITH JEFF SHEEHY, THAT IN THE HIV WORLD, THERE ARE REMARKABLE NONAFFILIATED MEMBERS WHO HAVE REALLY CONTRIBUTED TO THE SCIENCE BY ASKING TOUGH QUESTIONS AND LEARNING. THE POINT IS WHETHER ONE REPRESENTATIVE ON A COMMITTEE IS ENOUGH.

CO-CHAIR LANSING: WHY DON'T WE JUST SAY NO LESS THAN ONE AND LEAVE IT --

MR. TOCHER: CURRENTLY IT SAYS AT LEAST.

CO-CHAIR LANSING: AT LEAST ONE. SO THEN THAT LEAVES IT'S OPEN.

CO-CHAIR LO: CERTAINLY LEAVES IT OPEN. I JUST THINK JEFF RAISED THE QUESTION WAS ONE PERSON ON A COMMITTEE NOT GOING TO HAVE AS MUCH VOICE AS IF THERE WAS MORE THAN ONE.

CO-CHAIR LANSING: IT'S HARD TO GET PEOPLE SOMETIMES. I DON'T WANT -- AGAIN, I DON'T WANT TO, LIKE, SUDDENLY FIND THAT WE CAN'T GET THE PERSON. WE CAN'T FULFILL IT. IF THE ONE PERSON FEELS THAT THEY NEED ANOTHER PERSON, I FEEL COMFORTABLE THAT THEY'LL BE ABLE TO ACHIEVE THAT. I THINK WE SAY AT LEAST ONE, THEN WE'RE MAKING A STATEMENT.

CO-CHAIR LO: AGAIN, THIS COULD INCLUDED IN THE STATEMENT OF REASONS.

MS. CHARO: FIRST, JUST FOR THE RECORD, I DIDN'T MEAN, JEFF, TO EQUATE UNTRAINED WITH STUPID. I DON'T THINK YOU ACTUALLY THOUGHT I DID. I THINK YOUR POINT ABOUT ONE VOICE IS WELL TAKEN, AND I'VE CERTAINLY OBSERVED IT MYSELF ON AN IRB. I THINK A REQUIREMENT THAT THERE BE TWO PEOPLE WHO ARE UNAFFILIATED AND NONTECHNICALLY TRAINED IS EASILY ACCOMMODATED.

MY COMMENTS WERE REALLY DIRECTED AT THE SUGGESTION THAT A MAJORITY OF THE COMMITTEE BE MADE UP OF NONTECHNICALLY TRAINED PEOPLE, WHICH, I THINK, CHANGES THE DYNAMIC CONSIDERABLY WITH REGARD TO HOW IT CAN FUNCTION. BUT I WAS NOT TRYING TO ARGUE FOR HOLDING THE LINE AT ONE AND NO MORE THAN ONE.

MR. SHEEHY: THE ONLY REASON I SAY TWO IS IF WE WANT IT TO BE MEANINGFUL. THIS IS A NEW ADDITION. I'M NOT -- I HAVEN'T REALLY THOUGHT ABOUT IT, BUT IT ALSO SERVES, I BELIEVE, AN IMPORTANT -- AND I GO BACK TO THE COMMENT DR. KIESSLING MADE WHEN WE FIRST TALKED TO HER ABOUT BEING ON THIS COMMITTEE. SCIENTISTS NEED TO COME OUT FROM BEHIND THE BENCH. PEOPLE DO NOT UNDERSTAND STEM CELL RESEARCH, AND THE MORE THE LAY PUBLIC IS INVOLVED IN THIS PROCESS, THE MORE BENEFICIAL IT IS TO THE UNDERSTANDING. SO THAT'S...

CO-CHAIR LO: OTHER COMMENT ON THIS ISSUE?

MR. SHESTACK: WHAT'S THE PROCESS FOR SELECTING THE PUBLIC MEMBER THAT GOES ON AN IRB OR AN ESCRO TYPICALLY?

DR. KIESSLING: IT'S VERY AD HOC.

MS. CHARO: IT VARIES FROM INSTITUTION TO INSTITUTION. SO IN MANY CASES, IN IRB'S, THAT HAS ACTUALLY BECOME CODE FOR CLERGY. AND SO YOU GET ONE OF THE MORE LOCAL PROMINENT CLERGY PEOPLE SELECTED EITHER

BY THE DEAN OF THE MEDICAL SCHOOL OR THE CHANCELLOR AT THE CAMPUS. OTHER INSTITUTIONS, THEY HAVE PEOPLE WHO HAVE LONG BEEN INVOLVED IN PATIENT ADVOCACY AND PATIENT CARE GROUPS WHO COME ON BOARD. BUT THE SELECTION IS NOT AT ALL DEMOCRATIC. IT'S USUALLY BY VIRTUE OF AN INFORMAL NETWORK AND WHOEVER HAS THE POWER OF APPOINTMENT WITHIN THE INSTITUTION.

CO-CHAIR LO: JON, IN ANSWER TO YOUR QUESTION, WE HAVE TWO NONAFFILIATED MEMBERS ON OUR ESCRO. ONE IS A HIGH SCHOOL BIOLOGY TEACHER AND THE OTHER IS A LAW PROFESSOR AT A DIFFERENT INSTITUTION. WE'RE ACTUALLY TRYING TO ADD MORE MEMBERS BECAUSE WE ACTUALLY HAVE A REQUIREMENT THAT AT LEAST ONE OF THEM HAS TO BE PRESENT AT THE MEETING, NOT JUST ON THE COMMITTEE. IT'S ACTUALLY A REAL BURDEN ON THEM, WITH THEIR OTHER COMMITMENTS, TO BE THERE. WE THOUGHT THAT INCREASING THE NUMBER OF MEMBERS WE'D ALWAYS HAVE SOME NONAFFILIATED REPRESENTATION WITHOUT MAKING IT ONEROUS ON THOSE MEMBERS.

DR. WAGNER: THE ONLY THING THAT ACTUALLY BOTHERS ME, AS I READ THIS SECTION AGAIN ON MEMBERSHIP, IS REALLY THIS ISSUE OF PRESCRIBING THE EXPERTISE IN SPECIFIC AREAS. MY FEAR IS THAT, JUST LIKE YOU JUST SAID, MAKING SURE THAT THERE IS ONE PERSON FROM THE PUBLIC THAT'S AVAILABLE. WHAT HAPPENS IF I DON'T HAVE

ACCESS TO AN ASSISTED REPRODUCTIVE SPECIALIST WHO'S AVAILABLE FOR EVERY MEETING? I'M JUST AFRAID THAT THE INTENTION IS GOOD. AND CERTAINLY YOU NEED TO HAVE ACCESS IN GENERAL FOR SPECIFIC QUESTIONS. BUT IF YOU'RE SAYING THE COMMITTEE MUST BE COMPRISED OF AND AVAILABLE FOR EACH MEETING --

CO-CHAIR LO: WE DON'T SAY THIS IN THIS. IT SAYS NOTHING ABOUT WHO HAS TO BE AT THE MEETING.

DR. WAGNER: IT SAYS MEMBERSHIP SHALL BE COMPRISED OF. I GUESS TO MAKE SURE THAT PEOPLE ARE CLEAR THEN, SO THAT THE INSTITUTION DOESN'T SAY IT HAS TO BE IF THAT'S NOT THE INTENT.

CO-CHAIR LO: THEY MAY SAY THAT, BUT THAT'S NOT THE INTENT. THE REASON WE PUT THOSE SPECIFIC THINGS IN IS THAT ORIGINALLY IT WAS PERSONS WITH APPROPRIATE EXPERTISE. WE WERE TOLD THAT WILL GET THROWN OUT BY THE ADMINISTRATIVE LAW OFFICE BECAUSE NO ONE KNOWS WHO THEY NEED.

DR. WAGNER: FOR EXAMPLE, ALL THE STUDIES AT MY INSTITUTION, LET'S SAY, IN CALIFORNIA ARE WORKING WITH EMBRYOS THAT WERE DONATED. DO I NEED TO HAVE AN ASSISTED REPRODUCTIVE SPECIALIST PRESENT? THERE'S NO OTHER ASPECT OF THAT RESEARCH PRESENT IN MY INSTITUTION.

DR. PRIETO: COULD LANGUAGE BE SOMETHING LIKE

SHALL BE COMPRISED OF PERSONS WITH EXPERTISE IN AREAS INCLUDING, BUT NOT LIMITED TO?

CO-CHAIR LO: THAT WOULD WORK. I THINK JOHN'S QUESTION IS IS ASSISTED REPRODUCTION, SHOULD THAT NOT BE IN THERE. I GUESS THE QUESTION IS CAN WE CONCEIVE OF A PROTOCOL WHERE WE WOULDN'T WANT SOME KNOWLEDGE OF DEVELOPMENTAL BIOLOGY, STEM CELL RESEARCH, MEDICAL BIOLOGY TO BE ON THE COMMITTEE? IT'S REALLY THIS QUESTION OF WHAT'S APPROPRIATE TO THE KIND OF RESEARCH BEING DONE, OUR DESIRE TO HAVE TO SAY SOMETHING.

SCOTT, CAN YOU HELP US HERE? ARE WE FORCED TO ACTUALLY LIST THE TYPES OF EXPERTISE? I THINK THIS WAS IN RESPONSE TO A COMMENT.

DR. PRIETO: ONE FOLLOW-UP COMMENT. IT SEEMS TO ME THAT, DEPENDING ON THE RESEARCH PROPOSAL BEING EVALUATED, THAT THE ESCRO MIGHT WANT EITHER TO HAVE OR TO CONTRACT FOR PEOPLE WITH EXPERTISE IN DIFFERENT AREAS, INCLUDING THE ANIMAL RESEARCH, AS ANN MENTIONED, AND PERHAPS FOR SOME CERTAIN FUTURE RESEARCH, ASSISTED REPRODUCTION. MY LANGUAGE, I THINK, WAS INTENDED TO ALLOW A LITTLE BIT OF WIGGLE ROOM THERE. AND I THINK WE'RE NOT MANDATING THAT ALL OF THESE BE PRESENT AT EVERY MEETING ON EVERY COMMITTEE, BUT THESE ARE SOME OF THE AREAS THAT NEED TO BE REPRESENTED.

