

BEFORE THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
SCIENTIFIC AND MEDICAL ACCOUNTABILITY
STANDARDS WORKING GROUP
REGULAR MEETING

LOCATION: THE LUXE HOTEL
11461 SUNSET BOULEVARD
LOS ANGELES, CALIFORNIA

DATE: MONDAY, OCTOBER 24, 2005
10 A.M.

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

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1 LOS ANGELES, CALIFORNIA; MONDAY, OCTOBER 24, 2005

2

3 CO-CHAIR LANSING: READY. OKAY. I WANT TO
4 WELCOME ALL OF YOU TO THE THIRD MEETING OF OUR STANDARD
5 GROUP, AND I ALSO WANT TO THANK YOU IN PARTICULAR FOR
6 MAKING THE TRIP TO LOS ANGELES. I THINK THIS IS
7 ACTUALLY QUITE A LOVELY VENUE, AND I HOPE THAT WILL
8 ENCOURAGE US TO HAVE AN EQUAL NUMBER OF MEETINGS IN LOS
9 ANGELES. I ALSO ESPECIALLY WANT TO THANK YOU FOR THE
10 EXTRAORDINARY AMOUNT OF TIME THAT YOU'VE ALL PUT IN
11 BETWEEN THESE MEETINGS. AND I THINK THAT BETWEEN THESE
12 MEETINGS THE TIME THAT YOU PUT IN IS QUITE A BIT, AND
13 IT WILL LEAD TO A MORE PRODUCTIVE MEETING WHEN WE'RE
14 ALL TOGETHER. I'D LIKE TO NOW OFFICIALLY CALL THIS
15 MEETING TO ORDER AND, KATE, WOULD YOU LEAD THE ROLL
16 CALL.

17 MS. SHREVE: SHERRY LANSING.

18 CO-CHAIR LANSING: HERE.

19 MS. SHREVE: BERNARD LO.

20 CO-CHAIR LO: HERE.

21 MS. SHREVE: ALTA CHARO. JOSE CIBELLI.

22 DR. CIBELLI: HERE.

23 MS. SHREVE: KEVIN EGGAN.

24 DR. EGGAN: HERE.

25 MS. SHREVE: ANN KIESSLING.

1 DR. KIESSLING: HERE.

2 MS. SHREVE: ROBERT KLEIN.

3 MR. KLEIN: HERE.

4 MS. SHREVE: JEFFREY KORDOWER. KENNETH
5 OLDEN. TED PETERS.

6 MR. PETERS: HERE.

7 MS. SHREVE: FRANCISCO PRIETO.

8 DR. PRIETO: HERE.

9 MS. SHREVE: JANET ROWLEY.

10 DR. ROWLEY: HERE.

11 MS. SHREVE: JEFF SHEEHY.

12 MR. SHEEHY: HERE.

13 MS. SHREVE: JON SHESTACK. ROBERT TAYLOR.

14 DR. TAYLOR: HERE.

15 MS. SHREVE: JAMES WILLERSON.

16 DR. WILLERSON: HERE.

17 CO-CHAIR LANSING: I HOPE THAT YOU'VE ALL HAD
18 A CHANCE TO LOOK AT THE MINUTES FROM OUR LAST MEETING.
19 I JUST WANT TO ASK ARE THERE ANY COMMENTS OR
20 CORRECTIONS? THERE ARE NO CORRECTIONS OR COMMENTS.
21 CAN I HAVE A MOTION TO APPROVE?

22 DR. WILLERSON: SO MOVED.

23 CO-CHAIR LANSING: SECOND?

24 DR. KIESSLING: SECOND.

25 CO-CHAIR LANSING: OKAY. THE MOTION PASSES.

1 NOW, GEOFF, YOU WANT TO -- GEOFF LOMAX, I'M
2 GOING TO TURN IT OVER TO YOU FOR OUR STAFF REPORT.

3 MR. LOMAX: THANK YOU. GOOD MORNING,
4 EVERYONE. ONE OF OUR BIG ADVANCES HERE IS WE'VE NOW
5 MOVED THE SCREEN FROM DIRECTLY BEHIND OF EVERYONE TO
6 THE SIDE, SO PERHAPS THIS WILL BE A LITTLE BIT BETTER
7 IN TERMS OF BEING ABLE TO VIEW EVERYTHING.

8 THIS IS A QUICK SUMMARY OF THE STAFF UPDATE.
9 IF YOU WILL REMEMBER, BETWEEN THE DEPARTURE OF HARRIET
10 RABB AND THE UNFILLED SCIENTIST POSITION, THERE ARE TWO
11 VACANCIES ON THIS WORKING GROUP, AND WE'LL UPDATE YOU
12 ON THE PROGRESS IN FILLING THOSE VACANCIES.

13 IF YOU RECALL FROM OUR LAST MEETING, WE
14 RECOMMENDED INTERIM REGULATIONS TO THE ICOC. I'LL TAKE
15 A MOMENT TO UPDATE YOU ON THE STATUS OF THIS DOCUMENT,
16 INCLUDING SOME RECOMMENDED REVISIONS TO THE DOCUMENT,
17 DOCUMENT TERMINOLOGY. AND BECAUSE OF THE EVENTS AT THE
18 ICOC, OUR TIMELINE HAS SHIFTED. I'D LIKE EVERYONE
19 CLEAR ON WHAT OUR REVISED TIMELINE IS.

20 FINALLY, I'D LIKE TO PROVIDE A BRIEF REPORT
21 BACK ON THE THREE PUBLIC SESSIONS WE WERE ABLE TO HOLD
22 BETWEEN OUR LAST MEETING AND THE MEETING TODAY.

23 ON THE 27TH OF SEPTEMBER, THE ICOC STANDARDS
24 WORKING GROUP SUBCOMMITTEE MET, AND THEY NOMINATED JOHN
25 WAGGONER, THE SCIENTIFIC DIRECTOR OF CLINICAL RESEARCH

1 OF THE BLOOD AND MARROW TRANSPLANT PROGRAM AND STEM
2 CELL INSTITUTE AT THE UNIVERSITY OF MINNESOTA. AND
3 FROM HAVING SOME DISCUSSIONS WITH DR. WAGGONER, IT'S
4 VERY IMPRESSIVE THE SORT OF CLINICAL AND SCIENTIFIC
5 KNOWLEDGE WHICH HE BRINGS TO THIS POSITION. AND I
6 THINK IT WILL MAKE A TREMENDOUS CONTRIBUTION WHEN WE
7 DEAL WITH SOME OF THE MORE TECHNICAL ISSUES RELATED TO
8 OUR DELIBERATIONS.

9 PATRICIA KING, PROFESSOR OF LAW AND MEDICINE,
10 ETHICS, AND PUBLIC POLICY AT GEORGETOWN UNIVERSITY,
11 WILL BE FILLING THE POSITION VACATED BY HARRIET RABB.
12 AND, AGAIN, IN DISCUSSIONS WITH DR -- PROFESSOR KING,
13 AGAIN, A VERY KEEN EYE TO SORT OF THE SUBTLETIES AND
14 ISSUES THAT EMERGE IN THE CONTEXT OF LAW AND REGULATION
15 AND RESEARCH. REALLY IMPRESSED WITH HER ABILITY TO
16 REALLY UNDERSTAND THE SUBTLETIES OF HOW TO MAKE ALL
17 THOSE THINGS WORK IN A WAY THAT ADVANCES THE SCIENCE
18 AND PROVIDES FOR ETHICAL SUPPORT OF THE TYPE OF WORK
19 WE'RE DOING.

20 IN ADDITION, THERE IS A BRIEF OR A FURTHER
21 BIOGRAPHY OF EACH OF THE CANDIDATES IN YOUR BINDER. I
22 BELIEVE THAT'S SECTION 5. THANK YOU. AND, AGAIN,
23 WE'VE HAD THE OPPORTUNITY TO BRIEF EACH OF THE
24 CANDIDATES, AND WE EXPECT THEY'LL BE ELIGIBLE ON
25 DECEMBER 1ST TO -- IF CONFIRMED BY THE ICOC, WILL BE

1 ELIGIBLE ON DECEMBER 1ST TO PARTICIPATE IN THESE
2 DELIBERATIONS AS VOTING MEMBERS.

3 DR. ROWLEY: MAY I ASK A QUESTION? IN TERMS
4 OF PROFESSOR KING'S VIEW OF EMBRYONIC STEM CELL
5 RESEARCH AND SOMATIC CELL NUCLEAR TRANSFER, IS THAT
6 SOMETHING THAT SHE'S WILLING TO SUPPORT?

7 MR. LOMAX: IN TERMS OF OUR DISCUSSIONS,
8 THERE WAS NO INDICATION THERE THAT THAT WAS IN ANY WAY
9 SOMETHING SHE WOULDN'T SUPPORT. I HAVE NO INDICATION
10 THERE.

11 AND ARE THERE ANY MEMBERS FROM THE
12 SUBCOMMITTEE, THE SELECTION COMMITTEE.

13 DR. HALL: HAS SHE NOT BEEN IN SUPPORT IN THE
14 PAST?

15 DR. ROWLEY: SHE'S AT GEORGETOWN, AND THAT
16 JUST IS WHAT RAISED THE QUESTION IN MY MIND.

17 DR. HALL: SHE WAS CO-CHAIR ON THE POLICY IN
18 THE NIH -- SORRY -- CO-CHAIR --

19 CO-CHAIR LO: NIH PANEL ON HUMAN EMBRYO
20 RESEARCH IN 1994. HER APPOINTMENT -- GEORGETOWN LAW
21 IS -- THE LAW SCHOOL AT GEORGETOWN IS QUITE SEPARATE
22 FROM THE REST OF THE UNIVERSITY. THEY WERE VERY
23 CAREFUL NOT TO HAVE ANY LITMUS TEST OR SORT OF
24 LIMITATIONS ON WHAT PEOPLE EITHER SUPPORT OR NOT
25 SUPPORT. SHE HAS SUPPORTED HUMAN EMBRYONIC STEM CELL

1 RESEARCH. SHE, HOWEVER, HAS BEEN VERY GOOD AT RAISING
2 THE TOUGH ETHICAL QUESTIONS ABOUT HOW TO DO IT IN AN
3 APPROPRIATE WAY, BUT SHE HAS NO -- AS FAR AS I KNOW, NO
4 IN-PRINCIPLE OBJECTION TO SOMATIC CELL NUCLEAR TRANSFER
5 FOR RESEARCH PURPOSES.

6 DR. ROWLEY: THANK YOU.

7 CO-CHAIR LANSING: DID WE ASK THAT QUESTION?

8 MR. LOMAX: WAS JON SHESTACK ON THE --

9 MR. SHEEHY: I TALKED TO HER A COUPLE OF
10 TIMES. SHE SEEMS LIKE SHE HAS A LOT OF EXPERIENCE
11 LOOKING AT THESE ISSUES. I DIDN'T REALLY VET HER ON
12 WHETHER OR NOT SHE WOULD SUPPORT OR NOT SUPPORT ANY
13 PARTICULAR -- I DIDN'T VET HER ON WHETHER SHE WOULD
14 SUPPORT OR NOT SUPPORT ANY PARTICULAR SCIENTIFIC ISSUE.
15 SHE SEEMED TO HAVE HAD EXTRAORDINARY EXPERIENCE DOING
16 BIOMEDICAL, ETHICAL, ANSWERING THOSE QUESTIONS. AND,
17 FRANKLY, I THINK IF SHE'S AMBIVALENT, IT DOESN'T HURT,
18 TO BE PERFECTLY HONEST, WITH THE PROCESS. SHE SEEMED
19 TO ME TO BE A VERY INTELLIGENT PERSON, WHO WAS VERY
20 THOUGHTFUL, WHO HAD ENORMOUS AMOUNT OF EXPERIENCE IN
21 THESE ISSUES. AND SEEMED TO ME LIKE SHE WOULD MAKE A
22 GOOD MEMBER OF THIS COMMITTEE.

23 DR. HALL: WE DON'T KNOW SPECIFICALLY, BUT I
24 DON'T THINK WE HAVE ANY INFORMATION THAT SHE DOESN'T
25 SUPPORT IT. I THINK THE GEORGETOWN CONNECTION IS

1 PROBABLY, AS BERNIE SAYS, IT'S IRRELEVANT.

2 SHE HAS BEEN INVOLVED IN THESE ISSUES. SHE
3 WAS ON A 1994 COMMITTEE. THAT WAS THE THING THAT I --
4 SHE'S SUPPORTED FOR A LONG TIME. AND MANY PEOPLE KNOW
5 HER, HAVE WORKED WITH HER IN VARIOUS CONTEXTS. ALL
6 SPEAK HIGHLY OF HER, I WOULD SAY. THAT LITMUS TEST
7 HASN'T BEEN ASKED, BUT I WOULD BE SURPRISED IF SHE WERE
8 AN ADAMANT FOE.

9 MR. SHEEHY: I HAVE TO SAY WE TRIED TO AVOID
10 ASKING LITMUS TEST QUESTIONS WHEN WE SPOKE TO FOLKS.
11 PEOPLE PUT FORWARD THEIR NAMES IF THEY WANTED TO BE
12 CONSIDERED. AND I THINK THAT IN DR. KING'S CASE, SHE
13 CAME HIGHLY RECOMMENDED BY DR. KESSLER, BASED ON HIS
14 WASHINGTON REGULATORY EXPERIENCE, WHICH WAS SOMETHING
15 THAT MANY FOLKS THOUGHT THAT WE SHOULD HAVE A LITTLE
16 BIT OF BACKGROUND ON FOR THIS COMMITTEE.

17 DR. ROWLEY: I CERTAINLY AGREE THOSE ARE
18 STRENGTHS. AND I AGREE THAT A BIT MORE DIVERSITY ON
19 THE COMMITTEE IS NOT A PROBLEM. I JUST WAS CURIOUS.

20 CO-CHAIR LO: LET ME JUST ADD. I'VE WORKED
21 WITH PAT ON A NUMBER OF NATIONAL ACADEMY OF SCIENCES
22 AND INSTITUTE OF MEDICINE PANELS, AND SHE'S VERY
23 THOUGHTFUL. SHE HAS AN OPEN MIND, AND SHE DOESN'T TAKE
24 AUTOMATIC POSITIONS. THE PANEL THAT RECENTLY
25 CONCLUDED, SHE HAD LISTENED TO ARGUMENTS AND EVIDENCE

1 AND CHANGED HER MIND ON AN ISSUE FROM WHAT SHE HAD
2 THOUGHT AT THE BEGINNING. I THINK THAT SORT OF
3 WILLINGNESS TO GO BACK AND FORTH WOULD MAKE HER A
4 STRONG ADDITION.

5 MR. LOMAX: THANK YOU FOR THOSE COMMENTS.

6 I'LL MOVE NOW TO THE STATUS OF THE INTERIM
7 REGULATIONS. AND BY WAY OF REVIEW, BECAUSE THIS COVERS
8 SOME OF THE TIMELINE HERE, IF YOU RECALL, IN MAY OF
9 THIS YEAR, THE ICOC ADOPTED THE NATIONAL ACADEMY'S
10 GUIDELINES. AND THIS DOCUMENT, THEN, IN DISCUSSION IN
11 THE JULY MEETING AMONGST THIS WORKING GROUP WAS DEEMED
12 INADEQUATE AS A REGULATORY DOCUMENT BECAUSE IT WAS
13 REALLY A SET OF GUIDELINES AND DIDN'T HAVE APPROPRIATE
14 LANGUAGE. SO WE THEN DRAFTED CIRM INTERIM REGULATIONS
15 THAT ARE MODELED AFTER THE NATIONAL ACADEMY'S
16 GUIDELINES. AND THE POINT OF THAT REDRAFTING WAS TO
17 PUT FORWARD A DOCUMENT TO THE ICOC THAT WAS IN
18 APPROPRIATE REGULATORY LANGUAGE.

19 WE APPROVED THAT DOCUMENT ON AUGUST 30TH AT
20 OUR LAST MEETING. THAT DOCUMENT WAS THEN PRESENTED AS
21 INTERIM CIRM REGULATIONS TO THE ICOC AT ITS MEETING ON
22 SEPTEMBER 9TH. DURING THAT MEETING THERE WAS
23 DISCUSSION, BUT NO ACTION WAS TAKEN ON THE DOCUMENT.
24 IT WAS A VERY LONG DAY FOR THE ICOC WITH CONSIDERABLE
25 TIME AND DISCUSSION GOING INTO THE REVIEW OF TRAINING

1 GRANTS. AND SO BY THE TIME THIS ISSUE CAME UP, THERE
2 WERE SOME FURTHER DISCUSSIONS THAT ONE OF THE MEMBERS
3 WANTED TO HAVE, BUT THEY WERE NOT AVAILABLE. AND THEN
4 WE LOST OUR QUORUM, SO AS A RESULT, I THINK WE -- IT
5 PRECLUDED THE OPPORTUNITY TO FORMALLY APPROVE THE
6 DOCUMENT.

7 IN THE MEANTIME WE WERE ABLE TO FOLLOW UP
8 WITH THE ICOC MEMBER. AND THE CONCERN THAT WAS -- THE
9 ONE CONCERN WITH THE DOCUMENT WAS UNINTENTIONAL
10 DEVIATION FROM THE NATIONAL ACADEMY'S GUIDELINES THAT
11 WAS INTRODUCED DURING DRAFTING. AND WE ANTICIPATE THE
12 ICOC WILL REVIEW AND APPROVE THAT THE INTERIM CIRM
13 REGULATIONS, IF WE ADDRESS -- WITH ONE MODIFICATION,
14 WHICH WILL BE INTENDED TO ADDRESS THIS UNINTENTIONAL
15 MODIFICATION. I'LL DESCRIBE THAT IN THE NEXT SLIDE,
16 PLEASE.

17 THE MODIFICATION OF CONCERN IS IN THE SECTION
18 PERTAINING TO INFORMED CONSENT FOR DIFFERENT TYPES OF
19 RESEARCH. IN THE PROCESS OF REDRAFTING, IF YOU RECALL,
20 THE MAJORITY OF THE SUBSTANTIVE CHANGES WERE CHANGING
21 TERMS LIKE "COULD BE OFFERED" OR "MIGHT BE CONSIDERED"
22 TO "SHALL BE OFFERED" OR "SHALL BE CONSIDERED." IN ONE
23 CASE WE MADE SUCH A CHANGE, BUT THE PRACTICAL EFFECT
24 WAS TO CREATE A VERY PRESCRIPTIVE CONSENT REQUIREMENT,
25 WHICH WAS, IN FACT, A DEVIATION FROM THE INTENT OF THE

1 ORIGINAL NATIONAL ACADEMY'S GUIDELINES.

2 SO THIS SLIDE WHICH IS NOW UP, TO MAKE THIS
3 CLEAR, THE ORIGINAL LANGUAGE IN THE NATIONAL ACADEMY'S
4 GUIDELINES IS IN ADDITION DONORS COULD BE OFFERED THE
5 OPTION OF AGREEING TO SOME FORMS OF STEM CELL RESEARCH,
6 BUT NOT OTHERS. AND AS WE -- IN THE COURSE OF
7 REDRAFTING IT, WE STATED DONORS SHALL BE OFFERED THE
8 OPTION OF AGREEING TO SOME FORMS OF RESEARCH, BUT NOT
9 OTHERS. AGAIN, THIS IS WHERE WE'VE GONE FROM A
10 RECOMMENDATION TO A PRESCRIPTIVE SET OF LANGUAGE. AND
11 THE INTENT OF THE ICOC WOULD BE TO MODIFY BACK TO THE
12 ORIGINAL LANGUAGE, SO CHANGING THAT "SHALL" TO A
13 "COULD," WHICH WOULD THEN RETURN THE DOCUMENT TO ITS
14 ORIGINAL INTENT.

15 CO-CHAIR LANSING: I'M REALLY CONFUSED NOW.
16 WE'RE NOT GOING WITH THE SHALL OR WE ARE GOING WITH THE
17 SHALL?

18 DR. HALL: GOING WITH THE MAY, COULD. LET ME
19 JUST SAY SO WHAT THE ORIGINAL NA GUIDELINES, GEOFF, IF
20 I MAY JUST INSERT HERE, SAYS YOU HAVE TO DO THESE
21 VARIOUS THINGS. IF YOU WANT TO, YOU CAN ALSO DO THIS,
22 WHICH IS YOU CAN OFFER WHAT'S CALLED LAYERED CONSENT.
23 SO YOU LET PEOPLE SAY, WELL, I'LL LET MY EGG BE USED
24 FOR THIS, BUT NOT FOR THIS AND NOT FOR THIS.

25 DURING THE DRAFTING, THAT WAS CHANGED TO

1 SHALL BE OFFERED. SO IT SAYS THAT ANY DONOR HAS TO BE
2 OFFERED THAT OPTION. AND SINCE MOST UNIVERSITIES DON'T
3 HAVE THAT AS A RULE NOW, THIS WOULD MAKE A REALLY
4 SUBSTANTIVE CHANGE IN THEIR PRACTICES, AND WE DIDN'T
5 INTEND IT. IT JUST HAPPENED AND GOT BY US, ACTUALLY.

6 MOST OF THE CHANGES WERE SHOULD TO SHALL.
7 AND IN THIS CASE IT WAS A COULD TO A SHALL, IF YOU SEE
8 THE DIFFERENCE. SO IT CHANGED SOMETHING WHICH IS AN
9 OPTION TO SOMETHING THAT WAS REQUIRED, SO WE JUST WANT
10 TO GET RID OF THAT SMALL CHANGE AND THEN RESTORE IT TO
11 ITS ORIGINAL MEANING. AND IT JUST WAS A GLITCH, BUT IT
12 WAS ONE OF THOSE THINGS THAT COULD HAVE HAD BIG
13 CONSEQUENCES. SO WE'RE REALLY GRATEFUL TO PEOPLE FOR
14 PICKING IT UP.

15 MR. LOMAX: THANK YOU FOR THAT CLARIFICATION.
16 GO ON TO THE NEXT SLIDE, PLEASE.

17 MOVING NOW TO TERMINOLOGY, WE'VE LEARNED OVER
18 THE LAST FEW MONTHS THAT WE ARE DEALING WITH A NUMBER
19 OF DIFFERENT DOCUMENTS, AND IT'S CREATED SOME CONFUSION
20 AND A LITTLE BIT OF A NOMENCLATURE PROBLEM. SO WE'VE
21 COME UP WITH SOME TERMINOLOGY WHICH WE HOPE TO MAINTAIN
22 THROUGHOUT THE COURSE OF DELIBERATIONS SO WE CAN KEEP
23 THINGS FAIRLY STRAIGHT.

24 SO THE NATIONAL ACADEMY'S GUIDELINES FOR
25 HUMAN EMBRYONIC STEM CELL RESEARCH, THE SHORTHAND,

1 NATIONAL ACADEMY'S GUIDELINES. AGAIN, THAT WAS THE
2 DOCUMENT APPROVED IN MAY, AND WE'LL REFER TO THAT AS
3 THE NATIONAL ACADEMY'S GUIDELINES.

4 THE DOCUMENT RECOMMENDED TO THE ICOC FOR
5 ADOPTION, WHICH WOULD BE THE INTERIM REGULATIONS FOR
6 CIRM, REFERRED TO AS INTERIM CIRM REGULATIONS. THE
7 DOCUMENT WHICH WILL BE THE CURRENT WORK OF THIS WORKING
8 GROUP WILL BE THE DRAFT CIRM REGULATIONS. AND THAT'S
9 GOING -- WE WILL DISCUSS THAT DOCUMENT TODAY, AND WE'LL
10 HAVE MORE DETAIL ON THAT LATER. AND OUR GOAL IS TO
11 DEVELOP FINAL CIRM RECOMMENDATIONS -- FINAL CIRM
12 REGULATIONS.

13 AND SO THIS POINT LEADS ME TO OUR TIMELINE
14 FOR DEVELOPING SUCH A DOCUMENT. AGAIN, THE ICOC WILL
15 CONSIDER THE PROPOSED INTERIM CIRM REGULATIONS ON
16 NOVEMBER 2D. IF APPROVED, THOSE REGULATIONS WOULD BE
17 IN EFFECT FOR 270 DAYS. AND THAT 270 DAYS IS PROVISION
18 SPECIFIC TO PROPOSITION 71. SO IT SETS THE TIME COURSE
19 FOR DEVELOPING THE WORK OF THIS GROUP.

20 OUR SECOND STEP WILL BE TO DEVELOP DRAFT CIRM
21 REGULATIONS BY JANUARY 31, 2006. AND THE ICOC WILL
22 CONSIDER THOSE REGULATIONS AT ITS FEBRUARY 10TH MEETING
23 FOR APPROVAL. IF APPROVED, THE DRAFT REGULATIONS WOULD
24 BE SUBMITTED TO THE OFFICE OF ADMINISTRATIVE LAW.

25 AND IF WE MOVE TO THE TIMELINE THE OFFICE OF

1 ADMINISTRATIVE LAW PROCESS WOULD TAKE OVER, AND THE
2 FINAL REGULATIONS WOULD TAKE EFFECT IN JULY. I WANT TO
3 DRAW YOUR ATTENTION AGAIN TO CRITICAL DATES. IT'S THE
4 FEBRUARY 10TH ICOC MEETING WHICH IS THE DATE WHICH THEY
5 WOULD APPROVE THE DRAFT REGULATIONS DEVELOPED BY THIS
6 WORKING GROUP. AND IF YOU WILL NOTICE ON THAT TIMELINE
7 I REALIZE IT'S A BUSY SLIDE, WE COVERED IT IN THE LAST
8 SECTION, AND THERE'S A COPY IN THE BINDER IF YOU'RE
9 HAVING TROUBLE SEEING THE SLIDE.

10 CO-CHAIR LO: IT'S THE SECOND ITEM UNDER TAB
11 5.

12 MR. LOMAX: THERE ARE THREE MEETINGS,
13 INCLUDING TODAY, WHICH IS ON THE SLIDE AT 10/24.
14 THERE'S THREE MEETINGS OF THIS WORKING GROUP LEFT WHERE
15 WE'LL HAVE TIME TO --

16 DR. HALL: POINT TO THOSE.

17 MR. LOMAX: SO WE HAVE TODAY'S MEETING, WE
18 HAVE OUR DECEMBER 1ST MEETING, AND THEN WE HAVE A
19 MEETING AT THE END OF JANUARY. AND THAT IS THE THREE
20 TIMES WE'LL BE TOGETHER TO MEET TO APPROVE THE ENTIRETY
21 OF THAT DOCUMENT, WHICH, AGAIN, NEEDS TO GO TO THE ICOC
22 FOR APPROVAL ON THE 10TH OF FEBRUARY.

23 CO-CHAIR LANSING: IS IT JANUARY 31ST? IS
24 THAT WHAT IT IS?

25 MR. LOMAX: CORRECT.

1 CO-CHAIR LANSING: SO NO MORE JANUARY 27TH.
2 THAT WAS SOMETHING WE WERE HOLDING. IT'S THE 30TH AND
3 THE 31ST.

4 MR. LOMAX: IT'S THE 30TH AND THE 31ST. WE
5 PLANNED A TWO-DAY MEETING GIVEN THE IMPORTANCE OF
6 HAVING A FINAL DOCUMENT IN PLACE TO RECOMMEND TO THE
7 ICOC.

8 DR. HALL: GEOFF, BY NOT PASSING THE INTERIM
9 STANDARDS IN SEPTEMBER, THE ICOC ACTUALLY DID THIS
10 WORKING GROUP A GREAT FAVOR BECAUSE THE CLOCK NOW
11 DOESN'T START UNTIL NOVEMBER 1ST RATHER THAN SEPTEMBER
12 1ST. THAT ACTUALLY TURNED OUT TO BE CRITICAL.

13 MR. KLEIN: BRILLIANT.

14 DR. HALL: ABSOLUTELY. THERE'S NO WAY WE
15 WOULD HAVE FINISHED THIS BY DECEMBER 1ST, SO NOW WE'VE
16 GOT A LITTLE REPRIEVE.

17 MR. LOMAX: I THINK THAT WAS COMING OUT OF
18 THE LAST MEETING OR CERTAINLY COMING OFF OF THE DINNER
19 CONVERSATION OF THE LAST MEETING. I CAN'T TELL YOU THE
20 NUMBER OF COMMITTEE MEMBERS THAT SAID THIS IS A VERY
21 AMBITIOUS TIMELINE THIS GIVES US, I THINK, THE RIGHT
22 AMOUNT OF WIGGLE ROOM TO MOVE FORWARD AND DO OUR WORK
23 THOUGHTFULLY AND CONSTRUCTIVELY.

24 CAN WE MOVE ON TO THE PUBLIC SESSIONS,
25 PLEASE. IF YOU RECALL, WE HAD THREE PUBLIC SESSIONS

1 PLANNED. AND, AGAIN, THIS IS WAS A BENEFIT OF MOVING
2 THE TIMELINE BECAUSE WE WOULD HAVE BEEN TRYING TO DO
3 PUBLIC SESSIONS AND PLAN FOR A SEPTEMBER MEETING. WE
4 CANCELED THE SEPTEMBER MEETING, WHICH WAS, I THINK,
5 EXTREMELY HELPFUL BECAUSE IT ALLOWED US TO GO OUT AND
6 COLLECT INFORMATION AND DO SOME FACT-FINDING ON THE
7 DRAFT REGULATIONS.

8 SO AS PART OF THAT FACT-FINDING, THERE WERE
9 THREE PUBLIC SESSIONS, LOS ANGELES, SACRAMENTO, AND SAN
10 FRANCISCO. WE HAD EXCELLENT DISCUSSION AND EXCHANGE AT
11 EACH OF THE MEETINGS. TOPICS SUCH AS BANKING AND EGG
12 DONATION WERE OF PARTICULAR INTEREST. AND I THINK THAT
13 THE THINKING THAT EMERGED WILL PROVIDE VALUABLE IDEAS
14 FOR DRAFTING THE FINAL REGULATIONS.

15 AND IF YOU ARE INTERESTED, THERE'S A -- I
16 WOULDN'T SAY IF YOU'RE INTERESTED. I WOULD ENCOURAGE
17 YOU TO VIEW, AGAIN, IN TAB 5 THERE'S A VERY SORT OF
18 TERSE SUMMARY OF THE COMMENTS. AND IF YOU ARE -- IF
19 ANY OF THOSE COMMENTS IN PARTICULAR ARE OF INTEREST TO
20 YOU OR YOU WOULD LIKE SORT OF FURTHER DETAIL, THERE'S
21 PROBABLY ADDITIONAL SUPPORTING MATERIAL WHICH WE'D BE
22 HAPPY TO PROVIDE. IN SOME CASES COMMENTS WERE PROVIDED
23 IN WRITING, IN OTHER CASES WE'VE HAD PEOPLE SUBMIT
24 DRAFT MANUSCRIPTS. SO THERE'S QUITE A CONSIDERABLE
25 BODY OF MATERIAL TO SORT OF SUPPORT THOSE COMMENTS, AND

1 WE' D BE HAPPY TO FORWARD THAT TO ANYONE WHO TAKES AN
2 INTEREST.

3 DR. CIBELLI: IS THIS WHAT JENNIFER E-MAILED
4 TO THE WHOLE GROUP? IS THIS THE SAME THING THAT WE GOT
5 IN E-MAIL ABOUT TWO OR THREE WEEKS AGO?

6 MR. LOMAX: IT WAS IN ONE OF THE LARGER
7 E-MAILS. I DON'T REMEMBER WHICH ONE.

8 DR. ROWLEY: OCTOBER 19TH OR 18TH.

9 DR. CIBELLI: OKAY. THANKS.

10 MR. LOMAX: THE DOCUMENT IN YOUR BINDER WILL
11 REFLECT THE LATEST REVISIONS. BECAUSE COMMENTS ARE
12 COMING IN ON AN ONGOING BASIS, THE DOCUMENTS DO CHANGE
13 A BIT, AND WE WILL BE MUCH MORE THOROUGH IN ENSURING
14 THAT WE HAVE ACCURATE DATES ON ALL THOSE DOCUMENTS
15 BECAUSE THAT WAS POINTED OUT BY ONE MEMBER, AND WE NEED
16 TO ENSURE THOSE THINGS ARE KEPT UP TO DATE.

17 I' D ALSO LIKE TO THANK A NUMBER OF THE
18 MEMBERS OF THIS WORKING GROUP WHO PARTICIPATED IN THOSE
19 PUBLIC MEETINGS. I' D LIKE TO THANK THEM FOR THEIR
20 PARTICIPATION. IT REALLY MADE FOR EXCELLENT
21 DISCUSSION. I DON'T KNOW IF ANY OF THE MEMBERS AT THIS
22 TIME HAVE ANY FURTHER THOUGHTS IN TERMS OF -- I KNOW
23 ANN, TED PETERS, FRANCISCO, JEFF WERE ALL ATTENDING.

24 CO-CHAIR LANSING: I JUST WANT TO ADD JUST
25 FOR THE RECORD, ANYWAY, THE PUBLIC MEETINGS WERE REALLY

1 GREAT BECAUSE THE PUBLIC WAS HIGHLY INTELLIGENT AND
2 VERY HELPFUL. SO THEY WERE GOOD MEETINGS.

3 MR. LOMAX: ABSOLUTELY. AND ON THAT NOTE, I
4 THINK THAT COVERS ALL THE UPDATING WE WANTED TO COVER
5 AT THIS TIME. THANK YOU.

6 CO-CHAIR LANSING: THANK YOU, GEOFF. BEFORE
7 WE MOVE ON TO ITEM 6, I JUST WANT TO KIND OF
8 REEMPHASIZE AND REMIND EVERYBODY A LITTLE BIT ABOUT WHY
9 WE'RE ALL HERE.

10 DR. PRIETO: I HAVE ONE QUESTION ABOUT THE
11 MODIFICATION OF LANGUAGE THAT GEOFF MENTIONED. IS THAT
12 SIMPLY FOR OUR INFORMATION AND TO BE CORRECTED AT THE
13 ICOC? WE DON'T HAVE TO TAKE ANY ACTION ON THAT TODAY?

14 CO-CHAIR LANSING: JUST TO BE AWARE OF.

15 AGAIN, AS WE ALL KNOW, WE HAVE THESE NAS
16 GUIDELINES. AND I JUST WANT TO REMIND EVERYBODY THAT
17 THEY REALLY ARE OUR STARTING POINT, AND THAT SO MUCH
18 HAS HAPPENED SINCE THEY WERE PUT IN PLACE. AND IT IS
19 REALLY OUR RESPONSIBILITY TO BE CONSTANTLY EVALUATING
20 THEM AND TRYING TO MAKE THEM BETTER, AND NOT JUST TO BE
21 AN ORGANIZATION THAT RUBBER-STAMPS THEM.

22 I ALSO WANT TO SAY THAT OUR WORK HERE IS
23 CONTINUAL. WHEN WE HAVE OUR JANUARY 31ST MEETING AND
24 HAVE A DOCUMENT, WE HAVE TO KNOW THAT THIS GROUP REALLY
25 DOES NOT ABANDON AND DISSOLVE. IT'S REALLY AN ONGOING

1 GROUP THAT WILL CONTINUE MEETING FOR AS LONG AS THIS
2 RESEARCH IS GOING ON. AND IT'S A GROUP THAT IS
3 CONSTANTLY GOING TO BE EVALUATING THE GUIDELINES AS WE
4 GET MORE AND MORE INFORMATION AND CONSTANTLY EVOLVING
5 AND CHANGING THEM. SO THOUGH WE WILL HAVE GUIDELINES,
6 I WILL ALWAYS THINK OF THESE GUIDELINES IN A FUNNY WAY
7 AS A CONTINUAL WORK IN PROGRESS.

8 WITH THAT, I'D REALLY LIKE TO TURN IT OVER TO
9 BERNIE.

10 CO-CHAIR LO: THANKS VERY MUCH, SHERRY. I
11 THINK IT'S VERY IMPORTANT TO REMIND US THAT WE'RE
12 STARTING WITH THE NAS GUIDELINES, BUT WE'RE GOING TO
13 MAKE THEM BETTER.

14 I'VE SPOKEN -- I'VE TRIED TO THINK THROUGH, I
15 THINK WE ALL HAVE TRIED TO SORT OF THINK THROUGH HOW TO
16 MAKE THESE RECOMMENDED GUIDELINES AS GOOD AS POSSIBLE.
17 AND I KNOW I'VE SPOKEN TO A NUMBER OF YOU, AND I THINK
18 THERE'S SOME REAL CHALLENGES WE FACE. AND WE'RE GOING
19 HAVE JAMES HARRISON IN JUST A MINUTE SORT OF TALK TO US
20 ABOUT SOME OF THE TECHNICAL ASPECTS OF WRITING
21 REGULATIONS, WHICH WE REALLY HAVE TO BE VERY MINDFUL OF
22 IN TERMS OF BEING ABLE TO MEET OFFICE OF ADMINISTRATIVE
23 LAW APPROVAL.

24 I WANT TO JUST, AGAIN FOLLOWING THROUGH WITH
25 THE SPIRIT OF WHAT SHERRY SAID, SORT OF TRY AND

1 SUMMARIZE, I THINK, WHERE WE NOW STAND. WHEN I WENT
2 BACK AND READ THE NAS REPORT, THEY IN A VERY NICE SENSE
3 KIND OF TRIED TO STATE WHAT THE GOAL OF THEIR
4 RECOMMENDATIONS WERE. AND THEY SAID THAT IT WAS TO
5 ASSURE THAT RESEARCH WAS SUBJECT TO APPROPRIATE
6 OVERSIGHT, THAT CONTROVERSIAL RESEARCH IS WELL
7 JUSTIFIED, AND THAT INAPPROPRIATE RESEARCH IS NOT
8 CARRIED OUT. I THINK I WOULD JUST ADD TO THAT THAT WE
9 NEED TO ASSURE THAT RESEARCH FUNDED BY CIRM, WHICH IS
10 SORT OF A NARROWER FOCUS, IS CARRIED OUT IN AN
11 ETHICALLY RESPONSIBLE MANNER. THAT'S SORT OF THE GOAL
12 OF THESE REGULATIONS.

13 EVERY WEEK THERE'S A NEW ARTICLE, THERE ARE
14 NEW CLAIMS, THERE ARE NEW IDEAS. THIS IS A VERY
15 RAPIDLY DEVELOPING FIELD. I THINK IT'S WONDERFUL FOR
16 THE SCIENCE POINT OF VIEW TO SEE SO MANY THINGS
17 HAPPENING. BUT WE CLEARLY ARE GOING TO NEED
18 FLEXIBILITY TO TAKE INTO ACCOUNT THINGS THAT WILL
19 HAPPEN THAT SOME OF WHICH WE MAY NOT EVEN BE ABLE TO
20 ANTICIPATE AT THIS POINT. AND A LOT OF WHAT WE'VE BEEN
21 SAYING IN OUR DELIBERATIONS HAS BEEN THAT WE DO NOT
22 WANT TO BE OVERLY PRESCRIPTIVE AT THIS POINT IN TIME
23 BECAUSE IT MAY BE INAPPROPRIATE IN A RAPIDLY DEVELOPING
24 FIELD. AND TO HAVE REGULATIONS THAT ARE VERY SPECIFIC,
25 VERY DETAILED, AND VERY PRESCRIPTIVE MAY LEAVE US WITH

1 THINGS THAT ARE OUT OF DATE RATHER QUICKLY.

2 HOWEVER, WE CAN'T ALSO GO TO THE OTHER
3 EXTREME OF BEING SO FLEXIBLE, THAT WE'RE VAGUE TO THE
4 POINT THAT SCIENTISTS AND RESEARCH INSTITUTIONS DON'T
5 REALLY KNOW WHAT THEY NEED TO DO TO BE IN COMPLIANCE.
6 THIS IS SOMETHING THAT A NUMBER OF RESEARCH
7 INSTITUTIONS HAVE SAID TO US. WE NEED TO KNOW WHAT WE
8 HAVE TO DO TO BE IN COMPLIANCE WITH YOU, AND WE ALSO
9 ARE GOING TO TRY AND COMPLY IN A VOLUNTARY WAY WITH THE
10 NAS RECOMMENDATIONS. AND SO WE NEED TO SORT OF GIVE
11 PEOPLE AMPLE NOTICE OF WHAT WE'RE EXPECTING.