DR. KIESSLING: IRB'S FREQUENTLY FIND THE EXPERTISE THEY NEED. I THINK THAT SHOULD BE THE WAY THIS IS SET UP. YOU WANT -- YOU REALLY WANT MEMBERS OF THE PUBLIC, YOU WANT BIOETHICISTS, AND YOU WANT SCIENTISTS. AND THEN IF YOU NEED ASSISTED REPRODUCTION, YOU GO FIND SOMEBODY WHO HAS IT. BUT I THINK TO MANDATE THESE MANY SPECIFIC AREAS ON THE COMMITTEE IS A PROBLEM. IT'S HOW IRB'S WORK.

CO-CHAIR LO: I'M HEARING A LOT OF CONCERNS ABOUT SPECIFYING SPECIFIC TYPES OF EXPERTISE. SCOTT, HELP US HERE BECAUSE WE NEED TO GET THIS THROUGH OAL.

MR. TOCHER: I GUESS FROM A DRAFTING STANDPOINT, A LOT OF IT REALLY DOES SORT OF DEPEND ON WHAT IT IS YOU WANT. YOU MIGHT FIND, FOR INSTANCE, THAT THERE'S ONE INDIVIDUAL WHO SATISFIES MORE THAN ONE OF THE CRITERIA. THE PRESUMPTION MAY BE THAT THERE'S ONE INDIVIDUAL PERSON YOU'RE THINKING OF FOR EACH OF THESE, BUT, IN FACT, SOMEONE MAY BE BOTH AN EXPERT OR EXPERTISE IN STEM CELL RESEARCH AND ALSO ASSISTED REPRODUCTION OR MOLECULAR BIOLOGY. I'M NOT SURE. SO YOU MAY BE -- I'M NOT SURE IF THAT'S IMPORTANT OR NOT, BUT YOU MAY WANT TO LOOK AT THESE FOUR OR FIVE AREAS AND SAY, WELL, IF YOU SATISFY FOUR OF THE FIVE OR THREE OF THE FOUR OR WITH A MAJORITY OF THEM WITH EXPERTISE IN THIS, THAT, OR THE OTHER THING, BUT OTHERWISE I

THINK YOUR EARLIER ADVICE BEFORE I CAME ON BOARD THAT SIMPLY SAYING APPROPRIATE EXPERTISE ISN'T SUFFICIENT.

MR. LOMAX: SCOTT, CAN I REMIND YOU, TO REFRESH YOUR MEMORY, THE DISCUSSIONS WE DID HAVE WITH OFFICE OF ADMINISTRATIVE LAW, AND THEY ACTUALLY CALLED OUT THIS REQUIREMENT. AND THEY WERE EXPRESSING CONCERNS THAT IT NOT BE TOO VAGUE. THEY WERE EVEN SUGGESTING WE MAY NEED A NUMBER OF PEOPLE. SO WE ARE GETTING CAUGHT.

CO-CHAIR LO: SO IT'S PRETTY CLEAR WE DON'T HAVE THE OPTION OF LEAVING IT TOTALLY OPEN TO THE SCRO. THIS LANGUAGE ACTUALLY WAS TAKEN OVER PRETTY MUCH WORD FOR WORD FROM THE NAS GUIDELINES, WHICH LISTS, AGAIN, THESE DEVELOPMENTAL BIOLOGY, STEM CELL RESEARCH, MOLECULAR BIOLOGY, ASSISTED REPRODUCTION.

MR. TOCHER: ONE OF THE ISSUES, JUST TO GIVE SOME BACKGROUND ABOUT THE NAS GUIDELINES, IS THAT THE FEDERAL SYSTEM REG WRITING AND THE RULES ABOUT SPECIFICITY, AND THOSE REQUIREMENTS ARE DIFFERENT FROM THE STATE OF CALIFORNIA. STATE OF CALIFORNIA, GENERALLY SPEAKING, IS MUCH MORE PRECISE IN ITS REQUIREMENTS FOR SPECIFICITY.

SECONDLY, GUIDELINES, WHICH WE'RE FAMILIAR WITH AND ARE HELPFUL, THEY SORT OF ADD FLESH TO THE BONES, THAT SORT OF THING. THOSE ARE SORT OF

DISFAVORED AS A MODE OF GOVERNANCE IN THE STATE OF CALIFORNIA.

THERE SHOULD BE NOTHING IN A GUIDELINE THAT ISN'T ALREADY IN THE REGULATION SHOULD REALLY BE YOUR MODEL. SO IN SOME CASES, THEY'RE GREAT FOR INSPIRATION, BUT WE HAVE TO FINE-TUNE THEM A LITTLE MORE.

MS. CHARO: WELL, GIVEN THAT WE HAVE TO HAVE SOME DEGREE OF SPECIFICITY, JUST A COUPLE OF THINGS VERY BRIEFLY. FIRST, THE WAY IT'S WRITTEN NOW IT SAYS THAT IT SHALL BE COMPRISED OF PEOPLE WITH THE FOLLOWING EXPERTISE. AT A MINIMUM I THINK WE NEED TO SAY THAT IT SHALL BE COMPRISED OF PEOPLE REPRESENTING AT LEAST THE FOLLOWING AREAS OF EXPERTISE. SO THAT ESCRO'S THAT DETERMINE, FOR EXAMPLE, AS ANN WAS SUGGESTING, THEY'D REALLY LIKE SOMEBODY WHO'S FAMILIAR WITH ANIMAL PHYSIOLOGY OR DEVELOPMENTAL BIOLOGY OF A PARTICULAR ORGANISM THAT'S FREQUENTLY USED IN THEIR FACILITY CAN BE ADDED.

SECOND, THE AREAS THAT ARE OUTLINED HERE DON'T STRIKE ME AS BEING UNREASONABLE IN TERMS OF THE RANGE OF EXPERTISE THAT YOU REALLY WANT IN ORDER TO BE ASSURED THAT THE ESCRO IS TECHNICALLY COMPETENT TO PERFORM THE FUNCTIONS YOU'RE ASKING OF IT. SO RATHER THAN TRY TO RATCHET BACK. I UNDERSTAND THE FEAR THAT

YOU WON'T BE ABLE TO FIND PEOPLE, BUT WE FIND PEOPLE. WE DO. EVERY INSTITUTION FINDS THEM OVER TIME.

LAST, JUST GOING BACK TO THE LAY THING, I DON'T KNOW IF THIS IS THE COMMITTEE YOU WERE REFERRING TO, JESSE, BUT THERE ARE FOUR DIFFERENT COMMITTEES AT HFEA. AND THE CLOSEST IN ANALOG TO THIS ONE WOULD BE THE REGULATORY COMMITTEE -- THE REGULATION COMMITTEE. THEY'VE ALSO GOT A LAW AND ETHICS COMMITTEE. THEY'VE GOT A CLINICAL ADVANCES COMMITTEE. NEITHER OF THOSE PERFORM FUNCTIONS ANALOGOUS.

THE REGULATION COMMITTEE I FOUND FINALLY, AND IT IS ACTUALLY MUCH VAGUER THAN CALIFORNIA LAW, SCOTT. AND IT BASICALLY SAYS YOU HAVE AT LEAST FIVE MEMBERS, AND THAT THE COMMITTEE WILL BE CHAIRED BY A LAY MEMBER AND WILL INCLUDE LAY AND NONLAY MEMBERS, BUT IT DOES NOT SPECIFY THE PROPORTIONS OF LAY AND NONLAY MEMBERS.

THEY LIVE WITH A GREAT DEAL OF UNCERTAINTY OVER THERE IN MERRY OLD ENGLAND, WHICH WE'RE NOT ALLOWED TO HAVE HERE.

DR. PRIETO: DOES THE LANGUAGE THAT I SUGGESTED GIVE US OR GIVE THE ESCRO'S THE FLEXIBILITY THAT THEY NEED TO APPOINT THE APPROPRIATE MEMBERS AND NOT APPOINT THOSE WHOSE EXPERTISE --

CO-CHAIR LO: FLEXIBILITY TO INCLUDE MEMBERS BEYOND WHAT WE'VE LISTED. I'M NOT SURE IT GIVES THEM

THE FLEXIBILITY TO NOT HAVE EXPERTISE THAT'S LISTED IN OUR LANGUAGE.

MR. TOCHER: THAT'S RIGHT. WHEN YOU USE REPRESENTING AT LEAST THE FOLLOWING, THAT'S A FLOOR.

DR. PRIETO: I SAID INCLUDING, BUT NOT LIMITED TO, OR MAYBE WHICH MAY INCLUDE. WOULD THAT GIVE MORE LATITUDE?

MR. TOCHER: THAT MEANS IT MAY NOT INCLUDE ANY OF THEM. IF YOU USE MAY INCLUDE, THAT'S PERMISSIVE.

DR. PRIETO: CAN'T BE PERMISSIVE.

MR. TOCHER: THAT'S A POLICY CALL. IF YOU WANT IT TO BE PERMISSIVE. THERE'S NOTHING AT THE OAL THAT REQUIRES IT OTHER THAN IF YOU WANT IT TO BE PERMISSIVE. IF YOU WANT TO SPELL IT OUT, THAT'S UP TO YOU.