12 I THINK ANOTHER POINT THAT'S BECOME CLEAR TO
13 ME AS I'VE SORT OF TALKED TO A LOT OF PEOPLE THAT HAVE
14 EXPERIENCE WITH REGULATION SORT OF FROM ALL
15 PERSPECTIVES IS THAT REGULATION HAS BURDENS AS WELL AS
16 BENEFITS. AND CERTAINLY IF YOU TALK TO RESEARCHERS IN
17 SOME INSTITUTIONS WHO FEEL THEY HAVE TO GO THROUGH A
18 LOT OF PAPERWORK TO COMPLY WITH THE REGULATIONS THAT
19 THEY'RE NOT CONVINCED REALLY SERVE THE GOALS THEY'RE
20 MEANT TO SERVE. WE NEED TO MAKE SURE THAT WHATEVER WE
21 SET FORTH IN REGULATIONS BOTH DOES WHAT WE WANT IT TO
22 DO, BUT DOES IT IN AN EFFICIENT WAY AND DOESN'T TRY AND
23 DO TOO MUCH.

24 IN TALKING TO PEOPLE AND SORT OF THINKING
25 THROUGH THINGS WITH MEMBERS OF THIS COMMITTEE,

1 ESPECIALLY WITH ALTA CHARO, WHO CAN'T BE HERE TODAY,
2 BUT HAS HAD SUBSTANTIAL EXPERIENCE WITH REGULATORY
3 ISSUES CONCERNING INNOVATIVE RESEARCH, THE FEDERAL
4 MODEL THAT IS USED FOR FEDERAL REGULATIONS, SUCH AS THE
5 COMMON RULE FOR HUMAN SUBJECTS RESEARCH AND FOR HIPAA,
6 WHICH PROBABLY IS NOT A FAVORITE REGULATION OF ANY OF
7 US, IS TO HAVE RELATIVELY SPARSE REGULATIONS, BUT A LOT
8 OF COMMENTARY, PREFACE, AND SUPPLEMENTAL GUIDANCE.
9 THAT'S A TECHNIQUE THAT A LOT OF THE WASHINGTON
10 AGENCIES USE. UNFORTUNATELY, AS JAMES IS GOING TO
11 RELATE TO US IN A MINUTE, THAT OPTION IS REALLY NOT
12 OPEN TO US IN CALIFORNIA BECAUSE OF CALIFORNIA LAW.

13 I THINK IT WAS VERY IMPORTANT FOR ME TO
14 UNDERSTAND THAT GIVEN THE AMOUNT OF WORK I'VE TRIED TO
15 DO ON THE FEDERAL LEVEL. I THINK JAMES CAN REALLY HELP
16 US UNDERSTAND THAT. SO I'M GOING TO TURN IT OVER NOW
17 TO JAMES TO KIND OF -- HE'S SPOKEN WITH THE
18 ADMINISTRATIVE LAW OFFICE. HE SHOWED THEM OUR DRAFT
19 GUIDELINES, GOTTEN FEEDBACK, AND ACTUALLY ASKED SOME
20 SPECIFIC QUESTIONS ABOUT HOW WE MIGHT -- WHETHER
21 VARIOUS APPROACHES THAT WE HAVE THOUGHT ABOUT IN OUR
22 REGULATIONS WOULD PASS MUSTER WITH THE OAL.

23 MR. HARRISON: AS BERNIE SAID, TO AVOID SOME
24 UNPLEASANT SURPRISES THIS SPRING, WE APPROACHED THE
25 OFFICE OF ADMINISTRATIVE LAW AND HAVE BEEN IN CONTACT

1 WITH ONE OF THEIR STAFF LAWYERS, WHO HAS REVIEWED THE
2 DOCUMENT THAT IS AT TAB 6 OF YOUR BOOK, THE CURRENT
3 VERSIONS OF DRAFT REGULATIONS. AND THE GOOD NEWS IS
4 THAT SHE THOUGHT WE WERE OFF TO AN EXCELLENT START. WE
5 DO HAVE CHALLENGES AHEAD OF US, AND THAT'S WHAT I'D
6 LIKE TO DESCRIBE BRIEFLY.

7 FIRST OF ALL, BERNIE IS CORRECT. THE
8 CALIFORNIA ADMINISTRATIVE PROCEDURE ACT IS MORE
9 EXPANSIVE THAN FEDERAL LAW. EVERY STANDARD OR RULE
10 THAT THE CIRM ADOPTS THAT APPLIES TO AN OPEN CLASS OF
11 INDIVIDUALS OR INSTITUTIONS IS CONSIDERED TO BE A
12 REGULATION. AND THE APA EXPLICITLY PROHIBITS STATE
13 AGENCIES LIKE THE CIRM FROM UTILIZING OR ENFORCING ANY
14 GUIDELINE OR CRITERION, BULLETIN, OR MANUAL THAT SETS
15 FORTH RULES UNLESS THOSE RULES HAVE BEEN ADOPTED AS
16 REGULATIONS.

17 AND WHAT THAT MEANS IS THAT, FOR EXAMPLE,
18 MANY AGENCIES IN THE STATE OF CALIFORNIA HAVE
19 REGULATIONS THAT INCORPORATE FORMS. SO THE REGULATION
20 MIGHT PROVIDE THAT A GRANT RECIPIENT OR INSTITUTION IS
21 REQUIRED TO FILE A QUARTERLY STATUS REPORT REGARDING
22 ITS RESEARCH, SETTING FORTH THE FOLLOWING INFORMATION
23 IN A FORM TO BE PROVIDED BY THE AGENCY. IF THAT FORM
24 THEN INCLUDES ADDITIONAL REPORTING REQUIREMENTS, IT'S
25 CONSIDERED TO BE AN UNDERGROUND REGULATION. IN FACT,

1 MOST OF THE CASE LAW INVOLVING THE APA IN CALIFORNIA
2 INVOLVES ATTEMPTS BY AGENCIES TO USE FORMS OR MANUALS
3 OR BULLETINS TO SUPPLEMENT OR EMBELLISH THE
4 REGULATIONS. AND UNFORTUNATELY FOR US, CALIFORNIA LAW
5 STRICTLY PROHIBITS THAT.

6 SO WE REALLY HAVE TO THINK ABOUT WHAT RULES
7 WE WANT TO SET FORTH, AND THEN THOSE RULES ALL HAVE TO
8 BE CONTAINED WITHIN THE BODY OF REGULATIONS. WE CAN'T
9 ADD TO THEM SUBSEQUENTLY BY OFFERING ADVICE TO THE
10 EXTENT THAT THAT ADVICE IS BINDING.

11 MR. SHESTACK: HOW CAN WE ADD TO THEM
12 SUBSEQUENTLY?

13 MR. HARRISON: THE ONLY WAY TO ADD TO THEM
14 SUBSEQUENTLY IS TO AMEND THE REGULATIONS.

15 MR. SHESTACK: WHAT IS THIS PROCESS? IT
16 SOUNDS LIKE YOU ARE SAYING WE HAVE ONE BITE AT THE
17 APPLE. THAT CAN'T BE TRUE.

18 MR. HARRISON: NO, THAT'S NOT TRUE.
19 REGULATIONS, OF COURSE, CAN BE AMENDED. YOU HAVE TO GO
20 THROUGH THE SAME PROCESS THAT WE'RE GOING THROUGH NOW.

21 MR. SHESTACK: WHICH IS?

22 MR. HARRISON: SLIGHTLY DIFFERENT IN THE
23 SENSE THAT PROP 71 SETS FORTH A SPECIFIC PROCESS. BUT
24 UNDER THE ADMINISTRATIVE PROCEDURE ACT, ORDINARILY
25 REGULATIONS ARE PROPOSED BY THE AGENCY, THERE'S A

1 45-DAY PUBLIC COMMENT PERIOD, THEN THE OFFICE OF
2 ADMINISTRATIVE LAW HAS 30 WORKING DAYS IN WHICH TO
3 REVIEW THE AMENDMENT OR THE NEW REGULATION. THERE ARE
4 CIRCUMSTANCES WHERE THE ENACTMENT OF A REGULATION IS
5 NECESSARY TO PRESERVE THE HEALTH, SAFETY, OR GENERAL
6 WELFARE OF THE PUBLIC, AND AMENDMENTS OR REGULATIONS
7 CAN BE ADOPTED AS EMERGENCY REGULATIONS. THAT'S DONE
8 ON A FIVE-DAY PUBLIC COMMENT PERIOD AND A TEN-DAY OAL
9 REVIEW. SO THERE ARE WAYS TO EXPEDITE THE REVIEW AND
10 THE ADOPTION OF AMENDMENTS TO REGULATIONS, BUT YOU
11 STILL HAVE TO GO THROUGH THE FORMAL RULEMAKING PROCESS.

12 CO-CHAIR LANSING: BASICALLY WHAT JAMES IS
13 SAYING IS NOT IN CONFLICT WITH WHAT BERNIE AND I SAID.
14 YOU HAVE THESE REGULATIONS, WHICH WE ALL THINK ARE
15 GREAT FOR THIS TIME. THE FIELD IS MOVING SO QUICKLY,
16 THAT IN SIX MONTHS WE COULD SEE SOMETHING THAT IS
17 HINDERING THE RESEARCH, IS NOT HAVING THE EFFECT THAT
18 WE WANT, BUT YOU HAVE TO GO THROUGH A PROCESS. BUT
19 WE'D BE PREPARED TO GO THROUGH THE PROCESS, AND YOU CAN
20 GO THROUGH THE PROCESS ON ONE ITEM. WE STILL HAVE TO
21 DO IT IN A FAIR WAY.

22 MR. SHESTACK: MAYBE NOT A QUESTION, BUT WHAT
23 ACTUALLY QUALIFIES -- I MEAN THERE'S POLICIES -- THERE
24 ARE POLICIES AND PROCEDURES, FOR INSTANCE, THE GRANTS
25 STAFF OR GRANT WORKING GROUP WILL HAVE POLICIES AND

1 PROCEDURES ON WHAT IS ACCEPTABLE OVERHEAD, FOR
2 INSTANCE, FOR A GRANT AWARDED, WHAT REGULARITY OF
3 MIDCYCLE REPORTS ARE. ACTUALLY IT WOULD PROBABLY COME
4 OUT OF A STAFF STANDARD POLICY ON ACCESS, A TIMELINE
5 FOR ACCESS TO DATA BY OTHER RESEARCHERS. DO ALL OF
6 THOSE THINGS ACTUALLY HAVE TO BE CODIFIED, PUT IN
7 POLICIES AND PROCEDURES -- IN THE GUIDELINES BECAUSE
8 IT'S A LEVEL OF DETAIL THAT AND ON SUBJECT MATTER THAT
9 WE ARE NOT CONSIDERING IN THIS GROUP AT THIS POINT.

10 DR. HALL: SOME OF THOSE, JON, COME UNDER THE
11 GRANTS ADMINISTRATIVE POLICY. WE HAVE A GROUP THAT'S
12 BEEN WORKING ACTUALLY SINCE THE SUMMER, SINCE LAST MAY
13 OR JUNE, IN PUTTING TOGETHER A BIG DOCUMENT, WHICH IS
14 QUITE A JOB. AND THE ICOC WILL RECEIVE NEXT TIME A
15 STANDALONE DOCUMENT FOR TRAINING GRANTS, WHICH WILL BE
16 SOMEWHAT SIMPLER THAN THE ULTIMATE ONE. A LOT OF THOSE
17 THINGS WILL BE SPELLED OUT IN THAT. AND IN
18 CONVERSATIONS WITH JAMES, I THINK THAT WILL HAVE TO GO
19 THROUGH THE STANDARD PROCEDURES, BUT MOST OF THOSE
20 ISSUES ARE NOT ETHICAL ISSUES. THEY ARE ISSUES OF
21 ADMINISTRATIVE POLICY AND QUESTIONS LIKE HOW OFTEN DO
22 YOU REPORT THE RESULTS, WHAT HAPPENS IF YOU WANT TO
23 CHANGE YOUR BUDGET, WHO IS ELIGIBLE IN TERMS OF THE
24 FELLOWSHIPS OR EVEN TO BE A PRINCIPAL INVESTIGATOR. A
25 LOT OF THOSE ARE ADMINISTRATIVE THINGS. THE ICOC WILL

1 SEE THOSE, BUT THAT WILL NOT COME THROUGH THIS GROUP.

2 AND WE WILL HAVE A CHANCE AT THE UPCOMING
3 MEETING TO DISCUSS BOTH THE TRAINING GRANT ONE AND THEN
4 TO GO OVER SO EVERYBODY UNDERSTANDS WHAT KINDS OF
5 THINGS ARE IN THE DRAFT THAT WE'RE WORKING ON FOR THE
6 OTHER ONE.

7 MR. SHESTACK: I'D LIKE TO RETURN TO THIS
8 SUBJECT LATER IN THE MEETING WITH SOME DETAIL BECAUSE I
9 THINK SOME OF THOSE ITEMS MIGHT BE CONSIDERED BY AT
10 LEAST SOME OF THE PEOPLE ON THIS GROUP UNDER THE
11 PURVIEW OF STANDARDS AND ETHICAL STANDARDS THAT MIGHT
12 OVERLAP. AND CERTAINLY PEOPLE ON THE GRANTS GROUP, I
13 THINK, WOULD HAVE THOUGHT THAT THEY MIGHT HAVE HAD A
14 CHANCE TO CONTRIBUTE TO THAT. THE BODY THAT'S DOING
15 ALL THIS WORK, AND IT'S A LOT OF WORK, IS COMPLETELY
16 STAFF DRIVEN AND MEMBER GROUP.

17 DR. HALL: YES. IT WILL ALL GO TO THE ICOC.
18 THERE'S NO QUESTION ABOUT THAT. SO LET'S GO OVER AND
19 SEE WHAT IT IS AT THE NEXT MEETING. MY ONE CONCERN
20 HERE IS THAT THE PRINCIPAL JOB OF THIS GROUP IS THE
21 MEDICAL AND ETHICAL STANDARDS AS WE HAVE SORT OF
22 DEFINED THEM.

23 MR. SHESTACK: AS THEY'RE VERY NARROWLY
24 DEFINED.

25 DR. HALL: OKAY. BUT THAT'S A TREMENDOUS

1 JOB, AND I THINK WE HAVE A DEADLINE FOR THAT. AND MY
2 OWN PREFERENCE WOULD BE TO NOT TAKE THIS COMMITTEE TO
3 GO OVER ALL THE GRANTS ADMINISTRATION POLICY; BUT IF
4 THERE WERE ITEMS THAT YOU WANTED TO REFER TO IT FROM
5 THE OTHER DISCUSSION, I THINK THAT WOULD BE PERFECTLY
6 APPROPRIATE.

7 CO-CHAIR LO: I THINK ANOTHER WAY TO APPROACH
8 THIS, JON, I REALLY ENCOURAGE YOU IF YOU HAVE
9 IDENTIFIED SPECIFIC ISSUES THAT ARE NOW FALLING UNDER
10 THE PURVIEW OF THE GRANTS ADMINISTRATION YOU THINK
11 REALLY HAVE AN ETHICAL COMPONENT THAT THIS GROUP SHOULD
12 DEAL WITH, THEN WE SHOULD RAISE THOSE ISSUES SO THE
13 REST OF THE GROUP CAN UNDERSTAND.

14 MR. SHESTACK: I THINK THERE'S A COMBINATION
15 OF THERE'S SOME ISSUES THAT ARE HOUSEKEEPING, AND THEN
16 THERE ARE CERTAIN KEY ISSUES THAT TOUCH ON BOTH ETHICS
17 AND ON STRATEGIC PLANNING ACTUALLY AND BASIC, YOU KNOW,
18 VISION AND MISSION APPROACH OF CIRM. AND SO IT DOES
19 SEEM TO ME THAT THERE ARE ISSUES LIKE THAT. IF IT'S
20 SOMETHING AS SIMPLE AS REPORTING NEGATIVE -- A
21 REQUIREMENT TO REPORT NEGATIVE RESULTS, FOR INSTANCE,
22 WHERE DOES SOMETHING LIKE THAT FALL, BUT NOT
23 NECESSARILY PURELY A STAFF-DRIVEN THING.

24 DR. HALL: I'D BE HAPPY TO HAVE A DISCUSSION
25 WITH YOU ABOUT THAT OFF.

1 MR. SHESTACK: RULES AND REGULATION, POLICIES
2 AND PROCEDURES ALSO HAVE TO GO THROUGH THE
3 ADMINISTRATIVE PROCEDURE?

4 MR. HARRISON: THAT'S CORRECT.

5 MR. SHESTACK: AT THE SAME TIME AS OUR
6 STANDARDS? THEY WILL ALL GO THROUGH AS ONE GIANT
7 PACKAGE?

8 MR. HARRISON: NO.

9 MR. SHESTACK: THERE WILL ALSO BE A 45-DAY
10 PUBLIC COMMENT AND 30-DAY REVIEW PERIOD AND THEN
11 ENACTMENT?

12 MR. HARRISON: CORRECT.

13 DR. HALL: WE'LL NOT HAVE PUBLIC HEARINGS ON
14 OUR GRANTS ADMINISTRATION POLICY.

15 MR. SHESTACK: DOESN'T THE LAW REQUIRE IT?

16 DR. HALL: NO. THEY HAVE PUBLIC COMMENT
17 AFTER WE'VE SUBMITTED THE DRAFT. WE DO HAVE TO HAVE
18 PUBLIC COMMENT, BUT WE HAVE HAD IN THIS PROCESS
19 HEARINGS TO GATHER INFORMATION.

20 MR. SHESTACK: RIGHT. RIGHT. RIGHT.

21 MR. KLEIN: JAMES, BEFORE YOU GO ON TO THE
22 NEXT ITEM, IN TERMS OF REPORTING, FOR EXAMPLE, COULD
23 THERE BE A REPORTING STANDARD THAT IS CREATED THAT SAYS
24 THAT EVERY GRANT WILL HAVE REPORTING THAT WILL EITHER
25 BE MONTHLY, QUARTERLY, OR BI ANNUAL BASED UPON STAFF

1 DECISIONS ON WHAT IS APPROPRIATE TO THE SIZE OF THE
2 GRANT, TYPE OF GRANT, ETC.? SO YOU CREATED A RANGE OF
3 OPTIONS, NOT THAT WE'RE GOING TO SPECIFICALLY ADOPT
4 THAT, BUT I'M TRYING TO CREATE AN EXAMPLE. SO YOU
5 SPECIFY A RANGE UNDER WHICH REPORTING WOULD OCCUR,
6 ALLOWING FOR DISCRETION BASED UPON THAT RANGE AND THE
7 APPROPRIATE FACTUAL MATTERS RELATED TO THAT PARTICULAR
8 GRANT, OR DO YOU HAVE TO SAY THIS PARTICULAR TYPE OF
9 GRANT WILL BE MONTHLY?

10 MR. HARRISON: I BELIEVE IT'S THE LATTER.

11 DR. HALL: YOU CANNOT OFFER AN ALTERNATIVE
12 ACCORDING TO -- YOU CAN'T SAY THAT ACCORDING TO THE
13 KIND OF GRANT IT IS, THAT IT CAN BE ONE (A), (B), OR
14 (C), BUT IT CAN'T BE (D)?

15 MR. HARRISON: I THINK YOU CAN DO THAT. BUT
16 IF YOU'RE LEAVING IT ENTIRELY IN THE HANDS OF STAFF TO
17 EXERCISE DISCRETION, IF THERE ARE NO OBJECTIVE CRITERIA
18 BY WHICH THE STAFF EXERCISES THAT DISCRETION, I THINK
19 IT WILL RAISE QUESTIONS ABOUT WHETHER THE GRANTEEES KNOW
20 HOW TO CONFORM THEIR OWN BEHAVIOR.

21 DR. HALL: I SUGGEST WE PLOW ON WITH OUR WORK
22 HERE, KEEPING THESE COMMENTS IN MIND. WHEN WE COME TO
23 A QUESTION LIKE THAT, THEN WE PLAY IT OUT.

24 CO-CHAIR LO: AND WE WILL FOR THIS COMMITTEE,
25 I THINK, WHEN WE TALK ABOUT STEM CELL BANKING AND WHAT

1 DO WE MEAN BY TIMELY DEPOSITS, THIS VERY ISSUE OF HOW
2 SPECIFIC DO WE NEED TO BE OR CAN WE GIVE A RANGE WILL
3 COME UP. SO LET'S FLAG THIS.

4 MR. KLEIN: AT A LATER TIME I'D LIKE TO
5 DISCUSS, SINCE THERE WILL BE INDIVIDUAL GRANT
6 CONTRACTS, HOPEFULLY YOU CAN INDIVIDUALIZE A CONTRACT
7 WHERE THE TERMS OF THE CONTRACT DO NOT BECOME
8 REGULATORY. SO WE DON'T HAVE TO BURDEN OURSELVES WITH
9 THE FULL UNDERSTANDING OF THAT AT THIS MOMENT, BUT I'D
10 LIKE TO LATER HAVE A COMPLETE --

11 MR. HARRISON: THAT'S CORRECT. IF YOU'RE
12 TALKING ABOUT AN AGREEMENT THAT APPLIES TO ONLY ONE
13 INDIVIDUAL, NOT AN OPEN CLASS, LIKE ALL GRANT
14 RECIPIENTS, THEN IT DOES NOT HAVE TO BE ADOPTED AS A
15 REGULATION.

16 MR. SHESTACK: BUT THEY ARE POLICIES AND
17 PROCEDURES THAT ARE FORMED BY A GRANTING AUTHORITY THAT
18 THEY THEN PUT IN CONTRACTS WITH EVERY INDIVIDUAL
19 GRANTEE.

20 MR. HARRISON: IF THEY HAVE UNIFORM
21 APPLICATION.

22 DR. HALL: WE'RE GETTING OFF A LITTLE BIT,
23 BUT JUST TO, THE WAY THAT WORKS IS WE WILL HAVE OUR
24 GRANTS ADMINISTRATION POLICY. WE SAY TO AN
25 INSTITUTION, AND I THINK IT'S WORTH BRINGING UP BECAUSE

1 THE QUESTION HAS ARISEN HERE ABOUT HOW DO WE ENFORCE IT
2 AND HOW DO WE GET COMPLIANCE, WE SAY TO AN INSTITUTION,
3 OKAY. WE'VE AWARDED YOU THIS AMOUNT OF MONEY. NOW YOU
4 NEED TO SEND US A STATEMENT SAYING THAT YOU HAVE READ
5 OUR GRANTS ADMINISTRATION POLICY AND THAT YOU AGREE TO
6 ABIDE BY IT.

7 AND THEN ONE OF THE ISSUES THAT WE'LL FACE IN
8 THERE IS THEN WHAT HAPPENS IF IT TURNS OUT THEY DON'T.
9 WHAT LEVELS OF PENALTY AND REDRESS CAN ONE TAKE? SO
10 ALL OF THOSE -- ALL THAT'S SPELLED OUT THERE.

11 ALTHOUGH, AS BOB SAYS, THERE MAY BE CASES, PARTICULARLY
12 WITH PRIVATE COMPANIES, WHERE WE WILL WRITE SEPARATE
13 CONTRACTS. WE WOULD PREFER NOT TO WRITE A SEPARATE
14 CONTRACT WITH EACH INSTITUTION OR WITH EACH INDIVIDUAL,
15 SO WHAT WE'D LIKE TO DO, WE ARE THE GRANTING AGENCY,
16 AFTER ALL, SO WE SAY HERE'S WHAT WE EXPECT YOU TO DO.
17 AND IF YOU WANT OUR MONEY, YOU AGREE TO DO IT.

18 WE DON'T WANT TO ASK UNREASONABLE THINGS, BUT
19 WE ALSO DON'T WANT TO HAVE A HODGEPODGE OF DIFFERENT
20 CONDITIONS FOR DIFFERENT INSTITUTIONS. SO I THINK
21 THAT'S HOW THAT WILL BE HANDLED.

22 DR. KIESSLING: I WANT TO MAKE SURE THAT I
23 UNDERSTAND THIS DISCUSSION. DR. LO SAID THAT ONE
24 APPROACH TO GUIDELINES IS THE WASHINGTON APPROACH,
25 WHICH HAS SOME PRETTY BROAD-STROKES GUIDELINES,

1 FOLLOWED UP AND SUPPLEMENTED BY POLICIES AND
2 PROCEDURES. WHAT YOU'RE TELLING US IS THAT IT'S NOT
3 THAT SIMPLE IN CALIFORNIA. WE CAN'T DO IT THAT WAY.
4 AND THEN IN SOME INSTANCE WE'RE GOING TO HAVE TO DO
5 SOME KINDS OF DETAILS, EVEN IF IT'S AN A OR A B OR A C.
6 OKAY. OH, WOW.

7 DR. HALL: IT'S SCARY, ISN'T IT?

8 CO-CHAIR LO: OR AND BE WILLING TO THEN COME
9 BACK TO ISSUES LATER AND SAY WE'RE GOING TO GO THROUGH
10 THIS AMENDMENT PROCEDURE, WHICH IS 45 DAYS OF PUBLIC
11 NOTICE PLUS 30 DAYS FOR THE OAL.

12 DR. KIESSLING: WOULD IT BE EASIER TO ALTER
13 THE CALIFORNIA LAW?

14 MR. KLEIN: IN APPROXIMATELY 24 MONTHS THERE
15 CLEARLY WILL BE A BILL TO, IN QUOTES, ENHANCE. AND THE
16 INITIATIVE PERMITS ENHANCEMENT OF THE LAW BY A
17 70-PERCENT VOTE IN BOTH HOUSES. SO TO THE EXTENT
18 THERE'S AN ISSUE LIKE THIS WHERE POTENTIALLY IT CREATES
19 TOO MUCH OF AN ADMINISTRATIVE BURDEN AND A LACK OF
20 DISCRETION WITHIN AN OBJECTIVE RANGE, IT COULD BE A
21 SUBJECT FOR AMENDMENT. THERE LIKELY WILL BE A BILL AND
22 WE MIGHT AS WELL HAVE THINGS THAT WE THINK ARE
23 BENEFICIAL IN THAT BILL. SO WE SHOULD KEEP TRACK OF
24 THESE ITEMS.

25 DR. PETERS: WILL THAT BILL BE SPECIFIC FOR

1 US OR A HIGHER LEVEL OF GENERALIZATION?

2 MR. KLEIN: IT HAS TO BE SPECIFIC FOR US.

3 MR. HARRISON: THE FLIP SIDE TO THE
4 PROHIBITION AGAINST USING BULLETINS OR MANUALS TO
5 EMBELLISH REGULATIONS IS THAT THE REGULATIONS
6 THEMSELVES MUST BE SET FORTH IN CLEAR AND CONCISE
7 LANGUAGE THAT CAN BE READILY UNDERSTOOD BY THE
8 INDIVIDUALS WHO HAVE TO COMPLY WITH THEM. SO, FOR
9 EXAMPLE, THE USE OF AN UNDEFINED TERM THAT DOES NOT
10 HAVE A READILY UNDERSTOOD MEANING TO THE INDIVIDUALS
11 WHO ARE COVERED BY IT WOULD VIOLATE THAT STANDARD.
12 LIKewise, STATEMENTS OF INTENT AND ASPIRATIONAL
13 LANGUAGE DO NOT CONSTITUTE REGULATIONS BECAUSE THEY
14 DON'T HAVE ANY BINDING AUTHORITY.

15 THAT TYPE OF LANGUAGE, THOUGH, CAN GO INTO
16 THE STATEMENT OF REASONS THAT IS PART OF THE PUBLIC
17 RECORD AND THAT ACCOMPANIES THE REGULATIONS. THE
18 STATEMENT OF REASONS MUST SET FORTH THE PURPOSE AND
19 INTENT OF THE REGULATIONS AND THE RATIONALE FOR
20 ADOPTING. AS I SAID, THAT IS PART OF THE PUBLIC
21 RECORD, SO TO SOME EXTENT THAT CAN BE USED TO EXPLAIN
22 YOUR THINKING.

23 ONE WAY TO MAINTAIN SOME FLEXIBILITY, WHICH
24 BERNIE AVERTED TO EARLIER, IS TO USE WHAT ARE KNOWN AS
25 PERFORMANCE STANDARDS RATHER THAN PRESCRIPTIVE

1 STANDARDS. AS THE NAME SUGGESTS, A PERFORMANCE
2 STANDARD IS A REGULATION THAT IDENTIFIES A GOAL AND THE
3 CRITERIA FOR ACHIEVING THE OBJECTIVE, BUT LEAVES OPEN
4 HOW THE INDIVIDUALS WHO ARE COVERED BY THE REGULATION
5 COMPLY WITH IT.

6 BY CONTRAST, A PRESCRIPTIVE REGULATION IS A
7 REGULATION THAT SETS FORTH THE SOLE MEANS OF COMPLYING
8 WITH THE REGULATION. SO PERFORMANCE STANDARD
9 IDENTIFIES THE OBJECTIVE AND LEAVES IT TO THE REGULATED
10 PARTY TO DETERMINE HOW TO COMPLY.

11 DR. HALL: CAN YOU HAVE AN EXAMPLE FOR US?

12 MR. HARRISON: ONE EXAMPLE WOULD BE, FOR
13 EXAMPLE, AN INFORMED CONSENT. IF YOU WERE TO SET FORTH
14 A GENERAL PERFORMANCE STANDARD, INSTITUTIONS SHALL
15 OBTAIN INFORMED CONSENT FROM DONORS FOR THE USE OF
16 THEIR BIOLOGICAL MATERIALS FOR RESEARCH PURPOSES. THAT
17 WOULD BE A PERFORMANCE STANDARD. IT WOULDN'T TELL THE
18 INSTITUTIONS HOW THEY'RE TO GO ABOUT OBTAINING INFORMED
19 CONSENT. A PRESCRIPTIVE STANDARD WOULD BE ONE THAT
20 IDENTIFIES ALL OF THE THINGS THAT THE INSTITUTIONS MUST
21 DO IN ORDER TO OBTAIN INFORMED CONSENT.

22 AND THERE ARE SOME AREAS WHERE YOU WANT TO
23 USE PRESCRIPTIVE STANDARDS AND OTHERS WHERE YOU WANT TO
24 USE PERFORMANCE STANDARDS, AND PART OF THE CHALLENGE WE
25 FACE IS DETERMINING WHAT IS BEST FOR MEETING THE

1 OBJECTIVES OF THIS GROUP.

2 MR. KLEIN: WHAT WAS YOUR EXAMPLE AGAIN ON
3 THE PERFORMANCE STANDARD ON INFORMED CONSENT?

4 MR. HARRISON: PERFORMANCE STANDARD MIGHT BE
5 SOMETHING LIKE THE INSTITUTION SHALL OBTAIN INFORMED
6 CONSENT OF DONORS FOR USE OF THEIR BIOLOGICAL MATERIALS
7 FOR RESEARCH PURPOSES.

8 MR. SHESTACK: WHAT WOULD BE THE PRESCRIPTIVE
9 VERSION OF THAT?

10 MR. HARRISON: THE PRESCRIPTIVE VERSION WOULD
11 BE SOMETHING LIKE WHAT WE HAVE CURRENTLY, WHICH SETS
12 FORTH PRECISELY HOW THE INSTITUTIONS ARE TO OBTAIN THE
13 DONOR'S INFORMED CONSENT.

14 DR. TAYLOR: KIND OF THE COULD VERSUS SHALL
15 SITUATION.

16 MR. HARRISON: NO. IT'S A LITTLE BIT
17 DIFFERENT. IT'S DEFINING WHAT THE GOAL IS, OBTAINING
18 INFORMED CONSENT, VERSUS SPECIFYING HOW THE
19 INSTITUTIONS ARE TO ACCOMPLISH THAT GOAL.

20 DR. HALL: SO YOU COULD HAVE A MORE
21 COMPLICATED GOAL THAN THAT.

22 MR. HARRISON: ABSOLUTELY.

23 DR. HALL: YOU COULD SAY THAT THEY OFFER
24 INFORMED CONSENT AND GIVE EVIDENCE THAT THEY FULLY
25 UNDERSTAND. A FEW LINES LIKE THAT. WHAT YOU DON'T SAY

1 IS YOU HAVE TO -- HERE'S THE LANGUAGE YOU HAVE TO USE.

2 CO-CHAIR LO: I THINK THAT'S IMPORTANT. SO
3 THE NAS GUIDELINES, ACTUALLY THE CALIFORNIA LAWS THAT
4 GEOFF SORT OF COLLECTED AND GAVE ARE VERY PRESCRIPTIVE
5 IN THE SENSE THAT YOU MUST DISCLOSE THE FOLLOWING
6 THINGS. THAT'S A LONG LIST OF THINGS YOU HAVE TO
7 DISCLOSE, AND THAT'S VERY PRESCRIPTIVE, DURING THE
8 INFORMED CONSENT PROCESS. CERTAINLY THERE ARE RESEARCH
9 ISSUES, SAY, THAT THE RESULTS OF THAT FOR THEM ARE THAT
10 THE CONSENT FORMS GET LONGER AND LONGER AND LONGER, AND
11 THERE'S MORE AND MORE DETAIL, AND IT'S NOT CLEAR TO
12 THOSE WHO ARE SKEPTICAL THAT IT REALLY HELPS THE
13 POTENTIAL RESEARCH PARTICIPANT UNDERSTAND WHAT'S GOING
14 ON. IT'S A REAL CHALLENGE. AND IT'S DIFFERENT THAN
15 HOW WE HAVE TRIED IN OTHER SETTINGS TO KIND OF REGULATE
16 OR OVERSEE INFORMED CONSENT.

17 DR. HALL: SO THE CHALLENGE IS TO PICK OUT
18 THOSE IMPORTANT THINGS THAT YOU REALLY WANT PERFORMANCE
19 ON AND BE SURE AND IDENTIFY THOSE. AND THEN PEOPLE CAN
20 DO IT IN VARIOUS WAYS OR THAT GIVES ROOM UNDERNEATH
21 THAT TO HAVE OTHER MORE PRESCRIPTIVE STANDARDS THAT MAY
22 COME FROM SOMEWHERE ELSE, BUT IT HAS TO MEET THIS
23 GENERAL PERFORMANCE STANDARD.

24 MR. HARRISON: RIGHT. AND THE TWIN CHALLENGE
25 IS TO MAKE SURE THAT YOU USE LANGUAGE THAT'S PRECISE

1 ENOUGH THAT PEOPLE UNDERSTAND HOW IT IS THAT THEY GO
2 ABOUT -- WHAT STANDARD IT IS THEY'RE COMPLYING WITH.
3 SO, FOR EXAMPLE, IF YOU USE LANGUAGE LIKE THE ESCRO
4 MUST EVALUATE WHETHER THE RESEARCH IS ETHICALLY
5 APPROPRIATE, ETHICALLY APPROPRIATE IS NOT -- IF YOU
6 DON'T DEFINE THAT TERM, THEN THE INSTITUTIONS WON'T
7 KNOW PRECISELY WHAT THEY'RE SUPPOSED TO EVALUATE. WE
8 WANT TO BOTH SET PERFORMANCE STANDARDS THAT ARE
9 SOMEWHAT FLEXIBLE WHILE AT THE SAME TIME BEING
10 DEFINITIVE ENOUGH THAT WE PASS OFFICE OF ADMINISTRATIVE
11 LAW REVIEW AND THAT THE INSTITUTIONS KNOW HOW IT IS OR
12 WHAT IT IS THEY'RE SUPPOSED TO COMPLY WITH.

13 DR. HALL: SO IF I REMEMBER, JAMES, AND
14 PLEASE CORRECT ME IF I'M WRONG, ALTHOUGH YOU CANNOT
15 HAVE A MANUAL THAT SAYS, OKAY, HERE'S WHAT WE MEANT BY
16 GENERALLY ACCEPTABLE, WE MEANT THIS MANY DAYS AND THIS
17 MANY THIS AND THIS MANY THAT, BUT WHAT YOU CAN SAY IS
18 HERE ARE EXAMPLES AND COUNTER EXAMPLES. HERE'S A
19 POSITIVE EXAMPLE AND HERE'S A NEGATIVE EXAMPLE. THIS
20 WOULD BE ACCEPTABLE; THIS WOULD NOT BE; IS THAT
21 CORRECT? NOT CORRECT?

22 MR. HARRISON: IT'S A SOMEWHAT RISKY
23 ENTERPRISE. IT'S A RISKY ENTERPRISE FOR TWO REASONS.
24 ONE, IF THE SORT OF NEGATIVE EXAMPLE IS NOT CLEARLY SET
25 FORTH IN THE REGULATION ITSELF OR NOT EVIDENT TO THOSE

1 WHO ARE TRYING TO COMPLY WITH IT, THEN THE OFFICE OF
2 ADMINISTRATIVE LAW WOULD SAY THAT YOU'VE ADOPTED AN
3 UNDERGROUND REGULATION.

4 SECONDLY, IF THE INSTITUTIONS BELIEVE THAT
5 THESE EXAMPLES ARE IN A SENSE EXHAUSTIVE AND REQUIRED,
6 THEN THE OFFICE OF ADMINISTRATIVE LAW MIGHT ALSO
7 DETERMINE THAT YOU'RE BASICALLY USING THE MANUAL AND
8 THE EXAMPLES YOU'RE OFFERING AS A WAY OF IMPOSING NEW
9 RULES ON THE INSTITUTIONS. IT CAN BE DONE. IT JUST
10 HAS TO BE DONE VERY CAREFULLY.

11 DR. HALL: LET ME MAKE UP SOMETHING. I
12 HAVEN'T REALLY THOUGHT ABOUT IT. JUST WHAT WE WERE
13 TALKING ABOUT BEFORE, YOU HAVE TO UNDERSTAND -- YOU
14 HAVE TO GIVE EVIDENCE THAT THEY UNDERSTAND THE INFORMED
15 CONSENT OF WHAT YOU'VE TOLD THEM. THEN YOU COULD SAY,
16 FOR AN EXAMPLE, YOU COULD HAVE A STATEMENT, I HAVE READ
17 AND UNDERSTOOD THE STATEMENT ABOVE. THAT WOULD BE
18 ACCEPTABLE. BUT I'VE LOST -- NOW I DON'T HAVE A
19 NEGATIVE EXAMPLE.