CO-CHAIR LO: REMEMBER, WE IN PRINCIPLE ADOPTED NAS GUIDELINES THAT SPELLED OUT THESE SPECIFIC AREAS. SO I THINK IF WE WANT TO SAY WE'RE CHANGING THAT TO TAKE AWAY SOME EXPERTISE REQUIREMENTS, WE NEED TO THINK --

DR. PRIETO: I DON'T KNOW THAT WE WANT TO TAKE AWAY EXPERTISE SO MUCH AS WE WANT TO GIVE A LITTLE BIT OF FLEXIBILITY TO THE ESCRO TO DETERMINE WHAT EXPERTISE THEY NEED TO EVALUATE PARTICULAR RESEARCH

PROPOSALS.

CO-CHAIR LO: THERE'S NOTHING TO KEEP AN ESCRO FROM SAYING WE DON'T NEED THE FOLLOWING MEMBERS TO REVIEW THIS PROPOSAL BECAUSE YOUR EXPERTISE ISN'T PERFECT. ALL THIS IS SAYING IS THAT THE MEMBERS HAVE TO HAVE THIS EXPERTISE. DOESN'T SAY IT HAS TO REVIEW IT, DOESN'T SAY HAVE TO BE AT THE MEETING.

DR. PRIETO: THEN PERHAPS THIS IS PERMISSIVE ENOUGH.

CO-CHAIR LO: THAT'S WHAT I'M SAYING. I THINK IF WE SORT OF SAY WE DON'T WANT PEOPLE ON THE COMMITTEE WITH CERTAIN EXPERTISE, IT MAY SEND THE WRONG MESSAGE.

DR. PRIETO: OKAY.

CO-CHAIR LO: DOES THIS ADDRESS YOUR CONCERNS? IT WAS WRITTEN NOT TO REQUIRE REVIEWER PRESENCE AT THE MEETING, JUST THAT SOMEONE HAVE THAT EXPERTISE.

DR. WAGNER: I GUESS IT JUST DEPENDS ON HOW IT'S INTERPRETED BY THE INSTITUTIONS. AND IF I READ IT, I WOULD HAVE INTERPRETED THAT THE COMMITTEE MUST CONTAIN SOMEONE WHO'S EXPERT IN ASSISTED REPRODUCTION EVEN THOUGH NO ONE IS DOING ANY RESEARCH THAT INVOLVES ASSISTED REPRODUCTION AT THAT PARTICULAR INSTITUTION. AND ALTHOUGH, AS ALTA SAYS, WE CAN LIKELY FIND SOMEONE

THAT CAN FILL THAT ROLE, IT DOESN'T MEAN THAT PERSON NECESSARILY WILL WANT TO CONTINUE TO PARTICIPATE IF THERE IS NO RESEARCH IN THAT AREA THAT HE OR SHE HAS EXPERTISE IN.

SO, AGAIN, IF THE INTERPRETATION IS ABLE TO BE FREE, AND THE ESCRO CAN DECIDE WHETHER OR NOT IT'S APPROPRIATE FOR THAT INSTITUTION, THEN THAT'S GREAT. I'M JUST TRYING TO POINT OUT THE FACT THAT I THINK THAT THAT'S AT LEAST THE ONE THAT I SEE, THE ASSISTED REPRODUCTION, WHERE THAT MIGHT NOT BE NEEDED.

CO-CHAIR LO: PROBLEM IS IF WE LEAVE IT OUT, THEN IT LOOKS AS IF WE'RE ON THE ONE HAND ENCOURAGING SCNT AND NOT REQUIRING ON THESE OVERSIGHT COMMITTEES, SO IT'S A BALANCE. YOU MAY NOT NEED IT IN SOME INSTITUTIONS, BUT YOU'RE CERTAINLY GOING TO NEED IT IN OTHERS. AND IT'S WHERE WE STRIKE THE BALANCE.

DR. ROWLEY: AS I UNDERSTAND IT, THEN YOU ARE MAKING THE DISTINCTION THE ESCRO COMMITTEE COULD CONSIST OF THESE INDIVIDUALS, BUT AT A PARTICULAR MEETING, IF THERE ARE NO GRANTS OR PROPOSALS THAT ARE DIRECTLY RELEVANT TO THAT AREA, THAT PERSON WOULDN'T NECESSARILY HAVE TO COME. AND THAT PERSON COULD BE A CONSULTANT, NOT ON THE STAFF OF THE INSTITUTION, BUT A AVAILABLE FOR ADVICE WHERE RELEVANT PROPOSALS ARE BEING DISCUSSED; IS THAT CORRECT?

DR. PRIETO: THAT'S HOW I UNDERSTAND IT.

MS. CHARO: JUST BY WAY OF BACKGROUND INFORMATION, HOW THAT GOT INTO THE NATIONAL ACADEMY GUIDELINES, IT ORIGINALLY WASN'T THERE. AND THEN, YOU KNOW, THESE MEETINGS WERE PUBLIC, THERE WERE PUBLIC COMMENTS, THERE ARE EXTERNAL REVIEWS. AND ON SEVERAL SEPARATE OCCASIONS, THE COMMENT CAME BACK FAIRLY POINTEDLY THAT THE ESCRO'S COMPOSITION HAD LACKED SOMEBODY FAMILIAR WITH ASSISTED REPRODUCTION AND THAT IT REALLY NEEDED IT. SO IT WAS ADDED AS A RESULT OF INPUT FROM OTHERS WHO SEEMED TO THINK IT WAS IMPORTANT.

CO-CHAIR LO: ANY OTHER PUBLIC COMMENT?

MR. REYNOLDS: I'D LIKE TO CLARIFY MY EARLIER COMMENT. I THINK IT MAY HAVE JUST BEEN SLIGHTLY MISINTERPRETED. I DID NOT NECESSARILY MEAN TO IMPLY THAT MAJORITY IS WHAT I WAS ASKING FOR. I CERTAINLY DIDN'T MEAN TO IMPLY NONTECHNICAL STAFF. AND PERHAPS A BETTER ANALOGY OF WHAT I HAD IN MIND IF YOU'RE ON THE COMMITTEE. IF MY NUMBERS ARE RIGHT, THIS COMMITTEE HERE IS COMPOSED OF NINE RESEARCH SCIENTISTS, FIVE PATIENT ADVOCATES, AND FOUR BIOETHICISTS BROADLY DEFINED.

WHAT I HAD IN MIND WAS THE LAST TWO GROUPS, THE NONRESEARCH SCIENTISTS. HERE ON THIS COMMITTEE AMONG THAT GROUP INCLUDES A LAWYER, A PRACTICING

PHYSICIAN, AND SO FORTH. AND THIS IS SORT OF THE BROADER CATEGORY THAT I HAD IN MIND WITH NONRESEARCH SCIENTISTS, NOT NECESSARILY NONTECHNICALLY TRAINED, BUT BIOETHICISTS, LAWYERS, AND PRACTICING PRIMARY CARE PHYSICIANS, AND SO FORTH THAT I WOULD RECOMMEND CONSTITUTE A CERTAIN MINIMAL PERCENTAGE OF THE ESCRO.

MS. CHARO: JESSE, JUST TO BE REALLY CLEAR, THOUGH, THOSE OF US THAT HAVE TRAINING IN BIOETHICISTS OR LAW DON'T NECESSARILY REALLY KNOW ENOUGH BIOLOGY TO APPRECIATE THE DESCRIPTION OF SOMEBODY'S EXPERIMENT. WE PROBABLY ARE A LITTLE MORE FAMILIAR FROM EXPOSURE, BUT THERE'S STILL THIS CHASM THAT'S REPRESENTED BY AT LEAST 30 TO 40 CREDIT HOURS OF CLASSROOM TIME.

MR. REYNOLDS: I CERTAINLY -- THANKS FOR ADMITTING THAT. I THINK YOU'RE BEING QUITE HUMBLE. IF YOU LOOK AT THE COMMITTEE HERE, IT'S STILL 50 PERCENT RESEARCH SCIENTISTS. AND WHEN A TECHNICAL QUESTION COMES UP, THAT LEAVES THE POSSIBILITY THAT THAT CAN BE EXPLAINED AS WELL. YOU AND AS WELL AS THE OTHER BROADLY DEFINED BIOETHICISTS AND PATIENT ADVOCATES ON THIS COMMITTEE CLEARLY HAVE A WORKING KNOWLEDGE OF BASIC STEM CELL BIOLOGY. IT'S JUST WHEN QUESTIONS DO GET INTO A CERTAIN TECHNICAL AREA, THAT, YES, THERE IS RESEARCH HERE TO BE CALLED UPON.

I THINK WHEN YOU LOOK AT THE OVERALL

COMPOSITION OF THE COMMITTEE, I RECOMMEND THAT YOU CONSIDER TWO OVERALL AREAS, THE RESEARCH SCIENTISTS AND THE NONRESEARCH SCIENTISTS, AND WORK OUT AN APPROXIMATE OR MINIMAL RATIO OF THE NONRESEARCH SCIENTISTS, WHICH IS HOW THIS COMMITTEE IS STRUCTURED.

MS. DELAURENTIS: MY NAME IS SUSAN DELAURENTIS. I'M FROM THE ALLIANCE FOR STEM CELL RESEARCH. I WOULD ENCOURAGE YOU TO INCLUDE A PATIENT ADVOCATE. IN MY FORMER LIFE AS CO-FOUNDER OF THE ELIZABETH GLAZER PEDIATRIC AIDS FOUNDATION, I HAVE QUITE A BIT OF EXPERIENCE AS A LAYPERSON INVOLVED DIRECTLY IN THE RESEARCH PROGRAMS AND SERVED ON AN NIH ADVISORY COUNCIL. I BELIEVE THAT IT'S REALLY IMPORTANT TO CODIFY THAT BECAUSE I THINK THAT OTHERWISE YOU WILL END UP HAVING THESE COMMITTEES WITHOUT PATIENT INPUT. THAT I THINK ALSO PERHAPS HAVING A MINIMUM OF ONE PERSON AT THESE MEETINGS, AS BERNIE SAID, YOU HAVE TO HAVE A LAYPERSON AT EACH OF THESE MEETINGS. A PATIENT ADVOCATE WOULD BE PREFERABLE ON MY PART. THANK YOU.