20 SIMPLY TO HAVE A DOCUMENT READ TO THEM, OKAY,
21 AND THEN TO ASK THEM JUST TO SIGN YES OR NO WOULD NOT
22 BE ACCEPTABLE. HOW WOULD SOMETHING LIKE THAT -- I
23 THINK, AT LEAST TRYING TO THINK ABOUT WHERE WE CAN GO
24 HERE. WHAT ABOUT AN EXAMPLE LIKE THAT?

25 MR. HARRISON: I THINK YOUR POSITIVE EXAMPLE

1 WOULD PROBABLY BE FINE AS LONG AS IT WAS ACCOMPANIED BY
2 CLEAR LANGUAGE THAT THAT WAS NOT INTENDED TO BE A
3 REQUIREMENT, NOR --

4 DR. HALL: IT WASN'T THE ONLY WAY TO SOLVE
5 THE PROBLEM.

6 MR. HARRISON: -- IS IT AN EXHAUSTIVE LIST OF
7 HOW TO COMPLY. IF YOU'RE SETTING FORTH A SPECIFIC
8 EXAMPLE THAT WOULD NOT SATISFY THE STANDARD, THEN THAT
9 WOULD HAVE TO BE ADOPTED AS A REGULATION BECAUSE YOU'RE
10 TELLING PEOPLE IN THE BULLETIN THIS DOESN'T COMPLY.

11 DR. HALL: SO JUST LEAVE OUT THE NEGATIVE
12 EXAMPLES.

13 MR. HARRISON: RIGHT. YOU HAVE TO BE
14 ABUNDANTLY CLEAR, AS I SAID, THAT THESE ARE NOT
15 REQUIREMENTS AND THAT THEY'RE NOT EXHAUSTIVE.

16 DR. HALL: SO THEN YOU LEAVE IT TO THE
17 INSTITUTION TO DECIDE THAT BECAUSE YOU'VE LEFT
18 SOMETHING OUT, WHETHER OR NOT --

19 MR. HARRISON: SEE, THAT'S EXACTLY THE
20 DANGER. THAT'S EXACTLY THE DANGER. AND THAT'S WHAT
21 OAL WOULD BE CONCERNED ABOUT, THAT IT'S A WINK AND A
22 NOD IF YOU GIVE EXAMPLES, THAT THE INSTITUTIONS WILL
23 PERCEIVE THEM TO BE THE ONLY MEANS BY WHICH THEY CAN
24 COMPLY, IN WHICH CASE YOU BASICALLY ADOPTED THROUGH A
25 MANUAL PRESCRIPTIVE STANDARDS.

1 CO-CHAIR LO: WE WILL COME BACK TO THIS ISSUE
2 THROUGHOUT THE DAY AS WE TACKLE EACH SUBSTANTIVE ISSUE,
3 BUT THIS IS EXACTLY THE KIND OF THOUGHT PROCESS THAT WE
4 NEED TO ENGAGE IN. I THINK IF WE CAN ATTACK A COUPLE
5 OF ISSUES TODAY AND REALLY THINK THEM THROUGH AGAINST
6 THIS BACKGROUND THAT JAMES IS SKETCHING OUT, WE WILL BE
7 A VERY LONG WAY TO SORT OF GETTING PARTS OF THESE
8 REGULATIONS IN GOOD SHAPE.

9 DO YOU WANT TO KEEP GOING?

10 MR. HARRISON: NO. I THINK I'VE PROBABLY
11 GIVEN YOU MORE THAN ENOUGH TO CHEW ON FOR THE TIME
12 BEING.

13 MR. LOMAX: JAMES, COULD I JUST ADD ONE THING
14 FROM OUR DISCUSSION, WHICH I DID THINK WAS POTENTIALLY
15 QUITE RELEVANT TO THE COMMITTEE, WHICH IS THERE IS AN
16 OPPORTUNITY TO CITE EXISTING EITHER FEDERAL OR STATE
17 REGULATION SHOULD WE DEEM SUCH REGULATION TO BE
18 EFFECTIVE AND WHAT WE WANT. AND IT'S ALSO IMPORTANT TO
19 NOTE THAT UNDER CALIFORNIA LAW, WHEN YOU CITE A FEDERAL
20 REGULATION, YOU ARE CITING THE REGULATION IN EFFECT ON
21 THE DATE OF YOUR CITATION. SO IF A FEDERAL LAW WERE
22 THEN TO CHANGE, IT WOULDN'T BE A PREEMPTIVE TYPE OF
23 RULING.

24 MR. HARRISON: WELL, WHAT WE WOULD WANT TO DO
25 IF WE CITE FEDERAL LAW IN THE REGULATIONS IS TO SPECIFY

1 THAT WE'RE REFERRING TO THE FEDERAL REGULATION OR
2 FEDERAL LAW THAT'S IN EFFECT AS OF THE DATE THAT THESE
3 REGULATIONS ARE ADOPTED.

4 CO-CHAIR LO: WHEN YOU SAY CITE, DOES THAT
5 MEAN CITE AS REGULATION OR CITE AS ONE OF THESE
6 NONEXHAUSTIVE, NONREQUIRED EXAMPLES?

7 MR. HARRISON: EITHER.

8 CO-CHAIR LO: EITHER WAY. JAMES WILL BE HERE
9 ALL DAY. I THINK THROUGHOUT THE DAY WE'LL BE REFERRING
10 QUESTIONS. IS THIS WHAT YOU MEANT BY A STEALTH
11 REGULATION? IS THIS WHAT YOU MEANT AS SOMETHING THAT
12 IS TOO VAGUE AS TO NOT GIVE AMPLE NOTICE AS TO WHAT YOU
13 HAVE TO DO? ANY OTHER QUESTIONS? THIS IS GOOD.

14 THOSE OF YOU ON THE PHONE, ANY QUESTIONS?
15 STILL THERE?

16 DR. KORDOWER: STILL HERE, BUT NO QUESTIONS.

17 DR. EGGAN: STILL HERE, BUT NO QUESTIONS.

18 CO-CHAIR LO: WITH THAT IN MIND, LET'S SORT
19 OF TRY AND TACKLE SOME SUBSTANTIVE ISSUES. ON TAB 8,
20 THIS NICE COLOR SLIDE IS SORT OF BOTH A LIST OF TOPICS
21 AND IN A SENSE A TIMETABLE OF HOW WE'RE GOING TO GET TO
22 OUR GOAL OF HAVING THESE FINAL REGULATIONS IN PLACE BY
23 OUR DEADLINE. AND IN THE LEFT-HAND COLUMN, SOME OF THE
24 ISSUES I THOUGHT I'D LIKE TO TRY AND REACH CLOSURE ON
25 IN THE SENSE OF AT LEAST WHAT WE WOULD LIKE TO SEE

1 DONE, AND THEN THERE WILL STILL BE SOME DISCUSSION WITH
2 OUR LEGAL COUNSEL AS TO HOW TO MAKE THAT WORK IN
3 PRACTICE AND KEEP THE OAL HAPPY.

4 DIVERSITY AND SCOPE, ESCRO, AND BANKING. AND
5 ALL OF THESE PRESENT DIFFERENT CHALLENGES IN TERMS OF
6 WRITING REGULATIONS. I'M GOING TO ACTUALLY LIKE TO
7 START WITH ESCRO'S, SECTION 04. WHAT I WANTED TO DO
8 WAS TO START BY JUST SORT OF OFFERING SOME THOUGHTS TO
9 GET THE DISCUSSION GOING. WE HAVE A LOT OF IDEAS, I
10 THINK A LOT OF VERY GOOD IDEAS, ABOUT WHAT THESE
11 ESCRO'S SHOULD BE DOING AND HOW THEY SHOULD BE DOING.

12 GEOFF SORT OF LAID OUT THERE'S THREE
13 DIFFERENT WAYS WE CAN PUT INFORMATION TO OUR GRANTEEES
14 AND TO THE PUBLIC. ONE IS IN THE STATEMENT OF REASONS,
15 WHICH GIVES THE RATIONALE FOR THE REGULATION WE'RE
16 WRITING. SECOND IS IN THE REGULATIONS THEMSELVES. AND
17 JAMES REMINDED US THAT CALIFORNIA GIVES PREFERENCE TO
18 PERFORMANCE STANDARDS RATHER THAN PRESCRIPTIVE
19 STANDARDS.

20 AND THE THIRD POSSIBILITY IS TO HAVE GUIDANCE
21 BY GIVING EXAMPLES, WHICH ARE NOT EXHAUSTIVE AND NOT
22 REQUIRED, BUT REALIZING THAT MAY BE A TRICKY ISSUE. SO
23 LET ME JUST SORT OF OFFER SOME THOUGHTS, AND THEN
24 PERHAPS THIS WILL STIMULATE DISCUSSION.

25 IN THE STATEMENT OF REASONS, IT STRIKES ME

1 THAT WE MIGHT WANT TO SAY THINGS LIKE THE FOLLOWING.
2 WHY WE HAVE ESCRO' S. I THOUGHT THE NAS SENTENCE THAT I
3 READ AT THE BEGINNING MIGHT BE SOMETHING TO PUT THERE.
4 AND WE MIGHT ALSO WANT TO TALK EXPLICITLY ABOUT OUR
5 DECISION TO TRY AND HAVE FLEXIBILITY, SO DIFFERENT
6 INSTITUTIONS MIGHT TRY AND ACHIEVE OUR GOALS IN
7 DIFFERENT WAYS AND WORK OUT THINGS THAT NOT ONLY WORK
8 BEST IN THEIR SETTING, BUT ALSO HELP TO DEVELOP BEST
9 PRACTICES.

10 NOW, IN PERFORMANCE IN THE REGULATION, LET ME
11 SUGGEST SOME WAYS WE MIGHT TRY AND GIVE LANGUAGE THAT
12 IS A PERFORMANCE STANDARD. AND THIS IS SOMETHING I
13 THINK WE'RE GOING TO NEED TO GRAPPLE WITH AND THINK
14 ABOUT. WE MIGHT SAY SOMETHING LIKE THE ESCRO SHALL
15 ASSURE APPROPRIATE OVERSIGHT OF CIRM FUNDING RESEARCH,
16 INCLUDING, ONE, EVALUATION OF SCIENTIFIC MERIT; TWO,
17 EVALUATION OF ETHICAL APPROPRIATENESS; AND, THREE,
18 DOCUMENTATION OF COMPLIANCE WITH ALL CIRM-FUNDED
19 RESEARCH AT THE INSTITUTION. SO THOSE ARE PERFORMANCE
20 STANDARDS.

21 DR. HALL: BERNIE, YOU HAVE TEXT ON THAT?
22 CAN WE HOOK YOU UP?

23 CO-CHAIR LO: I GUESS THAT WOULD BE ONE WAY
24 TO DO IT. LET ME GIVE YOU A MEMORY STICK.

25 DR. ROWLEY: THERE ARE SOME THINGS ON PAGE 3

1 ON SOMETHING THAT'S UNDER TAB 5, SECTION 06,
2 ESTABLISHMENT OF AN OVERSIGHT.

3 CO-CHAIR LO: SO WHAT I WANTED TO DO, THOUGH,
4 SOME OF THE THINGS THAT WE NOW HAVE AS REGULATION MAY
5 BE TOO PRESCRIPTIVE, AND WE MAY WANT TO SAY IF WE'RE
6 GOING TO PERFORMANCE STANDARD, THESE ARE REALLY
7 EXAMPLES OF HOW AN INSTITUTION MIGHT DO IT, BUT THERE
8 MAY BE OTHER WAYS TO DO IT AS WELL. THINGS LIKE CAN IT
9 BE A SUBCOMMITTEE OF THE IRB? CAN THEY HAVE JOINT
10 INSTITUTIONS? THOSE TO ME ARE SORT OF EXAMPLES OF WAYS
11 THAT INSTITUTIONS MIGHT GO ABOUT SATISFYING A MORE
12 GENERAL PERFORMANCE STANDARD, BUT I'M NOT SURE WE
13 TOTALLY ARTICULATED WHAT THAT PERFORMANCE STANDARD IS.

14 LET ME GIVE GEOFF A MINUTE TO FLIP THIS UP.
15 SOMETHING CALLED BL-CIRM 10/22 WAS IN MY NOTES.

16 SO THE FIRST -- IF I COULD BORROW. IN THE
17 STATEMENT OF REASONS, THESE ARE THE THINGS THAT SORT OF
18 GIVE THE RATIONALE FOR OUR REGULATIONS AND THE THINKING
19 BEHIND IT. I'M NOT SURE WE NEED TO SPEND A LOT OF
20 ATTENTION ON THAT NOW. IT'S SORT OF WHAT'S BEEN IN THE
21 BACK OF OUR HEADS.

22 GEOFF, YOU CAN PUT THIS AT THE TOP OF THE
23 PAGE. PERFORMANCE STANDARDS, THESE ARE THE SORT OF
24 THINGS WE MIGHT WANT TO PUT IN REGULATIONS. ONE, THIS
25 IS WHAT THE ESCRO SHOULD DO: EVALUATE SCIENCE, ETHICS,

1 AND DOCUMENT COMPLIANCE, AND THAT THE ESCRO SHOULD HAVE
2 APPROPRIATE EXPERTISE TO CARRY OUT ITS FUNCTIONS. AND
3 HERE AGAIN, WE'RE NOT SAYING HOW MANY OF EACH TYPE, BUT
4 WE'RE SAYING THIS IS THE KIND OF EXPERTISE. AND,
5 AGAIN, WE'RE GOING TO HAVE TO CHECK WITH JAMES AS TO
6 WHETHER THIS IS TOO PRESCRIPTIVE OR NOT. WE MAY ALSO
7 WANT TO SAY RECIPIENTS OF FUNDING MUST DOCUMENT THEIR
8 INSTITUTION HAS AN ESCRO THAT CAN CARRY OUT SUCH
9 OVERSIGHT AND HAS APPROVED THEIR SPECIFIC PROJECT.

10 SO IT STRIKES ME THESE ARE THE PERFORMANCE
11 STANDARDS WE'D LIKE TO ACHIEVE. AND, OF COURSE,
12 THERE'S A LOT OF DIFFERENT WAYS TO DO THAT. AND SOME
13 OF THOSE WAYS WE MAY THINK ARE APPROPRIATE AND SOME
14 NOT. IF WE KNOW THAT, THEY HAVE TO BE IN THE
15 REGULATIONS, IT STRIKES ME. FRANCISCO.

16 DR. PRIETO: I'M WONDERING WHETHER THAT
17 MANDATES THAT EACH INSTITUTION HAVE AN ESCRO OR WHETHER
18 THAT SHOULD BE MORE GENERAL.

19 MR. SHESTACK: THAT'S A DIFFERENT SUBJECT.

20 CO-CHAIR LO: I DON'T THINK -- YOU'RE RIGHT.
21 SO WE NEED TO CHANGE THE LANGUAGE TO TAKE INTO ACCOUNT
22 THAT IT MAY BE A SHARED ESCRO OR THEY MAY USE ANOTHER
23 INSTITUTION'S ESCRO.

24 DR. PRIETO: OR PARTICIPATES IN OR UTILIZES
25 THE SERVICES OF.

1 CO-CHAIR LO: AN ESCRO WITH THE APPROPRIATE
2 EXPERTISE HAS CARRIED OUT OVERSIGHT AND APPROVED THE
3 PROJECT OR SOMETHING.

4 MR. KLEIN: AT THE TOP OF THAT DOCUMENT WE'RE
5 LOOKING AT, IT CALLS IT THE CONTROVERSIAL.

6 CO-CHAIR LO: THIS IS FROM THE NAS. THAT'S A
7 DIRECT QUOTE FROM NAS, THE VERY TOP. WE COULD PUT THAT
8 IN QUOTES. THAT'S WHAT THE NAS PUT.

9 MR. KLEIN: CONTROVERSIAL RESEARCH.

10 DR. HALL: THAT CONTROVERSIAL. I THINK
11 THERE'S A TYPO THERE. CONTROVERSIAL RESEARCH IS WELL
12 JUSTIFIED.

13 MR. KLEIN: I SEE.

14 CO-CHAIR LO: THIS IS NOT REGULATION. THIS
15 IS JUST SORT OF THE EXPLANATION OF WHY WE'RE DOING IT.

16 SO LET ME JUST, IF YOU COULD GO DOWN, GEOFF,
17 TO THE NEXT SECTION. THEN THE QUESTION IS WHAT
18 EXAMPLES DO WE WANT TO GIVE. AND THIS GETS TO THE FACT
19 THAT WHAT ZACH WAS DOING WITH INFORMED CONSENT. WE
20 HAVE TALKED IN THIS COMMITTEE ABOUT DIFFERENT
21 APPROACHES TO SETTING UP ESCRO'S, SO DID THE NAS. A
22 PREEXISTING MAY SERVE THE FUNCTIONS OF AN ESCRO. THE
23 ESCRO MAY CONTAIN IRB MEMBERS, BUT MAYBE IT SHOULDN'T
24 BE THE IRB, A SUBCOMMITTEE OF THE IRB. AND THEN STEVE
25 PECKAM SAID THAT HE WANTED TO BE CLEAR, HOW ABOUT IF

1 SEVERAL INSTITUTIONS GET TOGETHER AND FORM AN ESCRO, IS
2 THAT OKAY?

3 THESE ARE ALL SORT OF EXAMPLES OF
4 INSTITUTIONS TRYING TO FIGURE OUT HOW THEY WOULD COMPLY
5 WITH OUR PERFORMANCE STANDARDS AND SORT OF SAYING
6 HERE'S SOMETHING I MIGHT WANT TO TRY. IS THIS OKAY?
7 THEY'RE WANTING SOME CLARITY BEFORE THEY SET SOMETHING
8 UP THAT IT'S GOING TO BE AN OKAY APPROACH. AND THIS,
9 IT STRIKES ME, JAMES, IS AT THE HEART OF WHAT YOU
10 TALKED ABOUT IN GENERAL TERMS. HOW DO YOU MAKE A
11 PERFORMANCE STANDARD, WRITE A PERFORMANCE STANDARD THAT
12 IS CLEAR ENOUGH THAT INSTITUTIONS HAVE A SENSE OF WHAT
13 THEY NEED TO DO TO BE ABLE TO COMPLY.

14 MR. SHESTACK: WHICH ACTUALLY BRINGS ME TO A
15 QUESTION. WHERE WOULD BE THE APPROPRIATE TIME, FOR
16 INSTANCE, TO DISCUSS WHETHER OR NOT CIRM SHOULD SET UP
17 AND ENCOURAGE, SAY, TWO REGIONAL ESCRO'S, CENTRALIZED
18 REGIONAL ESCRO'S, THAT WOULD THEN GET RID OF ALL THESE
19 QUESTIONS?

20 DR. HALL: THAT'S ALLOWED UNDER THIS, BUT WE
21 DON'T SAY ONE WAY OR THE OTHER. THAT'S MY
22 UNDERSTANDING. IF SOMEBODY WANTED TO DO THAT, THEY
23 COULD DO THAT. IF SOUTHERN CALIFORNIA INSTITUTIONS
24 WANTED TO GET TOGETHER AND SAY WE HAVE A COMMON ESCRO,
25 THEY COULD DO THAT.

1 MR. SHESTACK: WHAT I'M ASKING IS, BECAUSE I
2 THINK IT CAME UP ACTUALLY IN THE LAST MEETING, SOME
3 PEOPLE BROUGHT IT UP, I HAVE SOME NOTES ON IT, WHY
4 WOULDN'T THE CALIFORNIA INSTITUTE OF REGENERATIVE
5 MEDICINE SPONSOR TO AID THE BUREAUCRACY AND SET UP TWO
6 REGIONAL ESCRO'S SO THAT THE PROCESS COULD BE, IF YOUR
7 DESIRE WAS TO STREAMLINE THE BUREAUCRATIC PROCESS AND
8 NOT HAVE SMALLER INSTITUTIONS, FOR INSTANCE, HAVE
9 ONEROUS REQUIREMENTS THAT MIGHT KEEP THEM OUT OF THE
10 GAME WHERE THEY HAD TALENTED RESEARCHERS, BUT NOT A BIG
11 BUREAUCRACY. IF YOU WANT TO FORM A JOINT ESCRO,
12 SOMEBODY HAS TO AGREE TO FORM A JOINT ESCRO WITH YOU.
13 MAYBE YOU CAN'T FIND A GOOD PARTNER. THIS HAS OFTEN
14 HAPPENED IN THE PAST. WHY WOULDN'T WE WANT TO AID THIS
15 PROCESS BY DOING IT OURSELVES?

16 DR. HALL: WE WOULD RUN IT, JON?

17 MR. SHESTACK: IT'S A QUESTION. IT SEEMED TO
18 COME UP AT THE LAST MEETING. YEAH, WHAT WE'RE SAYING
19 IS EVERY INSTITUTION NOW HAS -- THEY ALL HAVE IRB'S,
20 WHICH WE KNOW IS A PAINSTAKING PROCESS, AND THEY NOW
21 HAVE TO HAVE ESCRO'S. AND THEY HAVE TO SET THEM UP AND
22 FIND TALENTED PEOPLE TO BE ON THEM WITH A LARGE LIST OF
23 REQUIREMENTS.

24 DR. HALL: MANY INSTITUTIONS HAVE ALREADY
25 STARTED.

1 MR. SHESTACK: SOME. UCSF HAS AND MAYBE
2 STANFORD.

3 DR. HALL: STANFORD HAS. UCLA HAS BEEN
4 THINKING ABOUT IT CERTAINLY.

5 CO-CHAIR LO: I THINK IT'S FAIR TO SAY THAT
6 THE LARGE INSTITUTIONS HAVE. I THINK JON IS RAISING
7 THE POINT OF WHAT OF THE SMALLER INSTITUTIONS THAT MAY
8 NOT HAVE THE RESOURCES. WE'VE SPARKED A LOT OF --

9 MR. SHESTACK: IT'S A THING THAT I THINK THIS
10 COMMITTEE SHOULD SORT OF ADDRESS ONCE IN A WHILE, WHICH
11 IS WHAT IS -- ACTUALLY IN YOUR CHARGE IN LIKE A MONTH
12 OR TWO, AUGUST, THE COMMITTEE WAS MEDICAL, ETHICAL, AND
13 OTHER STANDARDS, CERTAIN OTHER STANDARDS. I THINK
14 THERE IS -- DO WE WANT TO TRY AND MAKE THE PROCESS GO
15 FASTER AND BE EASIER AND AID PEOPLE INTO GETTING THEIR
16 APPLICATIONS THROUGH A SYSTEM AND THEN JUDGE PURELY ON
17 SCIENTIFIC EXCELLENCE AND NOT HAVE TO BE WEIGHED DOWN
18 BY OTHER THINGS? CAN WE HELP THEM THROUGH THAT
19 PROCESS? MAYBE THE WAY TO DO IT IS TO SET UP A COMMON
20 ESCRO. IT'S A QUESTION, BUT I THINK IT'S THE PROPER
21 COMMITTEE.

22 MR. KLEIN: JON, ANOTHER OPTION WOULD BE FOR
23 US, SINCE WE'RE SO LIMITED ON STAFF, FOR US TO FUND A
24 JOINT ESCRO.

25 MR. SHESTACK: RIGHT.

1 CO-CHAIR LANSING: SAME THING. IN OTHER
2 WORDS --

3 MR. SHESTACK: BUT FOR US TO BASICALLY TAKE
4 ON THE CATALYTIC FUNCTION OF THAT.

5 MR. SHEEHY: AND THE RELATED QUESTION,
6 THOUGH, IS DOES THIS TAKE PLACE BEFORE OR AFTER
7 FUNDING?

8 DR. HALL: LET'S HOLD THAT FOR THE MOMENT.
9 BUT THE ISSUE I SEE IS DO WE TELL INSTITUTIONS WHAT
10 THEY WANT TO DO. EVEN IF YOU FUND THEM, YOU COULD DO
11 IT EITHER WAY. YOU COULD FUND A REGIONAL ONE OR YOU
12 COULD PROVIDE FUNDS TO THE INSTITUTION TO HELP SET
13 THESE UP TO EASE THE ADMINISTRATIVE BURDEN.

14 THE THING THAT I THINK IS A LITTLE -- I THINK
15 THE INSTITUTIONS THEMSELVES WILL HAVE POSITIONS ABOUT
16 THIS, AND THAT THEY WILL BE DIFFERENT DEPENDING ON THE
17 SIZE OF THE INSTITUTION. IT SEEMS TO ME THE THING TO
18 DO IS TO MAKE IT POSSIBLE FOR THOSE INSTITUTIONS THAT
19 WANT TO HAVE THEIR OWN AND ARE BIG ENOUGH AND WANT TO
20 KEEP IT, AS IT WERE, CLOSE TO HOME AND THOSE THAT -- SO
21 WE MAKE IT POSSIBLE FOR THEM TO DO THAT. AND THOSE
22 THAT WANT TO GET TOGETHER AND HAVE A JOINT ESCRO
23 BETWEEN THE THREE OF THEM OR THE TWO OF THEM OR
24 WHATEVER IT IS CAN ALSO DO THAT, OR THEY CAN MAKE
25 ARRANGEMENTS WITH ANOTHER UNIVERSITY.

1 MR. SHESTACK: THAT'S EXACTLY NOT WHAT I
2 SAID.

3 DR. HALL: WELL, WHAT I'M SAYING IS, THOUGH,
4 ISN'T IT BETTER TO LET INSTITUTIONS --

5 MR. SHESTACK: I WOULD SAY NO.

6 DR. HALL: -- RATHER THAN WE MAKE THE CHOICE
7 FOR THE INSTITUTION.

8 MR. SHESTACK: I WOULD SAY -- YOU, WHO KNOW
9 MORE ABOUT IT ARE NODDING, SO PLEASE. I WOULD SAY WE
10 HAVE A MOMENT IN TIME WHERE WE CAN MAKE SOME SLIGHT
11 EMENDATIONS TO THE SYSTEM THAT MIGHT HELP THIS GO MORE
12 SMOOTHLY. I DON'T SEE WHY THIS SHOULD BE INVESTIGATOR
13 DRIVEN WHATSOEVER.

14 DR. HALL: IT'S NOT INVESTIGATOR DRIVEN; IT'S
15 INSTITUTION DRIVEN.

16 MR. SHESTACK: OR INSTITUTION.

17 CO-CHAIR LO: WE'VE GOT A LOT OF OTHER PEOPLE
18 WHO WANT TO GET IN. LET'S TRY AND BRING THOSE IN AND
19 WE CAN COME BACK. FRANCISCO, JOSE, JEFF. ANYONE ELSE?
20 LET'S GET THOSE THREE AND THEN THERE WILL BE MORE.
21 ANN.

22 DR. PRIETO: I JUST WANTED TO SUGGEST
23 LANGUAGE THAT COULD BE NOT TOO PRESCRIPTIVE COULD READ
24 SOMETHING LIKE AN INSTITUTION, GROUP OF INSTITUTIONS,
25 OR THE CIRM ITSELF MAY ESTABLISH AN ESCRO PROVIDED

1 THAT, AND THEN THE LANGUAGE RELATING TO THE FUNCTIONS
2 OF THE ESCRO, BUT NOT PRESCRIBING THAT IT MUST BE THE
3 CIRM OR IT MUST BE THE INDIVIDUAL INSTITUTION.

4 DR. CIBELLI: I JUST WANT TO SAY THAT WE ARE
5 ASKING THAT INSTITUTIONS, THEY HAVE TO HAVE AN ESCRO
6 AND THE ESCRO HAVE TO PERFORM CERTAIN FUNCTIONS, BUT I
7 COULDN'T FIND IN THE REGULATIONS THAT WE HAVE RIGHT NOW
8 WHO IS GOING TO SUPERVISE THE ESCRO. THAT'S A BIG
9 HOLE.

10 MR. SHEEHY: MY POINT ON RAISING THE FUNDING
11 ISSUE IS DOES ESCRO REVIEW TAKE PLACE BEFORE GRANTS ARE
12 SUBMITTED? DOES IT TAKE PLACE ONCE GRANTS ARE
13 APPROVED? AT WHAT POINT IN THE FUNDING PROCESS?

14 AND SO DO YOU HAVE -- AND THE SECOND POINT IS
15 TO THE POINT OF ALLOWING INDIVIDUAL INSTITUTIONS -- AT
16 LEAST IN PUBLIC COMMENT, THERE WAS SOME CONCERN THAT
17 IRB'S, WHICH ARE INSTITUTION BASED, HAVE BEEN TO SOME
18 DEGREE IN SOME INSTANCES CAPTURED BY THE INSTITUTION.
19 AND THAT WAS A CONCERN THAT WAS EXPRESSED BY THE
20 PUBLIC.

21 DR. KIESSLING: I WANT TO STAY ON RECORD AS
22 WONDERING IF ESCRO'S ARE NEEDED. I WANT THAT TO BE --
23 I WANT US TO KEEP ASKING DO WE NEED TO PUT ANOTHER
24 LAYER OF REVIEW ON EACH OF THESE PROJECTS? I'M NOT
25 SAYING WE SHOULDN'T, BUT I WANT US TO KEEP THAT AT THE

1 VERY TOP OF THE LIST. WHY DID THE NATIONAL ACADEMY
2 RECOMMEND ANOTHER COMMITTEE ON TOP OF OTHER REVIEWS?

3 AS I REMEMBER, THERE ARE TWO REASONS. ONE,
4 IT'S VIEWED THAT INSTITUTIONAL IRB'S DON'T HAVE
5 NECESSARILY THE EXPERTISE TO DO THIS. TWO, AND THAT WE
6 WANT TO MAKE CERTAIN THAT THERE'S NOT A PRESUMPTION OR
7 THAT SOMEBODY DOESN'T GIVE THE INDICATION THAT THIS
8 RESEARCH INVOLVES HUMAN SUBJECTS WITH RESPECT TO
9 DESTROYING EMBRYOS. I THINK THOSE ARE TWO CRITICAL
10 ISSUES, THAT EMBRYOS EITHER CREATED BY NUCLEAR
11 TRANSPLANT OR HOWEVER THEY'RE CREATED ARE NOT
12 NECESSARILY SUBJECT TO HUMAN --

13 DR. CIBELLI: YOU ARE NOT HAPPY WITH THIS?

14 DR. KIESSLING: NO. NO. THOSE ARE THE TWO
15 REASONS THAT WE NEED ONE. AS I UNDERSTAND IT, THOSE
16 ARE THE TWO REASONS THAT YOU'D LIKE SOME KIND OF
17 INSTITUTIONAL OVERSIGHT OUTSIDE AND IN ADDITION TO A
18 HUMAN SUBJECTS COMMITTEE. THE QUESTION IS HOW TO
19 ACCOMPLISH THAT.

20 I THINK JOSE'S QUESTION IS REALLY GOOD. IF
21 WE CREATE A NEED FOR ANOTHER COMMITTEE ON TOP OF
22 INSTITUTIONAL REVIEW BOARDS, WHICH HAVE ENORMOUS
23 CONFLICT OF INTEREST ISSUES BUILT INTO THEM, IF WE
24 CREATE ANOTHER COMMITTEE ON TOP OF THAT, WHO IS GOING
25 TO PROVIDE OVERSIGHT FOR THAT PARTICULAR COMMITTEE? I

1 THINK THAT WHEN I REVIEW THIS ON MY OWN TIME, IT SEEMS
2 TO ME LIKE WHAT YOU WANT TO DO IS EXACTLY WHAT YOU ARE
3 SUGGESTING. YOU WANT THIS TO BE SOMETHING THAT'S DONE
4 FOR THE INSTITUTION, NOT BY THE INSTITUTION.

5 MR. SHESTACK: THAT WILL ULTIMATELY SERVE THE
6 INSTITUTION.

7 DR. KIESSLING: YOU WANT TO SERVE THE
8 INVESTIGATOR. AND THE GOAL HERE IS TO GET THE WORK
9 DONE, WHICH REALLY MEANS SERVING THE INVESTIGATOR, NOT
10 NECESSARILY SERVING THE INSTITUTION.

11 DR. ROWLEY: AS A MEMBER OF THE NATIONAL
12 ACADEMY COMMITTEE THAT WROTE THE GUIDELINES, I THINK
13 THE FIRST OF THOSE TWO POINTS WAS THE MAJOR CONCERN,
14 THAT MOST IRB'S ARE REALLY -- THEY'RE DEALING WITH
15 GOVERNMENT REGULATIONS THAT ARE WELL DEFINED, AND
16 THEY -- ALTA COULD GO INTO THIS FAR MORE KNOWLEDGEABLY
17 THAN I -- BUT THEIR FUNCTION IS DIFFERENT THAN
18 REVIEWING THE QUALITY OF THE SCIENCE IN TERMS OF IF
19 YOU'RE MAKING NEW STEM CELL LINES, IS THIS REALLY
20 NEEDED? WHY IS IT NEEDED? WHY IS THIS THE WAY TO DO
21 IT? PARTICULARLY AS YOU GET INTO CONTROVERSIAL
22 EXPERIMENTS INVOLVING ANIMALS AND HUMAN CELLS INTO
23 ANIMAL BRAINS, WHAT IS IT YOU'RE GOING TO LEARN? IS
24 THIS THE WAY TO DO IT? WHAT ARE THE HAZARDS OF THIS?
25 HOW CAN WE MAKE SURE THAT UNTOWARD CONSEQUENCES ARE

1 MINIMAL OR NONEXISTENT? AND THIS IS NOT SKILLS THAT
2 MOST IRB'S HAVE, AND THAT WAS OUR MAJOR CONCERN.

3 NOW, THE QUESTION OF WHO MONITORS THE ESCRO,
4 THAT'S A DIFFERENT ISSUE. AND ONE, IN FACT, THAT THE
5 ACADEMY DIDN'T DEAL WITH.

6 CO-CHAIR LO: WE HAVE TED AND THEN JOSE.
7 BOB, WAS YOUR HAND UP?

8 DR. PETERS: I'M GLAD ANN RAISED THE QUESTION
9 AS TO CAN WE PROVIDE JUSTIFICATION FOR ESCRO AT THE
10 BEGINNING, BUT I'D LIKE TO PICK UP WHERE JOSE WAS A
11 COUPLE OF MINUTES AGO. AT OUR SEPTEMBER PUBLIC
12 HEARING, THE ISSUE OR THE PROPOSAL FOR A SINGLE
13 STATEWIDE ESCRO CAME UP. AND I WOULD LIKE TO HAVE OUR
14 GROUP DISCUSS THE MERITS AND DEMERITS OF THAT BEFORE WE
15 MAKE A DECISION BECAUSE, AS JOSE WAS SUGGESTING, WE
16 MIGHT NEED AN ESCRO FOR THE DECENTRALIZED ESCRO'S
17 ANYWAY JUST IF OVERSIGHT IS GOING TO TAKE PLACE. AND
18 IT WOULD SEEM TO ME THAT IF WE'RE ALREADY GOING TO GO
19 THAT ROUTE, IF SUCH A THING WERE TO BE APPOINTED BY
20 THIS COMMITTEE, THEN WHERE DOES CENTRALIZATION AND
21 DECENTRALIZATION -- WHAT KIND OF A LINE DO WE DRAW
22 BETWEEN THEM?

23 DR. CIBELLI: I WOULD SUGGEST THAT IF WE ARE
24 GOING TO HAVE THAT OVERSIGHT, THIS WORKING GROUP SHOULD
25 BE SUPERVISING THE ESCRO'S, AND THAT WILL BE A LOT OF

1 WORK FOR US TOO. BUT ALSO I'M JUST REMEMBERING KEVIN
2 EGGAN TWO MEETINGS AGO SAYING, WELL, IF WE HAVE A
3 CENTRALIZED ESCRO, THE PI WILL BE TOO FAR REMOVED FROM
4 THE PEOPLE SITTING IN THOSE ESCRO'S, AND HE MAY RUN
5 INTO TROUBLE WHEN HE WANTS TO PUSH SOMETHING THROUGH.
6 SO THAT'S SOMETHING TO CONSIDER TOO.

7 DR. HALL: I WOULD ARGUE THAT -- I DON'T MEAN
8 TO CUT IN LINE. I WOULD NOT CUT IN LINE IN FRONT OF
9 BOB FOR ANYTHING.

10 MR. KLEIN: I WILL YIELD TO THE GENTLEMAN.

11 IT IS IMPORTANT TO GO BACK TO ANN'S POINT
12 HERE, THAT THERE'S A SIGNIFICANT AMOUNT OF THIS
13 RESEARCH THAT DOES NOT INVOLVE HUMAN SUBJECTS AND,
14 THEREFORE, THIS IS THE OVERSIGHT GROUP VERSUS THE IRB.
15 AND WE NEED TO SEPARATE OUR DISCUSSIONS, NOT ASSUMING
16 THAT THERE'S GOING TO BE AN IRB INVOLVED. I THOUGHT
17 THAT WAS AN IMPORTANT POINT OF EMPHASIS.

18 DR. HALL: I THINK THERE ARE SEVERAL ISSUES
19 INVOLVED, BUT ONE OF THEM CERTAINLY IS HOW CLOSE IS THE
20 COMMITTEE TO THE INVESTIGATOR. AND YOU CAN MAKE THE
21 ARGUMENT THAT IF IT IS TOO CLOSE, THEN THERE'S CONFLICT
22 OF INTEREST. AND BASICALLY IT'S THAT UNIVERSITY X HAS
23 A MAJOR STAKE IN APPROVING THE WORK DONE BY AN
24 INVESTIGATOR WHO BRINGS IN MILLIONS OF DOLLARS OF
25 GRANTS A YEAR.

1 ON THE OTHER HAND, HAVING BEEN THROUGH NOT
2 IRB'S, BUT CERTAINLY ANIMAL REGULATORY PROCEDURES AND
3 AN INVESTIGATOR HAVING OVERSEEN THE PROCESS, THE MOST
4 IMPORTANT FEATURE IN A REGULATORY PROCESS, I THINK, IS
5 TO HAVE AN EFFECTIVE MEANS OF COMMUNICATION BACK AND
6 FORTH BETWEEN THE INVESTIGATOR AND THE COMMITTEE SO
7 THAT YOU SUBMIT SOMETHING AND YOU HEAR IMMEDIATELY BACK
8 THAT YOU MAY NEED TO MODIFY THIS.

9 OFTEN THEY'RE TRAINING PROGRAMS THAT
10 BASICALLY HELP YOU TO DEAL WITH THIS SORT OF
11 BUREAUCRACY. AND IT SEEMS TO ME THAT THOSE COMMITTEES
12 ARE MOST RESPONSIVE WHEN THEY ARE LOCAL. IF YOU HAVE
13 AN EXTREMELY SMALL INSTITUTION, THEN THE NUMBER OF
14 PEOPLE WHO HAVE KNOWLEDGE ABOUT THIS IS APPROXIMATELY
15 EQUAL TO THE NUMBER OF PEOPLE WHO ARE DOING THE
16 RESEARCH. BUT CERTAINLY IN A LOT OF THE INSTITUTIONS
17 THAT WE HAVE HERE, THE INSTITUTIONS ARE LARGE ENOUGH
18 WITH THOUSANDS LITERALLY OF INVESTIGATORS OR FACULTY
19 MEMBERS TO CHOOSE FROM IN PRINCIPLE OF THESE, THAT I
20 THINK THE COMMUNITY IS LARGE ENOUGH SO THAT IT DOESN'T
21 DEAL WITH THAT.

22 AND I THINK ALSO, MY OWN VIEW, AND THIS MAY
23 REFLECT MY OWN HISTORY, BUT MY OWN VIEW IS THAT THE
24 INSTITUTION SHOULD BE RESPONSIBLE FOR THE WORK THAT
25 GOES ON ON ITS GROUNDS. IF SOMEBODY WANTS TO DO A VERY

1 CONTROVERSIAL, UNORTHODOX KIND OF EXPERIMENT AT
2 UNIVERSITY X, THEN I THINK THE UNIVERSITY ITSELF NEEDS
3 TO GRAPPLE WITH WHETHER IT IS WILLING TO SPONSOR THAT
4 RESEARCH OR NOT. I THINK TO HAVE A CENTRAL COMMITTEE
5 EITHER KNOCK IT DOWN OR TO SAY, WELL, IT'S OKAY, THEN
6 IF THERE'S A LAWSUIT OR IF THERE'S UNPLEASANT PUBLICITY
7 OR WHATEVER IT IS, THE INSTITUTION THEN IS ABLE TO SAY
8 WE MADE THIS DECISION. WE STAND BEHIND IT. AND ALSO
9 WE'LL FIX THE PROBLEM. I THINK THAT ONE'S SENSE OF
10 WHETHER THE RULES ARE BEING FOLLOWED ARE MUCH BETTER
11 LOCALLY THAN THEY ARE CENTRALLY.

12 SO I OBVIOUSLY THINK THAT FOR THE LARGER
13 INSTITUTIONS THAT WANT TO, MY OWN VIEW IS THAT A LOCAL
14 ESCRO WOULD BE THE BETTER SOLUTION. FOR THE SMALLER
15 ONES, THEY CAN BAND TOGETHER.

16 THE ONE PROBLEM, JON, WITH DOING IT STATEWIDE
17 OR EVEN REGIONALLY IS WHO RUNS IT. WE CAN'T DO IT, NOT
18 WITH OUR STAFFING BUDGET. WE SIMPLY CAN'T DO IT. THAT
19 MEANS EVERY APPLICATION ON STEM CELL RESEARCH OR HUMAN
20 STEM CELL RESEARCH ANYHOW IN THE WHOLE STATE, HALF OF
21 THEM WOULD GO THROUGH THOSE COMMITTEES. AND SO THAT'S
22 A BIG JOB. IT'S LIKE SETTING UP A WHOLE NOTHER --

23 MR. SHESTACK: POST AWARD. THEY WOULD GO
24 THROUGH THE ESCRO COMMITTEE POST AWARD.

25 DR. HALL: WELL, THE QUESTION OF WHEN YOU DO

1 IT IS A QUESTION OF WHO DOES THE WORK BASICALLY.

2 MR. SHESTACK: IT'S A QUESTION OF --

3 DR. HALL: LET ME JUST FINISH. IN GENERAL,
4 IT'S THE SAME PROBLEM WITH IRB'S. IRB'S DON'T WANT TO
5 REVIEW GRANTS THAT AREN'T GOING TO GET FUNDED. ON THE
6 OTHER HAND, NIH DOESN'T WANT TO REVIEW GRANTS THAT
7 AREN'T GOING TO PASS IRB APPROVAL. SO EVERYBODY WANTS
8 TO PUT THE WORK OFF ON SOMEBODY ELSE.

9 AND SPEAKING FOR CIRM, MY FEELING IS THAT WE
10 SHOULD NOT -- THAT THE INSTITUTION SHOULD SAY THAT IT
11 SHOULD PASS CIRM APPROVAL BEFORE IT COMES TO US, NOT
12 AFTER. AND THEN IT ENTERS THE COMPETITIVE THING.

13 AN INTERESTING THING IS THE SORT OF NUMBERS
14 THAT ARE GOING TO BE INVOLVED.

15 MR. SHESTACK: THAT WAS A QUESTION. WHAT DO
16 YOU THINK THEY ARE?

17 DR. HALL: WELL, WE ARE VERY WORRIED ABOUT
18 WHETHER OUR GRANTS WORKING GROUP IS GOING TO BE UP TO
19 THE TASK OF DEALING WITH ALL THE GRANT APPLICATIONS
20 THAT COME THROUGH. AND THE ISSUE -- THE NICE THING
21 ABOUT A GRANT APPLICATION IN A WAY IS IF IT DOESN'T
22 PASS, IT DOESN'T PASS AND THAT'S THE END OF IT. WITH
23 ESCRO'S, AND, ANN, I'M SURE YOU KNOW THIS WITH IRB'S,
24 THERE'S VERY OFTEN BACK AND FORTH AND BACK AND FORTH
25 AND BACK AND FORTH. AND THAT NEEDS TO BE FACILITATED.

1 IT NEEDS TO HAPPEN IN A CONSTRUCTIVE WAY. AND THE LAST
2 THING YOU WANT IS THIS SORT OF BUREAUCRATIC THING WHERE
3 IT'S VERY HARD TO DEAL WITH. THAT'S MY VIEW.

4 I JUST DON'T KNOW WHO WOULD RUN IT. I DON'T
5 KNOW -- I DON'T THINK IT WOULD HAVE INSTITUTIONAL --
6 THE KIND OF INSTITUTIONAL RESPONSIBILITY THAT WE WANT
7 TO ENCOURAGE. AND I JUST WOULD --

8 MR. SHESTACK: MIGHT HAVE A TREMENDOUS AMOUNT
9 OF EXPERTISE. IT WOULD HAVE HAND-PICKED, WELL-DESIGNED
10 EXPERTISE. I DON'T KNOW THE ETHICS OF COMMERCIAL
11 IRB'S. I DON'T KNOW.

12 DR. HALL: THOSE IN GENERAL ARE NOT RELIABLE.
13 YOU DON'T WANT TO DO THAT. THEIR OBJECT IS TO MAKE
14 MONEY OUT OF IT. AND THE PROBLEM IS YOU PUT YOUR OWN
15 REPUTATION ON LINE WITH THESE. IF SOMETHING HITS THE
16 PAPERS, AND I CAN CERTAINLY SAY THIS FROM MY EXPERIENCE
17 AT UCSF, SOMETHING HITS THE PAPERS JUST ABOUT ANIMAL
18 RESEARCH, THEN IT'S YOUR RESPONSIBILITY TO MAKE SURE IT
19 GETS FIXED OR TO SAY WE BACK THIS RESEARCH UP. WE
20 THINK IT'S DONE FOR GOOD REASON AND WE BACK IT UP AND
21 WE STAND BEHIND IT. WE'VE PUT IT THROUGH A PROCESS.
22 WE BELIEVE IN IT. AND I THINK THAT'S THE INSTITUTION
23 AND NOT US THAT SHOULD BE MAKING THOSE DECISIONS.

24 CO-CHAIR LO: WE'VE GOT VIRTUALLY EVERYONE
25 WANTING TO GET IN THE DISCUSSION, WHICH I THINK IS

1 GREAT, BUT LET'S TRY AND KEEP A LIST. TED, JEFF, AND
2 ANN ON THAT SIDE, AND THE HANDS ON THIS SIDE I SAW JOSE
3 AND JAMES.

4 DR. TAYLOR: I'M DOING A LOT OF NODDING.

5 DR. PETERS: IF WE GO THE ROUTE THAT ZACH IS
6 SUGGESTING AND WE KEEP ALL THIS WORK AT THE LOCAL
7 LEVEL, A SINGLE INSTITUTION OR A SMALL SYNDICATE OF
8 INSTITUTIONS, WHAT ABOUT STATEWIDE OVERSIGHT? WOULD IT
9 BE WORTH CONSIDERING THAT WE STILL HAVE AN ESCRO OF
10 ESCRO'S THAT WOULD NOT KEEP TRACK OF EVERY GRANT, BUT
11 WOULD BE AVAILABLE IF THERE'S A COMPLAINT OR IF THERE'S
12 A PROBLEM OF ADJUDICATION AT THE LOCAL INSTITUTION,
13 THAT THE STATEWIDE ESCRO WOULD BE THE FIRST COURT OF
14 APPEALS, SO TO SPEAK, BEFORE IT GOES FURTHER?

15 DR. ROWLEY: CAN I JUST SAY FROM THE
16 STANDPOINT OF THE ACADEMY, IF YOU READ THE REPORT,
17 THERE WAS THE CONSIDERATION OF A NATIONAL ESCRO, WHICH
18 WOULD BE MORE A CLEARINGHOUSE OF PEOPLE WHO HAVE HAD
19 PROBLEMS, AND WHAT DO WE THINK ON A NATIONAL LEVEL.
20 NOW, SINCE IT'S NOT AT ALL CLEAR THAT'S GOING TO
21 HAPPEN, I THINK CALIFORNIA WOULD BE WELL ADVISED TO
22 HAVE SOME KIND OF AN ESCRO APPEAL IF AN INVESTIGATOR
23 FEELS THAT HE OR SHE HAS BEEN UNFAIRLY JUDGED.

24 MR. SHEEHY: IT JUST SEEMS THAT THIS
25 DISCUSSION IS KIND OF FOCUSED ALMOST ON THE IDEA THAT

1 LARGE ACADEMIC INSTITUTIONS ARE GOING TO RECEIVE ALL
2 THE MONEY THAT WE GIVE OUT. AND THERE'S NO RECOGNITION
3 OF SMALLER INDUSTRY-TYPE PARTICIPANTS, SMALLER RESEARCH
4 INSTITUTIONS. THIS CAN END UP SETTING UP A BARRIER TO
5 PARTICIPATION. BEFORE YOU CAN EVEN SUBMIT A GRANT, YOU
6 MUST PUT IN PLACE AN ESCRO. WHETHER OR NOT YOU EVER
7 GET A GRANT, THAT BARRIER HAS BEEN PUT UP. I THINK THE
8 LIABILITY ISSUES THAT ZACH RAISED IS PRECISELY WHY WE
9 WON'T GET INDEPENDENT CONSORTIA OF SMALLER INSTITUTIONS
10 SETTING UP AN ESCRO BECAUSE WHO'S GOING TO ASSUME THE
11 LIABILITY FOR THAT ESCRO. SO IT LEAVES -- IT'S GREAT
12 FOR UCSF AND STANFORD AND UCLA. IT'S BAD FOR A SMALL
13 INSTITUTION, IT'S BAD FOR A COMPANY THAT WANTS TO ENTER
14 THIS FIELD AND COMPETE FOR OUR GRANTS.

15 AND IT'S NOT CLEAR TO ME WHY WE COULDN'T PUT
16 OUT AN RFA FOR AN ESCRO AND HAVE SOME ENTITY STEP UP TO
17 THE PLATE. IT WOULD BE MY BELIEF THAT IF WE SET UP
18 REGIONAL ONES, THAT THEY WOULD PRIMARILY DRAW FROM THE
19 INSTITUTIONS IN THAT REGION. AND THAT WAY THERE WOULD
20 BE THAT FAMILIARITY WITH THE RESEARCH THAT'S GOING ON
21 ON THE GROUND. THERE WOULDN'T BE QUITE THIS
22 DISCONNECT. IF YOU HAD A NORTHERN CALIFORNIA ONE AND
23 YOU HAD A SOUTHERN CALIFORNIA ONE, I THINK MOST PEOPLE
24 WOULD KNOW EACH OTHER AND KNOW WHO'S DOING THE WORK.
25 AND THROUGH THE INFORMAL NETWORKS THAT WE KNOW EXIST,

1 THERE WOULD BE THAT KIND OF COMMUNICATION THAT WOULD
2 PROVIDE THAT OPPORTUNITY.

3 CO-CHAIR LANSING: CAN YOU USE THE UC SYSTEM
4 TO HAVE THEM -- I DON'T KNOW THIS AT ALL -- TO HAVE
5 THEM, SINCE THEY WILL ALL PROBABLY HAVE ESCRO'S, THAT
6 PART OF THEIR RESPONSIBILITY IS TO PROVIDE ESCRO
7 SERVICE FOR SMALLER INSTITUTIONS?

8 MR. KLEIN: WE KNOW A REGENT WHO COULD
9 SUGGEST IT.

10 CO-CHAIR LANSING: I CAN SUGGEST IT, BUT I'M
11 ASKING IT IT'S LEGAL. CAN YOU SAY THAT THAT'S PART OF
12 THEIR RESPONSIBILITY? PROBABLY NOT.

13 MR. HARRISON: NO.

14 DR. HALL: THERE'S ANOTHER ISSUE HERE. AND
15 THAT IS THAT NOT ALL THIS WORK WILL BE DONE UNDER CIRM
16 FUNDING.

17 MR. SHEEHY: WE COULD PUT OUT -- ASK FOR A
18 CONTRACT, NORTHERN AND SOUTHERN CALIFORNIA, AN
19 INSTITUTION CAN DO IT, BUT COME BACK AND PROPOSE A
20 NORTHERN AND SOUTHERN CALIFORNIA ESCRO. IF WE WERE TO
21 PROVIDE FUNDING TO ALLOW THIS TO TAKE PLACE, I THINK
22 THAT THAT MIGHT BE SOMETHING THAT SOMEBODY MIGHT WANT
23 TO APPLY FOR FUNDING FOR. IT COULD BE UC THAT COULD DO
24 IT, AND LET THEM FIGURE OUT THEIR LIABILITY ISSUES AND
25 BUILD THAT INTO THE CONTRACT AND LIMIT IT TO CIRM

1 RESEARCH.

2 YOU KNOW, PART OF THE PROBLEM WE'RE GOING TO
3 HAVE IS THAT THERE'S GOING TO BE RESEARCH THAT'S TAKING
4 PLACE THAT'S BEING FUNDED IN DIFFERENT WAYS. WE
5 ALREADY KNOW THAT THERE'S STATE LAW THAT REQUIRES ALL
6 STEM CELL RESEARCH TO GO THROUGH IRB'S, EXCLUDING CIRM
7 RESEARCH, SO THAT WE CAN MAKE SURE THAT, AT LEAST FOR
8 CIRM RESEARCH, WE HAVE A HANDLE ON WHAT WE'RE FUNDING,
9 THE ETHICS OF WHAT WE'RE FUNDING, AND THE ENFORCEMENT
10 OF THOSE ETHICAL RULES. WE COULD BE THE APPELLATE BODY
11 OF LAST RESORT IN THAT INSTANCE.

12 DR. KIESSLING: I WOULD LIKE TO PUT OUT AN
13 ARGUMENT THAT'S ACTUALLY ABSOLUTELY COUNTER TO ONE THAT
14 ZACH JUST PROPOSED IN THAT INSTITUTIONS FREQUENTLY HAVE
15 THEIR OWN BIASES. SO IF YOU'RE AN INVESTIGATOR IN AN
16 INSTITUTION THAT IS OPPOSED TO STEM CELL RESEARCH,
17 YOU'RE NOT GOING TO GET YOUR PROJECT APPROVED AT THAT
18 INSTITUTION. THERE'S A LOT OF EXAMPLES OF HUMAN
19 SUBJECTS RESEARCH THAT IS REALLY BIASED FROM
20 INSTITUTION TO INSTITUTION.

21 SO I THINK RIGHT NOW IF YOU REALLY WANT TO
22 FACILITATE THIS WORK GOING FORWARD AS RAPIDLY AS
23 POSSIBLE IN CALIFORNIA, YOU WILL PROVIDE, NOT A
24 REGIONAL COMMITTEE, YOU'LL JUST PROVIDE A CIRM
25 STATEWIDE COMMITTEE WHICH IN THE ELECTRONIC AGE CAN

1 GIVE YOU AN ANSWER IN 24 HOURS WITH SOME KIND OF
2 GUIDELINES SO THAT THAT INVESTIGATOR HAS HAD -- HIS
3 PROJECT HAS BEEN REVIEWED BY A SINGLE GROUP OF PEOPLE
4 IN CALIFORNIA, THEY'RE LOOKING AT ALL -- THEY COME INTO
5 THIS WITH EXACTLY THE SAME KIND OF BACKGROUND SO THAT
6 ALL INSTITUTIONS, AT LEAST FOR THE FIRST FEW YEARS OF
7 FUNDING, ARE GOING TO HAVE THE SAME KIND OF OVERSIGHT
8 FOR THE RESEARCH THAT'S GOING TO BE UNIFORM. AND IT
9 MIGHT EVEN GIVE INVESTIGATORS AT SOME INSTITUTIONS A
10 LITTLE WEDGE TO SAY, LOOK, THIS HAS BEEN REVIEWED BY
11 THE ESCRO, THEY THINK THE RESEARCH IS GOOD; THEREFORE,
12 LET ME GO FOR THE FUNDING BECAUSE NOT ALL INSTITUTIONS
13 ARE GOING TO BE UNIFORMLY BEHIND THIS WORK.

14 CO-CHAIR LO: WE HAD THREE PEOPLE HERE AND
15 THEN DR. ROWLEY.

16 DR. WILLERSON: I DON'T WANT TO OFFER
17 SOMETHING ENTIRELY DIFFERENT -- CAN YOU ALL HEAR ME? --
18 EITHER, BUT I DO WANT TO KEEP SOMETHING IN MIND. ALL
19 OF US WHO SUBMIT GRANTS KNOW HOW DIFFICULT THE PROCESS
20 IT IS TODAY, AND THAT THERE ARE LONG TIMES REQUIRED AND
21 A LOT OF RED TAPE. YOU'RE TRYING TO ENCOURAGE THIS
22 RESEARCH IN CALIFORNIA AND NOT MAKE IT EXTREMELY
23 DIFFICULT TO DO, AND YET HAVE IT DONE WELL AND
24 CORRECTLY AND WITH APPROPRIATE ETHICAL STANDARDS.

25 I THINK AT A LOCAL INSTITUTION THERE IS THE

1 BEST ABILITY TO REVIEW A GRANT LIKE THIS; BUT IN THE
2 SPIRIT OF TRYING TO KEEP IT AS SIMPLE, BUT AS WATCHING
3 AS POSSIBLE, YOU COULD USE AN IRB AND YOU COULD ADD
4 SOME MEMBERS TO AN IRB WHO ACTUALLY REPRESENTED THIS
5 ESCRO GROUP. IRB'S REVIEW A LOT OF GRANTS. THEY'RE
6 NOT JUST STEM CELL GRANTS, BUT THERE WOULD BE A SMALL
7 SUBSET THAT COMES TO JOIN AN IRB TO CONSIDER STEM CELL
8 PROPOSALS FROM INSTITUTIONS. WITH SMALLER
9 INSTITUTIONS, THEY PROBABLY SHOULD COME TOGETHER AND
10 MAYBE USE AN EXISTING IRB AT ONE OF THEM OR AT A LARGER
11 INSTITUTION THAT'S IN THE SAME NEIGHBORHOOD.

12 THERE WILL BE COMPLAINTS AND THERE WILL BE
13 DISAGREEMENTS, AND THERE PROBABLY NEEDS TO BE A GROUP
14 THAT CAN ADDRESS THOSE. THAT COULD EITHER BE DONE BY A
15 STATEWIDE ESCRO, AS HAS BEEN SUGGESTED, OR REGIONAL
16 ESCRO'S, WHICH MIGHT BE EVEN BETTER. BUT THEY WOULD BE
17 SEEING THINGS ABOUT WHICH THERE ARE DISAGREEMENTS, AND
18 THEY WOULD BE CHARGED WITH REVIEWING THESE THINGS
19 QUICKLY, AND IT WOULD NOT BE REPRODUCING THE WHOLE
20 THING. IT WOULD JUST BE SORT OF LIKE A SUPREME COURT
21 THAT RENDERED A DECISION IN A TIMELY WAY. BUT DON'T
22 MAKE THIS SO DIFFICULT WITH SO MANY HURDLES AND SO MANY
23 COMMITTEES AND SO MUCH TIME INVOLVED THAT IT TURNS OUT
24 TO BE A DISINCENTIVE.

25 DR. CIBELLI: I JUST WANT TO MAKE SURE THAT

1 WE' RE MAKING PROGRESS. DO WE HAVE TO HAVE A MOTION
2 THAT WE AGREE OR DISAGREE TO HAVE ESCRO' S IN PLACE? IT
3 LOOKS TO ME THAT WE TALK ABOUT HAVING OR NOT HAVING
4 THEM, AND THEN WE' RE MOVING TO REGIONAL AND LOCAL OR
5 CIRM.

6 CO-CHAIR LO: A LOGICAL WAY TO APPROACH IT,
7 FIRST, TO SEE IF THERE' S AGREEMENT THERE SHOULD BE AN
8 ESCRO-TYPE REVIEW. AND THEN IF THE ANSWER IS YES, WHAT
9 KIND OF LOCAL VERSUS --

10 MR. SHESTACK: THIS GROUP ALREADY -- ONE OF
11 THE REASONS, MY UNDERSTANDING IS EVERYBODY LOOKED AT
12 THE NAS GUIDELINES AND DECIDED FOR ALL SORTS OF
13 REASONS, INCLUDING MERIT, BUT NOT ONLY INCLUDING MERIT,
14 THAT WE WOULD ADOPT THEM, REDRAFT THEM, BUT BY AND
15 LARGE ADOPT THEM. THE NAS SUGGESTED ESCRO' S. PROBABLY
16 NOT, IT SOUNDS LIKE, TO TAKE CARE OF A SMALL NUMBER OF
17 ISSUES THAT MIGHT COME UP. NOT EVERY GRANT WOULD
18 REALLY NECESSARILY HAVE BIG DISCUSSION OR CONFLICT IN
19 THE ESCRO PROCESS, BUT IT WAS THERE' S SMALL HOLES, BUT
20 DEEP. AND NOW WE ARE SUGGESTING THAT EVERY INSTITUTION
21 CREATE AN ESCRO COMMITTEE.

22 IT WAS JUST A SIMPLE QUESTION, IF WE REALLY
23 WANT TO PROMOTE THE SCIENCE IN AS SPEEDY A WAY AS
24 POSSIBLE, IS THERE A LAYER -- WE ACCEPT THE FACT THAT
25 WE' RE GOING TO DO SOMETHING ABOUT ESCRO' S BECAUSE THE

1 NAS SUGGESTED IT, AND WE'RE NOT GOING TO BUCK THAT
2 BECAUSE WHAT'S THE POINT. IS THERE A WAY TO CREATE A
3 SLIGHTLY STREAMLINED BUREAUCRACY THAT MIGHT ULTIMATELY
4 HELP? YOU SUGGESTED THE INVESTIGATORS, BUT I THINK
5 MORE OF IT IN TERMS OF HELPING THE STAKEHOLDERS, BUT
6 IT'S THE SAME. GETTING MORE, BETTER RESEARCH DONE
7 FASTER. THAT IS THE QUESTION. IT JUST SEEMS THAT THIS
8 IS THE APPROPRIATE COMMITTEE AND FORUM TO RAISE IT, BUT
9 MAYBE NOT. SEEMED LIKE THIS WAS THE TIME.

10 DR. ROWLEY: WELL, I WANT TO MAKE TWO
11 COMMENTS. ZACH WAS NOT SPECIFIC IN HOW MANY GRANTS YOU
12 THINK YOU MIGHT BE GETTING. BUT IF YOU GET, SAY, 200
13 OR 300 GRANTS, AND YOU'RE SAYING A SINGLE STATEWIDE
14 ESCRO COMMITTEE IS GOING TO LOOK AT 300 GRANTS, I THINK
15 THAT THAT'S UNREALISTIC. AND TO GO BACK AND THINK THAT
16 IT'S GOING TO HAPPEN IN A TIMELY FASHION IS, I THINK,
17 HIGHLY UNLIKELY. IT IS TRUE THAT MANY OF THE GRANTS
18 YOU MAY GET WILL BE USING ALREADY ESTABLISHED CELL
19 LINES TO DO VARIOUS BASIC RESEARCH. AND IT WAS AGREED
20 THAT THOSE REALLY DIDN'T REQUIRE ESCRO REVIEW EXCEPT
21 THAT FOR INSTITUTIONS IT WOULD BE PRUDENT FOR THEM TO
22 KNOW WHO'S DOING WHAT ON WHAT CELL LINES. SO THAT
23 IT'S, IF YOU WILL, A BOOKKEEPING FUNCTION, BUT ONE THAT
24 IN A SENSE THE ESCRO WOULD HAVE THE OVERSIGHT OF. BUT
25 I THINK IT'S UNREALISTIC TO THINK THAT YOU ARE GOING TO

1 FIND BUSY INVESTIGATORS GOING TO SOME CENTRAL PLACE AND
2 SPENDING A COUPLE OF DAYS REVIEWING GRANTS FOR A
3 CENTRAL ESCRO.

4 CO-CHAIR LANSING: I FEEL BECAUSE THE NAS HAD
5 IT, BECAUSE WE ARE NEW AND INCREDIBLY WATCHED BY
6 EVERYBODY, THAT WERE WE -- THOUGH I UNDERSTAND THE
7 MERIT OF WHAT YOU'RE SUGGESTING -- WERE WE NOT TO HAVE
8 ESCRO'S, I THINK WE WOULD BE CONDEMNED. WE MAY GET
9 THERE, YOU KNOW, A YEAR FROM NOW OR TWO YEARS FROM NOW,
10 BUT I THINK NOW WE NEED THE REGULATION. THE NAS HAS
11 IT. WE'RE BEING WATCHED. WHAT ARE WE DOING? SO I
12 THINK WE NEED THE REGULATIONS.

13 BUT THE THING THAT BOTHERS ME, AND I HEAR IT
14 LOUD AND CLEAR, AND I ACTUALLY WOULD LIKE JUST A LITTLE
15 BIT MORE INFORMATION AS A LAYPERSON. I KNOW THAT THE
16 BIGGER INSTITUTIONS ARE GOING TO BE ABLE TO DO THIS.
17 BUT WHAT I'M HEARING IS THAT IT'S QUITE COSTLY, AND SO
18 I THINK WE HAVE TO COME UP WITH SOME RECOMMENDATION. I
19 DON'T KNOW WHETHER IT'S PRESCRIPTIVE OR NOT, BUT WE
20 HAVE TO BE MINDFUL OF THE FACT THAT WE'RE NOT LIMITING
21 WHO GETS THESE GRANTS, AND HOW DO WE HELP THE SMALLER
22 INSTITUTIONS? WHAT DO WE DO? I DON'T KNOW THE ANSWER
23 TO THAT. HOW MUCH DOES IT COST TO SET UP AN ESCRO?
24 MAYBE --

25 DR. KIESSLING: JANET'S CONCERN IS WELL

1 RAISED, BUT I THINK THAT 90 PERCENT OR MAYBE EVEN 95
2 PERCENT OF THE APPLICATIONS ARE NOT GOING TO REQUIRE
3 IN-DEPTH REVIEW. I THINK IT'S GOING TO BE VERY EASY TO
4 PUT IN PLACE A PROCESS WHERE A GRANT APPLICATION IS
5 PROPOSED. THIS IS EXPEDITED REVIEW. WE WANT TO STUDY
6 THIS PATHWAY IN THIS CELL LINE, AND THAT'S WHAT WE'RE
7 DOING. I THINK THAT'S GOING TO BE A LOT OF THE WORK AT
8 LEAST INITIALLY. I THINK THAT'S A 10- OR 15-MINUTE
9 DECISION BY SOMEBODY.

10 CO-CHAIR LANSING: BY WHO?

11 DR. KIESSLING: THE MORE WE TALK ABOUT THIS
12 AND THE MORE I THINK ABOUT IT, I'VE DONE BOTH
13 INSTITUTIONAL REVIEWS AND I'VE DONE REVIEWS WITH
14 COMPANIES THAT WERE COMMERCIAL COMPANIES, AND IT WAS A
15 DIFFERENT SITUATION WHEN EVERYTHING WAS DONE BY PAPER.
16 BUT YOU CAN NOW GET AN ELECTRONIC VIEWPOINT FOR
17 SOMETHING YOU WANT TO DO IN A TWINKLING. AND I DON'T
18 THINK YOU NEED TO HAVE THIS SET UP REGIONALLY. TO
19 START YOU WOULD BE REALLY WELL ADVISED TO ESTABLISH ONE
20 STATEWIDE COMMITTEE TO GET THIS GOING WITH THE IDEA
21 THAT MAYBE IN TWO OR THREE YEARS IT WOULD BREAK DOWN
22 INTO INSTITUTIONAL COMMITTEES. EACH INSTITUTION CAN
23 DECIDE IF THEY WANT THE RESPONSIBILITY FOR THE WORK.

24 CO-CHAIR LANSING: BUT MY QUESTION -- I'M
25 ACTUALLY TRYING TO BE PRACTICAL NOW. MY QUESTION --

1 AGAIN, I DON'T KNOW THE ANSWER TO THIS. WHAT I HEARD
2 LOUD AND CLEAR FROM SOME MEMBERS IS THAT, OKAY, THE UC
3 WILL HAVE THEIR ESCRO AND DIFFERENT PEOPLE WILL HAVE
4 THEIR ESCRO, BUT WHAT HAPPENS TO THE SMALLER
5 INSTITUTIONS AND THIS BECOMES AN IMPEDIMENT FOR THEM TO
6 APPLY FOR GRANTS, WHICH I WOULD NOT WANT. I WOULD WANT
7 EVERYBODY TO FEEL FREE.

8 MR. SHESTACK: WHAT'S THE MECHANISM FOR
9 INDUSTRY AS WELL?

10 CO-CHAIR LANSING: DO WE SAY -- I'M MAKING
11 THIS UP BECAUSE I DON'T KNOW. TWICE A YEAR YOU HAVE TO
12 SUPPLY -- EACH INSTITUTION HAS TO SUPPLY SOMEBODY TO AN
13 ESCRO FOR THE SMALLER INSTITUTIONS THAT DON'T HAVE AN
14 ESCRO SO THEIR GRANTS CAN BE REVIEWED. THAT'S LIKE A
15 FIVE-MINUTE IDEA. THAT'S PART OF BEING PART OF, YOU
16 KNOW, THE STATE OF CALIFORNIA. YOU HAVE TO SUPPLY
17 SOMEONE. IT COULD BE DONE ELECTRONICALLY. IT DOESN'T
18 HAVE TO BE DONE IN PERSON, THAT AN INSTITUTION WHO
19 CAN'T AFFORD TO HAVE AN ESCRO COMMITTEE, WE, YOU KNOW,
20 THIS BODY OR THIS BODY DOES IT. I DON'T KNOW.

21 CO-CHAIR LO: WE HAVE A LOT OF PEOPLE HERE.
22 LET ME TRY AND KEEP ORDER. BOB KLEIN, FRANCISCO, ROB
23 TAYLOR, TED PETERS. DID I MISS ANYBODY?

24 MR. KLEIN: I'D LIKE TO FOLLOW DR. CIBELLI'S
25 LEAD. I THINK THE FUNDAMENTAL THRESHOLD ISSUE IS DO WE

1 REQUIRE AN ESCRO? I THINK HAVING A VOTE ON THAT, THEN
2 GOING TO THE ISSUE OF WHETHER IT'S REGIONAL AND LOCAL,
3 SO WE CREATE A CHOICE. THOSE ISSUES ARE SUBSEQUENT,
4 BUT I'D LIKE TO SECOND DR. CIBELLI'S MOTION, PUTTING A
5 MOTION ON THE TABLE FOR A VOTE SO WE GET PAST THE
6 THRESHOLD QUESTION.

7 DR. KIESSLING: I THOUGHT WE ALREADY VOTED ON
8 IT.

9 MR. KLEIN: WE VOTED ON THE NAS GUIDELINES,
10 BUT WE HAVEN'T SEPARATELY VOTED.

11 DR. CIBELLI: SO IF WE VOTED ON IT, WHY DO WE
12 KEEP TALKING ABOUT IT?

13 CO-CHAIR LO: SO THERE'S A MOTION TO SORT OF
14 REAFFIRM IN SOME SENSE OUR PREVIOUS MOTION, THAT BY
15 ADOPTING NAS GUIDELINES --

16 MR. SHESTACK: WHY BOTHER? WHY DO IT? WE
17 ALREADY ADOPTED IT.

18 DR. CIBELLI: BUT WE KEEP TALKING ABOUT IT.
19 WE NEED TO MOVE ON. LET'S VOTE. THE MOTION IS TO HAVE
20 ESCRO'S FOR FUNDED RESEARCH FROM CIRM.

21 CO-CHAIR LO: SO LET'S -- WHY DON'T WE VOTE
22 ON THAT JUST TO SORT OF GET IT OUT OF THE WAY. SO HOW
23 MANY PEOPLE SUPPORT THERE BEING SOME REQUIREMENT FOR
24 ESCRO REVIEW OF CIRM-FUNDED?

25 MR. KLEIN: I'M THE SECOND.

1 CO-CHAIR LO: THE MOTION IS TO REQUIRE SOME
2 FORM OF ESCRO REVIEW A LA NAS GUIDELINES. ALL THOSE IN
3 FAVOR. ANYBODY OPPOSED?

4 MR. SHESTACK: I ABSTAIN.

5 CO-CHAIR LO: SO WE HAVE ONE OPPOSED AND ONE
6 ABSTENTION. FOR THOSE ON THE CONFERENCE CALL.

7 DR. KIESSLING: I'D LIKE TO ABSTAIN.

8 CO-CHAIR LO: ANYONE STILL ON THE CONFERENCE
9 CALL?

10 DR. KIESSLING: I'D LIKE TO ABSTAIN AS WELL.

11 CO-CHAIR LO: SO YOU HAVE TWO ABSTENTIONS,
12 ONE IN OPPOSITION. THOSE ON THE CONFERENCE CALL, DO
13 YOU WANT TO VOTE ON THAT, THAT WE REQUIRE SOME FORM OF
14 ESCRO REVIEW FOR CIRM FUNDING?

15 DR. EGGAN: I VOTE IN FAVOR OF THE ESCRO
16 REVIEW.

17 DR. KORDOWER: I DO AS WELL.

18 MR. KLEIN: WHAT ARE THE NAMES?

19 DR. KORDOWER: JEFF KORDOWER.

20 DR. HALL: JEFF KORDOWER AND KEVIN EGGAN.

21 CO-CHAIR LO: IT'S NOT UNANIMOUS, BUT I THINK
22 THERE'S A SUBSTANTIAL. NOW THE QUESTION IN JOSE'S
23 FORMULATION IS, OKAY, NOW WHAT FORM SHOULD THIS TAKE.
24 I GUESS THE NAS HAD CONCEIVED IT AS BEING A LOCAL
25 INSTITUTIONAL REVIEW, AND I GUESS UNDER THAT I WOULD

1 SORT OF LUMP VOLUNTARY ASSOCIATIONS OF MORE THAN ONE
2 LOCAL ESCRO. BUT NOW THE ISSUE IS EITHER TO SUPPLEMENT
3 OR SUBSTITUTE FOR LOCAL REVIEW, AND THOSE MAY BE VERY
4 DIFFERENT. WE'RE TALKING ABOUT SOMETHING MORE
5 CENTRALIZED, EITHER REGIONAL OR STATEWIDE.

6 CO-CHAIR LANSING: I'M ADDING SOMETHING ELSE.
7 MAYBE I'M WRONG. HOW MUCH DOES IT COST TO SET UP AN
8 ESCRO? WHAT KIND OF COST ARE YOU TALKING ABOUT?

9 DR. HALL: WELL, IT'S NOT JUST MONEY. IT'S
10 GETTING THE PERSONNEL. AND I THINK THE POINT THAT
11 SOMEBODY MADE, IF THE ESCRO IS IN YOUR OWN INSTITUTION,
12 THEY MEET GENERALLY, LIKE IRB'S, THEY MEET EVERY TWO
13 WEEKS FOR TWO OR THREE HOURS, AND YOU CAN GO AS PART OF
14 YOUR REGULAR DAY. IF YOU HAVE TO GO TO SACRAMENTO,
15 IT'S A DIFFERENT STORY. THEY'RE VERY COMPLICATED
16 THINGS.

17 LET ME JUST MAKE A POINT, IF I MAY. I REALLY
18 THINK THAT IT'S NOT AN ETHICAL ISSUE WHETHER OR NOT THE
19 ESCRO IS LOCAL OR STATEWIDE. I THINK IT'S
20 ADMINISTRATIVE, SCIENTIFIC, IT HAS VARIOUS COMPONENTS
21 TO IT. AND I REALLY THINK THAT THE INSTITUTIONS
22 THEMSELVES WILL WANT TO HAVE SOME INPUT ON THIS. I
23 JUST DON'T SEE THAT IT'S PART OF THE ETHICAL ISSUE FOR
24 THIS COMMITTEE TO SAY IT SHOULD BE ONE OR THE OTHER.

25 SO MY SUGGESTION WOULD BE TO WRITE SOMETHING

1 THAT WOULD ALLOW INSTITUTIONS THEN TO DO WHAT THEY
2 WOULD LIKE TO DO. I THINK THE SMALL ONES, I WAS JUST
3 TRYING TO THINK OF THE ONES AROUND THE STATE, ALMOST
4 ALL SMALL INSTITUTIONS HAVE RELATIONSHIPS WITH LARGER
5 INSTITUTIONS CLOSE-BY. THAT WOULD MAKE IT VERY EASY
6 FOR THEM TO GRAFT ONTO OR TO BE PART OF THOSE REVIEWS.

7 AND BURNHAM -- BUCK INSTITUTE WITH UCSF.
8 BURNHAM WITH SAN DIEGO, CHILDREN'S HOSPITAL WITH USC,
9 PROBABLY CITY OF HOPE WITH USC, CEDARS-SINAI. ALL OF
10 THESE ARE -- CHILDREN'S HOSPITAL OAKLAND WITH BERKELEY.
11 ALL OF THESE ARE INSTITUTIONS THAT HAVE RELATIONSHIPS
12 WITH THEIR FACULTY AND OTHERWISE. I SIMPLY DON'T
13 BELIEVE THAT THEY WILL BE UNABLE TO COMPETE.

14 CO-CHAIR LANSING: IS IT WRONG TO SAY --

15 DR. HALL: I THINK THEY SHOULD BE OFFERED THE
16 CHOICE. WHATEVER WORKS FOR THE INSTITUTION, I THINK
17 THEY SHOULD DO, AND WE SHOULD SET THE OVERALL
18 GUIDELINES TO BE SURE THAT THERE IS ADEQUATE ETHICAL
19 SCIENTIFIC REVIEW. THAT'S OUR CONCERN.

20 CO-CHAIR LO: A LOT OF PEOPLE WANT TO JOIN IN
21 HERE. FRANCISCO, ROB I HAD BEFORE, AND THIS END OF THE
22 TABLE TED AND ANN.

23 DR. PRIETO: I'M KIND OF INTRIGUED BY
24 SHERRY'S SUGGESTION OF REQUIRING THAT LARGER
25 INSTITUTIONS PARTICIPATE. BUT MY SUGGESTION IS THAT WE

1 PUT IN GENERAL LANGUAGE, AS I SAID EARLIER, THAT AN
2 INSTITUTION, GROUP OF INSTITUTIONS, OR THE CIRM MAY
3 CONVENE AN ESCRO TO SERVE THESE FUNCTIONS, AND LEAVE IT
4 AT THAT.