CO-CHAIR LANSING: VERY GOOD IDEA.

(SIMULTANEOUS DISCUSSION.)

MS. FLORES: I'M REBECCA FLORES. I'M FROM CEDARS-SINAI MEDICAL CENTER, THE OFFICE OF RESEARCH COMPLIANCE. I JUST WANT TO REITERATE A COMMENT THAT WAS MADE YESTERDAY FROM THE VICE CHANCELLOR AT BERKELEY

IN TERMS OF PUTTING THESE GUIDELINES AND REGULATIONS INTO PLACE. THE IRB'S ARE GOING TO NEED A LOT OF DIRECTION. THERE WERE A LOT OF GOOD POINTS BROUGHT UP DURING THIS DISCUSSION. NO. 1 BEING THAT WE DON'T WANT TO CREATE ANY UNNECESSARY BURDENS OR NEW BARRIERS TO GETTING THIS RESEARCH GOING.

I THINK THAT THE POINT THAT WAS VERY WELL TAKEN ON MY PART WAS DISTINGUISHING THE PURPOSE OF THE SCRO FROM THE IRB AND SEEING WHAT AREAS THAT THE IRB'S UNABLE TO COVER THAT THEN THE SCRO CAN COME IN AND MEET THOSE OBLIGATIONS. I ASK THE COMMITTEE TO REALLY CONSIDER THAT CAREFULLY AND TO NOT HAVE DIFFERENT REGULATORY BODIES MAKING DIFFERENT RECOMMENDATIONS, HAVING DIFFERENT CONCERNS BECAUSE THE IMPLEMENTATION OF THOSE TYPES OF GUIDELINES ARE VERY DIFFICULT AND RESULTS IN DELAYS IN RESEARCH AND THE INVENTIONS THAT CAN BE USED FOR PATIENT CARE. SO I THINK THAT THAT'S SOMETHING THE IMPLEMENTATION HAS TO BE CLEAR.

AND ALSO IN TERMS OF DEFINING SPECIALTIES AND EXPERTISE ON THE REGULATION, HAVING WORKED BOTH AT CEDARS AND AT UCLA, IF A REGULATION STATES THAT A SCRO MUST BE COMPRISED OF AND LIST SPECIFIC SPECIALTIES, THE LEGAL COUNSEL AT THAT INSTITUTION IS GOING TO REQUIRE IN THAT CASE. SO IF THERE'S LEEWAYS THERE, IF THERE'S WAYS TO HAVE THIS LEEWAY THAT YOU'RE DISCUSSING HERE,

THAT'S GOING TO HAVE TO BE SPELLED OUT SOMEWHERE IN THE GUIDELINES OR IN THE REGULATIONS THEMSELVES IN ORDER TO ALLOW THIS TO PROCEED LIKE THAT.

CO-CHAIR LO: THANK YOU. IF I MAY JUST COMMENT. THE CONCERN ABOUT NOT HAVING DUPLICATION OF EFFORT IN REVIEW BODIES OR CONTRADICTORY REVIEWS WAS ALSO SOMETHING WE HEARD VERY STRONGLY FROM THE RESEARCH INSTITUTIONS THAT ATTENDED THIS MEETING IN SAN FRANCISCO. WE HAVE SPECIFICALLY LEFT THE RELATIONSHIPS BETWEEN THE ESCRO, THE IRB, AND THE IACUC UP TO THE INDIVIDUAL INSTITUTION WITH A VIEW TO RECOGNIZE THAT WHAT WORKS IN ONE INSTITUTION IN TERMS OF STRICT OVERSIGHT, BUT EFFICIENT OVERSIGHT, MAY NOT WORK IN ANOTHER, TO LEAVE A LOT OF INDIVIDUAL DISCRETION FOR THAT. THAT'S A CHANGE FROM THE NAS GUIDELINES.

MR. REED: JUST A THOUGHT ON THE IDEA OF A QUOTA OR A RATIO FOR THE PUBLIC ON SUCH AN ESCRO. I THINK THE PURPOSE OF THE PUBLIC THERE IS SO THAT EVERYONE -- EVERY EXPERT THERE CAN COMMUNICATE TO HIM OR HER AND MAKE THEIR POSITION CLEAR IN PEOPLE TALK, WHICH HE OR SHE CAN THEN ALSO SHARE WITH THE COMMUNITY AT LARGE. I DON'T SEE IT AS AN ADVERSARY-TYPE SITUATION WHERE THE NUMBERS HAVE TO BE EVENLY MATCHED AS IF IT'S SOME SORT OF A WAR. I THINK A COMMUNICATIVE FUNCTION.

CO-CHAIR LO: THANK YOU FOR THOSE COMMENTS. ONE COMMENT THAT I THOUGHT STRUCK RESONANCE WITH SOME PEOPLE ON THE COMMITTEE WAS THIS IDEA OF HAVING A PATIENT ADVOCATE SERVE ON THIS BOARD, THE ESCRO. I WANTED TO GET REACTIONS FROM THE COMMITTEE ON THAT.

MR. SHEEHY: SOUNDS LIKE A GREAT IDEA TO ME.

CO-CHAIR LO: SHERRY WAS VERY MUCH FOR IT.

DR. PRIETO: MY ONLY QUESTION IS HOW DO WE SPECIFY THAT, AND IS THAT IN ADDITION TO REPRESENTATIVES OF THE LAY PUBLIC?

CO-CHAIR LO: THAT'S WHAT WE NEED TO SORT OUT IN THE NEXT BIT OF TIME HERE BEFORE WE CAN ADJOURN THIS MEETING.

MS. FEIT: I THINK IT'S A GOOD IDEA. WE WERE CHOSEN TO BE PATIENT ADVOCATES BECAUSE WE HAVE SPECIAL BACKGROUND ALSO, BUT WE BRING A DIFFERENT PERSPECTIVE. AND I THINK IT'S BEEN HELPFUL FOR THE ICOC.

CO-CHAIR LO: SO HOW DO WE CHANGE THIS, WITH AT LEAST ONE PATIENT ADVOCATE AND ONE REPRESENTATIVE OF THE PUBLIC WHO'S NOT OTHERWISE AFFILIATED.

MR. TOCHER: I HAD IT AS WITH AT LEAST ONE REPRESENTATIVE OF THE PUBLIC AND ONE PATIENT ADVOCATE, NEITHER OF WHOM IS AFFILIATED WITH THE RESEARCH INSTITUTION.

MR. SHEEHY: I THINK WE SHOULD ADD WITH NO

FINANCIAL INTEREST IN THE OUTCOME.

CO-CHAIR LO: ABSOLUTELY. I THOUGHT THAT WAS UNANIMOUS, THAT THESE TWO MEMBERS SHOULD HAVE NO FINANCIAL CONFLICTS.

DR. WAGNER: CAN I ASK ONE QUESTION, THOUGH, ABOUT THE WAY YOU WORDED THAT, SCOTT, ABOUT THE PATIENT ADVOCATE HAVING NO RELATIONSHIP AT ALL WITH THE INSTITUTION. THE WAY YOU READ IT, COULD YOU READ THAT AGAIN?

MR. TOCHER: I JUST USED AFFILIATED.

CO-CHAIR LO: THE WAY IT'S WRITTEN IN THE FEDERAL REGULATIONS IS NOT OTHERWISE AFFILIATED WITH THE INSTITUTION. CAN'T BE SOMEONE WHO RUNS YOUR VOLUNTEER AUXILIARY AT THE HOSPITAL.

DR. KIESSLING: COULD IT BE A PATIENT?

MR. SHEEHY: I WOULD THINK NOT.

MR. TOCHER: YOU COULD SAY NOT PROFESSIONALLY AFFILIATED.

MR. SHEEHY: I DON'T THINK, YOU KNOW, WHEN YOU ARE A PATIENT, THAT GETS TO -- THAT'S A LITTLE BIT TOO INTIMATE WITH THE ADVOCATE, I THINK, THAT RELATIONSHIP BETWEEN A PATIENT AND --

CO-CHAIR LO: INSTITUTION PROVIDING THE CARE.

MR. SHEEHY: YEAH. I LOOK TO OTHER FOLKS OR MAYBE SUSAN HAS A THOUGHT OR SOMEBODY ELSE, OR MAYBE

SHERRY DOES. I CAN JUST IMAGINE THAT THEY THINK THAT APPROVING THIS PROTOCOL MIGHT ACTUALLY HELP THEM. THAT'S LIKE THE WORST SORT OF CONFLICT.

CO-CHAIR LO: THERE WAS A SUGGESTION --

MS. DELAURENTIS: WOULD THIS PRECLUDE SOMEONE THAT WAS ON ANOTHER ADVISORY COMMITTEE OF THAT HOSPITAL BECAUSE IS THAT A WAY THEY WOULD BE AFFILIATED?

DR. WAGNER: THAT'S ACTUALLY WHAT I WAS THINKING OF. IT IS A FORM OF AFFILIATION. AND SO I WASN'T SO MUCH THINKING ABOUT WHAT YOUR ISSUE WAS. I WAS THINKING MORE LIKE WHAT YOU ARE SAYING, IS THAT THERE IS AN AFFILIATION IN ANOTHER WAY.

MS. DELAURENTIS: WHAT IF THEY'RE PART OF AN ORGANIZATION THAT GIVES FUNDING TO THAT INSTITUTION?

DR. WAGNER: FOR EXAMPLE, WE HAVE BREAST CANCER RESEARCH FUNDS, WE HAVE CHILDREN'S LEUKEMIA FUNDS THAT ARE ASSOCIATED WITH THE INSTITUTION.