5 CO-CHAIR LANSING: SAY THAT AGAIN.

6 DR. PRIETO: AN INSTITUTION, GROUP OF
7 INSTITUTIONS, OR THE CIRM MAY CONVENE AN ESCRO TO
8 FULFILL THESE FUNCTIONS, AND LEAVE IT AT THAT.

9 DR. ROWLEY: AMEN.

10 DR. WILLERSON: LOT OF FLEXIBILITY IN IT,
11 THAT WOULD BE GOOD.

12 CO-CHAIR LANSING: DOES THAT TAKE CARE OF
13 WHAT YOU'RE TALKING ABOUT, JEFF, THAT THEN SOMEONE WHO
14 DIDN'T HAVE THE MEANS TO GET AN ESCRO WOULD BE ABLE TO
15 FIND A WAY TO GET IT REVIEWED?

16 MR. SHEEHY: MY THING IS THAT WHAT WAS
17 RAISED, THE QUESTION I HAVE IS ONE OF LIABILITY, WHICH
18 IS WHY SOME OF THE BIGGER INSTITUTIONS MAY NOT HAVE
19 QUITE SO MUCH WILLINGNESS TO ADOPT KIND OF STEWARDSHIP
20 FOR ANOTHER INSTITUTION'S RESEARCH. SO THE IDEA THAT
21 THEY WOULD BENEVOLENTLY AGREE TO PROVIDE REVIEW FOR
22 ANOTHER INSTITUTION OVER WHICH THEY HAVE NO EFFECTIVE
23 CONTROL, BUT WOULD HAVE ALL THE LIABILITY FOR HAVING
24 PROVIDED THE REVIEW, GIVES ME PAUSE. IT STILL DOESN'T
25 DEAL WITH ANY OF THE COMMERCIAL --

1 DR. HALL: COMMERCIAL IS A SEPARATE PROBLEM.

2 MR. SHEEHY: WE'RE MAKING A REGULATION THAT
3 DOESN'T EVEN REALLY SEEM TO TOUCH ON WHAT MAY BE
4 HAPPENING IN THE COMMERCIAL SENSE.

5 MR. KLEIN: HOW DO YOU RESPOND TO HIS
6 SUGGESTION THAT ALLOWS INSTITUTION, GROUP OF
7 INSTITUTIONS, OR THE CIRM?

8 DR. PRIETO: I VERY MUCH LIKE SHERRY'S
9 SUGGESTION, ALTHOUGH I THINK IT'S A SEPARATE ISSUE,
10 THAT WE COULD, AND MAYBE THIS IS AN ISSUE FOR THE ICOC,
11 WE COULD REQUIRE THAT INSTITUTIONS PARTICIPATE. I
12 DON'T THINK THAT'S AN ETHICAL QUESTION.

13 MS. LANSING: I DON'T KNOW THAT WE CAN DO IT.
14 I WISH WE COULD. CAN WE BE AN ESCRO, THIS GROUP HERE?
15 LOOK, I DON'T KNOW HOW TO DO ANY OF THIS.

16 DR. HALL: VOLUNTEER. THAT WOULD BE FINE.
17 THAT WOULD BE WONDERFUL. ALL THE PROBLEMS WOULD BE
18 SOLVED.

19 CO-CHAIR LANSING: I'M ASKING A QUESTION.
20 HERE'S THIS GROUP OF DISTINGUISHED PEOPLE, AND YOU'RE
21 SAYING, ANN, I MEAN I DON'T THINK, THAT YOU CAN DO THESE
22 IN 15 MINUTES AND YOU CAN DO THEM ELECTRONICALLY. CAN
23 WE SAY THAT SHOULD THERE NOT BE AN ESCRO PROVIDED, THAT
24 WE WOULD BE WILLING TO --

25 DR. HALL: LET ME JUST SAY THIS IMPOSES --

1 DR. PETERS: COULD WE HAVE A POINT OF ORDER
2 HERE BECAUSE I THINK THAT WE'VE GOT A SUGGESTION FROM
3 FRANCISCO. ALL OF ITS RAMIFICATIONS NEED TO BE
4 SUPPORTED BEFORE WE CHANGE THE SUBJECT.

5 MR. KLEIN: ARE YOU MAKING A SECOND SO IT CAN
6 BE A MOTION ON THE FLOOR?

7 DR. PETERS: I WANT TO ELABORATE ON IT BEFORE
8 THE MOTION IS MADE.

9 DR. PRIETO: I SAID MAY CONVENE BECAUSE I
10 DON'T WANT TO SAY THAT THE CIRM -- I USE THAT WORD
11 BECAUSE I DON'T WANT TO SAY THAT THE CIRM WILL
12 ESTABLISH OR THAT IT WILL NECESSARILY --

13 DR. HALL: YOU CAN SAY OR SOME STATE AGENCY,
14 I WOULD SUGGEST.

15 DR. PRIETO: OKAY. OR SOME STATE AGENCY.
16 THE WAY THAT JEFF PROPOSED, WE COULD DO THIS -- PUT OUT
17 AN RFA AND FUND IT, BUT NOT -- I WOULD CONSIDER THAT
18 FOR US TO BE CONVENING IT.

19 DR. PETERS: MAY I TRY AN ALTERNATIVE, WHICH
20 I HOPE HAS THE SAME SPIRIT, BUT IT GOES A SLIGHTLY
21 DIFFERENT DIRECTION. ONE OF THE POINTS I THINK I GOT
22 FROM A CONVERSATION WITH JON EARLIER IS THAT WE REALLY
23 WANT TO ACCOMPLISH THE GOALS OF THE ESCRO, BUT WITH
24 MINIMUM OBSTRUCTION. WOULD IT BE A PROBLEM IF WE WERE
25 TO SAY TO AN INSTITUTION FILING A GRANT APPLICATION

1 THAT HERE ARE THE WRITTEN GUIDELINES OF WHAT THE ESCRO
2 COMMITTEE NEEDS TO BE CONSTITUTED BY AND WHAT IT NEEDS
3 TO ACCOMPLISH. AND YOU CAN DO IT ANY WAY YOU WANT TO.
4 YOU CAN MAKE IT AN AUGMENT TO YOUR EXISTING IRB, WHICH
5 WOULD BE A VERY SIMPLE PROCESS. YOU CAN DO IT AS AN
6 INDIVIDUAL INSTITUTION. YOU CAN DO IT AS A CONSORTIUM
7 OF INSTITUTIONS. YOU CAN HIRE IT. WE'LL JUST MAKE
8 SUGGESTIONS. ALL WE CARE ABOUT THEN IS THAT WHEN THE
9 CHECKLIST COMES IN, THAT THEY'VE CHECKED OFF THE RIGHT
10 BOXES. AND WE DON'T EVEN NEED TO MONITOR IT UNLESS
11 THERE'S A COMPLAINT OF SOME KIND OR ANOTHER, AND THEN
12 WE WOULD HAVE TO RESPOND TO IT.

13 IT WOULD SEEM TO ME THAT WOULD ACCOMPLISH THE
14 GOALS, BUT IT WOULD BE UP TO THE INSTITUTION TO DECIDE
15 JUST HOW STREAMLINED A PROCESS THAT THEY WANT.

16 CO-CHAIR LO: WE HAD A LOT OF OTHER PEOPLE
17 WHO WANTED TO GET IN. I THINK ANN WAS NEXT.

18 DR. KIESSLING: FOR THE SHORT TERM, I THINK
19 IT'S IMPORTANT TO POINT OUT THAT MOST OF THESE GRANT
20 APPLICATIONS ARE NOT GOING TO INVOLVE HUMAN SUBJECTS.
21 THEY'RE GOING TO INVOLVE ANIMAL RESEARCH. EACH
22 INSTITUTION, IF THEY ARE INVOLVED ANY KIND OF IN VIVO
23 WORK AT ALL, IT'S GOING TO BE THE IACUC AT THE
24 INSTITUTION. SO ARE YOU GOING TO REQUIRE THAT YOUR
25 INSTITUTION HAVE BOTH SUPPLEMENTS TO ITS IRB AND TO ITS

1 IACUC, WHICH IS THE ANIMAL CARE AND USE COMMITTEE.

2 ANIMAL CARE AND USE COMMITTEES ARE REALLY
3 WELL -- THIS IS A -- THESE COMMITTEES ARE COMPOSED OF
4 PEOPLE WHO REALLY UNDERSTAND IN MANY RESPECTS A LOT
5 MORE OF THE BASIC SCIENCE BEHIND STEM CELL WORK THAN
6 HUMAN SUBJECTS REVIEW COMMITTEES BECAUSE THE PURPOSE OF
7 A HUMAN SUBJECTS REVIEW COMMITTEE IS DIFFERENT FROM
8 THAT OF AN ANIMAL USE COMMITTEE.

9 SO EACH INSTITUTION HAS THREE BODIES THAT ARE
10 INVOLVED WITH EVERY GRANT APPLICATION. THEY HAVE A
11 RESEARCH ADMINISTRATION OFFICE. THAT OFFICE IS GOING
12 TO KNOW EXACTLY WHAT THE RESEARCH IS INVOLVED. THEY
13 HAVE AN ANIMAL CARE AND USE COMMITTEE, AND THEY HAVE A
14 HUMAN SUBJECTS COMMITTEE. I KNOW THIS BECAUSE ALL OF
15 MY GRANTS HAVE TO GO THROUGH BOTH. SO IT ISN'T SIMPLY
16 AUGMENTING THE IRB THAT'S INVOLVED IN CREATING A GOOD
17 ESCRO. YOU ARE GOING TO HAVE TO DO SOMETHING WITH THE
18 WORK THAT DOESN'T INVOLVE HUMAN SUBJECTS AT ALL.

19 DR. PETERS: MY POINT WAS TO DECENTRALIZE
20 THAT, SO WE WOULDN'T TELL THEM THEY HAD TO AUGMENT THE
21 IRB. THAT'S JUST ONE OPTION AMONG MANY.

22 DR. CIBELLI: SO I THINK, JEFF, YOU HAD A
23 VERY GREAT IDEA ABOUT THE RFA. IF WE CAN ACTUALLY HAVE
24 AN RFA FOR NORTHERN CALIFORNIA -- I THINK THIS IS GOING
25 TO TURN OUT TO BE, LIKE JANET SAID, A LOT OF WORK.

1 EVEN THOUGH, LIKE ANN WAS SAYING, IT'S NOT GOING TO
2 HAVE TOO MANY PEOPLE DOING CONTROVERSIAL RESEARCH. YOU
3 STILL HAVE READ THE GRANT TO BE ABLE TO CHECK THE BOX.
4 SO I THINK THAT AN RFA WILL BE GREAT.

5 AND ALSO, THE ISSUE OF LIABILITY IS VERY
6 SIMPLE. YOU JUST HAVE DISCLAIMER THAT YOU'RE NOT
7 LIABLE, THAT YOUR INSTITUTION, THE RECIPIENT OF THE
8 GRANT IS THE ONE THAT'S GOING TO BE LIABLE. SO AS SOON
9 AS YOUR INSTITUTION IS ASKING FOR MONEY, THEY HAVE TO
10 BE RESPONSIBLE HOW THEY USE IT.

11 AND WITH ANN'S COMMENTS ON THE IACUC, I
12 AGREE. THIS IS GOING -- WE'RE GOING -- WE HAVE TO
13 REQUEST THE -- MAKE SURE THE ANIMALS ARE TREATED RIGHT
14 AND ALL THAT. THAT'S STANDARD FOR ANY GRANT.

15 CO-CHAIR LO: ROB AND THEN JANET.

16 DR. TAYLOR: I ACTUALLY THINK THERE'S QUITE A
17 CONFLUENCE OF IDEAS HERE. FROM WHAT ZACH SAID, I THINK
18 ABOUT INSTITUTIONAL SORT OF LOCALITY AND BEING ABLE TO
19 HANDLE THOSE THINGS TO SHERRY'S IDEAS ABOUT LETTING
20 SOME OF THE BIGGER ACADEMIC INSTITUTIONS MAYBE TAKE ON
21 MORE OF THE RESPONSIBILITY FOR THIS. IF THERE WERE AN
22 RFA THAT WAS SORT OF ATTRACTIVE TO BRING IN THE
23 STANFORDS AND UCSF'S AND UCLA'S TO THEN OVERSEE, NOT
24 ONLY THEIR OWN, BUT TO SORT OF TAKE ON MORE LOCAL
25 INDUSTRY SPONSORED OR SMALLER INSTITUTIONAL SPONSORED

1 GRANTS, THEN YOU KIND OF HAVE THE BEST OF ALL POSSIBLE
2 WORLDS.

3 I THINK THAT THE ISSUES ABOUT LIABILITY COULD
4 BE DEALT WITH AS YOU'VE KIND OF JUST SUGGESTED, JOSE,
5 THAT THAT BE TAKEN OFF THE PLATE A LITTLE. AND THEN
6 EVERYBODY, I THINK, WOULD BENEFIT FROM THIS. IF A BIG
7 INSTITUTION DECIDED THAT THEY DIDN'T WANT TO TAKE ON
8 THAT RESPONSIBILITY, I'M SURE THAT THERE WOULD BE
9 OTHERS THAT WOULD. AND I PUT IN A PLUG THAT THIS
10 SHOULD ALL PROBABLY BE DONE ON MORE OF A JUST-IN-TIME
11 BASIS. I KNOW WE KIND OF SKIRTED THE ISSUE ABOUT
12 WHETHER THIS SHOULD BE UP FRONT OR KIND OF POSTLOADED
13 EVALUATION. BUT I THINK IF YOU WERE TO KIND OF TRY TO
14 STREAMLINE IT, IT WOULD BE BETTER TO TRY AND DO THIS
15 ONCE A GRANT HAS BEEN GRANTED BUT NOT AWARDED WOULD BE
16 THE SUGGESTION THAT I'D MAKE.

17 CO-CHAIR LO: JANET AND THEN BOB KLEIN.

18 DR. ROWLEY: I WANTED TO MAKE THE POINT THAT
19 I THINK THAT WE DO NOT WANT TO UNDERESTIMATE THE WORK
20 THAT THE ESCRO IS GOING TO HAVE, AT LEAST IN THE
21 BEGINNING. LOOK AT THE DISCUSSIONS WE'VE HAD AND THE
22 GOING BACK AND FORTH. CAN YOU IMAGINE THIS
23 ELECTRONICALLY? IT'S NOT GOING TO WORK. THE THINGS
24 THAT THE ESCRO HAS TO FIGURE OUT, WHICH ARE EXCLUDING
25 ALL OF THE THINGS THAT ANN AND I AGREE ARE GOING TO BE

1 EXCLUDED ARE THE DIFFICULT ISSUES, WHICH YOU REALLY
2 HAVE TO BE TOGETHER AND DISCUSS AS A GROUP, NOT VIA
3 E-MAIL. IS THIS A GOOD IDEA? WHAT ARE THE DOWNSIDES?
4 AND ALL OF THE REST OF IT.

5 MR. KLEIN: WELL, TWO POINTS. ONE, WHAT'S
6 PREVIOUSLY BEEN REFERENCED IS THAT IF THE CONTROL IS
7 EXCLUSIVELY AT THE INSTITUTIONAL LEVEL, YOU MAY HAVE
8 INVESTIGATORS AT LOMA LINDA UNIVERSITY WHO, BECAUSE OF
9 RELIGIOUS ISSUES WITH THEIR INSTITUTION, CAN'T GET ONE
10 DONE THROUGH THEIR INSTITUTION, AND THEIR INSTITUTION
11 WON'T PARTICIPATE IN THE PROCESS.

12 DR. HALL: I DON'T THINK THEIR INSTITUTION,
13 IF THEY REALLY BELIEVE THEY DON'T WANT IT DONE, THEY
14 WON'T HAVE IT DONE. IT DOESN'T MATTER WHO APPROVES IT.

15 MR. KLEIN: WELL, YOU'RE AT LEAST PUTTING
16 YOUR INVESTIGATOR --

17 DR. HALL: THEY'RE NOT GOING TO SAY, WELL,
18 IT'S THE SAME AT THE UNIVERSITY OF PITTSBURGH RIGHT NOW
19 AND JERRY SCHATTEN. IT DOESN'T MATTER WHO APPROVES IT.
20 UNIVERSITY OF PITTSBURGH SAYS WE'RE NOT GOING TO HAVE
21 YOU DO THAT WORK UNDER OUR NAME.

22 MR. SHESTACK: WHAT WAS THE --

23 MR. KLEIN: THE ISSUE IS, ZACH, IF WE CAN
24 CREATE A MECHANISM WHERE IT AT LEAST PUTS THEM INTO A
25 STRONGER POSITION TO NEGOTIATE WITH THEIR INSTITUTION,

1 IT'S NOT DISPOSITIVE, BUT RATHER THAN HAVING THEM
2 PREEMPTIVELY CUT OFF FROM THIS AREA OF DISCOVERY.

3 THE SECOND QUESTION, ZACH, I'D LIKE YOU TO
4 COMMENT ON IS RELATED TO THIS WHOLE DISCUSSION ABOUT
5 WHETHER IT GOES THROUGH AN ESCRO BEFORE OR AFTER
6 APPROVAL AT THE SEED MONEY LEVEL VERSUS THE PRINCIPAL
7 INVESTIGATOR MONEY. IT WOULD SEEM MAYBE YOU WANT TO GO
8 THROUGH AND LET PEOPLE GET APPROVALS FIRST BECAUSE A
9 LARGE NUMBER OF SEED MONEY GRANTS, RUNNING THEM THROUGH
10 AN ESCRO APPROVAL FIRST MIGHT BE DIFFICULT TO
11 ACCOMPLISH, PARTICULARLY IN THE TIME FRAME. I REALIZE
12 IT HAS A SCREENING EFFECT.

13 DR. HALL: I JUST DON'T THINK IT'S AN ETHICAL
14 ISSUE. I THINK IT'S AN ADMINISTRATIVE ISSUE, AND I
15 THINK WE HAVE TO WORK IT OUT. THERE ARE PROS AND CONS
16 ON BOTH SIDES. I JUST DON'T SEE THAT WE NEED TO WORRY
17 ABOUT THAT HERE.

18 MR. SHEEHY: WHETHER IT'S AN ETHICAL OR
19 ADMINISTRATIVE ISSUE DOESN'T SEEM TO ME TO BE A
20 RELEVANT METRIC TO TRY TO MAKE A DECISION AT THIS
21 POINT.

22 DR. HALL: THERE ARE BIG ETHICAL ISSUES THAT
23 THIS GROUP NEEDS TO DEAL WITH. AND I THINK THE
24 QUESTION OF WHETHER YOU DO ESCRO BEFORE OR AFTER THE
25 REVIEW, I WOULD JUST SAY IS NOT ONE OF THEM. I'D BE

1 HAPPY TO HAVE THAT DISCUSSION WITH YOU. I THINK WE CAN
2 TALK ABOUT IT AT OTHER TIMES. AS BOB INDICATED, IT
3 MIGHT BE DIFFERENT FOR DIFFERENT KINDS OF GRANTS, BUT,
4 SURELY, THAT'S NOT A BIG ISSUE.

5 MR. KLEIN: JUST TO FINISH MY COMMENTS HERE.
6 IT WOULD SEEM THAT GIVEN THE COMPLEXITY OF THE STATE,
7 THAT DR. PRIETO'S SUGGESTION THAT WE CREATE THESE
8 VARIOUS OPTIONS IS A PREFERABLE APPROACH THAN LIMITING
9 OURSELVES TO JUST A STATEWIDE GROUP OR A LOCAL
10 RESOLUTION BECAUSE WE WANT TO ACCOMMODATE THE
11 INSTITUTIONS IN OUR STATE WHICH HAVE RESEARCH
12 HOSPITALS, RESEARCH INSTITUTIONS, AND UNIVERSITIES, ALL
13 WITH VERY PROUD DISTINGUISHED FACULTIES WHO MAY OPT FOR
14 DIFFERENT SOLUTIONS TO THIS PROCESS. AND PROVIDING
15 THOSE OPTIONS WOULD REALLY SEEM TO FACILITATE A BROADER
16 PARTICIPATION RATHER THAN BEING DIRECTIVE AND VERY
17 LIMITING IN OUR APPROACH.

18 CO-CHAIR LO: LET ME TRY AND DRAW TOGETHER
19 WHAT'S BEEN A VERY RICH AND COMPLICATED DISCUSSION. WE
20 HAVE A PROPOSAL TO HAVE A BROAD SET OF OPTIONS AS TO
21 HOW AN INVESTIGATOR MIGHT GO ABOUT GETTING ESCRO REVIEW
22 AND APPROVAL. I THINK WE'VE SAID WE WANT SOME SORT OF
23 ESCRO PROCESS TO SORT OF MAKE SURE IRB-TYPE ISSUES,
24 IACUC ISSUES, AND OTHER ETHICAL ISSUES THAT DON'T FALL
25 UNDER THOSE DOMAINS TO BE REVIEWED. AND THAT'S SORT OF

1 THE SPIRIT, AS I UNDERSTAND IT, OF THE NIH GUIDELINES.

2 FRANCISCO PROPOSED THAT WE HAVE A NUMBER OF
3 OPTIONS. THE INSTITUTION CAN DO IT THEMSELVES OR WITH
4 A VOLUNTARY CONSORTIUM OF OTHER INSTITUTIONS. CIRM MAY
5 CHOOSE TO SET UP EITHER A REGIONAL OR STATEWIDE ESCRO.
6 AND WE'RE GOING TO ALLOW EACH OF THOSE OPTIONS TO BE
7 AVAILABLE TO AN INVESTIGATOR.

8 WHAT I'M NOT CLEAR ABOUT IS, AND I MAY NOT
9 HAVE GOTTEN THAT QUITE RIGHT, BUT I THINK THE SPIRIT
10 WAS TO HAVE A RANGE OF OPTIONS. YOU WANT TO CLARIFY?

11 DR. PRIETO: NO. I HAVEN'T MADE IT AS A
12 MOTION, BUT I'LL DO SO NOW. BUT I JUST WANTED TO GET A
13 LITTLE MORE FEEDBACK FROM ZACH ABOUT HIS -- HE
14 SUGGESTED RATHER THAN THE CIRM, JUST TO SAY A STATE
15 AGENCY.

16 DR. HALL: SAY CIRM OR OTHER STATE AGENCY.
17 YOU KNOW, THE ISSUE PARTLY FOR US IS WE ARE LIMITED IN
18 RESOURCES. WE'RE LIMITED BY LAW IN BOTH THE AMOUNT OF
19 MONEY THAT WE HAVE TO DO OUR WORK AND THE NUMBER OF
20 PEOPLE THAT WE HAVE. AND IT IS JUST NOT CLEAR TO
21 ME -- ALSO LET ME JUST SAY AS A PRACTICAL ISSUE, WE ARE
22 TRYING TO SET A LOT OF THINGS UP SO THAT ONCE WE GET
23 OUR MONEY, WE CAN HIT THE GROUND RUNNING. WE DON'T
24 HAVE THE STAFF TO SET THIS UP RIGHT NOW.

25 DR. PRIETO: I'M VERY SENSITIVE TO THAT.

1 DR. HALL: BUT IF ANOTHER STATE AGENCY WERE
2 TO STEP IN WITH A PLAN FOR DOING THIS, I THINK THAT
3 WOULD ALSO BE FINE. I DON'T THINK WE NECESSARILY HAVE
4 TO DO IT, BUT I WOULD SAY CIRM OR ANOTHER STATE AGENCY.
5 LEAVE IT OPEN.

6 DR. PRIETO: WITH JEFF'S SUGGESTION OF OUR
7 FUNDING, YOU KNOW, PUTTING AN RFA OUT AND FUNDING THE
8 CREATION OF THAT ESCRO.

9 MR. KLEIN: YOU COULD RUN A CHARGE-BASED
10 SYSTEM.

11 DR. HALL: THAT'S A PLAN THAT NEEDS TO BE
12 THOUGHT ABOUT IN MORE DETAIL. WHO WOULD WE LET BID ON
13 SUCH A THING? IF SOME PRIVATE GROUP WERE TO COME UP
14 AND SAY WE'LL DO ALL YOUR ESCRO'S FOR YOU, WOULD WE
15 ACCEPT THAT?

16 DR. PRIETO: IF WE HAVE THE CAPABILITY.

17 DR. HALL: I THINK WE'D BE VERY -- I WOULD
18 WANT TO LOOK AT THAT VERY, VERY CAREFULLY. I THINK
19 WE'RE THE ONES THAT TAKE THE LIABILITY THEN. IF
20 THERE'S A PROBLEM WITH IT, WE'RE THE ONES THAT TAKE THE
21 LIABILITY. SO WE WOULD HAVE TO BE VERY, VERY CAREFUL
22 IF IT IS US THAT IS TAKING ON THE RESPONSIBILITY FOR
23 THIS. THIS GROUP, IT SEEMS TO ME, IS SETTING THE
24 STANDARD. AND IT IS UP TO THE INSTITUTIONS, I THINK,
25 TO IMPLEMENT THOSE STANDARDS. AND I SEE OUR ROLE GOING

1 FORWARD IS TO COORDINATE THE ESCRO'S IN THE STATE, TO
2 IDENTIFY BEST PRACTICES. AND IF WE FEEL IT'S NOT
3 WORKING, THEN WE WOULD HAVE SOME, PROBABLY THROUGH THIS
4 COMMITTEE, SOME WAY OF ADJUSTING WHAT WE WERE DOING.

5 AND I HOPE THAT IF THERE IS SET UP A NATIONAL
6 COMMITTEE THROUGH THE NATIONAL ACADEMIES, THAT WE WOULD
7 BE IN CLOSE CONTACT WITH THEM AND WORK WITH THEM. THEY
8 MIGHT EVEN DO THAT IN CALIFORNIA ACTUALLY.

9 SO I SEE THAT THE JOB OF THIS GROUP IS TO SET
10 THE STANDARD, IS TO OVERSEE IT IN BROAD GENERALITY, BUT
11 NOT TO TAKE RESPONSIBILITY FOR JUDGING INDIVIDUAL
12 PROJECTS, BUT TO LEAVE THAT TO THE INSTITUTIONS TO
13 IMPLEMENT.

14 SO BACK TO YOUR RESOLUTION, IT DOESN'T -- I'M
15 VERY WARY. I WANT TO LEAVE PLENTY OF OPTIONS FOR
16 OTHERS TO TAKE ON THE RESPONSIBILITY.

17 DR. PRIETO: I AGREE. I'M VERY SENSITIVE TO
18 THE FACT THAT WE HAVE VERY LIMITED STAFF, AND I DON'T
19 WANT THE CIRM TO FEEL LIKE WE HAVE TO RUN EVERY LITTLE
20 THING, BUT ALSO TO JEFF'S POINT, THAT WE HAVE TO ALLOW
21 OTHER POSSIBILITIES FOR PEOPLE TO MOVE IN AND MOVE THE
22 RESEARCH FORWARD.

23 SO MY MOTION WOULD BE THAT THE LANGUAGE WE
24 INCORPORATE WOULD SAY THAT AN INSTITUTION, GROUP OF
25 INSTITUTIONS, THE CIRM, OR OTHER STATE AGENCY MAY

1 CONVENE AN ESCRO TO FULFILL THESE FUNCTIONS.

2 DR. HALL: THERE ARE A VARIETY OF MECHANISMS,
3 ANY OF WHICH WOULD BE --

4 CO-CHAIR LO: LET ME TRY AND AGAIN DRAW
5 TOGETHER WHAT HAVE BEEN A NUMBER OF STANDS TO THE
6 CONVERSATION. SO WE CAN CERTAINLY REFINE THE IDEA THAT
7 FRANCISCO FIRST PUT FORWARD OF HAVING A NUMBER OF
8 OPTIONS FOR HAVING AN ESCRO-TYPE REVIEW. IT STRIKES ME
9 THAT THERE ARE A NUMBER OF OTHER ISSUES THAT HAVE BEEN
10 RAISED THROUGHOUT THE MORNING THAT DON'T REALLY GET
11 ADDRESSED BY THAT PROPOSAL.

12 ONE, IT'S A PERMISSIVE PROPOSAL, RIGHT? YOU
13 MAY DO ANY OF THE FOLLOWING, AND WE MAY ADD SOME MORE
14 THINGS IN, BUT IT DOESN'T SAY THAT TO HELP SMALL
15 INSTITUTIONS, WE WILL SET UP OR SOMEBODY WILL SET UP A
16 MECHANISM. SO THAT'S ONE THING, THAT IT'S PERMISSIVE,
17 BUT DOESN'T GUARANTEE THAT THIS STATEWIDE OR REGIONAL
18 ESCRO WILL COME IN.

19 LET ME JUST FINISH.

20 DR. HALL: ARE YOU PROPOSING -- IS THERE A
21 MOTION ON THE FLOOR?

22 CO-CHAIR LO: NO. NO. I'M JUST TRYING --
23 WE'VE SAID A LOT OF DIFFERENT THINGS. I'M JUST TRYING
24 TO HELP CLARIFY WHAT ARE THE ISSUES HERE. ONE ISSUE IS
25 LET'S GIVE A LOT OF OPTIONS FOR ESCRO REVIEW. THAT'S

1 FINE. STRIKES ME THERE'S ANOTHER ISSUE OF IF PEOPLE
2 DON'T CHOOSE TO PICK UP AN OPTION, THERE WILL BE
3 CONSEQUENCES FOR, FOR EXAMPLE, THE SMALL INVESTIGATORS.
4 SO THAT WE NEED TO DEAL WITH, OR WE NEED TO AT LEAST
5 KEEP IN MIND.

6 I GUESS THE OTHER ISSUE IS THAT THERE'S
7 ANOTHER POINT THAT NO MATTER WHO IS DOING -- IF YOU
8 TAKE THE OPTION OF HAVING PURELY LOCAL REVIEW, DO WE
9 WANT SOME ADDITIONAL LAYER OF OVERSIGHT, APPEAL OR
10 WHATEVER, IN CASE SOMEONE THINKS THERE'S A PROBLEM WITH
11 THAT LOCAL REVIEW? AND IF SO, HOW DOES THAT GET SET
12 UP? AND, AGAIN, THERE'S A RISK OF SAYING, YOU KNOW,
13 YOU CAN GO TO THE STATEWIDE ESCRO, BUT IF NO ONE IS
14 SETTING IT UP, IT'S NOT GOING TO DO.

15 DR. HALL: POINT OF INFORMATION HERE. THERE
16 ARE TWO THINGS THAT WE NEED TO DISTINGUI SH. OVERSIGHT
17 AND APPEAL ARE NOT THE SAME. ONE, WHICH I THINK IS A
18 ROLE THAT I THINK WE VERY DEFINITELY SHOULD DO, IS THAT
19 OF OVERSIGHT. ARE THE ESCRO'S WORKING? DO WE HAVE A
20 CASE WHERE THERE IS SOMETHING THAT'S NOT WORKING WELL?
21 DO WE NEED TO GO BACK AND REJIGGER TO THINK ABOUT HOW
22 WE DO IT AGAIN? CAN WE HELP EVERYBODY DO THEIR JOB IN
23 A CONSISTENT WAY? ALL OF THAT, I THINK, IS VERY MUCH
24 FOR US.

25 AN APPEAL IS TO SAY SOMEBODY DOESN'T GET IT

1 THROUGH THEIR INSTITUTION, AND NOW THEY APPEAL TO SOME
2 OTHER BODY TO GIVE THEM PERMISSION TO DO THIS. AND I
3 THINK THAT'S SOMETHING THAT WE WOULD WANT TO EXPLORE.
4 I PRESUME THAT OTHER BODY WOULD BE THIS WORKING GROUP,
5 AND I THINK THAT'S SOMETHING YOU'D WANT TO EXPLORE.

6 AND THEN WHETHER -- TAKE AN INSTITUTION. IF
7 UCLA SAYS IT TURNS THIS DOWN AND THEN WE APPROVE IT,
8 DOES UCLA HAVE TO DO THE WORK? THAT HAS TO BE THOUGHT
9 OUT. OVERSIGHT SEEMS TO BE VERY CLEAR. THE OTHER
10 ONE --

11 MR. KLEIN: I THINK THERE'S A MOTION THAT I'D
12 JUST LIKE TO SECOND SO IT'S PROPERLY ON THE FLOOR FOR
13 DEBATE. I'D LIKE TO SECOND.

14 CO-CHAIR LO: DO YOU WANT TO STATE YOUR
15 MOTION, FRANCISCO, TO MAKE SURE WE'VE GOT IT?

16 DR. PRIETO: MY MOTION IS TO INCLUDE THE
17 LANGUAGE "AN INSTITUTION, GROUP OF INSTITUTIONS, THE
18 CIRM, OR OTHER STATE AGENCY MAY CONVENE AN ESCRO."

19 MR. KLEIN: SECOND.

20 DR. WILLERSON: SECOND.

21 CO-CHAIR LO: WE'RE GOING TO PUT THIS UP ON
22 THE SCREEN. SO LET'S FOCUS ON THIS ISSUE NOW. AND
23 PRESUMABLY THIS IS TIED TO OUR PERFORMANCE STANDARDS
24 THAT WE HAVEN'T TALKED ABOUT YET, BUT ARE IN THE --
25 JAMES, DID YOU HAVE SOME TECHNICAL ADVICE HERE ON THIS

1 DISCUSSION?

2 MR. HARRISON: WELL, THE ONLY TECHNICAL
3 ADVICE I'D OFFER IS THAT GETTING THIS LANGUAGE INTO THE
4 PROPER FORMAT IS GOING TO TAKE SOME WORK. WHAT I WOULD
5 RECOMMEND IS THAT YOU LEAVE THAT TO THE STAFF AND THAT
6 YOU FOCUS ON A SUBSTANTIVE POLICY, AS YOU'VE JUST DONE.
7 AND WE CAN TAKE THE SUBSTANTIVE POLICY AND PUT IT INTO
8 A FORMAT AND BRING IT BACK TO YOU IN AN EFFORT TO
9 SATISFY BOTH THE SUBSTANTIVE POLICY GOALS THAT YOU'VE
10 ESTABLISHED AS WELL AS THE OFFICE OF ADMINISTRATIVE LAW
11 REQUIREMENTS.

12 DR. CIBELLI: I HAVE A QUESTION. DO YOU
13 HAVE -- JUST TO MOVE ON TO THE NEXT. DO YOU HAVE AN
14 IDEA -- THIS IS GOING TO BE A GROUP OF PEOPLE SITTING
15 AROUND THE TABLE WORKING PRETTY HARD TO SEE IF THE
16 GRANT PROPOSAL ACTUALLY MEET THE STANDARDS OR NOT. SO
17 DO WE HAVE AN IDEA OF HOW MANY GRANT PROPOSALS YOU'RE
18 GOING TO ENTERTAIN IN A YEAR?

19 DR. HALL: NO. WE IMAGINE SEVERAL HUNDRED.
20 SEVERAL HUNDRED.

21 MR. SHESTACK: OF DIFFERENT TYPES. SEVERAL
22 DIFFERENT.

23 DR. HALL: DIFFERENT TYPES.

24 MR. SHESTACK: LARGE INSTITUTIONAL.

25 DR. HALL: MOSTLY WILL BE FROM THE -- IN

1 TERMS OF NUMBERS, MOSTLY IT WILL BE FROM INDIVIDUAL
2 INVESTIGATORS. JUST THE WAY IT WORKS OUT. DOLLARS,
3 THAT WON'T BE TRUE.

4 DR. CIBELLI: THAT IS SOMEWHERE BETWEEN A
5 HUNDRED TO --

6 DR. HALL: SEVERAL HUNDRED. I WOULD SAY
7 PULLING NUMBERS OUT OF THE AIR, BUT I WOULD SAY 2 TO
8 300. WHEN WE'RE UP AND GOING FULL SWING, I WOULD SAY
9 MAYBE 2 TO 300, MAYBE 400 A YEAR.

10 DR. CIBELLI: SO IT APPEARS TO ME THAT WE
11 HAVE SET A LIMIT OF HOW MANY PROPOSALS A GROUP OF
12 PEOPLE CAN ACTUALLY REVIEW PROPERLY AS PART OF AN
13 ESCRO.

14 DR. HALL: WE ARE VERY WORRIED ABOUT THAT IN
15 TERMS OF THE GRANTS REVIEW COMMITTEE.

16 DR. CIBELLI: HOW DO YOU DEAL WITH THAT?

17 DR. HALL: WELL, WE MAY -- I DON'T KNOW. WE
18 HAVE RUN UP AGAINST PROP 71. WE ORIGINALLY THOUGHT
19 WE'D TRY TO HAVE SOME ARRANGEMENT FOR MULTIPLE
20 COMMITTEES. WE MIGHT HAVE SOME WAY OF SPLITTING THE
21 GRANT. I'M NOT SURE WE'LL BE ABLE TO DO THAT. SO I
22 DON'T KNOW. AT THE BEGINNING WE WILL TRY TO TARGET
23 THEM VERY CAREFULLY SO THAT WE TAKE A SMALL BITE UNTIL
24 WE SEE HOW; THAT IS, WE WILL HAVE PEOPLE -- WE WILL SAY
25 WE WANT GRANTS IN THIS PARTICULAR AREA, AND THEN WE'LL

1 HAVE PEOPLE SEND A LETTER OF INTENT SO THEN WE KNOW HOW
2 MANY WE'VE GOT COMING. AND THEN WE WILL TRY TO
3 MANEUVER FROM THAT.

4 LET ME JUST GIVE YOU A RULE OF THUMB. LET'S
5 JUST SAY WE'VE GOT, WHAT, ROUGHLY \$250 MILLION A YEAR
6 WE'RE GIVING OUT. LET'S SAY THAT AN AVERAGE-SIZE GRANT
7 OR MEDIUM-SIZED GRANT WOULD BE ONE TO TWO MILLION,
8 SOMETHING LIKE THAT. LET'S SAY WE'RE GOING TO HAVE A
9 HUNDRED SUCCESSFUL GRANTS EVERY YEAR, A HUNDRED TO 200,
10 150.

11 NOW, WHAT'S OUR ACCEPTANCE RATE GOING TO BE?

12 DR. CIBELLI: LET ME WORK THE OTHER WAY. DO
13 YOU KNOW, FOR EXAMPLE, FROM EXPERIENCE, NIH PEOPLE
14 PROBABLY CAN ANSWER THIS VERY QUICKLY, HOW MANY
15 REVIEWERS DO YOU NEED FOR X AMOUNT OF PROPOSALS THAT
16 ARE COMING TO A STUDY SECTION?

17 DR. TAYLOR: TWENTY REVIEWERS FOR 70 GRANTS.

18 DR. HALL: THEY MEET THREE TIMES A YEAR. SO
19 THAT'S A LOT.

20 DR. TAYLOR: SEVENTY GRANTS A SHOT. SOME OF
21 THEM ARE REPEAT OFFENDERS.

22 DR. HALL: SO THAT'S PRECISELY WHAT WE'RE
23 WORRIED ABOUT.

24 CO-CHAIR LO: THAT'S A HUNDRED REVIEWERS.

25 DR. KIESSLING: THAT'S JUST TWO OR THREE DAYS

1 TIME FOR A DOZEN PEOPLE.

2 DR. CIBELLI: JANET COMMENTS IT'S A LOT OF
3 WORK. SO THIS IS GOING TO HAVE TO HAVE AN RFA, AND YOU
4 HAVE TO HAVE -- I'M TRYING TO FIND OUT IF IT'S GOING TO
5 BE -- HOW SMALL WE GOING TO HAVE TO SLICE THE PIE.
6 FIRST OF ALL, WE CAN'T DO IT. WE AS A STANDARD GROUP,
7 WE HAVE TO QUIT OUR DAY JOBS TO BE DOING THIS EVERY
8 DAY.

9 DR. KIESSLING: JOSE, WE'RE TALKING ABOUT TWO
10 OR THREE DAYS' WORK FOR A GROUP OF A DOZEN PEOPLE.

11 DR. HALL: I THINK WHAT JANET SAID BEFORE I
12 VERY MUCH ENDORSE. PARTICULARLY AT THE BEGINNING,
13 THERE'S JUST GOING TO BE A LOT OF WORK TO BE DONE OF
14 PEOPLE SAYING SHALL WE DO THIS, SHALL WE NOT. JUST TO
15 FIGURE OUT WHAT THE JOB IS AND TO DO IT IS GOING TO BE,
16 I THINK, VERY, VERY HARD, AND I THINK IT'S GOING TO
17 TAKE FACE-TO-FACE TALK. I JUST THINK IT'S GOING TO BE
18 A LOT OF WORK. LOOK AT --

19 DR. ROWLEY: WE'VE SPENT MORE THAN TWO HOURS
20 ON A RELATIVELY NARROW ISSUE.

21 MR. HARRISON: COULD I JUST MAKE ONE POINT OF
22 CLARIFICATION? THE REQUIREMENT THAT YOU'RE IMPOSING IS
23 THE REQUIREMENT THAT AN INVESTIGATOR OBTAIN ESCRO
24 REVIEW AND APPROVAL. WHAT YOU'RE SETTING FORTH THROUGH
25 FRANCISCO'S LANGUAGE ARE THE VARIOUS OPTIONS BY WHICH

1 THE INVESTIGATOR CAN OBTAIN SUCH APPROVAL.

2 DR. HALL: ONE QUESTION THAT I'M A LITTLE
3 UNCLEAR ABOUT IS WHETHER WE REQUIRE THE INSTITUTION TO
4 HAVE SOME ARRANGEMENT FOR AN ESCRO OR AN INDIVIDUAL?
5 AND IF -- IT'S A LITTLE COMPLICATED. AN INDIVIDUAL
6 PRESUMABLY CAN'T GO OUTSIDE THEIR INSTITUTIONAL
7 ARRANGEMENT. AND MY ORIGINAL WAY OF THINKING ABOUT
8 THIS IS ACTUALLY THAT WE REQUIRE -- I THINK LEGALLY WHO
9 APPLIES TO US IS NOT THE INVESTIGATOR. IT'S THE
10 INSTITUTION. AND WE REQUIRE ANY INSTITUTION THAT
11 APPLIES TO US TO HAVE AN ESCRO, HAVE THE GRANTS BE
12 APPROVED BY ESCRO, EITHER THEIR OWN ESCRO, ONE THEY'VE
13 AGREED TO THROUGH THEIR INSTITUTION, OR ONE THAT'S BEEN
14 SET UP ON A STATE LEVEL THAT THEY PARTICIPATE IN.
15 THAT, I THINK, WOULD BE THE RIGHT WAY TO DO IT.

16 MR. HARRISON: THAT'S ABSOLUTELY CORRECT. I
17 THINK IT HIGHLIGHTS THAT POINT THAT YOU RAISED EARLIER
18 WITH RESPECT TO THE APPEAL ISSUE. IF THE INSTITUTION
19 WILL NOT APPROVE ITS PROJECT, IT'S THE INSTITUTION
20 THAT'S APPLYING FOR THE GRANT. SO THERE WOULD BE A BIT
21 OF A DISCONNECT THERE.

22 DR. KIESSLING: THAT'S GOING TO BE REALLY
23 HARD FOR SMALL BUSINESSES, THAT KIND OF A CONCEPT.

24 DR. HALL: SMALL BUSINESSES?

25 DR. KIESSLING: YEAH.

1 DR. HALL: YES. THERE MAY HAVE TO BE A
2 SPECIAL ARRANGEMENT.

3 DR. KIESSLING: THE NIH STANDARD IS REALLY
4 THAT THIS IS THE JOB OF THE PRINCIPAL INVESTIGATOR.
5 IT'S MY RESPONSIBILITY TO GET INSTITUTIONAL REVIEW.

6 DR. HALL: IT'S YOUR INSTITUTION'S
7 RESPONSIBILITY TO HAVE THAT BOARD.

8 DR. KIESSLING: IT'S MY INSTITUTION ONLY IF
9 THEY WANT TO ACCEPT THE MONEY. IF I DON'T LIKE WHAT MY
10 INSTITUTION DOES, AND I HAVE AN NIH GRANT, I CAN GO TO
11 ANOTHER INSTITUTION. IT'S MY RESPONSIBILITY AS A
12 PRINCIPAL INVESTIGATOR TO GET THE APPROPRIATE REVIEW
13 FOR THE PROJECT I'VE PROPOSED. PRINCIPAL INVESTIGATOR
14 DRIVEN RESEARCH IS VERY INDIVIDUAL. I CAN SHOP
15 INSTITUTIONS.

16 MR. HARRISON: SO THE GRANT IS WITH THE
17 PRINCIPAL INVESTIGATOR, NOT THE PRINCIPAL
18 INVESTIGATOR'S INSTITUTION.

19 DR. HALL: I'M SORRY. I'M SORRY. IT'S THE
20 INSTITUTION -- THE GRANT IS AWARDED TO THE INSTITUTION.
21 IF YOU DECIDE TO MOVE, THE INSTITUTION WILL LET YOU
22 MOVE YOUR GRANT, BUT THE GRANT IS TO THE INSTITUTION.

23 DR. KIESSLING: IF THAT INSTITUTION ACCEPTS
24 IT.

25 DR. HALL: ABSOLUTELY THE CASE. AND IT IS --

1 DR. KIESSLING: IT'S MY RESPONSIBILITY TO GET
2 THE APPROPRIATE OVERSIGHT.

3 DR. HALL: THE INSTITUTION SIGNS OFF ON IT,
4 ANN, THAT ALL OVERSIGHT -- THAT IT'S GOTTEN ANIMAL --
5 ALL APPROPRIATE OVERSIGHT COMMITTEES HAVE BEEN DONE.
6 THE INSTITUTION SIGNS OFF ON IT. NIH WILL NOT ACCEPT
7 THE GRANT UNLESS IT DOES.

8 DR. ROWLEY: THOSE ARE FEDERAL REGULATIONS.

9 DR. HALL: I'VE BEEN ON BOTH SIDES OF THAT.

10 DR. KIESSLING: THOSE ARE BLANKET ASSURANCE
11 COMPLIANCE KINDS OF THINGS THAT INSTITUTIONS GET.

12 DR. HALL: FOR EACH GRANT, THE PERSON IN YOUR
13 CONTRACTS AND GRANTS OFFICE SAYS ALL APPROPRIATE
14 REGULATIONS HAVE BEEN DONE, AND THEY SIGN ON BEHALF OF
15 THE INSTITUTION.

16 DR. KIESSLING: THAT'S RIGHT.

17 DR. HALL: IT'S NOT YOU THAT SAYS I HAVE ALL
18 THIS STUFF. THE INSTITUTION SAYS IT'S GONE THROUGH.

19 DR. KIESSLING: I KNOW THAT, BUT IT WAS MY
20 JOB TO GET IT DONE.

21 DR. HALL: OTHERWISE, THEY WON'T DO IT. THEY
22 WON'T SIGN OFF ON IT. IN TERMS OF WHO STANDS BEHIND
23 IT, IT'S THE INSTITUTION.

24 MR. SHEEHY: IT SEEMS LIKE WE HAVE A MOTION
25 ON THE FLOOR. I'M NOT REALLY SURE IN TERMS OF PROCESS

1 BECAUSE WE'RE KIND OF ALL OVER THE PLACE. BUT I DON'T
2 WANT TO -- I REALLY HAVE A DIFFERENT OPTION THAT I
3 DON'T KNOW IF I NEED TO MAKE A MOTION TO BE CONSIDERED
4 IN OPPOSITION OR HOW. I REALLY FEEL FIRMLY THAT WE
5 SHOULD AT LEAST TAKE A VOTE AND CONSIDER THE NOTION OF
6 SETTING UP TWO REGIONAL ESCRO'S, A NORTHERN AND
7 SOUTHERN CALIFORNIA, THAT WOULD BE FUNDED BY CIRM AS AN
8 RFA SO THAT IT DOESN'T INVOLVE THE STAFF, DOESN'T
9 INVOLVE STAFF, THAT EVERYONE WOULD HAVE TO GO THROUGH,
10 DEPENDING ON WHERE YOU WERE LOCATED. I FEEL LIKE -- I
11 THINK THAT'S WHAT INITIATED THIS WHOLE DISCUSSION TODAY
12 WITH JONATHAN WAY BACK WHEN, AND I'D LIKE TO AT LEAST
13 HAVE SOME CONSIDERATION OF A CENTRALIZED ESCRO VERSUS A
14 DECENTRALIZED RATHER THAN HAVING A MOTION THAT IS
15 FUNDAMENTALLY DECENTRALIZED WITHOUT EVER HAVING
16 DIRECTLY ADDRESSED THE CENTRALIZED MOTION.

17 CO-CHAIR LO: THIS IS THEN PRESCRIPTIVE, THAT
18 YOU DON'T HAVE OPTIONS. YOU MAY HAVE -- YOU HAVE TO GO
19 TO THIS CIRM SET-UP ESCRO. YOU MAY, I SUPPOSE, ALSO GO
20 TO YOUR INSTITUTIONAL ESCRO IF YOU WANT TO, BUT THAT'S
21 NOT GOING TO BE GOOD ENOUGH.

22 MR. SHEEHY: MIGHT HAVE TO DO THEIR COMMITTEE
23 ON ANIMALS. MIGHT HAVE TO DO THEIR OWN IRB.

24 CO-CHAIR LO: ACTUALLY THERE'S A MOTION ON
25 THE FLOOR. SO I AM NOT REAL UP ON MY ROBERT'S RULES OF

1 ORDER.

2 DR. HALL: YOU HAVE COMMENT FROM THE
3 COMMITTEE, COMMENT FROM THE PUBLIC, AND THEN VOTE.

4 DR. ROWLEY: HAS IT BEEN SECONDED?

5 CO-CHAIR LO: THAT MOTION WAS SECONDED.

6 DR. PETERS: WE COULD JUST INTERPRET WHAT
7 JEFF IS DOING AS SPEAKING AGAINST THE MOTION.

8 COULD I ASK JEFF A QUESTION OF CLARIFICATION?
9 ARE YOU SERIOUS ABOUT HAVING TWO SEPARATE ESCRO'S, OR
10 WOULD IT BE ONE CENTRALIZED ESCRO THAT WOULD HAVE TWO
11 DIVISIONS?

12 MR. SHEEHY: I'M -- IT REALLY -- IT'S
13 SOMETHING THAT, IF THE RFA WERE PUT OUT PROPERLY, WOULD
14 HAVE THE ABILITY TO GROW IN ACCORDANCE WITH THE -- TO
15 SHRINK AND GROW IN ACCORDANCE WITH THE NUMBER OF
16 APPLICATIONS IN THAT FIELD.

17 CO-CHAIR LO: LET'S TRY AND --

18 MR. SHEEHY: A REGIONAL COMPONENT MIGHT --
19 GIVEN THAT THERE HAS BEEN A SENSE THAT THERE MIGHT BE
20 THE NEED FOR SOME FACE-TO-FACE COMMUNICATION, I DO KIND
21 OF THINK HAVING A REGIONAL COMPONENT MIGHT BE AN
22 IMPORTANT ASPECT.

23 CO-CHAIR LO: JOSE, AND THEN WE NEED TO GET
24 SOME PUBLIC COMMENT.

25 DR. CIBELLI: I THINK IT'S GOING TO BE

1 IRRESPONSIBLE FOR US TO SAY HOW MANY ESCRO'S ARE NEEDED
2 BECAUSE WE HAVE NO IDEA OF THE WORKLOAD, NO IDEA HOW
3 MANY PROPOSALS. AND IF YOU REALLY WANT TO HAVE QUALITY
4 PEOPLE, THEY ARE GOING TO HAVE OTHER JOBS TO DO. I
5 MEAN THEY'RE PROBABLY PROFESSORS IN DIFFERENT
6 UNIVERSITIES OR CONSULTANTS. SO I THINK I DISAGREE IN
7 THIS CASE WITH JEFF ABOUT THE --

8 CO-CHAIR LO: I SUGGEST THERE WAS A MOTION
9 MADE AND SECONDED THAT'S UP THERE. WE NOW KNOW THERE'S
10 ANOTHER MOTION THAT'S GOING TO BE MADE, BUT LET'S VOTE
11 ON THIS. I THINK WE'VE TALKED ABOUT IT, BUT LET'S GET
12 PUBLIC COMMENT ON THIS PARTICULAR MOTION THAT'S ON THE
13 SCREEN.

14 MR. REED: MY GUT INSTINCT IS TO --

15 CO-CHAIR LO: FOR THE RECORD COULD YOU JUST
16 INTRODUCE YOURSELF?

17 MR. REED: DON REED, PUBLIC PERSON. MY GUT
18 INSTINCT IS TO OPPOSE ANY FURTHER LAYERS OF
19 BUREAUCRACY. I THINK THAT WE HAVE OUTSTANDING
20 SCIENTISTS, ETHICISTS, AND PEOPLE IN EVERY FIELD THAT
21 ARE ALREADY HIGHLY QUALIFIED AND COMPETENT TO MAKE THE
22 DECISIONS THAT AN ESCRO MIGHT BE INVOLVED IN. HOWEVER,
23 IF FOR WHATEVER REASON AN ESCRO IS DETERMINED TO BE
24 USEFUL, THEN I THINK IT MIGHT WANT TO INCLUDE SOME
25 SENTENCE IN THERE, A, THAT IT CANNOT OVERRIDE THE

1 CIRM'S DECISION AND, B, THAT THE DECISION ON ESCRO
2 INVOLVEMENT BE MADE ON AN INDIVIDUAL BASIS.

3 FOR INSTANCE, THE ROMAN REED ACT HAS FUNDED
4 ROUGHLY 50 SCIENTIFIC PROJECTS. ONLY ONE HAS BEEN
5 CONTROVERSIAL. WHY SHOULD AN ESCRO HAVE TO TAKE UP ALL
6 THEIR TIME, DO A STUDY OVER A NONCONTROVERSIAL ITEM?
7 PERHAPS IT MIGHT BE THAT IF THE SCIENTISTS ON THE
8 REVIEW BOARD SAY THIS IS GOING TO BE KIND OF IFFY, WE
9 HAVE SOME OPPOSITION, THEY MIGHT RECOMMEND THAT AN
10 ESCRO LOOK IT AT, BUT I DON'T THINK IT SHOULD BE AN
11 AUTOMATIC THING BECAUSE IT WILL BE AN OVERWHELMING
12 BURDEN ON THE SYSTEM.

13 ALSO, AN ITEM THAT WAS MENTIONED EARLIER THAT
14 THERE WAS NO COMMENT ALLOWED ON OR THOUGHT OF, WHICH I
15 THINK IS A VERY GOOD IDEA, AND THANK YOU FOR LETTING US
16 HAVE THIS BEFORE THE VOTE, THE ONLY TIME PUBLIC COMMENT
17 MATTERS IS BEFORE THE VOTE, WAS THAT WAS IT APPROPRIATE
18 TO ASK DR. PATRICIA KING WHAT HER STAND WAS ON SCNT.
19 SCNT IS IN THE CALIFORNIA STATE CONSTITUTION. SO I
20 THINK IT'S ENTIRELY APPROPRIATE TO ASK IS THERE ANY
21 PORTION OF PROPOSITION 71, WHICH IS IN THE STATE
22 CONSTITUTION, WHICH YOU DO NOT SUPPORT, WHICH YOU WOULD
23 HAVE PROBLEMS OPPOSING?

24 EVERY PERSON THAT'S IN THE SENATE OR HOUSE OF
25 REPRESENTATIVES HAS TO SWEAR TO UPHOLD THE

1 CONSTITUTION. SCNT IS IN THE STATE CONSTITUTION. IF A
2 PERSON HAS A PROBLEM AND THEY CANNOT SUPPORT IT, THEY
3 SHOULD NOT BE A PART OF THIS. THOSE ARE MY THOUGHTS.

4 CO-CHAIR LO: ANY OTHER PUBLIC COMMENTS?
5 HEARING NONE, DOES SOMEONE WANT TO CALL THE QUESTION?

6 MR. KLEIN: CALL THE QUESTION.

7 CO-CHAIR LO: ALL THOSE IN FAVOR OF THE
8 MOTION, THAT AN INSTITUTION, GROUP OF INSTITUTIONS, THE
9 CIRM, OR OTHER STATE AGENCY MAY CONVENE AN ESCRO.

10 MR. KLEIN: YOU WANT HANDS?

11 CO-CHAIR LO: WHY DON'T YOU DO HANDS. TWO ON
12 THE PHONE?

13 DR. KORDOWER: AYE.

14 DR. EGGAN: AYE.

15 CO-CHAIR LO: TWO MORE AYES ON THE PHONE.
16 OPPOSED? TWO OPPOSED. ANY ABSTENTIONS?

17 DR. KIESSLING: I'M GOING TO ABSTAIN.

18 CO-CHAIR LO: TWO NOES AND THREE ABSTENTIONS.
19 KATE, YOU WANT TO GIVE ME THE TALLY ON THAT?

20 MS. SHREVE: EIGHT IN FAVOR, TWO NOES, TWO
21 ABSTENTIONS -- THREE ABSTENTIONS.

22 CO-CHAIR LO: DO THE NUMBERS ADD UP? LET'S
23 HAVE A REVOTE. ALL THOSE IN FAVOR RAISE YOUR HANDS,
24 AND KATE WILL WRITE YOU DOWN. THERE SHOULD BE NINE
25 HANDS UP, PLUS THE TWO ON THE PHONE. AND OPPOSED?

1 THERE WERE TWO LAST TIME. STILL ARE TWO. AND
2 ABSTENTIONS, THERE WERE THREE LAST TIME. STILL THREE.
3 THAT SHOULD ADD UP. OKAY.

4 JEFF, DID YOU WANT TO MAKE A FORMAL MOTION?

5 MR. SHEEHY: MAYBE THE MOTION SHOULD BE THAT
6 THIS COMMITTEE AS A TANGENT TO THIS RECOMMEND TO THE
7 ICOC THAT THE ICOC CONSIDER, AS PART OF ADOPTING THESE
8 REGULATIONS, THE ISSUANCE OF AN RFA TO CREATE A
9 STATEWIDE ESCRO THAT WOULD SERVE FOR INDUSTRY, FOR
10 INSTITUTIONS THAT EITHER FOR SIZE OR WHATEVER OTHER
11 REASON MAY NOT WISH TO SET UP AN ESCRO, BUT KIND OF A
12 CATCHALL JUST BECAUSE WHAT WE'VE DONE NOW IS SET UP A
13 SITUATION WHERE, IF YOU'RE A BIG INSTITUTION AND YOU'RE
14 APPLYING TO DO STEM CELL RESEARCH, YOU'RE FINE, BUT
15 EVERYBODY ELSE, WELL, GOOD LUCK. WE'RE KIND OF
16 COUNTING ON THE BENEVOLENCE OF THE BIG INSTITUTIONS NOW
17 TO KIND OF BRING EVERYBODY ELSE ALONG.

18 CO-CHAIR LO: DOES SOMEONE WANT TO SECOND
19 THAT?

20 DR. PETERS: I'LL SECOND IT. AS I SECOND IT,
21 I WANT TO ASK PERMISSION FROM THE MOTION MAKER HERE IS
22 IT YOUR INTENTION THAT THOSE WHO WOULD GO TO THE
23 STATEWIDE ESCRO WOULD DO SO ON A VOLUNTARY OR A
24 MANDATED BASIS?

25 MR. SHEEHY: THAT WOULD BE THE ESCRO THAT

1 THEY WOULD APPEAL TO, THAT THEY COULD GO TO IN THE
2 ABSENCE OF ONE SET UP BY THEIR INSTITUTION.

3 CO-CHAIR LANSING: IT'S VOLUNTARY.

4 MR. SHEEHY: EVERYONE HAS TO GET THEIR
5 RESEARCH APPROVED BY AN ESCRO IN ORDER TO BE FUNDED.
6 SO THIS DOES NOT DENY SOMEONE AN OPPORTUNITY TO BE
7 FUNDED BECAUSE THEIR INSTITUTION OR THEIR COMPANY DOES
8 NOT HAVE AN ESCRO.

9 CO-CHAIR LANSING: IN OTHER WORDS, IF THERE'S
10 NO PLACE -- YOU SAID IT BETTER -- IF YOUR INSTITUTION
11 DOESN'T HAVE AN ESCRO OR THERE'S NO ESCRO AVAILABLE FOR
12 YOU, YOU CAN ALWAYS COME TO THIS ESCRO. SO, THEREFORE,
13 NO ONE WOULD BE DENIED THE OPPORTUNITY TO HAVE THEIR
14 RESEARCH REVIEWED.

15 CO-CHAIR LO: LET'S HAVE DISCUSSION ON JEFF'S
16 MOTION.

17 DR. CIBELLI: I HAVE A QUESTION FOR PEOPLE
18 THAT HAVE DONE A LOT OF HUMAN RESEARCH. IF YOU'RE A
19 SMALL COMPANY AND YOU'RE GETTING INTO CLINICAL TRIAL
20 WITH HUMAN SUBJECTS, YOU DON'T HAVE AN IRB IN YOUR
21 INSTITUTION, HOW DO YOU DEAL WITH THAT? SO THIS WILL
22 BE A SIMILAR SITUATION. IT OCCURS TO ME THAT WE'RE
23 GOING TO HAVE A SIMILAR SITUATION. YOU GO TO A
24 COMMERCIAL PLACE OR SOMETHING SPONSORED BY CIRM. IS
25 THAT THE WAY YOU WOULD DO IT?

1 DR. HALL: I THINK COMPANIES SHOULD PAY FOR
2 IT. IF THEY -- SHOULD BE PART OF THEIR EXPENSE OF
3 DOING BUSINESS IS TO PAY FOR THE ESCRO. I DON'T SEE
4 THAT WE SHOULD DO THAT.

5 DR. PRIETO: CAN AN ESCRO CHARGE?

6 MR. KLEIN: YOU COULD HAVE A CHARGE-BASED
7 SYSTEM, WHICH MEANS THAT THE STATE ENTITY, RATHER THAN
8 COMING OUT OF OUR OVERHEAD ALLOWANCE, COULD HAVE A
9 CHARGE-BASED SYSTEM SO THAT WHEN YOU APPLY FOR A GRANT,
10 YOUR GRANT INCLUDES THE MONEY TO PROCESS THIS THROUGH
11 THE STATE-BASED SYSTEM.

12 DR. TAYLOR: UNIVERSITY IRB'S DO THAT.

13 MR. SHEEHY: IT COULD BE AN EXISTING ESCRO
14 LIKE UCSF OR UCLA THAT COMPETE FOR THIS AND RECOUP THE
15 COST.

16 DR. PRIETO: IF THEY'RE WILLING TO DO THE
17 WORK FOR PEOPLE COMING FROM OUTSIDE THEIR INSTITUTION.

18 CO-CHAIR LO: JOSE AND JON, THEN BOB, AND
19 THEN JANET.

20 MR. SHESTACK: THIS IS THE PERSON WHO SORT OF
21 STARTED THIS CASCADE. JEFF'S MOTION MIGHT BE THE BEST
22 SORT OF AD LIB RESPONSE, BUT I GUESS WHAT I WANTED TO
23 POINT OUT WAS THE PROCESS. AND THAT CHOICES -- I DON'T
24 KNOW WHAT A BETTER PROCESS IS, BUT WE'RE BEING ASKED TO
25 GO THE NEXT STEP ON THE INTERIM GUIDELINES, BASICALLY

1 TO POLISH THESE GUIDELINES FOR ADOPTION. AND THE
2 CHOICES THAT WE ARE GIVEN, FOR INSTANCE, ON THIS ISSUE,
3 FOR ME PERSONALLY IS ABSOLUTELY THE LEAST INTERESTING
4 ISSUE OF ALL, WERE EXTREMELY THIN AND DIDN'T ACTUALLY
5 TAKE INTO CONSIDERATION FOR OUR -- TAKE INTO
6 CONSIDERATION THINGS LIKE INDUSTRY USE, THINGS LIKE
7 STREAMLINING THE PROCESS FOR INVESTIGATORS, SPEEDING IT
8 UP FOR STAKEHOLDERS.

9 WE'RE FORCED TO NOW MAKE A DECISION AND COME
10 UP WITH SOMETHING ON THE FLY THAT MAYBE IS GOOD, MAYBE
11 ISN'T, HARD TO KNOW. HOW CAN WE CHANGE THE PROCESS A
12 LITTLE BIT SO THAT MAYBE JEFF'S MOTION SHOULD BE MORE
13 PROPERLY IS THAT THE CIRM SHOULD HIRE SOMEBODY TO DO A
14 LITTLE STUDY AND COME BACK WITH LIKE WINICOFF'S PAPER,
15 COME UP WITH SOME REAL CONSIDERATION CHOICES. WHAT IS
16 THE BEST WAY FOR US TO DO IT?

17 I FEEL LIKE WE'RE NOT -- IT'S ACTUALLY AN
18 IMPORTANT ISSUE, AND WE'RE NOT GIVEN VERY MANY CHOICES,
19 AND THEN WE ARE TOLD TO DECIDE IT BEFORE LUNCH, WHICH
20 WE SHOULD BECAUSE OTHERWISE WE'LL NEVER GET OUT OF
21 HERE. WHAT'S A BETTER WAY? THIS WAY, IT DOESN'T
22 SEEM -- I DON'T FEEL LIKE I'M SERVING CALIFORNIANS THIS
23 WAY. I JUST DON'T. I FEEL LIKE WHAT I'M DOING IS I'M
24 BASICALLY SAYING WE WILL DO BUSINESS EXACTLY THE WAY IT
25 HAS BEEN DONE BEFORE, WHICH IS NOT BAD, WORKS OKAY FOR

1 A \$28-BILLION INSTITUTION, BUT I DON'T THINK IT WORKS
2 SO GOOD FOR A \$300-MILLION INSTITUTION. THAT'S WHAT
3 WE'RE BEING ASKED TO DO. JUST DO IT THE WAY IT'S BEEN
4 DONE BEFORE AND NOT TAKE THE OPPORTUNITY MAYBE DO IT
5 BETTER.

6 I DON'T KNOW THE ANSWER, BUT I FEEL LIKE IT
7 IS -- WE'RE MISSING THE MARK A LITTLE BIT.

8 MR. KLEIN: JUST TO ADD TO MY COMMENTS THAT
9 RELATE TO JON'S POSITION, PART OF THE CONCEPT OF THE
10 STANDARDS COMMITTEE WAS TO BRING TOGETHER TREMENDOUS
11 EXPERTISE THAT YOU COULD NEVER AFFORD TO INCORPORATE IN
12 A STAFF LEVEL, PARTICULARLY WITH THE LIMITED STAFF WE
13 HAVE, SO THAT WE WOULD HAVE IN REAL TIME RESEARCHERS,
14 ETHICISTS, AND PEOPLE FROM PATIENT ADVOCACY GROUPS WHO
15 WOULD PUT TOGETHER A BETTER MODEL. AND WHAT JEFF, FOR
16 EXAMPLE, IS SUGGESTING RIGHT HERE IS AN INNOVATION TO
17 CREATE A BETTER MODEL, BETTER THAN THE STANDARD SYSTEM.
18 AND, YES, WE'RE OPERATING IN REAL TIME BECAUSE OF THE
19 CONSTRAINTS UPON US, BUT WE'RE CREATING INTERIM
20 PROCESSES THAT WILL GO UNDER A MORE RIGOROUS SCRUTINY
21 THROUGH A PUBLIC HEARING PROCESS.

22 BUT THE PURPOSE OF THIS STANDARDS COMMITTEE
23 IS TO BRING TOGETHER THE EXPERTISE TO MOVE FORWARD
24 QUICKLY, BUT WITH THE THOUGHTFUL BENEFIT OF MORE THAN A
25 HUNDRED YEARS OF RESEARCH AT THIS TABLE IN THE

1 AGGREGATE, INCLUDING ON THE PHONE, BY THE WAY. SO I DO
2 THINK THAT THAT'S VERY EFFECTIVE.

3 BUT I WANTED TO ASK JEFF IN TERMS OF THIS
4 STATEWIDE ESCRO, THEORETICALLY, AT LEAST, IN
5 IMPLEMENTING THIS ESCRO, YOU COULD PUT OUT AN RFP, BUT
6 THAT WOULDN'T STOP THIS COMMITTEE OR THE ICOC FROM, IN
7 FACT, RECRUITING PEOPLE VOLUNTARILY WHO WOULD SERVE ON
8 THE STATEWIDE ESCRO WHO WERE FROM VARIOUS INSTITUTIONS
9 AND/OR THE PRIVATE SECTOR WHO COULD CONTRIBUTE TO THAT
10 ESCRO REVIEW.

11 THE COMMERCIAL ENTITY COULD RUN IT, BUT
12 THEORETICALLY YOU COULD BRING EXPERTISE TO THAT GROUP
13 IN ITS COMPOSITION.

14 NOW, I'M GOING TO VOTE ON YOUR MOTION AS IT
15 STANDS, BUT YOU MIGHT WANT TO IN THIS MEETING OR IN A
16 LATER MEETING GO FURTHER IN TERMS OF LAYING OUT THE
17 IMPLEMENTATION.

18 MR. SHEEHY: I DEFINITELY THINK THIS IS
19 SOMETHING -- MAYBE SINCE WE'RE MAKING THE
20 RECOMMENDATION TO THE ICOC, MAYBE THIS IS SOMETHING
21 THAT CAN BE KICKED UP, MAYBE RUN THROUGH THE GOVERNANCE
22 SUBCOMMITTEE. SORRY, SHERRY. BUT I WONDER -- I THINK
23 THE CHANGE TO THE FIRST WORD SHOULD BE REQUIRE RATHER
24 THAN RECOMMEND THAT THE ICOC.

25 DR. HALL: DO YOU WANT TO SAY THAT FUNDING BE

1 APPROVED OR TO ISSUE AN RFA? FUNDING BE APPROVED FOR
2 AN RFA?

3 MR. SHEEHY: I'LL BE BLUNT. MY ISSUE HERE IS
4 I THINK WE CREATED A BARRIER TO ENTRY. IF I CAN BE
5 PERSUADED THAT BY LEAVING THIS UP TO LARGE INSTITUTIONS
6 ALREADY ARE DOING THIS AND WE HAVEN'T CREATED A BARRIER
7 TO ENTRY, I FEEL UNCOMFORTABLE. WHATEVER LANGUAGE,
8 THAT WOULD ALLOW FOR THE ESTABLISHMENT -- I THINK
9 PEOPLE ARE PRETTY GOOD ABOUT RECOUPING THEIR COST FROM
10 THESE KINDS OF THINGS. WE SEE IT WITH CORE LABS ALL
11 THE TIME. I THINK IRB'S ARE ABLE TO RECOUP SOME COST.
12 SOMETHING THAT ALLOWS FOR SOME THIRD -- SOME SEPARATE
13 ENTITY THAT WOULD TAKE AN APPLICATION FROM ANYWHERE IN
14 THE STATE, REVIEW IT SO THAT NO RESEARCHER WOULD BE
15 DENIED THE OPPORTUNITY TO SUBMIT AN APPLICATION FOR
16 THESE FUNDS. I DON'T WANT TO REQUIRE THAT SOMEONE HAS
17 TO BE ASSOCIATED --

18 DR. CIBELLI: CHANGE THE LANGUAGE.

19 DR. PRIETO: CAN I MAKE A FRIENDLY AMENDMENT?

20 DR. HALL: ALL WE WANT IS THE ICOC TO DISCUSS
21 THIS. WE HAVE ON THE ICOC REPRESENTATIVES OF THE
22 PRIVATE SECTOR, WE HAVE INSTITUTIONAL REPRESENTATIVES,
23 WE HAVE PATIENT ADVOCATES. AND SO I THINK I WOULD
24 SUGGEST, RATHER THAN SPEND A LOT OF TIME ON THIS, JUST
25 GET SOMETHING THAT WILL GET THE ISSUE BEFORE THE ICOC,

1 AND THEN WE JUST MOVE ON. I THINK YOUR SUGGESTION IS A
2 VERY GOOD ONE, JEFF, IN THAT THAT'S THE RIGHT PLACE TO
3 DISCUSS IT.

4 MR. SHEEHY: THAT'S FINE WITH ME.

5 DR. PRIETO: COULD I MAKE A SUGGESTION -- A
6 FRIENDLY AMENDMENT, THAT RECOMMEND TO THE ICOC THAT AN
7 RFA BE GENERATED TO ESTABLISH A STATEWIDE ESCRO.

8 CO-CHAIR LANSING: I DON'T THINK THAT'S WHAT
9 HE SAID. WHAT YOU REALLY WANT TO RECOMMEND TO THE ICOC
10 IS THAT A MECHANISM BE PUT IN PLACE TO MAKE SURE THAT
11 NO INSTITUTION IS DENIED RESEARCH BECAUSE THEY DON'T
12 HAVE AN ESCRO.

13 MR. SHEEHY: OR NO INVESTIGATOR.

14 CO-CHAIR LANSING: INVESTIGATOR IS DENIED.

15 DR. HALL: THAT DISCUSSION CAN BE MADE -- THE
16 POINT CAN BE MADE -- THAT'S THE PURPOSE OF HAVING THIS,
17 AND THEN YOU CAN MAKE THE POINT WHEN IT COMES UP.

18 MR. SHEEHY: MAYBE IF WE COULD COUNT ON STAFF
19 TO TAKE THAT LAST COMMENT AND MAKE THAT PART OF THE
20 RECOMMENDATION, AND WE CAN JUST MAYBE QUICKLY PUT THIS
21 THROUGH AS A RECOMMENDATION TO THE ICOC AS PART OF THE
22 STAFF REPORT AND TRUST STAFF TO BRING THIS UP AT THE
23 APPROPRIATE TIME.

24 DR. HALL: SO THAT NO INVESTIGATOR BE DENIED
25 AN OPPORTUNITY TO APPLY FOR A CIRM GRANT.

1 MR. KLEIN: WHY DON'T YOU JUST ADD THAT TO
2 THE END, SO THAT NO INVESTIGATOR BE DENIED THE
3 OPPORTUNITY.

4 CO-CHAIR LANSING: HE DOESN'T EVEN KNOW IF HE
5 WANTS AN RFA YET. ALL YOU'RE SAYING IS YOU JUST WANT A
6 MECHANISM THAT'S PUT IN PLACE SO THAT NO INVESTIGATOR
7 BE DENIED AN OPPORTUNITY TO HAVE A FIRM GRANT DUE TO A
8 LACK OF AN ESCROW AT HIS FACILITY, PERIOD. AND WE WANT
9 THEM TO COME UP WITH SOMETHING THAT WILL ENSURE THAT
10 EVERYONE GETS EQUAL ACCESS.

11 CO-CHAIR LO: I SUGGEST THAT SINCE THIS IS
12 REALLY SOMETHING WE'RE REFERRING TO THE ICOC TO WORK
13 OUT, THAT WE SHOULDN'T SPEND A WHOLE LOT OF TIME
14 WORKING ON IT HERE.

15 WHY DON'T WE -- LET ME MAKE A SUGGESTION,
16 THAT WE -- MAYBE STAFF CAN WORK ON THIS A LITTLE BIT,
17 BUT WE'RE OVERDUE FOR LUNCH. DO WE HAVE LUNCH?

18 MR. KLEIN: I'D LIKE TO CALL THE QUESTION ON
19 THIS MOTION. THERE'S A SECOND, A MOTION AND A SECOND
20 PENDING. I THINK WE'VE HAD A GOOD DISCUSSION. I'D
21 LIKE TO CALL THE QUESTION.

22 CO-CHAIR LO: OKAY.

23 DR. HALL: WOULD YOU ACCEPT A FRIENDLY
24 AMENDMENT TO ADD THE PURPOSE TO THIS, SO THAT NO
25 INVESTIGATOR -- SO THAT NO INVESTIGATOR BE DENIED AN

1 OPPORTUNITY TO APPLY FOR CIRM FUNDING. NO CALIFORNIA
2 INVESTIGATOR.

3 DR. ROWLEY: IT SEEMS TO ME THAT THIS IS
4 REALLY AN EXTENSION OR AN IMPLEMENTATION OF THE THIRD
5 PART OF WHAT WE'VE ALREADY VOTED ON, CIRM OR OTHER
6 STATE AGENCY. THIS JUST SAYS THIS IS ONE WAY TO DO IT.
7 I THINK IT'S SUPERFLUOUS.

8 MR. KLEIN: WELL, YOU NEED TO KNOW THAT
9 YOU'RE GOING TO HAVE THAT PORTION IN PLACE.

10 DR. HALL: THE PREVIOUS MOTION, JANET, OFFERS
11 YOU THE OPTION. WHAT JEFF IS DOING IS SUGGESTING TO
12 THE ICOC THAT THEY ACT ON THAT OPTION.

13 CO-CHAIR LO: THEY MAKE THE OPTION AVAILABLE
14 IN A TANGIBLE WAY.

15 PUBLIC COMMENT ON THIS MOTION? QUESTION HAS
16 BEEN CALLED.

17 MR. KLEIN: CALL THE QUESTION.

18 CO-CHAIR LO: OKAY. MOTION, GEOFF IS STILL
19 TYPING IT OUT. AND WE SHOULD READ IT FOR THOSE MEMBERS
20 ON THE PHONE.

21 DR. KORDOWER: THANK YOU.

22 CO-CHAIR LO: SORRY ABOUT THAT.

23 MR. LOMAX: REALLY IT'S AN INSURANCE
24 MECHANISM, INSURANCE THAT THE --

25 DR. HALL: WHY NOT JUST --

1 CO-CHAIR LO: HOW ABOUT THE FIRST FULL
2 PARAGRAPH, RECOMMEND THAT THE ICOC GENERATE AN RFA --

3 DR. HALL: RECOMMEND TO THE ICOC.

4 MR. KLEIN: IT'S FINE THE WAY IT IS, ISN'T
5 IT?

6 CO-CHAIR LO: LET ME TRY AND READ THIS.
7 RECOMMEND THAT THE ICOC -- IT SEEMS TO ME WE NEED A
8 VERB THERE -- ESTABLISH OR GENERATE AN RFA TO ESTABLISH
9 A STATEWIDE ESCRO TO PROVIDE REVIEW (ON A CHARGE-BASED
10 SYSTEM) SO THAT NO CALIFORNIA INVESTIGATOR BE DENIED
11 ACCESS TO CIRM FUNDING.