MS. DELAURENTIS: LIKE PEDIATRIC THAT WE FUND AT UCLA. WE'VE FUNDED INSTITUTIONS. WOULD THAT PRECLUDE SOMEONE FROM THAT? I DON'T THINK IT SHOULD.

MR. SHEEHY: WE SHOULD EXCLUDE SOMEONE WHO HAS A PATIENT RELATIONSHIP WITH THE INSTITUTION OR COULD RECEIVE FINANCIAL BENEFIT. IF WE LIMIT IT TO --

DR. PRIETO: WELL, WE'RE ALREADY SAYING THAT WITH NO FINANCIAL INTEREST IN THE RESEARCH.

CO-CHAIR LANSING: WAY CAN'T YOU JUST RECUSE YOURSELF FROM CERTAIN THINGS WHEN IT COMES TO THAT, WHEN IT COMES TO VOTING? YOU ARE NOT GOING TO BE ABLE TO FIND SOMEBODY.

CO-CHAIR LO: AGAIN, WE MAY HAVE CONFOUNDED TWO DIFFERENT CATEGORIES IN THE COMMON RULE FOR IRB'S, COMMUNITY MEMBERS AND NONAFFILIATED MEMBERS AND NONAFFILIATED. WE MAY BE CONFUSING. IF WE JUST ARE GETTING PEOPLE ARE WHO NOT SCIENTISTS, THEN THAT'S ONE THING. IF WE'RE TRYING TO PEOPLE WHO AREN'T OTHERWISE AFFILIATED IN THE SENSE THAT THEY'RE REALLY INDEPENDENT OF THE INSTITUTION, AND THE ARGUMENT IS THAT, NOW, IF I'VE DONATED MONEY TO AN INSTITUTION AND SORT OF WORKED AS A VOLUNTEER, I HAVE A LOYALTY TO THAT INSTITUTION THAT MAY PREVENT ME FROM BEING AS CRITICAL AS ONE MIGHT LIKE.

I THINK THAT'S THE NOTION OF THE IRB OF NOT OTHERWISE AFFILIATED. NOW, WE MAY NOT WANT THAT HERE. BUT I THINK WE NEED TO MAYBE THINK THROUGH A LITTLE BIT MORE. I'M HEARING STRONG SUPPORT FOR HAVING A PATIENT ADVOCATE, AND I'M NOT QUITE SURE NOW WHETHER WE'RE SAYING THE OTHER SKILL IS THE LAY PERSPECTIVE OR THE NONAFFILIATED PERSPECTIVE.

DR. TAYLOR: I RECOGNIZE THE CONFLICT OF INTEREST ISSUES, BUT, AGAIN, IT SEEMS TO ME THAT ONE OF

THE MOST IMPORTANT FUNCTIONS OF THE ESCRO IS GOING TO BE A CONSISTENT, COMMITTED RELATIONSHIP TO SORT OF TRACK THE PROTOCOLS AND FOLLOWING THE EVOLUTION OF STEM CELL RESEARCH. I THINK AT SOME LEVEL WE MAY BE BETTER SERVED BY PEOPLE WHO ACTUALLY DO HAVE THE COMMITMENT TO THE INSTITUTION. AND THERE MAY BE MORE RISKS OF HAVING A TRANSIENT COMMITTEE. I THINK THE IDEA OF THESE PEOPLE KIND OF COMING AND GOING AS THE EXPERTISE IS REQUIRED IS MAYBE A DANGEROUS MODEL.

CO-CHAIR LO: TRACKING MAY NOT BE DONE BY THE COMMITTEE MEMBERS, BUT BY STAFF. THE TRACKING IS RECORDKEEPING, AND COMMITTEE MEMBERS ARE PROBABLY NOT THE ONES DOING THE TRACKING.

I WANT TO MAKE SURE IT'S A QUESTION OF ADVOCACY IS SORT OF A DIFFERENT DIMENSION AFFILIATED OR NONAFFILIATED OR LAY VERSUS SCIENTIFIC EXPERT. I HAVE AN ADVOCATE WHO'S EITHER AFFILIATED OR NOT AFFILIATED OR A SCIENTIST.

DR. PRIETO: I'M TRYING TO IMAGINE HOW THIS WOULD PLAY OUT, AND I'M THINKING OF AT LEAST A COUPLE OF US, JEFF AND HIS RELATIONSHIP WITH UCSF, AND MINE WITH UC DAVIS. I RECEIVE NO SALARY; JEFF DOES FROM THE INSTITUTION, BUT I HAVE A RELATIONSHIP, AND I'VE ACTUALLY BEEN A PATIENT THERE, SO THAT WOULD RULE ME OUT. I THINK WE NEED TO DEFINE WHAT IS THE LINE AND

WHO IS ELIGIBLE AND WHO'S NOT.

CO-CHAIR LO: SOMEONE WANT TO MAKE A PROPOSAL?

MS. DELAURENTIS: COULD I JUST ASK WHAT'S THE DOWNSIDE? WHAT'S THE POTENTIAL CONFLICT OR THE POTENTIAL PR ISSUE OF YOU WHO ARE NOT PAID A SALARY BEING PART OF THE ESCRO AS A PATIENT ADVOCATE?

DR. PRIETO: I THINK THE POINT THAT BERNIE BROUGHT UP AND JEFF'S POINT, THAT PERHAPS THE ADVOCATE OR THE LAY REPRESENTATIVE WOULD HOPE TO DERIVE SOME FAVORABLE CONSIDERATION OR BE TREATED MORE FAVORABLY BY THE INSTITUTION.

MS. DELAURENTIS: HOW DO YOU DEFINE THAT IN REALITY? THE FLIP SIDE OF IT IS THAT IF YOU HAVE A VESTED INTEREST IN THE INSTITUTION, YOU COULD BE MORE CRITICAL BECAUSE YOU WANT THE INSTITUTION TO PERFORM IN THE HIGHEST POSSIBLE WAY INSTEAD OF --

DR. PRIETO: THAT WOULD BE IDEAL, YEAH. I'M NOT SURE EVERYONE WOULD BEHAVE THAT WAY.

MS. DELAURENTIS: THAT'S HUMAN NATURE ON ALL THE PEOPLE.

DR. PRIETO: I'M KIND OF THINKING OUT LOUD HERE. I'M NOT SURE WHAT THE ANSWER IS.

MS. DELAURENTIS: I CAN'T PICTURE A SITUATION LIKE THAT.

DR. PRIETO: YOU DON'T THINK THERE WOULD BE A PROBLEM?

CO-CHAIR LO: THERE HAVE BEEN SEVERAL EGREGIOUS EXAMPLES OF IRB'S APPROVING PROJECTS THAT IN RETROSPECT WERE VERY, VERY ETHICALLY FLAWED. ONE OF THE CONCERNS THAT'S BEEN RAISED IS THAT IRB'S ARE TOO INBRED, THAT THEY'RE PEOPLE PRIMARILY FROM THE SAME INSTITUTION, THAT OFTEN THE SO-CALLED PUBLIC MEMBERS ALSO HAVE SOME SORT OF INDIRECT AFFILIATION. THEY'RE NOT TAKING THAT FRESH LOOK, AND THEY'RE NOT BEING AS CRITICAL. SUSAN, I THINK YOU SAID OUR HOPE WOULD BE THAT PEOPLE WHO LOVE THE INSTITUTION ARE THE MOST CRITICAL, BUT, IN FACT, THERE HAVE BEEN CASES IN WHICH APPARENTLY THE ALLEGATION HAS BEEN RAISED THAT PEOPLE WERE TOO CLOSE AND WANTING THE RESEARCH TO PROCEED AND REALLY DIDN'T OPEN THEIR EYES TO PROBLEMS.

MS. DELAURENTIS: BUT ISN'T EVERY ESCRO MEMBER GOING TO BE AFFILIATED WITH THAT PARTICULAR INSTITUTION ANYWAY?

DR. PRIETO: TO LOOK AT THIS FROM ANOTHER ANGLE, IS IT REALLY GOING TO BE A BURDEN ON THE INSTITUTION TO FIND A PATIENT ADVOCATE AND LAY REPRESENTATIVES WHO ARE NOT AFFILIATED? I'M NOT SURE. IT DOES ENSURE MORE INDEPENDENCE.

MS. CHARO: IT MAY BE THAT WE WANT TO TRY TO

WORK THIS OUT IN A DRAFTING SESSION. I THINK NONAFFILIATED IS PROBABLY THE RIGHT LANGUAGE. WE MIGHT WANT TO ADD IN THE DEFINITIONAL SECTION A DEFINITION OF AFFILIATED. IT MAY BE WORTH OUR WHILE TO FIRST CHECK ON OTHER PLACES WHERE THAT'S BEEN DEFINED TO MAKE SURE WE'RE NOT GOING AWAY FROM STANDARD DEFINITIONS. I SUSPECT THAT THEY CIRCLE AROUND THE FOLLOWING THINGS THAT WE CAN USE. THAT AFFILIATED MEANS EMPLOYED BY, IN A CONTRACTUAL RELATIONSHIP WITH, OR HAVING A FORMAL ONGOING APPOINTMENT WITH. THAT WOULD BE ACADEMIC INSTITUTIONS THAT MAKE CLINICAL PHYSICIANS, FOR EXAMPLE, PART OF THEIR DEPARTMENTS EVEN IF THEY'RE NOT ON THE PAYROLL.

THAT WOULD NOT INCLUDE PEOPLE WHO ARE MEMBERS IN A VOLUNTEER CAPACITY OF AD HOC COMMITTEES, WHICH I DON'T THINK EVER IN COMMON PARLANCE UNDERSTANDS TO MEAN AFFILIATED WITH, WHICH I THINK ADDRESSES YOUR CONCERN.