12 JEFF, YOU'RE HAPPY THAT WE'VE GOT IT RIGHT?
13 OKAY. ALL THOSE IN FAVOR. ANYONE OPPOSED? ANYONE
14 ABSTAINING?

15 CO-CHAIR LO: MEMBERS ON THE PHONE?

16 DR. KORDOWER: AYE.

17 CO-CHAIR LO: KEVIN, ARE YOU STILL THERE?
18 KEVIN STEPPED AWAY. SO THAT PASSES UNANIMOUSLY.

19 MAY I SUGGEST THAT WE BREAK FOR LUNCH. IS
20 LUNCH AVAILABLE? LUNCH IS AVAILABLE AND WAITING. AND
21 THEN WE COME BACK, THERE ARE A NUMBER OF OTHER ISSUES
22 WITH REGARD TO ESCRO'S THAT WE NEED TO SORT OF GIVE
23 APPROVAL TO SO THEY CAN BE PUT IN REGULATORY LANGUAGE.
24 AND I'D LIKE TO SORT OF COME BACK TO THAT.

25 (A RECESS WAS TAKEN.)

1 CO-CHAIR LO: IF I COULD ASK PEOPLE TO PLEASE
2 RECONVENE. I WANTED TO WELCOME PEOPLE BACK FROM LUNCH.
3 I GOT INTO A NUMBER OF VERY INTERESTING CONVERSATIONS
4 OVER LUNCH AND I HEARD A NUMBER OF THINGS. FIRST, I
5 THINK IT'S FAIR TO SAY THERE WAS A MODERATE AMOUNT OF
6 SORT OF FRUSTRATION AT THIS MORNING. THERE WERE A
7 NUMBER OF PEOPLE WHO THOUGHT THAT WE KIND OF WERE
8 SPINNING OUR WHEELS AND PERHAPS WERE GETTING INVOLVED
9 IN WHAT EVENTUALLY TURNED OUT TO BE SORT OF WHAT
10 SOMEONE CALLED RUBBER-STAMPING NAS GUIDELINES. AS I
11 THOUGHT BACK OVER THIS MORNING, I THINK THERE ARE A
12 NUMBER OF THINGS THAT HAPPENED. ONE IS I THINK WE'RE
13 LEARNING SORT OF WHAT IS GOING TO PASS MUSTER WITH THE
14 OFFICE OF ADMINISTRATIVE LAW AND WHAT WON'T. THAT'S
15 DIFFICULT.

16 I ALSO MUST SAY THAT I THINK THAT, AS I
17 CHAIRED THE MEETING THIS MORNING, SOMETIMES THE
18 DISCUSSION GOT A LITTLE BIT KIND OF EITHER OUT OF HAND
19 OR OVERWEIGHTED. WHAT I'M GOING TO TRY AND DO THIS
20 AFTERNOON, WITH YOUR AGREEMENT, IS KEEP A LITTLE
21 TIGHTER REIN ON THE DISCUSSION AND MAKE SURE THAT --
22 I'M GOING TO ASK YOU ALL TO SORT OF INDICATE TO ME THAT
23 YOU WANT TO SPEAK, AND I'M GOING TO TRY AND GO IN TURN.
24 I KNOW THERE'S ALWAYS A TENSION BETWEEN SORT OF HAVING
25 A SPONTANEOUS DISCUSSION AND HAVING THE DISCUSSION BE

1 DIFFICULT FOR SOME PEOPLE TO ENTER INTO BECAUSE SOME
2 PEOPLE SEEM TO BE A LITTLE MORE AGGRESSIVE SPEAKING
3 OUT. I'M GOING TO ASK YOU TO INDICATE TO ME. I'LL
4 KEEP A LIST AND TRY AND GET TO EVERYBODY TO MAKE SURE
5 EVERYONE HAS A CHANCE TO BE HEARD.

6 OVER LUNCH WE HAD A NUMBER OF DIFFERENT
7 DISCUSSIONS WHICH I HOPE MAY COME TOGETHER ON THE ISSUE
8 OF BANKING. AND A NUMBER OF YOU SAID THAT THIS IS A
9 REALLY IMPORTANT SUBSTANTIVE ISSUE. ESCRO'S ARE SORT
10 OF MORE PROCEDURE AND ORGANIZATION. AND IF YOU'RE FROM
11 ANOTHER PERSPECTIVE, THE BANKING REALLY SORT OF GOES TO
12 MORE OF THE GUTS OF PROP 71. SO I THOUGHT WE MIGHT
13 START WITH THAT.

14 WITH THE HELP OF JAMES HARRISON, WE'VE SORT
15 OF GONE BACK TO TRY AND ADDRESS THE ISSUE OF, FIRST,
16 WHAT CAN WE SAY IN REGULATIONS TO REALLY MAKE IT CLEAR
17 THAT CIRM-FUNDED RESEARCHERS HAVE GOT TO COMPLY WITH
18 THE SPIRIT OF PROP 71, WHICH IS TO MAKE THE RESULTS OF
19 THE RESEARCH FUNDED BY CIRM WIDELY AVAILABLE TO OTHER
20 RESEARCHERS SO THAT THEY CAN BUILD ON IT, THE WORK CAN
21 GO FORWARD, AND ULTIMATELY NEW THERAPIES DEVELOP.

22 THE PROBLEM FROM A REGULATORY POINT OF VIEW
23 IS WE DON'T QUITE KNOW HOW TO DO THAT YET IN TERMS OF
24 IS CIRM GOING TO SET UP ITS OWN BANK, ETC. AND ALMOST
25 CERTAINLY WE'LL NEED TO COME BACK AND AMEND THE

1 REGULATIONS AS THE MECHANISMS OF BANKING BECOME CLEAR.
2 SO THERE ARE TWO THINGS. FIRST, TO TRY AND CRAFT SOME
3 LANGUAGE AS A REGULATION TO SORT OF SAY WHAT WE EXPECT
4 CIRM-FUNDED RESEARCHERS TO DO WITH REGARD TO SHARING
5 THEIR MATERIALS. AND, SECONDLY, I THINK THERE'S SOME
6 INFORMATION ABOUT WHAT CIRM MIGHT BE PLANNING TO DO OR
7 ABLE TO DO IN TERMS OF REALLY THINKING OF EFFECTIVE
8 WAYS TO MAKE THIS BANKING HAPPEN, BUT THEY'RE PERHAPS
9 SEPARATE ISSUES IN TERMS OF ONE IS A REGULATORY
10 RECOMMENDATION. THE OTHER IS SORT OF WHAT ELSE SHOULD
11 CIRM BE DOING TO MAKE BANKING REALLY WORK EFFECTIVELY.

12 SO I'M GOING TO START BY -- THIS IS A SORT OF
13 SUGGESTED RECOMMENDATION FOR BANKING, WHICH IS TO TRY
14 AND SORT OF SAY WHAT WE CAN SAY AT THIS POINT IN TERMS
15 OF CELL LINES DERIVED THROUGH CIRM-FUNDED RESEARCH
16 SHALL BE SHARED WITH OTHER INVESTIGATORS EITHER
17 THROUGH --

18 DR. HALL: SOMETHING IS WRONG WITH THE
19 WORDING THERE. STRAIGHTEN IT OUT IF WE COULD. WHAT'S
20 INTENDED? CELLS DERIVED THROUGH CIRM-FUNDED RESEARCH
21 SHALL BE SHARED WITH OTHER INVESTIGATORS.

22 CO-CHAIR LO: AND THEN WE'RE GOING TO GIVE
23 SOME MECHANISMS WHICH ARE FOR EXAMPLE, BUT NOT LIMITED
24 TO.

25 DR. HALL: THROUGH THEIR INSTITUTIONS,

1 THROUGH AN ESTABLISHED STEM CELL BANK, OR A CIRM-FUNDED
2 STEM CELL BANK.

3 MR. SHESTACK: RAPID FASHI ON, TIMELY FASHI ON,
4 URGENT FASHI ON.

5 CO-CHAIR LO: SO THAT GETS -- LET' S FIX THIS,
6 AND THEN JON RAISES AN IMPORTANT POINT HERE. IT' S A
7 REGULATORY ISSUE AS WELL. LET' S TRY AND GET THI S
8 LANGUAGE. WE' RE TRYING TO SAY YOU HAVE TO DO. HERE' S
9 SOME EXAMPLES OF HOW YOU MIGHT DO IT, BUT THERE MAY BE
10 OTHER WAYS THAT YOU COULD DO IT THAT WE HAVEN' T THOUGHT
11 OF.

12 DR. HALL: EITHER THROUGH THEIR INSTITUTIONS.

13 MR. SHESTACK: ONE SECOND.

14 DR. HALL: LET' S JUST GET THE WORDING
15 STRAIGHT.

16 CO-CHAIR LO: LET GEOFF AND JAMES WORK THI S
17 OUT.

18 MR. KLEIN: DR. LO, WHILE THEY' RE CORRECTING
19 THE WORDING, IF I COULD JUST CLARIFY THE RECORD ON ONE
20 POINT. I THINK YOUR REFERENCE TO DI SCUSSIONS DURING
21 LUNCH WAS YOU' RE JUST REFERRING TO YOUR SEAT MATES AT
22 YOUR TABLE. I WANT FOR THE PUBLIC RECORD TO REFLECT
23 THERE WERE NO GROUP DI SCUSSIONS DURING LUNCH. MY TABLE
24 WAS DI SCUSSIONG SOME OTHER TOPICS AT LEAST WITH JUST A
25 COUPLE OF PEOPLE SEATED NEXT TO ME. AND YOU WERE

1 TALKING ABOUT SOMETHING WITH A COUPLE OF PEOPLE SEATED
2 NEXT TO YOU. THERE WERE NO GROUP DISCUSSIONS DURING
3 LUNCH ON ANY TOPIC.

4 CO-CHAIR LO: THANK YOU FOR THAT
5 CLARIFICATION, BOB.

6 MR. SHESTACK: MY QUESTION WAS IF YOU SAY
7 THROUGH INSTITUTIONS, DOES THAT MEAN SOMEONE CAN OPT --
8 DOES THAT MEAN SOMEBODY CAN OPT OUT? MY CONCERN IS IF
9 ZACH SAYS THERE'S GOING TO BE A STRONG CIRM BANKING
10 POLICY, AND THERE MIGHT EVEN BE A CIRM-FUNDED BANK
11 ITSELF, WHICH, OF COURSE, I THINK WOULD BE THE MOST
12 IDEAL SOLUTION. BY SAYING THROUGH THEIR INSTITUTIONS
13 OR OTHER THINGS, WILL THEY GET TO OPT OUT?

14 CO-CHAIR LO: ZACH, LET ME TRY. ON THE LIST
15 OF PEOPLE, JOSE AND TED. LET ME RESPOND TO JON HERE.
16 I THINK THIS IS AN IMPORTANT REGULATORY ISSUE. THAT
17 RIGHT NOW, SINCE THERE IS NO CIRM-FUNDED BANK, WE HAVE
18 TO GIVE THEM OPTIONS -- WE HAVE TO MAKE IT POSSIBLE FOR
19 THEM TO SATISFY THE REQUIREMENT TODAY. IF THERE IS A
20 CIRM-FUNDED BANK LATER, FOR EXAMPLE, AND WE DECIDE TO
21 MAKE THAT MANDATORY, THEN WE WOULD NEED TO GO BACK AND
22 REVISE, AMEND THIS TO SAY NOW WE'RE REQUIRING YOU TO
23 PUT IT INTO THE CIRM-FUNDED BANK OR THE UK BANK OR
24 SOMETHING LIKE THAT. SO ALMOST CERTAINLY THIS WILL
25 NEED TO BE REVISED.

1 JON RAISED ANOTHER ISSUE, WHICH I THINK,
2 AGAIN, IS IMPORTANT -- I'M GOING TO MAKE SURE JAMES
3 COMMENTS ON THIS -- IN TERMS OF THE TIME FRAME. WE
4 ORIGINALLY HAD THOUGHT OF SOMETHING LIKE TIMELY. THE
5 OFFICE OF ADMINISTRATIVE LAW SAY THAT'S NO GOOD BECAUSE
6 YOU HAVE TO BE ABLE TO -- PEOPLE HAVE TO BE ABLE TO
7 KNOW WHAT YOU MEAN BY TIMELY. IDEALLY THEY WOULD LIKE
8 LITERALLY A NUMBER OF MONTHS OR YEARS. IF WE DON'T
9 FEEL COMFORTABLE DOING THAT, THEN IT'S A REGULATORY
10 ISSUE OF WHAT WE CAN SAY IN THE REGULATIONS THAT WILL
11 NOT BE SORT OF STRUCK DOWN BY THE OAL AS BEING TOO
12 VAGUE. JAMES, IS THAT A FAIR STATEMENT?

13 MR. HARRISON: THAT IS A FAIR STATEMENT. IF
14 ONE WERE TO SAY WITHIN A REASONABLE PERIOD OF TIME,
15 THAT WOULD NOT BE SPECIFIC ENOUGH.

16 DR. HALL: AS A SOLUTION, I WOULD ASK THE
17 SCIENTISTS HERE TO SAY WHETHER THEY THINK IT'S
18 REASONABLE OR NOT. COMMONLY WITH BACTERIAL GENETICS,
19 WHERE YOU MAKE A MUTANT OR OTHER THINGS LIKE THAT, YOU
20 SAY AT THE TIME OF PUBLICATION, AFTER THE TIME OF
21 PUBLICATION IT SHOULD BE MADE AVAILABLE. IT'S VERY
22 HARD TO PUT A DEFINITE TIME LIMIT ON BECAUSE WHEN DO
23 YOU -- WITHIN THREE MONTHS OF ITS DERIVATION OR SIX
24 MONTHS, WHEN IS IT DERIVED? WHEN IT'S ISOLATED? WHEN
25 IT'S CHARACTERIZED, WHATEVER? SO ONE POSSIBILITY WOULD

1 BE JUST THAT. AND I WOULD ASK OTHER PEOPLE, THAT IS,
2 AT THE TIME YOU PUBLISH IT, ANY TIME AFTER THAT, IF
3 ANOTHER INVESTIGATOR REQUESTS IT, IT SHOULD BE MADE
4 AVAIL ABLE.

5 CO-CHAIR LO: LET ME TRY AND KEEP STRAIGHT.
6 SO JOSE, TED, AND THEN FRANCISCO.

7 DR. CIBELLI: LAST WEEK THERE WAS A GREAT
8 PAPER PUBLISHED BY A VERY, VERY WELL-KNOWN STEM CELL
9 RESEARCHER. AND HE PRODUCED A CELL LINE THAT COULD BE
10 AT -- IT IS HIGHLY VIABLE. IT'S A CELL LINE THAT CAN
11 HELP SOLVE A LOT OF PROBLEMS. HE PRODUCED THAT CELL
12 LINE WITH NIH-FUNDED RESEARCH. SO I WROTE AN E-MAIL
13 AND SAID CONGRATULATIONS ON YOUR PAPER. WE WOULD LOVE
14 TO HAVE A VIAL OF THE CELL LINE. AND THE ANSWER WAS
15 THANK YOU FOR YOUR KIND WORDS, BUT WE WOULD RATHER NOT
16 SHARE AT THIS TIME BECAUSE WE'RE COMPETING. THAT'S
17 TRUE, WE'RE COMPETING. SO WE HAVE TO BUILD -- I
18 PROBABLY WOULD DO THE SAME THING IF I WERE HIM, BUT HOW
19 DO YOU ENFORCE THIS? THIS IS VERY NICE. SO WHAT DO
20 YOU DO?

21 CO-CHAIR LO: TED AND THEN FRANCISCO.

22 DR. PETERS: I HAVE TWO POINTS. FIRST, I'D
23 LIKE US TO CONSIDER MAINTAINING THE LANGUAGE OF BANKING
24 AS MANDATORY. IT SEEMS TO ME THAT CIRM COULD ESTABLISH
25 ITS OWN BANK IN STAGES. IF CURRENTLY IT'S BEST THAT

1 STEM CELL LINES REMAIN ON-SITE, THE FIRST STAGE OF THE
2 BANK COULD BE NOTHING MORE THAN A COMPUTER WEBSITE. WE
3 COULD BUILD RIGHT INTO THE GRANTS THAT THEY MAINTAIN
4 THE STEM CELL LINES ON-SITE, AND THAT WE SIMPLY CHANNEL
5 THE INFORMATION. AT SOME LATER POINT WHEN PHYSICALLY
6 THERE COULD ACTUALLY BE A BANK THAT HOLDS THEM, THEN
7 THAT COULD BE ESTABLISHED.

8 I THINK IT'S IMPORTANT THAT WE START OFF
9 RATHER FIRM AND UNAMBIGUOUSLY ABOUT THIS. LET ME LEAD
10 TO MY SECOND POINT NOW.

11 I THINK I'D LIKE TO SEE THIS GROUP TAKE SOME
12 TIME AND TO DISCUSS THE PHILOSOPHICAL ISSUES
13 SURROUNDING BANKING. I REALLY THINK THAT WE NEED TO
14 START WITH THE VISION OF WHAT IT IS THAT PROPOSITION 71
15 WANTS TO ACCOMPLISH, WHAT PEOPLE ARE EXPECTING. AND I
16 THINK WHAT AN ETHICIST WOULD CALL JUSTICE OR WHAT WE'VE
17 BEEN CALLING ACCESS IS VERY IMPORTANT. IT COMES IN TWO
18 PHASES. FIRST IS ACCESS TO RESEARCH, WHICH IS WHAT THE
19 BANKING IS GOING TO CONTRIBUTE TO. AND THEN FINALLY,
20 ACCESS TO THE THERAPEUTIC PRODUCTS ON DOWN THE LINE.

21 THE KINDS OF DECISIONS WE MAKE NOW ARE SIMPLY
22 GOING TO RAMIFY. I'D LIKE TO START WITH THAT VISION OF
23 WHERE WE FINALLY WANT TO GET AND HOW WE'RE GOING TO GET
24 FROM HERE TO THERE. AND I THINK THAT BANKING IS GOING
25 TO BE INEXTRICABLY TIED WITH INTELLECTUAL PROPERTY, AND

1 I WONDER TO WHAT EXTENT WE NEED TO CONNECT OUR
2 DECISIONS HERE WITH WHAT THE SUBCOMMITTEE ON
3 INTELLECTUAL PROPERTY WILL BE DOING.

4 DR. PRIETO: WELL, I'D LIKE TO SAY I AGREE.
5 I THINK IT IS IMPORTANT THAT WE MAKE A STRONG STATEMENT
6 ABOUT BANKING, AND I UNDERSTAND THE ISSUES OF NOT
7 HAVING A PHYSICAL BANK RIGHT NOW. BUT I THINK THAT WE
8 COULD BEGIN TO CENTRALIZE SOME OF THE INFORMATION AT
9 THE CIRM. AND I'M NOT SURE THAT THE BANK EVER NEEDS TO
10 HAVE ONE AND ONLY ONE PHYSICAL LOCATION. THAT'S
11 PROBABLY THE LEAST IMPORTANT FACTOR IN BANKING. SO
12 LONG AS THE INFORMATION AND THE CELL LINE AVAILABILITY
13 IS THERE, PHYSICAL LOCATION IS VERY SECONDARY.

14 DR. TAYLOR: I DON'T KNOW THAT I'M NEXT. SO
15 ACTUALLY I'M GLAD THAT YOU RAISED THIS KIND OF IP KIND
16 OF ISSUE. AND THIS CAME UP IN OUR LAST PHONE
17 CONVERSATION WHEN WE WERE TALKING ABOUT SOME OF THESE
18 THINGS. BUT I THINK ACTUALLY WHAT ZACH HAS SUGGESTED
19 IN TERMS OF A POLICY AND WHAT JOSE HAS KIND OF
20 RESPONDED TO, I THINK THERE IS -- I'M ASSUMING THAT
21 CALIFORNIA STATE LAW AND U.S. FEDERAL LAW ARE THE SAME,
22 THAT WITH PUBLIC DISCLOSURE, MAYBE THAT WOULD BE THE
23 TIME RATHER THAN PUBLICATION, IF THAT WOULD PERHAPS BE
24 THE MORE APPROPRIATE TIME TO MAKE THESE CELL LINES
25 AVAILABLE.

1 AND, AGAIN, I THINK THAT WE AREN'T GOING TO
2 BE ABLE TO DIVORCE THE ISSUES OF PATENTS AND
3 INTELLECTUAL PROPERTY FROM THE OTHER SORT OF
4 DISTRIBUTION OF CELLS OR PUTTING THEM INTO THE BANK AND
5 GETTING THEM OUT. MY FEELING IS ULTIMATELY WHEN WE
6 HAVE A MANDATORY -- A REAL LIVE BANK, IT SHOULD BE
7 MANDATORY AND EVERYTHING COULD BE MANAGED THROUGH THAT.
8 I THINK THAT'S THE CLEANEST SYSTEM.

9 CO-CHAIR LO: COULD YOU JUST CLARIFY WHAT YOU
10 MEAN BY PUBLIC DISCLOSURE?

11 DR. TAYLOR: I THINK THAT'S ACTUALLY THE WAY
12 THE LAW IS INTERPRETED, AS I UNDERSTAND IT. A
13 PRESENTATION OF DATA AT A NATIONAL MEETING IN THE FORM
14 OF AN ABSTRACT. I DON'T THINK TALKING ABOUT A NEW CELL
15 LINE OVER THE LUNCH TABLE CONSTITUTES PUBLIC
16 DISCLOSURE, AND I DON'T UNDERSTAND THE LAW WELL ENOUGH
17 TO BE ABLE TO SAY PRECISELY WHAT IT IS, BUT THERE MAY
18 BE A POINT BEFORE PUBLICATION THAT UNDER PATENT LAW
19 THESE CELLS HAVE NOW BEEN SORT OF DESCRIBED SO THAT
20 THAT WOULD BE A REASONABLE POINT IN TIME. AGAIN, IF WE
21 WANT TO ACCELERATE THE DISTRIBUTION PROCESS, TO SAY
22 WHEN THAT PUBLIC DISCLOSURE, WHICH I THINK IS A LEGALLY
23 DEFINABLE POINT IN TIME, THAT THEN THOSE CELLS WOULD BE
24 MADE AVAILABLE TO OTHER INVESTIGATORS.

25 CO-CHAIR LO: JEFF AND THEN ZACH.

1 MR. SHEEHY: I THINK THIS IS PROBABLY THE
2 CENTRAL THING THAT WE'RE DEALING WITH. THIS IS THE
3 WHOLE REASON WE HAVE PROP 71 IS BECAUSE WE DON'T HAVE
4 ENOUGH SOURCE MATERIAL.

5 IT SEEMS TO ME TOO, I MEAN WHAT OUR KEY
6 PROBLEM HERE IS THAT WE NEED TO PUT IN PLACE GUIDELINES
7 THAT ARE SUFFICIENT TO ALLOW RESEARCH TO GO FORWARD
8 UNTIL A BANK IS ESTABLISHED. I MEAN IT SEEMS THAT THE
9 CLEAR INTENT, AT LEAST COMING OUT OF THE VARIOUS
10 SCIENTIFIC MEETINGS AND DISCUSSIONS THAT HAVE BEEN
11 HELD, IS THAT CIRM WILL SET UP A BANK. SO THESE
12 REGULATIONS NEED TO MAKE SURE THAT ALL THE LINES THAT
13 WE HELP CREATE END UP IN THAT BANK.

14 I ALSO THINK THAT WE NEED TO THINK ABOUT COST
15 BECAUSE COST CAN BE A BARRIER TO PEOPLE ACCESSING THE
16 LINE. YOU OBVIOUSLY WANT SOMEONE TO RECOUP THE COST OF
17 MAKING THE LINE AVAILABLE. YOU DO NOT WANT THE COST TO
18 BE IN INTELLECTUAL PROPERTY ENTANGLEMENTS OR THROUGH
19 ACTUAL PHYSICAL COST TO IN THAT WAY PREVENT THE ACCESS
20 TO THE LINES AS WELL.

21 DR. HALL: SEVERAL ISSUES. I GUESS, ROB,
22 WHAT YOU WERE TALKING ABOUT IS IN PATENT LAW, ONCE IT'S
23 DISCLOSED, THEN SO WHAT COUNTS IS ANY KIND OF
24 PRESENTATION THAT'S OPEN TO THE PUBLIC, I THINK, IS
25 WHAT IT WOULD BE, A SEMINAR AT A MEETING OR ANYTHING

1 LIKE THAT. I THINK IT'S SOMETHING -- THE PROBLEM WITH
2 THAT IS, AND ONE OF THE ISSUES THAT I THINK THE BANK
3 WILL HAVE TO DEAL WITH, IS THE BANK WILL HAVE TO HAVE
4 STANDARDS FOR WHAT'S IN THE BANK, RIGHT. AND THE
5 QUESTION IS IF SOMEBODY PRESENTS PRELIMINARY DATA, BUT
6 USUALLY THE IDEA IS UNTIL IT'S BEEN THROUGH PEER REVIEW
7 FOR PUBLICATION, THEN EVERYBODY AGREES IT'S STRONG
8 ENOUGH TO THEN BE PRESENTED SORT OF FORMALLY TO THE
9 SCIENTIFIC PUBLIC.

10 AND I THINK I WOULD ARGUE THAT, THE PATENT
11 ISSUE ASIDE, THAT THAT IS A BETTER TIME DATE THAN
12 PRESENTATION SIMPLY BECAUSE THE BACKGROUND INFORMATION
13 IS NOT PUBLICLY AVAILABLE. YOU CAN'T CHARACTERIZE IT.
14 ALL YOU'VE GOT IS WHAT SOMEBODY SAID IN A TALK, AND
15 THEN YOU DON'T EVEN KNOW WHEN YOU GET IT WHAT YOU HAVE.

16 LET ME JUST SAY ALSO THAT I THINK WE WILL
17 HAVE A BANK. WE MAY EVEN HAVE TWO TO MAKE SURE WE
18 DON'T HAVE ALL OUR EGGS IN ONE BASKET.

19 MR. SHESTACK: DO YOU MEANS TWO SITES OR TWO
20 SEPARATE KINDS OF BANK?

21 DR. HALL: NOT KINDS, JUST TWO SITES OF
22 STORAGE.

23 MR. SHESTACK: TWO DIFFERENT REPOSITORIES.

24 DR. HALL: TWO DIFFERENT REPOSITORIES. THEY
25 WOULD ABSOLUTELY HAVE THE SAME STANDARDS. AND ONE OF

1 THE ISSUES IN THE BANK IS TO BE SURE THAT WHATEVER GOES
2 IN HAS, NO. 1, BEEN DERIVED ACCORDING TO ETHICAL
3 STANDARDS AND, NO. 2, IS WELL CHARACTERIZED AND
4 EVERYTHING CAN BE REPRODUCED.

5 WE ARE IN TOUCH PARTICULARLY WITH THE UK STEM
6 CELL BANK. AND THE PERSON WHO RUNS THAT BANK IS GOING
7 TO BE HERE LATER THIS MONTH, AND WE WILL BE TALKING TO
8 HIM ABOUT WHAT PROBLEMS THEY'VE HAD, HOW THEY SET IT
9 UP, WHAT THE RIGHT WAY TO DO IT IS.

10 IT'S ALSO TRUE THAT IN THE EARLY DAYS OF
11 THIS, IT MAY BE THAT PEOPLE WILL HAVE THE LINES IN
12 THEIR LABS AND NEED JUST TO SEND THEM OUT FROM THEIR
13 LABS. THAT QUICKLY MOUNTS UP. I'M TOLD DOUG MELTON
14 HAS TWO FULL-TIME PEOPLE IN HIS LAB WHO DO NOTHING BUT
15 SEND OUT THEIR LINES, AND MOST INVESTIGATORS CAN'T
16 AFFORD THAT. SO I THINK ALL THESE ISSUES OF WHAT THE
17 TIME SCALE IS, AND WE NEED TO APPROACH THAT, BUT THEN
18 THE OTHER IS TO THINK OVER TIME, AS WE SET ALL THIS UP,
19 WHAT THE BEST WAY TO DO IT IS. AND ALTHOUGH WE MIGHT
20 HAVE TO GO BACK IN AND CHANGE THAT, ONE OF THE THINGS
21 THAT'S APPEALING ABOUT THE VERSION ON THE BOARD IS THAT
22 IT SAYS EVEN IF OUR BANK ISN'T READY, YOU'RE OBLIGATED
23 TO SEND OUT LINES SO FAR AS YOU'RE ABLE.

24 MR. SHESTACK: AND IS IT MORE THAN LINES THAT
25 ANYBODY WANTS BACK, OR JUST THE LINES?

1 DR. HALL: WELL, WHAT WILL BE IN THE BANK ARE
2 THE LINES. IF THERE ARE OTHER REAGENTS, WE WOULD HAVE
3 TO SPECIFY THAT, AND I THINK IT WOULD BE FINE. WE
4 WON'T HAVE A REPOSITORY PRESUMABLY FOR OTHER REAGENTS,
5 BUT I THINK WE WILL JUST SAY THAT THEY'RE EXPECTED TO
6 SHARE.

7 AND LET ME JUST ADD ONE POINT TO WHAT JOSE
8 SAID. WHEN I WAS EDITOR OF NEURON, WE HAD A POLICY
9 THAT ANY PAPER THAT WAS PUBLISHED THERE, PEOPLE HAD TO
10 SHARE. ANYTHING DESCRIBED IN THAT PAPER THEY HAD TO
11 SEND TO OTHERS. AND WE HAD A CASE A COUPLE OF TIMES IN
12 WHICH PEOPLE CALLED UP AND SAID SO-AND-SO, AND I WOULD
13 CALL THEM AND SAY EITHER SEND THE LINE OR SEND US A
14 LETTER SAYING THAT YOU'RE NOT GOING TO SEND THE LINE.
15 AND I SAID IN THE LATTER CASE PLEASE DON'T APPLY TO US
16 AGAIN FOR PAPERS, AND IT WORKED JUST FINE.

17 NIH IS BIG AND WHO DO YOU CALL, BUT I THINK
18 CIRM, I THINK WE COULD SET THAT UP EASILY ENOUGH. MY
19 PREDICTION IS WE WOULD HAVE PEOPLE CALLING IN, AND THEN
20 WE WOULD SORT IT OUT.

21 DR. PRIETO: AND YOU'RE THE SHERIFF.

22 DR. HALL: RIGHT. RIGHT. YES. WE GIVE OUT
23 THE MONEY.

24 CO-CHAIR LO: WE HAVE A NUMBER OF PEOPLE.
25 ROB, TED, JOSE, AND THEN JON.

1 DR. TAYLOR: I WAS JUST GOING TO RESPOND
2 REALLY TO ZACH ON A COUPLE OF POINTS. YOU'RE RIGHT.
3 THE ONUS OF ACTUALLY DISTRIBUTING THESE CELLS CAN BE
4 QUITE HUGE. AT UCSF WE ACTUALLY HAD AN R 24 GRANT, AN
5 NIH GRANT THAT SORT OF ALLOWED US TO SEND THOSE,
6 SUPPORTED SENDING THAT OUT. THAT'S REALLY AN IMPORTANT
7 COMPONENT.

8 AND I GUESS THE OTHER POINT IS INHERENT
9 INSTABILITY OF THESE CELL LINES IS KIND OF AN IMPORTANT
10 ISSUE. GETTING THEM OUT TOO EARLY ACTUALLY MAY BE A
11 DETRIMENT. I KNOW THAT WE HAD A COUPLE OF PUBLICATIONS
12 FROM OUR OWN GROUP THAT WERE HELD UP UNTIL THE CELLS
13 WERE PASSAGE 20 TIMES. SOME OF OUR CELL LINES HAD
14 QUITE A BIT OF CHROMOSOMAL INSTABILITY. SO IN SOME
15 WAYS GETTING THEM RIGHT OUT THE DOOR IMMEDIATELY MAY
16 HAVE SOME DETRIMENT.

17 DR. HALL: YES. LET ME JUST PUT AN ADDENDUM
18 ONTO THAT. THAT'S ACTUALLY A REAL PROBLEM BECAUSE WHAT
19 HAPPENS IS THIS. WE'VE HEARD THIS ANECDOTALLY NOW IN
20 SEVERAL CASES. AN INVESTIGATOR SENDS THEIR LINES INTO
21 THE BANK, THE BANK GROWS THEM UP, AND THEY SAY THEY
22 DON'T GROW THE WAY THEY'RE SUPPOSED TO. AND THEY SAY,
23 OH, WELL, YOU DIDN'T DO, AND THEN YOU DIDN'T GROW THEM
24 EXACTLY THE RIGHT WAY. IF A BANK CAN'T SEND SOMETHING
25 OUT AND BE SURE THAT -- IN A WAY THE BANK IS THE

1 GUARANTOR BETWEEN THE DONOR AND THE RECIPIENT BECAUSE
2 IT'S ALSO COMMON FOR PEOPLE TO SEND SOMETHING AND THEN
3 THEY GROW IT UP AND NOTHING GROWS OUT OR IT GROWS
4 BADLY, AND THEY SAY, OH, WELL, WE FORGOT TO TELL YOU TO
5 PUT IN OR MAYBE THEY DON'T TELL YOU, BUT THE POINT
6 ABOUT A BANK IS THAT IT ASSURES THAT REPRODUCIBILITY.
7 SO THAT IS AN EXTREMELY IMPORTANT POINT.

8 CO-CHAIR LO: TED AND THEN JOSE AND THEN JON
9 AND BOB.

10 DR. PETERS: TWO THINGS ABOUT THE BANK IN
11 LIGHT OF THEIR CONVERSATION. I THINK WHETHER WE LIKE
12 IT OR NOT, THE BANK IS GOING TO BE THE SOURCE OF
13 INFORMATION FOR PEOPLE. WHAT WE'RE TALKING ABOUT WITH
14 REGARD TO DISCLOSURE, THE BANK IS GOING TO DO IT. AND
15 IT SEEMS TO ME THE BANK WILL BE SETTING THE STANDARDS.
16 THE BANK WILL DECIDE WHAT INFORMATION IS DISTRIBUTED
17 BECAUSE IT'S CONFIRMED AND WHAT INFORMATION IS STILL
18 SUSPECT AND PROBABLY WON'T BE DISTRIBUTED, AND PEOPLE
19 WILL RELY UPON THE BANK FOR THAT.

20 I THINK SECONDLY, JUST TO REPEAT THE POINT I
21 HAD MADE EARLIER, I WOULD LIKE TO HAVE IT CLEAR AND
22 UNEQUIVOCAL THAT THE BANK EXISTS, EVEN IF WE JUST
23 DECLARE BY FIAT. WHEN IT COMES TO THE KINDS OF
24 TECHNICAL PROBLEMS ABOUT THE STABILITY OF STEM CELL
25 LINES AND THE DESIRABILITY OF HAVING THE LOCAL

1 INSTITUTION DISTRIBUTE IT, THAT'S FINE. YOU CAN BUILD
2 THAT RIGHT INTO THE FUNDING OF EITHER THE BANK OR INTO
3 THE FUNDING OF THE GRANTS THAT THE HOST INSTITUTIONS
4 WOULD HAVE. IT'S THAT THE BANK WOULD BE THE
5 INFORMATION SOURCE FIRST, AND ONLY SECONDLY WOULD IT
6 ITSELF HANDLE THE ACTUAL PHYSICAL TRANSMISSION.

7 CO-CHAIR LO: JAMES, DO YOU HAVE A REGULATORY
8 ISSUE HERE?

9 MR. HARRISON: IT JUST STRIKES ME THAT SOUNDS
10 MORE LIKE A REGISTRY, WHICH I THINK WE'VE ALSO TRIED TO
11 COVER THROUGH THE PROPOSED DRAFT REGULATIONS AS WELL.
12 THAT IS, THERE'S BOTH A BANKING REQUIREMENT AND A
13 REGISTRY REQUIREMENT.

14 DR. HALL: IF THE PEOPLE WANT THE CELLS. IF
15 THEY WANT THE INFORMATION, THEY WANT THE CELLS.

16 CO-CHAIR LO: I WANT TO AGAIN TRY --

17 DR. HALL: THAT'S WHAT PEOPLE WANT IS THE
18 CELLS SO THEY CAN DO EXPERIMENTS THEMSELVES.

19 CO-CHAIR LO: LET'S TRY AND KEEP IT
20 ORGANIZED. JOSE AND THEN JON AND THEN BOB KLEIN.

21 DR. CIBELLI: GOING BACK TO THE EXAMPLE THAT
22 I GAVE BEFORE, IF I TRIED TO MIMIC THAT WORK, IT WILL
23 TAKE ME A YEAR, AT LEAST ONE POST DOC WORKING JUST FULL
24 TIME FOR THAT. I CAN UNDERSTAND WHY THESE GUYS DON'T
25 WANT TO SHARE. THAT'S NOT THE PURPOSE, I GUESS, OF

1 THIS INITIATIVE IN CALIFORNIA. YOU WANT THINGS TO
2 HAPPEN FAST, SO YOU DON'T WANT TO GET STRANDED BECAUSE
3 OF THE EGO OF THIS SCIENTIST IS GOING TO GET HURT IF
4 YOU SHARE THE CELL LINE. SO YOU HAVE TO BUILD IN THE
5 LANGUAGE TO MAKE VERY CLEAR THE CONSEQUENCES IF THE GUY
6 DOESN'T SHARE. SHALL SHARE IS NOT GOOD ENOUGH. SHALL
7 SHARE OR --

8 DR. HALL: OR DIE.

9 DR. HALL: I WOULD THINK YOU COULD JUST SAY
10 FUTURE FUNDING BY CIRM WOULD DEPEND ON FOLLOWING THESE
11 GUIDELINES.

12 MR. SHESTACK: IT'S PART OF HIS CONTRACT.
13 IT'S PART OF HIS AGREEMENT WHEN HE TAKES YOUR MONEY THE
14 FIRST TIME OUT.

15 DR. HALL: YES. YES.

16 CO-CHAIR LO: VIOLATION OF CONTRACT.

17 DR. CIBELLI: YOU ARE A SCIENTIST AND YOU
18 KNOW HOW -- ONCE YOU HAVE A REAGENT THAT IS UNIQUE,
19 THAT PUTS YOU IN A POSITION THAN YOU APPLY FOR FUNDING
20 AND NOBODY ELSE CAN COMPETE WITH YOU. SO --

21 MR. SHESTACK: YOU SHOULD HAVE THAT ADVANTAGE
22 FOR A BRIEF PERIOD OF TIME.

23 DR. CIBELLI: IT DOESN'T HAPPEN THAT WAY.
24 THE OTHER THING IS THAT IN THE LANGUAGE OF THE
25 REGULATORY GUIDELINES, INTERIM ONES, THE CELL LINES

1 HAVE TO BE WELL CHARACTERIZED AND SCREENED FOR SAFETY.
2 SO I'M HOPING THAT WE CAN DEFINE SAFETY, BUT THAT HAS
3 TO BE DEFINED.

4 CO-CHAIR LO: JAMES, YOU WANT TO COMMENT ON
5 WHETHER THAT'S TOO VAGUE, WELL CHARACTERIZED, SCREENED
6 FOR SAFETY?

7 DR. CIBELLI: THE CHARACTERIZATION WILL
8 CONTINUE TO EVOLVE. I UNDERSTAND THAT. BUT FOR
9 SAFETY, WHAT DO YOU MEAN BY SAFETY?