I WOULD SUGGEST IF WE HAVE A FAIRLY SHARED UNDERSTANDING OF WHAT WE'RE TRYING TO GET AT, THAT WE MIGHT TAKE A LITTLE TIME BEHIND THE SCENES TO JUST CHECK AND SEE IF THERE ARE DEFINITIONS THAT ESSENTIALLY CONTROL ANYWAY THAT WE MIGHT BORROW, ONCE AGAIN, TRYING TO NOT HAVE US OUT OF STEP WITH CALIFORNIA LAW AND REGULATION IN GENERAL.

CO-CHAIR LO: WHAT I'M HEARING ALTA SAY IS

THAT WE USE THE TERM "AFFILIATED" IN THE REGULATION, AND THEN TRY AND FLESH IT OUT IN THE DEFINITION SECTION, THAT WHAT WE WANT TO EXCLUDE ARE PEOPLE WHO ARE EMPLOYEES OF THE INSTITUTION, THAT HAVE CONTRACTUAL RELATIONSHIPS AS INDIVIDUAL CONTRACTORS. NOW, THE ONGOING APPOINTMENT, THAT WOULD APPEAR TO ME TO EXCLUDE SOMEONE LIKE FRANCISCO WHO HAS A CLINICAL APPOINTMENT NOT FOR SALARY.

MS. CHARO: THAT'S RIGHT. I THINK THAT MIGHT BE FAIR BECAUSE THAT TOUCHES ON YOUR POINT, BERNIE, THAT THE CONCERN IS THAT, IN A SENSE, YOU ARE TRYING TO GET NOT ONLY AT FINANCIAL CONFLICTS, BUT ALSO AT KIND OF THE INTERPERSONAL LOYALTIES THAT COME FROM JUST WORKING REGULARLY TOGETHER AND FEELING LIKE YOU'RE PART OF THEIR TEAM.

CO-CHAIR LO: BUT IT WOULD EXCLUDE -- AFFILIATED MEMBERS MAY INCLUDE VOLUNTEERS AT THE INSTITUTION.

MS. CHARO: THESE LINES ARE BLURRY, AND NONE OF THEM ARE PERFECT.

MS. FEIT: THERE'S A REAL EMPHASIS TODAY ON ANY BOARDS WITH PEOPLE COMING IN FROM EITHER THE COMMUNITY OR WITHIN AN ORGANIZATION AND WANTING TO HAVE MEMBERSHIP ON A BOARD, THAT THERE'S A PROCESS FOR DECLARED CONFLICTS OF INTEREST. AND THAT ALLOWS THE

BOARD TO REALLY LOOK AT AN INDIVIDUAL AND SAY IS THERE A CONFLICT OF INTEREST. THEY MUST DECLARE ANY RELATIONSHIP OR ACKNOWLEDGE ANY APPOINTMENT OR ANYTHING. AND THEN IT'S UP TO THE BOARD TO DECIDE IS THAT A CONFLICT OF INTEREST. THE IDEA IS TO HAVE A PROCESS. IT'S ACTUALLY A WRITTEN DOCUMENTATION THAT EACH INDIVIDUAL SERVING ON THE BOARD HAS DECLARED THEIR CONFLICTS OF INTEREST WITH WHATEVER BOARD THEY'RE SERVING ON.

I THINK THAT WAY YOU TAKE INTO CONSIDERATION ALL THE NUANCES THAT GO ON. OTHERWISE, YOU ELIMINATE THE WORLD AND YOU HAVE TROUBLE FINDING YOUR BOARD. AND SO IT MAY BE APPROPRIATE, ALTHOUGH HE SERVES AT UC DAVIS, HAS AN APPOINTMENT, BUT IF HE'S ASKED TO SERVE ON A PARTICULAR RESEARCH BOARD, IT MAY BE UNRELATED TO HIS APPOINTMENT, AND THEY MAY SAY HE'S A VERY GOOD CANDIDATE AND WE NEED HIM. AS LONG AS IT'S DECLARED, IT'S MADE OBVIOUS AND PUBLIC TO EVERYBODY, THEN I THINK INDEPENDENT DECISIONS CAN BE MADE AS TO THE QUALIFICATIONS OF THOSE INDIVIDUALS.

CO-CHAIR LO: SO YOU ARE SUGGESTING THAT WE REQUIRE EACH INSTITUTION TO ASK ALL MEMBERS ON THE COMMITTEE, I THINK, TO DECLARE CONFLICTS OF INTEREST AND HAVE A PROCESS IN PLACE FOR DETERMINING WHETHER THOSE CONFLICTS PRECLUDE SERVING ON THE COMMITTEE OR

REQUIRE RECUSAL ON A PARTICULAR CASE.

MS. FEIT: I WOULD BE SURPRISED IF THEY DIDN'T HAVE THEM NOW. MOST INSTITUTIONS ARE MOVING IN THAT DIRECTION THROUGH ADVICE OF THEIR LEGAL COUNSEL.

CO-CHAIR LO: IT SOUNDS LIKE IT WOULD BE WORTH REQUIRING AS A GOOD PRACTICE.

MR. TOCHER: MY CONCERN WITH CONFLICT OF INTEREST IS THAT IT'S BIT OF A TERM OF ART. THERE ARE CONFLICTS OF INTEREST UNDER THE POLITICAL REFORM ACT, WHICH PROBABLY WOULD NOT APPLY, WHICH MAY OR MAY NOT APPLY IF THESE ARE STATE INSTITUTIONS, WHICH WOULD GOVERN WHAT A CONFLICT OF INTEREST IS. THE INSTITUTIONS MAY HAVE THEIR OWN DEFINITIONS OF WHAT A CONFLICT OF INTEREST IS. THAT MAY DIFFER FROM INSTITUTION TO INSTITUTION. SO YOU MIGHT HAVE A DISCREPANCY THERE AS TO A PERSON WHO PARTICIPATES IN ONE INSTITUTION ON ONE PROGRAM MIGHT NOT BE ABLE TO IN ANOTHER. I JUST THROW THAT OUT.

IT MAY NOT NECESSARILY BE A UNIFORM SYSTEM OF GUIDANCE. NOT ALL CONFLICTS OF INTEREST ARE REPORTED PUBLICLY, SUCH AS DISCLOSURE DOCUMENTS AND THAT SORT OF THING. SO I DON'T KNOW HOW IMPORTANT THAT IS, BUT I JUST THROW THAT OUT. JUST KEEP THAT IN MIND.

CO-CHAIR LO: WELL, THIS MAY BE ONE OF THOSE ISSUES THAT WOULD NOT BE WISE TO TRY AND SETTLE TODAY.

I THINK WE PROBABLY SHOULD JUST GO IN THERE WITH SOME LANGUAGE THAT TRIES TO CAPTURE THE SPIRIT OF WHAT WE'RE TRYING TO DO. IF IT DOESN'T PASS OAL MUSTER, I THINK WE HAVE A CHANCE -- THERE WILL BE PUBLIC COMMENT FOR THE PUBLIC TO COMMENT. I THINK WE HAVE SOME OPPORTUNITIES TO REVISE TO SATISFY THE OAL.

IT STRIKES ME THAT, ESPECIALLY GIVEN WHAT SCOTT AND MARCY HAVE SAID ABOUT A LOT OF OTHER WORK GOING ON IN SORT OF SELECTING MEMBERS OF BOARDS THAT GIVE ADVICE, THAT WE NOT TRY AND CRAFT SOMETHING HERE THAT DOESN'T TAKE ADVANTAGE OF WHAT EXPERIENCE IS. AND I THINK WE HAVE A SENSE OF WHERE WE WANT TO GO, BUT THE WORDS AND DETAILS ARE NOT QUITE THERE.

CO-CHAIR LANSING: CAN WE IN OUR RECOMMENDATION PUT A SENTENCE IN THAT SAYS -- I KNOW THIS SOUNDS A LITTLE SELF-SERVING, BUT ACTUALLY -- YOU KNOW, IN ADDITION TO A NONAFFILIATED MEMBER, WE SAID WHENEVER POSSIBLE A PATIENT ADVOCATE WOULD BE DESIRABLE OR SOMETHING.

CO-CHAIR LO: I ACTUALLY HEARD SOMETHING STRONGER. I THOUGHT THEY WERE SAYING THERE MUST BE -- LET'S GET A SENSE OF THAT. HOWEVER WE DEFINE PATIENT ADVOCATE, WE HAVEN'T REALLY DONE SO YET. DO WE WANT TO SAY THE SCRO MUST HAVE A PATIENT ADVOCATE, OR WE DEFINE THAT.

DR. KIESSLING: I THINK THAT'S A GOOD IDEA.

CO-CHAIR LO: YEAH. I WOULD LIKE TO JUST TAKE A VOTE. SOMEONE WANT TO MOVE THAT?

DR. KIESSLING: I SO MOVE.

CO-CHAIR LO: THAT WE INCLUDE A PATIENT ADVOCATE AS A REQUIRED SCRO MEMBER. AND SECOND ON THAT? DO WE HAVE --

MS. CHARO: SECOND.

CO-CHAIR LO: WE DON'T HAVE A QUORUM. WE LOST SOMEBODY. JON WOULD CERTAINLY WANT TO HAVE A PATIENT ADVOCATE. WE CAN'T ASSUME THAT.

MS. CHARO: I THINK FROM NOW ON ANYBODY THAT GOES TO THE BATHROOM HAS TO LEAVE A PROXY.

CO-CHAIR LO: SO WE CAN'T OFFICIALLY DO THAT. MY SENSE IS THAT PEOPLE HERE, THAT'S OUR STRONG SENTIMENT WITH NO OBJECTION.

ALL RIGHT. THIS IS SOMETHING WE'LL TRY AND -- I THINK AT THIS POINT WE SHOULD SORT OF PUT IN ASPIRATIONAL LANGUAGE SO THAT IT'S CLEAR WHAT WE'RE HEADING TOWARDS, AND THEN TRY TO WORK OUT THE LANGUAGE AND DETAILS LATER. IT MAY NOT BE POSSIBLE FOR THE FEBRUARY 2D ICOC.

MR. TOCHER: I THINK ALTA'S POINT IS WELL TAKEN ABOUT DEFINING AFFILIATED MORE SPECIFICALLY. AND THERE ARE -- THE TERM IS DEFINING OTHER AREAS OF LAW

WHICH MAY BE FRUITFUL TO SORT OF CULL FROM. AND I WOULD RECOMMEND ACTUALLY PUTTING THE DEFINITION IN THE SUBDIVISION ITSELF AS OPPOSED TO EVEN IN THE DEFINITION.

CO-CHAIR LO: OKAY. FINE. JON, THERE'S A MOTION ON THE FLOOR THAT THE SCRO COMMITTEE HAVE A PATIENT ADVOCATE ON IT AT EACH INSTITUTION. IT'S BEEN MADE AND SECONDED, AND WE'RE GOING TO CALL FOR A VOTE.

CO-CHAIR LANSING: WE NEEDED YOUR VOTE.

CO-CHAIR LO: WE THOUGHT THIS WOULD BE OF PARTICULAR INTEREST TO YOU. SINCE THE MOTION HAS BEEN MADE, CAN I ASK FOR A SHOW OF HANDS. ALL THOSE IN FAVOR OF REQUIRING SCRO'S HAVE A PATIENT ADVOCATE. PRETTY MUCH EVERYBODY. NOT JANET. ARE YOU ABSTAINING OR OPPOSING?

DR. ROWLEY: I HAVE CONCERNS THAT A PATIENT ADVOCATE FOR ONE PARTICULAR TYPE OF RESEARCH MAY BE INFLUENCED IN THEIR ASSESSMENT OF THE RESEARCH BY WHETHER IT'S RELATED TO THEIR AREA OR NOT. I'M GOING TO ABSTAIN.

MR. SHESTACK: DO YOU MEAN SPECIFICALLY OR IN GENERAL? THERE'S ONE SPECIFIC TYPE OF RESEARCH WHERE THIS IS A CONCERN?

DR. ROWLEY: IT WOULD JUST BE IN GENERAL.

CO-CHAIR LANSING: IN GENERAL.

DR. ROWLEY: IF YOU WANT YOUR AREA OF RESEARCH, JUVENILE DIABETES, THEN YOU WILL BE ALL IN FAVOR OF ANY RESEARCH PROJECT THAT COMES THROUGH RELATED TO THAT. BUT IF YOU WERE INTERESTED IN PARKINSON'S -- IF IT'S RELATED TO PARKINSON'S DISEASE, YOU MAY VIEW THAT THROUGH DIFFERENT EYES. I DON'T KNOW. THAT'S WHY I'M ABSTAINING.

MR. SHESTACK: I WOULD LIKE TO ADDRESS THIS. I'VE ADDRESSED IT BEFORE. AND IT'S A SORT OF PARTICULARLY ANNOYING POINT, SO I WOULD ACTUALLY -- PEOPLE COME SAY IT BEFORE -- HAVE SAID IT BEFORE.

THERE IS -- I BELIEVE THERE IS NO JEALOUSY BETWEEN THE ADVOCATES. IT IS NOT A COMPETITIVE SPORT. WHAT IS LIKELY TO HAPPEN IS THAT YOU WILL HAVE AN ADVOCATE ON A COMMITTEE WITH A BUNCH OF PEOPLE WHO WILL SAY, WELL, GEE, THERE'S NO BENEFIT FROM THIS RESEARCH, AND ACTUALLY IT'S INVASIVE BECAUSE IT INVOLVES A BUCCAL SWAB; THEREFORE, LET'S NOT VOTE FOR THIS RESEARCH PROJECT. AND YOU NEED AN ADVOCATE TO SAY, PARTICULARLY, FOR INSTANCE, MY AREA WOULD BE ADVOCATE OF VULNERABLE POPULATIONS, TO SAY, NO, THAT'S OKAY.

CERTAINLY WE HAVE NO EXPERIENCE OF ADVOCATES SAYING I DON'T THINK I'M GOING TO VOTE FOR THAT DIABETES THING BECAUSE A PARKINSON'S THING WHICH AFFECTS ME MIGHT COME UP NEXT WEEK. IT'S REALLY SORT

OF -- IT DOESN'T COME UP, IT PROBABLY WON'T, AND IT SORT OF TAKES THE CUSTOMER OF THE RESEARCH AND CASTS THEM REALLY IN THE WORST POSSIBLE LIGHT. AND WE'RE HERE TO SERVE THAT CUSTOMER, SO I THINK IT IS WORTH STATING IT AGAIN.

IF YOU WANT TO ADD A STIPULATION THAT THE ADVOCATE IDENTIFY THAT THEY HAVE AN ACTUAL INTEREST IN THAT DISEASE RESEARCH AND IDENTIFY IT VOCALLY TO THE ESCRO COMMITTEE OR EVEN RECUSE HIMSELF, THAT'S FINE. BUT TO THINK THAT THEY ARE THAT PETTY IS KIND OF -- I THINK IT'S JUST INCORRECT THINKING.

DR. ROWLEY: OKAY. BUT WE'RE ACCUSING SCIENTISTS ON THE ESCRO OF BEING EQUALLY PETTY. SO --

MR. SHEEHY: COULD I RAISE THIS POINT AS SOMEONE WHO'S LIVING --

MR. SHESTACK: NOT FOR THE SAME REASONS ACTUALLY.

MR. SHEEHY: AS SOMEONE WHO'S LIVING WITH HIV, WHOSE FATHER HAS ALZHEIMER'S, WHOSE MOTHER HAS CANCER, WHOSE MAIN HEALTH RISK IS CARDIOVASCULAR DISEASE DUE TO SIDE EFFECTS FROM HIV MEDICATIONS, I THINK TO SOMEHOW SUGGEST THAT CHRONIC DISEASE -- THAT ANYBODY IS ONLY IMPACTED IN AMERICAN SOCIETY BY CHRONIC DISEASE AND WOULD ONLY ADVOCATE FOR THAT DISEASE SEEMS A LITTLE SPECIOUS.

WHAT YOU'RE LOOKING FOR IS THE EXPERIENCE OF LOOKING FROM THE PERSPECTIVE OF SOMEONE IMPACTED BY CHRONIC DISEASE AND REPRESENTING THAT VIEW. I DON'T THINK THAT YOU COULD FIND ANYBODY IN THIS ROOM WHO'S ONLY BEEN AFFECTED BY ONE MAJOR DISEASE AND WOULD ONLY CARE ABOUT THAT DISEASE TO THE EXCLUSION OF ALL OTHERS.

CO-CHAIR LO: I'M GOING TO ASK --

MR. SHEEHY: AND BY THE WAY, TO BE A DISEASE ADVOCATE IS TO MAKE A SACRIFICE AND IS RARELY EVER REMUNERATED, SO YOU'RE TALKING ABOUT SOME SORT -- THERE IS SOME ALTRUISTIC IMPULSE TO BEGIN WITH; WHEREAS, SCIENTISTS GET FAME AND FORTUNE. THERE'S NO NOBEL PRIZE FOR DISEASE ADVOCACY.

DR. KIESSLING: WANT TO TALK ABOUT THE FORTUNE PART?

CO-CHAIR LO: I'M GOING TO ASK THAT WE CONTINUE THIS CONVERSATION OFFLINE. I THINK WE DO NEED TO ACKNOWLEDGE THAT SCIENTISTS, ADVOCATES, OTHER MEMBERS OF THE PUBLIC ALL HAVE VERY IMPORTANT ROLES TO PLAY HERE, AND ALL OF US BEING HUMAN ARE IN DANGER OF SORT OF OVERSTEPPING OR BEING BLINDED, BUT I THINK WE ALL HAVE GOOD INTENTIONS.

CO-CHAIR LANSING: I DO THINK YOU CAN RECUSE YOURSELF. I THINK THAT PATIENT ADVOCATES ARE AS SENSITIVE AS SCIENTISTS ARE, AND I KNOW THAT WE'VE ALL

BEEN IN SITUATIONS WHERE WE HAVE RECUSED OURSELVES. AND I THINK THE INTEGRITY OF THE SCIENTISTS AND THE PATIENT ADVOCATE IS THE SAME, AND I THINK WE WOULD RECUSE OURSELVES FROM ANY POTENTIAL CONFLICTS.

DR. PRIETO: I THINK I WOULD ALSO ECHO WHAT MARCY SAID EARLIER ABOUT BEING IN FAVOR OF VERY STRONG CONFLICT OF INTEREST POLICIES. AND THE PATIENT ADVOCATES, LIKE ANYONE ELSE, NEED TO REVEAL THEIR CONFLICTS.

CO-CHAIR LO: OKAY. ONE LAST THING I WANT TO DO IS JUST CALL YOUR ATTENTION TO 100006, WHICH WE TALKED ABOUT AT PREVIOUS MEETINGS. THE ONLY CHANGES THERE ARE TO BRING IT IN LINE WITH NEW TERMINOLOGY SUCH AS COVERED STEM CELL LINES AND, TWO, APPROPRIATE, AGAIN, WAS ONE OF THOSE RED-FLAG WORDS THAT THE OAL DELETED. UNLESS THERE ARE OBJECTIONS TO THAT SECTION THAT NEEDS TO BE REOPENED, I WOULD SUGGEST THAT WE ACCEPT WHAT WE DID BEFORE.

DO I NEED TO HAVE AN OVERALL MOVEMENT TO APPROVE?

MR. TOCHER: YOU MEAN THE OVERALL DOCUMENT? YEAH. OR TO SEND IT FORWARD.

CO-CHAIR LO: COULD I HAVE A MOTION, THEN, TO TAKE THE AMENDED DOCUMENT AS TO BE WORD CRAFTED BY LEGAL COUNSEL AND STAFF TO MAKE IT PRESENTABLE TO THE

OAL, THAT WE ACCEPT THIS?

CO-CHAIR LANSING: MOVE IT FORWARD TO THE ICOC. SO MOVED.

CO-CHAIR LO: PRESENTED TO THE ICOC.

DR. PRIETO: SECOND.

CO-CHAIR LO: WHO'S THE SECOND?

DR. PRIETO: I AM.

DR. KIESSLING: THIS ENTIRE DOCUMENT?

CO-CHAIR LO: THE ENTIRE DOCUMENT. ALL THE THINGS WE TALKED ABOUT --

CO-CHAIR LANSING: WE'RE NOW VOTING ON THE ENTIRE DOCUMENT, EVERYTHING WE TALKED ABOUT.

CO-CHAIR LO: ALL THE THINGS WE TALKED ABOUT THE LAST TWO DAYS, WE NEED TO MOVE IT TO THE ICOC WITH THE UNDERSTANDING THAT -- WE VOTED ON INDIVIDUAL SECTIONS. WE NEED A FORMAL MOTION TO TAKE THE WHOLE THING TO THE ICOC.

CO-CHAIR LANSING: BASICALLY WHAT WE'RE DOING IS ALL THE WORK THAT WE'VE DONE OVER THE TWO DAYS OR WHATEVER, WE'RE NOW MOVING TO HAVE THIS CRAFTED PROPERLY AND MOVED FORWARD TO THE ICOC WITH THE CHANGES THAT WE TALKED ABOUT, CORRECT.

DR. WAGNER: OTHERWISE ARE YOU SAYING THAT WE'RE DONE?

CO-CHAIR LO: WE'RE DONE FOR THIS STAGE.

CO-CHAIR LANSING: WE ALSO HAVE TO OPEN IT UP TO THE PUBLIC.

DR. WAGNER: THERE'S SOME QUESTIONS ABOUT DIFFERENT SECTIONS THAT I STILL WANT TO ASK. IS THAT APPROPRIATE FOR NOW OR FOR LATER?

CO-CHAIR LO: DO IT NOW BECAUSE WE CAN'T -- UNLESS WE'RE WILLING -- SHERRY HAS TO LEAVE. SO THE QUESTION IS WE CAN'T MOVE ANYTHING TO THE ICOC UNLESS WE APPROVE IT TODAY AS A GROUP.

DR. WAGNER: THE QUESTION I HAVE, AND IF I MISSED IT, I APOLOGIZE. IT IS SECTION 100008, INFORMED CONSENT REQUIREMENTS. AND THAT ONLY RELATED TO THE FACT THAT WE SPENT A LOT OF TIME TALKING ABOUT GAMETE DONATION. IS THE WORDING OF THIS SECTION COMPLETELY APPROPRIATE FOR EMBRYO DONATION? SO, FOR EXAMPLE, AS FAR AS I KNOW, WE'VE NOT REALLY TALKED ABOUT THE POSSIBILITY OF RETROSPECTIVE CONSENT AFTER THEY'VE ALREADY DONATED FOR OTHER PURPOSES. MAYBE I MISSED IT. BUT IN TERMS OF -- I SHOULDN'T SAY RETROSPECTIVE CONSENT. OBVIOUSLY THEY'VE COLLECTED THE EMBRYOS FOR OTHER REASONS, THEY'VE BEEN STORED --

CO-CHAIR LO: THEN YOU CAN CONSENT. THAT'S FINE.

DR. WAGNER: -- TEN YEARS, WHATEVER. IS THERE ANYTHING THAT WE NEED TO DO DIFFERENTLY FOR

EMBRYO DONATION, FOR EXAMPLE, THOSE FROM PREIMPLANTATION GENETIC DIAGNOSIS? I'M JUST TRYING TO MAKE SURE THAT WE HAVE NOT SKIPPED SOMETHING BECAUSE WE SPENT SO MUCH TIME ON GAMETE DONATION. DID WE MISS SOMETHING FOR SPECIFIC SUBPOPULATIONS OF EMBRYO DONATION?

CO-CHAIR LO: I GUESS THE QUESTION IS IS THAT SOMETHING WE CAN COME BACK TO? AGAIN, ALL WE'RE DOING IS MOVING THIS FORWARD TO THE NEXT STEP. THERE'S A PUBLIC COMMENT PERIOD, THERE'S A REVISION PERIOD. WE CAN ALWAYS REVISE THIS AFTER THESE ARE PASSED. I'M JUST TRYING TO MOVE THIS FORWARD. IF THERE'S AN OMISSION -- IF THERE'S OMISSION, THAT'S OF LESS CONCERN.

DR. WAGNER: RIGHT. FROM MY POINT OF VIEW, THIS WOULD ONLY BE SOMETHING THAT WOULD BE ADDED LATER ON IF THERE WAS SOMETHING WE MISSED.

CO-CHAIR LO: AS SHERRY SAID, THIS IS A WORK IN PROGRESS. I DO NEED A FORMAL VOTE TO CARRY THIS FORWARD.

MS. FEIT: WHEN WE MOVE THIS DOCUMENT UP TO THE ICOC, THERE WILL BE DISCUSSION THERE. SO YOU COULD RAISE YOUR QUESTIONS ABOUT THAT SECTION THEN.

MS. CHARO: I DON'T THINK ACTUALLY THERE'S A PROBLEM THE WAY IT'S WRITTEN NOW. YOU HAVE TO GET

CONSENT AT THE MOMENT THAT THEY'RE RELEASING IT FOR RESEARCH WHETHER IT WAS STORED FOR TEN YEARS OR WHETHER IT WAS JUST CREATED THE DAY BEFORE. WE'RE OKAY, I THINK.

DR. TAYLOR: JOHN, I WAS GOING TO SAY THIS IS PRETTY GAMETE-CENTRIC, BUT ON PAGE 8 --

CO-CHAIR LO: IF IT'S JUST TO REASSURE JOHN, I NEED A VOTE BECAUSE SHERRY NEEDS TO LEAVE. WITHOUT A VOTE, WE CAN'T DO ANYTHING.

MS. CHARO: SO MOVED.

DR. EGGAN: SECOND.

CO-CHAIR LO: LET'S CALL THE QUESTION. I'M GOING TO ASK YOU TO PUT YOUR HAND UP IF YOU AGREE TO MOVING THESE FORWARD TO THE ICOC FOR THE NEXT MEETING. THANK YOU VERY MUCH, LADIES AND GENTLEMEN.

(APPLAUSE.)

CO-CHAIR LO: FIRST, I WANT TO THANK MY CO-CHAIR, SHERRY. AS SHE SAID VERY NICELY AT THE BEGINNING, THIS IS THE END OF THE BEGINNING, THE FIRST STEP, BUT WE ARE NOT DISBANDING. IN FACT, WE'RE GOING TO CALL YOU FOR CALENDAR, AND WE'RE GOING TO CONTINUE TO WORK TOGETHER TO MAKE THIS SET OF REGULATIONS AS GOOD AS POSSIBLE. I WANT TO THANK THE MEMBERS OF THE PUBLIC.

CO-CHAIR LANSING: I ALSO, BEFORE I LEAVE,

WANT TO THANK BERNIE, WHICH I THINK JUST DID THE MOST EXTRAORDINARY JOB IN CONDUCTING ALL OF THIS. AND I WANT TO THANK ALL OF YOU AGAIN. I WANT TO THANK THE PUBLIC FOR ITS INCREDIBLE INPUT. YOU'VE BEEN WITH US FROM THE BEGINNING, A LOT OF YOU, AND YOUR INPUT HAS BEEN JUST EXTRAORDINARY. I HOPE YOU'RE SATISFIED, AS I AM, WITH THE INTERCHANGE THAT WENT ON AND THE DEPTH OF DISCUSSION.

AND JUST TO REMIND YOU THAT THIS DOCUMENT GOES TO THE ICOC, WHICH IS NOT GOING TO RUBBER-STAMP IT, AND IS GOING TO VIEW IT AND LOOK AT IT. AND I THINK I SPEAK ON BEHALF OF ALL OF US WHEN I SAY WE REALLY VALUE THEIR INPUT. AND THEN THERE WILL BE A 45-DAY PUBLIC COMMENT PERIOD AGAIN, AND WE REALLY VALUE THAT. AND THEN WE WILL BE MEETING AGAIN, AND WE'RE GOING TO SET UP A DATE, I GUESS, THE END OF APRIL OR THE BEGINNING OF MAY IS WHAT WE'RE AIMING FOR, BUT WE'RE GOING TO GET EVERYBODY'S SCHEDULES AND TRY AND CIRCULATE THE TIME THAT WORKS BEST FOR EVERYBODY.

SO THANK YOU FOR NOT JUST TODAY, BUT FOR THE HUNDREDS, MAYBE THOUSANDS OF HOURS IN BETWEEN ALL OF THESE MEETINGS. ESPECIALLY THANK YOU TO BERNIE.

CO-CHAIR LO: MOTION TO ADJOURN.

MS. CHARO: SO MOVED.

DR. ROWLEY: SECOND.

CO-CHAIR LO: MEETING IS ADJOURNED. THANKS VERY MUCH.

(THE MEETING WAS THEN CONCLUDED.)

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 GROUPS OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

THE LUXE HOTEL
11461 SUNSET BOULEVARD
LOS ANGELES, CALIFORNIA
ON
TUESDAY, JANUARY 31, 2006

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
BARRISTER'S REPORTING SERVICE
1072 S.E. BRISTOL STREET
SUITE 100
SANTA ANA HEIGHTS, CALIFORNIA
(714) 444-4100