10 MR. HARRISON: WELL CHARACTERIZED MAY BE A
11 TERM OF ART THAT'S READILY UNDERSTOOD BY INVESTIGATORS.
12 IN TERMS OF SCREENED FOR SAFETY, I THINK YOU MIGHT NEED
13 TO ELABORATE A LITTLE BIT MORE ABOUT WHAT THAT MEANS.

14 DR. HALL: I THINK THIS WOULD BE THE CHORE OF
15 A STEM CELL BANK TO FIGURE OUT EXACTLY HOW CELL LINES
16 SHOULD BE CHARACTERIZED AND WHAT SHOULD BE THE
17 STANDARDS THAT THEY HAVE TO PASS BEFORE THEY'RE PASSED
18 AROUND THE FIELD AS REAGENTS.

19 LET ME JUST SAY ONE OTHER WORD. I'M OF
20 ANCIENT ENOUGH VINTAGE TO HAVE SEEN SEVERAL DIFFERENT
21 FIELDS AT VARIOUS TIMES IN MY CAREER. AND IT'S VERY
22 MUCH A CULTURAL THING. SOME FIELDS SHARE AND OTHERS
23 DON'T. I THINK IT DEPENDS ON THE CULTURAL NORM. MY
24 SENSE IS THAT WE HAVE A CHANCE HERE TO SET THE NORM FOR
25 STEM CELL RESEARCH IN CALIFORNIA, THAT IT'S EXPECTED

1 THAT YOU PASS THE LINES AROUND. THAT'S JUST THE WAY
2 IT'S GOING TO WORK. I KNOW PEOPLE WILL TRY TO EVADE
3 IT, AND I UNDERSTAND, BUT WE WILL TRY TO SET THAT. IN
4 FACT, I WILL TELL YOU A COUPLE OF STORIES LATER.

5 CO-CHAIR LO: AGAIN --

6 DR. CIBELLI: THAT'S NOT GOING TO HAPPEN. I
7 CAN TELL YOU WITH 10 PERCENT FUNDING AT NIH FOR THIS
8 KIND OF RESEARCH, EVERY SINGLE RESEARCHER IN CALIFORNIA
9 IS GOING TO BE A STEM CELL RESEARCHER FROM NOW ON. SO
10 THEY WON'T SHARE. I CAN TELL YOU THEY WON'T SHARE
11 BECAUSE THEY HAVE THESE UNIQUE CELL LINES, AND THEY
12 WON'T BE WILLING TO SHARE UNLESS YOU ARE VERY, VERY
13 STRICT.

14 DR. PRIETO: THE SPIGOT GETS TURNED OFF THEN.

15 CO-CHAIR LO: LET ME TRY AND GO BACK. I KNOW
16 THERE'S A LOT OF GOOD IDEAS. I WANT TO TRY AND KEEP
17 SOME ORDER. I THINK I HAD JON NEXT, THEN BOB KLEIN,
18 AND THEN SHERRY HAD HER HAND UP. WHO ELSE WANTS TO GET
19 ON THE LIST?

20 MR. SHESTACK: COUPLE OF THINGS. MY
21 EXPERIENCE IS I COME FROM A CULTURE WHERE THERE WAS NO
22 SHARING IN THE FIELD THAT I HAVE MOST EXPERIENCE, WHICH
23 IS AUTISM. AND THERE WAS NO PROGRESS, NO SHARING, AND
24 IT WAS ACTUALLY IMPOSSIBLE TO LEGISLATE IT BECAUSE WE
25 WEREN'T THERE IN THE BEGINNING TO DO IT. AND THE ONLY

1 SOLUTION WAS TO CREATE OUR OWN GENE BANK. MUCH SIMPLER
2 PROCESS. IT'S JUST SAMPLES, JUST BLOOD SAMPLES,
3 WELL-ASCERTAINED SAMPLES AND DNA AND THEN IMMORTALIZED
4 CELL LINES. THIS IS MUCH MORE COMPLICATED, BUT I CAN'T
5 STRESS ENOUGH HOW IMPORTANT IT IS THAT WE ARE
6 AGGRESSIVE ABOUT THIS WHEN WE ARE AT THE INCEPTION.

7 BOTH OF WHAT ZACH AND JOSE SAID IS TRUE. I
8 THINK -- WE WANT THEM TO SHARE. THERE WILL BE PEOPLE
9 WHO DON'T WANT TO SHARE. IF WE ARE VERY AGGRESSIVE AS
10 WE CAN BE WITHIN THE LAW NOW BY SAYING, YOU SAY
11 PUBLICATION, I MIGHT SAY 18 MONTHS AFTER FUNDING IF
12 SOMETHING IS PRODUCED. I DON'T KNOW WHAT THE ANSWER
13 IS, BUT SHOW THAT IT IS A CONDITION OF FUNDING THAT
14 CELL LINES, BY THE WAY, WILL BE MADE AVAILABLE INSIDE
15 CALIFORNIA AND OUTSIDE CALIFORNIA -- IT'S NOT JUST TO
16 CIRM-FUNDED RESEARCHERS -- SEEMS AN ESSENTIAL THING.
17 WE WANT TO GET OUT IN FRONT OF THE WORLD ON THIS AND BE
18 THE BEST, MOST PRO SOCIAL CELL BANK THAT THERE IS.

19 AND THEN, ZACH, WHEN YOU SAY, WELL, WE'VE GOT
20 PLANS, WE'RE GOING TO DO THAT, I THINK WE JUST HAVE TO
21 UNDERSTAND MORE ABOUT THAT, THAT YOU ACTUALLY DO, THAT
22 YOU'RE GOING TO ALLOCATE A SUBSTANTIAL AMOUNT OF MONEY
23 IF YOU NEED TO FROM THE CIRM BUDGET TO DO IT. OR DO WE
24 HAVE TO CREATE A RESOLUTION THAT EMPOWERS YOU TO DO IT?
25 WHAT'S THE MECHANISM BY WHICH PEOPLE IN THIS ROOM CAN

1 MAKE SURE THAT THIS HAPPENS ACCORDING TO THE VISION YOU
2 JUST STATED RIGHT NOW OF WHAT A BANK SHOULD BE?

3 MR. KLEIN: I THINK A RELATED ISSUE HERE IS
4 THAT IN ADDITION TO PROVIDING THE LINES TO A STEM CELL
5 BANK, WE SHOULD REQUIRE THEM TO PROVIDE FULLY ENABLING
6 INFORMATION UNDER THE PATENT LAW DEFINITION, THAT IF
7 YOU CAN'T FUNCTIONALLY DUPLICATE IT, IF YOU DON'T HAVE
8 ENABLING INFORMATION, YOU HAVEN'T PROVIDED THE
9 INFORMATION THAT QUALIFIES YOU FOR A PATENT. AND WE
10 SHOULD USE THAT PATENT STANDARD SO THAT WE'RE NOT IN A
11 SITUATION WHERE THEY PROVIDE THE LINES, BUT THE
12 PUBLICATION DOESN'T HAVE ALL THE INFORMATION YOU NEED
13 TO REALLY DUPLICATE THOSE LINES. SO WE NEED TO BE, I
14 THINK, FAIRLY PRESCRIPTIVE IN GETTING THE INTENT
15 ACCOMPLISHED HERE AND DIRECTIVE THAT THEY SUPPLY IT
16 WITH FULLY ENABLING INFORMATION.

17 CO-CHAIR LANSING: I JUST WANT TO REEMPHASIZE
18 I THINK WHAT JON SAID IN PARTICULAR, THAT WHEN WE
19 STARTED THIS, AND THE WHOLE ICOC IS SO DIFFERENT THAN
20 ANY OTHER GROUP THAT'S EVER BEEN FORMED, AND IT IS A
21 GROUP THAT'S BEEN ENTRUSTED WITH SOMETHING THAT'S NEVER
22 HAPPENED BEFORE, \$3 BILLION FOR STEM CELL RESEARCH, AND
23 THE GROUP IS COMPRISED OF PEOPLE WHO ARE NOT USED TO
24 SHARING. YOU KNOW, IN DIFFERENT INSTITUTIONS WHO HAVE
25 BEEN COMPETITIVE, WHO ARE NOT USED TO SHARING, AND WHO

1 IN THIS PERHAPS MOST IDEALISTIC SETTING THAT'S EVER
2 BEEN CREATED ARE SHARING AND ARE WORKING TOGETHER.

3 I THINK WE HAVE TO SET THAT SAME STANDARD FOR
4 THE RESEARCH. I THINK -- I KNOW IT'S A BIG TASK, AND I
5 REALLY UNDERSTAND WHAT YOU'RE SAYING. BUT IF IT'S A
6 REQUIREMENT, THEN IF THEY WANT OUR MONEY, THEY'RE NOT
7 GOING TO HAVE ANY OTHER CHOICE BUT TO DO IT. I THINK
8 THAT WE OWE THAT TO THE TAXPAYERS AND TO THE PATIENTS.

9 DR. TAYLOR: I WAS JUST GOING TO SAY THAT I
10 ACTUALLY THINK THAT THE STEM CELL FIELD IS A LITTLE BIT
11 DIFFERENT AND THE CULTURE IS MORE ALTRUISTIC. ONE
12 COULD SAY CYNICALLY THAT MAYBE THE WI-CELL PATENTS HAVE
13 ALLOWED THEM TO BE A LITTLE BIT MORE OPEN, BUT I THINK
14 BETWEEN WI-CELL, AT SOME OF THE OTHER U.S.-BASED STEM
15 CELL GROUPS, THE DISTRIBUTION HAS BEEN, I THINK, MORE
16 GENEROUS THAN SOME OF THE OTHER FIELDS. SO I'M HOPING
17 THAT ZACH IS RIGHT, THAT THERE ARE SOME CULTURES WITHIN
18 THE BIGGER CULTURE AND WE MIGHT BE MORE ALTRUISTIC.

19 THE OTHER POINT THAT I THINK A NUMBER OF YOU
20 HAVE BROUGHT UP IS THAT FOR THE BANK TO REALLY OPERATE
21 PROPERLY WITH KIND OF REPRODUCING AND REALLY GENERATING
22 AND DEMONSTRATING THAT THESE CELLS ARE, IN FACT, INTACT
23 AND STABLE IS GOING TO INVOLVE INVESTING A HUGE AMOUNT
24 OF MONEY. THE BANK HAS TO BE A RESEARCH INSTITUTE OF
25 ITS OWN TO INDEPENDENTLY CONFIRM THE VALIDITY OF ALL OF

1 THESE THINGS THAT WE GET. I THINK THERE ARE A LOT OF
2 TIMES WHEN YOU SEND REAGENTS AROUND YOU DON'T REALLY
3 KNOW THAT YOUR CONDITIONS ARE SLIGHTLY DIFFERENT THAN
4 SOMEONE ELSE'S. TO HAVE TO REPRODUCE THAT IS GOING TO
5 REQUIRE SUPERB SCIENTISTS AND A BIG COMMITMENT TO
6 MAKING THAT WORK.

7 I COULD ACTUALLY SEE THAT BECOMING AN
8 IMPORTANT RESEARCH INSTITUTE IN THE STATE OF
9 CALIFORNIA, FRANKLY.

10 DR. CIBELLI: GOING BACK TO WHAT BOB WAS
11 SAYING ABOUT THE QUALITY OF THE RESEARCH, THAT WILL
12 TAKE CARE OF ITSELF, I THINK. THAT SCIENCE, IF YOU
13 CAN'T REPLICATE WHAT -- PEOPLE CANNOT REPLICATE WHAT
14 YOU JUST PUBLISHED, YOUR GRANT WILL NOT BE RENEWED.
15 YOU'RE GOING TO PUBLISH IN LOW QUALITY JOURNALS, IF YOU
16 ARE LUCKY. THAT WILL TAKE CARE OF ITSELF.

17 THE ISSUE OF SHARING, YOU HAVE TO BE VERY
18 EXPLICIT OF THE CONSEQUENCES BECAUSE TEN YEARS, IT
19 LOOKS LIKE A LONG TIME, BUT IT'S GOING TO GO VERY, VERY
20 FAST. AND IF PEOPLE KEEP THE CELL LINES BECAUSE THEY
21 THINK THEY CAN GET MORE MONEY, IT'S HUMAN NATURE. IF
22 YOU'RE AN ASSISTANT PROFESSOR, YOU'RE WAITING FOR
23 TENURE, AND YOU WANT TO MILK THE CELL LINE AS MUCH AS
24 POSSIBLE, YOU'RE NOT GOING TO SHARE.

25 DR. HALL: LET'S DISCUSS IT LATER BECAUSE I

1 THINK THERE IS REALLY SOME ANECDOTAL EVIDENCE ON BOTH
2 SIDES, AND I'D BE HAPPY TO SHARE WHAT I HAVE.

3 CO-CHAIR LO: FRANCISCO. AND, ANN, DID YOU
4 WANT TO GET BACK IN? THEN BOB, AND I WANT TO TRY AND
5 PROPOSE SOME LANGUAGE. JEFF, DID YOU WANT TO GET IN AS
6 WELL?

7 DR. PRIETO: I THINK I'D ECHO MANY OF THE
8 OTHER COMMENTS, THAT WE JUST HAVE TO BE PRESCRIPTIVE IN
9 THIS PARTICULAR INSTANCE. IT HAS TO BE VERY UP FRONT,
10 THAT THIS IS THE EXPECTATION. IT'S THE EXPECTATION
11 THAT THE PEOPLE OF CALIFORNIA HAVE FOR THEIR MONEY,
12 WHICH IS WHAT'S ON THE TABLE HERE. I THINK IT'S ONE OF
13 THE REASONS WHY THERE ARE PATIENT ADVOCATES ON THE ICOC
14 BECAUSE WE'RE GOING TO DEMAND THAT. AND IT JUST HAS TO
15 BE PUT IN LANGUAGE UP FRONT THAT'S CLEAR AND
16 UNAMBIGUOUS. THEN I THINK PEOPLE WILL ABIDE BY IT.

17 DR. KIESSLING: IN ANCIENT HISTORY FOR
18 SHARING CELL LINES, JOSE, WHICH WAS BEFORE YOU WERE
19 BORN, PEOPLE SHARED CELL LINES. AND THAT'S HOW GILA
20 TOOK OVER EVERY LABORATORY. SO I THINK THERE IS A REAL
21 INTEREST. THERE'S A TIME WHEN GETTING YOUR CELL LINE
22 INTO SOMEBODY ELSE'S HANDS WAS MORE IMPORTANT THAN
23 ANYTHING ELSE.

24 DR. CIBELLI: YOU WERE NOT HERE WHEN I SAID
25 THAT LAST WEEK THERE WAS A PAPER --

1 DR. KIESSLING: NO. NO. I KNOW. TIMES ARE
2 DIFFERENT NOW.

3 DR. CIBELLI: THAT CELL LINE IS A VERY UNIQUE
4 CELL LINE. VERY DIFFICULT TO MAKE. IT WAS SPONSORED
5 BY NIH. I OFFERED A PI TO BE A COLLABORATOR.

6 DR. KIESSLING: I UNDERSTAND. THAT'S NOW.
7 AND 25 OR 30 YEARS AGO IT WAS DIFFERENT.

8 MR. KLEIN: DR. CIBELLI, MY COMMENT WAS AN
9 ATTEMPT, MY UNDERSTANDING IS IT PROBABLY VARIES A LOT
10 FROM CIRCUMSTANCE TO CIRCUMSTANCE, BUT SOMETIMES THE
11 PERSON WHO HAS SOMETHING THEY WANT TO PUBLISH REALLY
12 COOPERATES WITH ANOTHER LAB OR TWO LABS SO THEY CAN
13 REPLICATE THE WORK AND FULLY INFORM THOSE LABS, BUT IN
14 THE PUBLICATIONS THEMSELVES DOESN'T PUT EVERYTHING IN
15 THERE BECAUSE THEY'RE TRYING TO CREATE A TIME ADVANTAGE
16 WHERE THEY CAN MAINTAIN THEIR EDGE AND MOVE FORWARD IN
17 THE FIELD. AND THAT IS NOT CONDUCIVE TO GETTING THE
18 FULL COOPERATION AND SHARING WE NEED. SO THAT IF WE
19 INSTRUCT THAT THEY NEED TO DELIVER THE LINES WITH FULLY
20 ENABLING INFORMATION, WE CREATED A BURDEN THAT THEY
21 ATTEMPT TO FOLLOW OUR INTENT OF PROVIDING THE KNOWLEDGE
22 TO REALLY REPLICATE AT THE STEM CELL BANK VERSUS THE
23 LABS THAT VALIDATED THE PUBLICATION.

24 MR. SHEEHY: I WAS GOING TO ASK FOR SOME
25 LANGUAGE BECAUSE WE'RE TALKING ABOUT SOME SORT OF TEETH

1 IN THIS. SO WHAT ARE TEETH?

2 AND THE OTHER THING THAT I'M A LITTLE UNCLEAR
3 ABOUT IS THAT PUBLICATION SEEMS A TERM OF ART HERE,
4 THAT IT IS NOT ONE THAT'S READILY -- I SEE STUFF THAT
5 SITS FOR MONTHS BEFORE IT'S PUBLISHED. MAYBE STEM CELL
6 LINES ARE THE TYPE OF SCIENTIFIC INFORMATION THAT IS
7 EASILY AND READILY PUBLISHED, THAT SCIENTISTS RUSH TO
8 PUBLISH.

9 I ALSO WANT TO SAY THAT WHEN WE TALK ABOUT --
10 WHEN WE IMPOSE AN ACADEMIC MODEL, I WANT US TO HAVE IN
11 MIND A COMMERCIAL MODEL. DO COMMERCIAL ENTITIES, IF
12 THEY WERE TO MAKE A STEM CELL LINE WITH THE FUNDS FROM
13 US, WOULD THEY EVEN PUBLISH? WOULD THAT EVEN BE WITHIN
14 THE REALM OF SOMETHING THEY WOULD CONSIDER? SO I THINK
15 JUST WHEN WE CAST OUR NET, LET'S NOT LEAVE IT JUST
16 WITHIN AN ACADEMIC SETTING BECAUSE WE DO WANT TO ALLOW
17 INDUSTRY TO COMPETE AS WELL.

18 CO-CHAIR LO: LET'S TRY AND SEE WHAT WE CAN
19 COME UP WITH FOR LANGUAGE HERE. THERE'S SORT OF A
20 TRUNK STATEMENT. I GUESS ORIGINALLY IT SOUNDED LIKE
21 THERE'S A LOT OF SUPPORT FOR TIMELY PUBLICATION, BUT
22 JEFF JUST SORT OF RAISED THE ISSUE OF WHAT IF YOU DON'T
23 PUBLISH AT ALL. SOUNDS LIKE WE NEED TO HAVE SOMETHING
24 ON THE TIMELINE, SOMETHING ON ENFORCEMENT. I'VE HEARD
25 THAT FROM A NUMBER OF PEOPLE. IT STRIKES ME THAT MAYBE

1 WHAT WE WANT TO SAY IS FAILURE TO COMPLY WITH THIS WILL
2 BE GROUNDS FOR SUSPENSION OF THE GRANT OR
3 DISQUALIFICATION FROM FUTURE CIRM FUNDING, SOMETHING
4 LIKE THAT.

5 DR. HALL: I THINK THE SECOND, FAILURE TO
6 COMPLY WITH THESE WILL MEAN DISQUALIFICATION FROM
7 FUTURE CIRM FUNDING.

8 DR. PRIETO: WHY NOT SUSPENSION OF THE GRANT?

9 CO-CHAIR LO: IF IT'S LIKE A FIVE-YEAR GRANT
10 AND THEY PUBLISH SOMETHING THE FIRST YEAR, DON'T SHARE
11 IT, WOULD YOU GIVE THEM THE REST OF THE FUNDING?

12 DR. HALL: WELL, I GUESS YOU SAY IF YOUR
13 FUTURE CIRM FUNDING, IF THEY HAVE TO COME IN EVERY
14 YEAR, I THINK TO GO IN THE MIDDLE OF THE YEAR IS JUST
15 COMPLICATED TO SORT OUT WHAT THEY'VE SPENT. AND IF YOU
16 HAVE TO COME IN EVERY YEAR --

17 MR. SHESTACK: WE WANT TO MAKE CLEAR IT'S
18 RENEWAL. IT'S NOT LIKE A NEW GRANT, THAT IF YOU HAVE A
19 SECOND OR THIRD YEAR ON THE GRANT, YOU DON'T GET IT.

20 DR. HALL: JEOPARDIZE FUTURE CIRM FUNDING.

21 DR. ROWLEY: CONTINUATION OF FUNDING.

22 DR. PRIETO: CONTINUATION OF OR ANY FUTURE.

23 CO-CHAIR LO: JAMES, YOU WANT TO COMMENT ON
24 THE REGULATORY?

25 MR. HARRISON: ONE POINT OF CLARIFICATION.

1 CIRM GRANTEEES WILL BE REQUIRED TO COMPLY WITH ALL OF
2 THESE REGULATIONS THAT YOU'RE DEVELOPING AS A TERM OF
3 THEIR GRANT. IN OTHER WORDS, FAILURE TO COMPLY WITH
4 ANY ONE OF THESE REGULATIONS WILL JEOPARDIZE THEIR
5 GRANT. AND I ASSUME THAT'S SOMETHING THAT WILL BE
6 COVERED BY THE GRANTS ADMINISTRATION POLICY AND THE
7 TERMS AND CONDITIONS OF THE GRANT AGREEMENT ITSELF.

8 MR. SHESTACK: SOME THINGS YOU GOT TO SAY
9 TWICE.

10 MR. HARRISON: THAT MAY BE, BUT THE ONLY
11 CAUTION I RAISE IS THAT BY SPECIFYING THE ENFORCEMENT
12 MECHANISM WITH RESPECT TO ONE REQUIREMENT RAISES A
13 QUESTION ABOUT THE COMPLIANCE WITH THE OTHER CONDITIONS
14 AS WELL.

15 DR. HALL: THERE IS A POINT THAT A LOT OF
16 THOSE THINGS ARE AIMED AT THE INSTITUTIONS. IT'S THE
17 INSTITUTION'S FAILURE TO COMPLY AND THEY SIGN THE
18 AGREEMENT. MAYBE THIS SHOULD SAY IN THE GUIDELINES
19 WILL JEOPARDIZE AN INVESTIGATOR'S CONTINUED OR FUTURE
20 CIRM FUNDING.

21 MR. SHESTACK: BUT THERE'S A PHILOSOPHICAL
22 DIFFERENCE. IT'S NOT LIKE THE ESCRO QUESTION OR
23 SOMETHING LIKE THAT. CIRM HAS CREATED THIS, FULLY
24 FINANCED THE ASSET THAT IS BEING CREATED, AND SO IS
25 ASKING FOR A RETURN ON IT. AND I THINK IT'S A

1 DIFFERENT DESIGNATION. THERE'S A REASON TO SAY IT THIS
2 WAY AND TWICE.

3 DR. HALL: I'D LIKE TO SUGGEST THAT SOME
4 WORDING COMPARABLE TO WHAT BOB SAID ALSO BE PUT IN. I
5 THINK THAT MY GUESS IS THAT IN PRACTICE, ONCE THE BANK
6 IS SET UP, IF AN INVESTIGATOR CAN'T GET HIS CELL LINE
7 QUALIFIED THROUGH THE BANK, THEN THIS IS BAD NEWS. AND
8 IT'S BAD NEWS FOR THE INVESTIGATOR. AND WHAT THE BANK
9 WILL DO IS TO MAKE SURE THAT THEY CAN REPRODUCE IT
10 BEFORE THEY SEND IT OUT. SO ALL OF THOSE, YOU CAN'T
11 WITHHOLD YOUR INFORMATION FROM THE BANK OR ELSE YOU
12 LOSE OUT. I THINK THAT WILL SOLVE THAT PROBLEM, BUT WE
13 MIGHT WANT TO PUT IN CELL LINES ALONG WITH INFORMATION.

14 MR. KLEIN: ENABLING INFORMATION TO
15 FUNCTIONALLY REPLICATE THE LINES.

16 DR. HALL: YES.

17 MR. HARRISON: AGAIN, I DON'T KNOW WHETHER
18 FULLY ENABLING IS A TERM OF ART IN THE PATENT LAW. IT
19 MAY BE. I THINK WHAT WE REALLY MEAN IS THAT THEY HAVE
20 TO PROVIDE THE INFORMATION THAT'S NECESSARY TO
21 FUNCTIONALLY REPLICATE THE LINES.

22 MR. KLEIN: THE WORD "ENABLING" IS OUT OF THE
23 PATENT LAW, AND THE REFERENCE IS THERE'S STANDARDS THAT
24 HAVE BEEN LITIGATED AND PEOPLE HAVE SOME BENCHMARK.
25 BUT WHETHER --

1 DR. HALL: DEPENDS ON HOW YOU WANT TO DO IT.
2 I THINK WHAT JAMES SAID WOULD PROBABLY BE MORE
3 RECOGNIZABLE TO A SCIENTIST, ALTHOUGH I KNOW THE TERM
4 "ENABLING" --

5 MR. KLEIN: IF YOU SAID FULLY ENABLING TO
6 FUNCTIONALLY REPLICATE, THEY HAVE IT BOTH WAYS. THEIR
7 LAWYERS UNDERSTAND WHAT IT MEANS AND THEY UNDERSTAND
8 WHAT IT MEANS.

9 MR. LOMAX: THIS IS A GOOD EXAMPLE OF WHERE
10 WE'VE GOT ENOUGH OF THE INTENT UNDERSTOOD THAT WE WILL
11 SANDPAPER IT DOWN AND PUT THE EDGES.

12 CO-CHAIR LANSING: I THINK THIS IS A GOOD
13 RULE BECAUSE WE'RE GOING TO HAVE A CHANCE TO LOOK AT
14 THE LANGUAGE OVER AND OVER AGAIN.

15 CO-CHAIR LO: GOOD POINT.

16 DR. HALL: COULD YOU PUT SOMETHING UP.

17 CO-CHAIR LO: WE HAVE THIS UP HERE. WHAT I
18 SUGGEST IS WE CONTINUE THIS DISCUSSION, BUT AT THE END
19 I'D LIKE TO SORT OF SAY THIS IS WHAT WE MEAN IN TERMS
20 OF THE INTENT. KEEP IN MIND THAT BOTH STAFF AND JAMES
21 AND WE'RE PROBABLY GOING TO CHECK THIS WITH THE OAL TO
22 MAKE SURE THAT THE LANGUAGE --

23 DR. PETERS: IT IS POSSIBLE TO USE A LARGER
24 FONT FOR THAT? IT'S KIND OF DIFFICULT TO SEE FROM OUR
25 SIDE OF THE ROOM.

1 DR. CIBELLI: I THINK THAT THE ISSUE OF WHEN
2 IS SOMETHING THAT WE HAVE TO GET SOME CONSENSUS. I
3 HAVE BEEN TOLD AT ONE INTERNATIONAL MEETING THERE WERE
4 MORE LIKE 400 POSTERS, AND SOMEONE DID A STUDY HOW MANY
5 OF THOSE PRESENTATIONS TURNED INTO A PAPER IS ABOUT
6 ONE-THIRD, A QUARTER TO ONE-THIRD. SO THAT MEANS THEY
7 COULDN'T REALLY SUSTAIN THE CLAIMS OF THE ABSTRACT
8 BECAUSE EVERY SCIENTIST WANTS TO PUBLISH. IF YOU TELL
9 THEM THAT THEY HAVE TO SEND THE CELL LINE TO THE BANK
10 AS SOON AS THEY GIVE THE PRESENTATION OR THE ABSTRACT,
11 YOU ARE GOING TO END UP WITH A LOT OF CRAP.

12 SO I THINK YOU HAVE TO -- I THINK AT THE TIME
13 OF PUBLICATION IN A PEER REVIEW ARTICLE, THEN THAT
14 MEANS IT HAS PASSED PEER REVIEW. AND EVEN THOUGH YOU
15 MAY END UP WITH A LOT OF THE CRAP TOO, BUT IT CLEANS UP
16 A LITTLE BIT. MY SUGGESTION --

17 DR. PETERS: COULD I SPEAK DIRECTLY TO THAT?
18 THE DIFFICULTY WITH -- THE ADVANTAGE OF WHAT YOU ARE
19 SAYING IS THAT WHEN IT PASSES PEER REVIEW, THAT'S A
20 PLUS FOR THE KIND OF INFORMATION THAT THE BANK IS GOING
21 TO GET. HOWEVER, IN LIGHT OF WHAT JEFF WAS SAYING
22 EARLIER, I DON'T THINK WE SHOULD MAKE THE INFORMATION
23 THE BANK GETS CONTINGENT UPON PUBLICATION. IT SEEMS TO
24 ME THAT THE GRANTEES ARE GOING TO BE FILING PERIODIC
25 REPORTS, THEY MIGHT FILE SUMMARY REPORTS, AND THOSE

1 REPORTS WOULD CONTAIN THIS INFORMATION. AND IF THE
2 INVESTIGATOR WOULD LIKE TO KEEP INFORMATION EMBARGOED
3 FOR A PERIOD OF TIME, THAT COULD BE AGREED ON BETWEEN
4 THE INVESTIGATOR AND THE BANK. BUT IT WOULD SEEM TO ME
5 THAT WE WOULDN'T WANT THE BANK'S INFORMATION TO BE
6 CONTINGENT UPON PUBLICATION. THAT'S NOT WHAT YOU
7 SUGGEST?

8 DR. CIBELLI: I DON'T UNDERSTAND WHAT YOU ARE
9 SAYING. I'M SORRY.

10 DR. PETERS: WHETHER A RESEARCHER PUBLISHES
11 OR DOESN'T PUBLISH, THE BANK STILL WANTS THE
12 INFORMATION IT NEEDS TO DECIDE WHETHER OR NOT THIS IS A
13 CELL LINE THAT CAN BE DISTRIBUTED TO OTHER RESEARCHERS.

14 DR. CIBELLI: BUT YOU DIDN'T GET THE CELL
15 LINE YET. WE'RE TALKING ABOUT WHEN WE WILL ENFORCE
16 THIS AND TELL THE PERSON, THE PI, THEY HAVE TO DEPOSIT
17 THE CELL LINE IN THE BANK. SO THAT'S WHAT WE'RE
18 TALKING ABOUT.

19 DR. PETERS: WHAT I'M SUGGESTING IS THE
20 RESEARCHER WILL HAVE SOME KIND OF SCHEDULE FOR PERIODIC
21 REPORTING ANYWAY, WON'T THE RESEARCHER? AND WOULDN'T
22 THAT INFORMATION, THE FULLY ENABLING INFORMATION,
23 APPEAR IN THOSE REPORTS?

24 DR. CIBELLI: AND?

25 DR. TAYLOR: INDUSTRY INVESTIGATORS MIGHT NOT

1 BE INCENTED TO PUBLISH PARTICULARLY.

2 DR. CIBELLI: INDUSTRY WILL BE HARD TO DO.

3 DR. TAYLOR: WE'RE DEALING WITH THEM ALSO. I
4 THINK JEFF'S BRINGING THIS UP.

5 CO-CHAIR LO: IT SOUNDS LIKE THERE'S TWO
6 ISSUES. ONE, FOR PEOPLE WHO ARE GOING THROUGH THE PEER
7 REVIEW PUBLICATION, IS THAT THE BENCHMARK AT WHICH TIME
8 WE WANT THEM TO DEPOSIT BOTH THE LINE AND THE FULLY
9 ENABLING INFORMATION, WITH THE ARGUMENT THAT JOSE MADE,
10 OTHERWISE YOU ARE GOING TO GET STUFF THAT REALLY ISN'T
11 VERY GOOD VERSUS TED'S POINT THAT MAYBE YOU WANT IT
12 EARLIER. BUT THEN WE HAVE TO GO BACK TO JEFF'S
13 QUESTION EARLIER ABOUT WHAT ABOUT CIRM-FUNDED
14 RESEARCHERS WHO ARE IN FOR-PROFIT COMMERCIAL ENTITIES
15 TRYING TO DEVELOP PRODUCT WHO DON'T HAVE THE NECESSARY
16 INCENTIVE TO PUBLISH. AT WHAT POINT DO WE EXPECT THEM
17 TO DEPOSIT CIRM-FUNDED MATERIALS? I JUST DON'T KNOW
18 ENOUGH ABOUT THE FIELD TO KNOW WHAT'S REASONABLE.

19 DR. TAYLOR: THEY WOULDN'T BE FILING PATENTS
20 AND THINGS LIKE THAT.

21 MR. KLEIN: I THINK THAT'S A VERY GOOD
22 DIRECTIVE. WHY NOT SAY OR WITHIN 12 MONTHS AFTER
23 FILING THE PATENT APPLICATION? NOW, GENERALLY IF YOU
24 ARE IN THE PRIVATE SECTOR, MY UNDERSTANDING IS THAT IF
25 YOU ARE GOING TO MAKE A PRESENTATION TO A NATIONAL

1 SOCIETY, FOR EXAMPLE, THEY'RE GOING TO FILE YOUR PATENT
2 APPLICATION BEFORE YOU EVER MAKE THAT PRESENTATION.
3 BUT IF YOU SAY, LOOK, WITHIN 12 MONTHS AFTER THE FILING
4 OF THE PATENT --

5 DR. CIBELLI: THEY WOULDN'T TELL YOU. WHY
6 WOULD THEY TELL YOU WHEN THEY FILE THE PATENT?

7 MR. KLEIN: WELL, IF THEY'RE GETTING FUNDING
8 FROM US --

9 DR. CIBELLI: ONLY AFTER 18 MONTHS AFTER
10 FILING THE FULL PATENT. SO YOU HAVE PROVISIONAL
11 PATENT, THEN YOU HAVE 12 MONTHS, AND THEN AFTER THOSE
12 12 MONTHS, YOU HAVE 18 MONTHS TO BE PUBLIC INFORMATION.

13 MR. KLEIN: IT'S NOT PUBLIC INFORMATION
14 BECAUSE WE'RE ONLY TALKING ABOUT THE PEOPLE THAT HAVE A
15 CONTRACT WITH US. SO IF THEY FILE FOR A PROVISIONAL
16 PATENT, THEY'D HAVE TO REPORT THAT TO US.

17 DR. CIBELLI: WHY?

18 MR. KLEIN: BECAUSE WE PUT IT IN OUR CONTRACT
19 TO SAY IF YOU WANT TO GET GRANT FUNDING FROM US, IT'S A
20 REQUIREMENT. THAT'S WHAT I'M SUGGESTING.

21 DR. CIBELLI: THIS IS A HUGE DEPARTURE FROM
22 WHAT NIH DOES. NIH ALLOWS YOU TO JUST THIS IS YOUR
23 MONEY, GO BUILD A BUSINESS AROUND THIS. WE DON'T WANT
24 TO HAVE ANY RIGHTS. WE DON'T WANT TO HAVE ANY PATENT.

25 DR. HALL: WE DON'T WANT NECESSARILY THE

1 PATENTS, BUT WE WANT TO BE INFORMED.

2 DR. PRIETO: AND WE WANT THEM TO SHARE.

3 MR. KLEIN: WE WANT TO BE INFORMED, AND WE'RE
4 JUST SETTING UP A STANDARD. IF WE SAY 12 MONTHS AFTER
5 THEY FILE FOR A PROVISIONAL PATENT.

6 MR. SHESTACK: WHAT YOU ARE SAYING IMPLICITLY
7 IS THAT YOUR PATENT MUST -- IF YOU ARE DOING STUFF WITH
8 OUR MONEY, YOU MUST AGREE TO MANDATORY RESEARCH
9 LICENSING. THAT IS WHAT YOU'RE DE FACTO SAYING BY
10 SAYING IT HAS TO GO IN THE BANK, RIGHT?

11 MR. SHEEHY: WE ALSO NEED TO MAKE SURE THAT
12 THEY DECLARE WHEN THEY APPLY FOR A PATENT.

13 MR. KLEIN: WHEN THEY DECLARE FOR A
14 PROVISIONAL PATENT --

15 CO-CHAIR LO: LET'S HAVE -- JON WAS SPEAKING.

16 MR. SHESTACK: IT WAS JUST FOR CLARIFICATION.

17 CO-CHAIR LO: SO WE'RE GOING TO HAVE JON AND
18 THEN JEFF AND BOB FILL US IN.

19 MR. SHESTACK: TWO DIFFERENT THINGS. I THINK
20 THE POINT OF CLARIFICATION IS IF YOU ARE PUTTING
21 SOMETHING IN THE BANK, IT IS FOR DISTRIBUTION. SO
22 WHATEVER ANYBODY'S PATENTS ON IT ARE, WE ARE REQUIRING
23 THAT THEY MAKE THEIR PATENTED MATERIAL AVAILABLE FOR
24 RESEARCH USE. AND THAT IS THE DE FACTO BOTTOM LINE.
25 IF YOU HAVE A CELL BANK, THAT IS WHAT YOU'RE DOING. I

1 DON'T KNOW PATENT LAW VERY WELL, BUT IT SEEMS THAT IS
2 THE MINIMUM REQUIREMENT.

3 CO-CHAIR LO: JEFF, BOB, AND THEN JOSE.

4 MR. SHEEHY: I THINK WHAT JOSE WAS
5 REFERENCING IS THAT THERE'S NO PREREQUISITE THAT WHEN
6 PEOPLE -- PEOPLE DON'T HAVE TO TELL ANYBODY WHEN THEY
7 APPLY FOR A PATENT. UNLESS WE PUT THAT IN LANGUAGE IN
8 HERE THAT REQUIRES PEOPLE WHO ATTEMPT TO PATENT A CELL
9 LINE, THEY HAVE TO LET US KNOW WHEN THEY FILE THE
10 PATENT APPLICATION, WE WON'T BE ABLE TO START THAT
11 CLOCK. THAT DOES LEAD US INTO THE TRICKY IP ISSUES,
12 WHICH WE KIND OF SKIRTED, BUT WE CAN'T ASSUME THAT
13 WE'RE GOING TO GET THAT INFORMATION BECAUSE WE ARE
14 TALKING ABOUT BAYH-DOLE AND AN NIH-TYPE MODEL. THAT'S
15 WHAT CCST GAVE US. WE CAN'T ASSUME THAT WE'RE GOING TO
16 GET THIS PATENT KNOWLEDGE -- WE CAN'T ASSUME WE'RE
17 GOING TO HAVE ANY BETTER INFORMATION ABOUT PATENTING
18 THAN WHAT ALREADY EXISTS IN THE WORLD TODAY.

19 EITHER WE PUT THAT LANGUAGE IN HERE, BOTH
20 REQUIRING THAT THE INVESTIGATOR INFORM US WHEN THE
21 PATENT APPLICATION IS SOUGHT, AND THEN PUT IT IN THE
22 CRITERIA WITHIN 12 MONTHS OF THAT, THEY MAKE IT
23 AVAILABLE, OR SOMETHING ELSE.

24 MR. KLEIN: I THINK IT'S GOING TO BE
25 IMPORTANT TO GET COOPERATION FROM THE PRIVATE SECTOR,

1 THAT THEY CAN CONFIDENTIALLY INFORM US OF THE
2 PROVISIONAL FILING FOR A PATENT. IT'S 12 MONTHS AFTER
3 THAT DATE WE'RE GOING TO REQUIRE THEM TO CONTRIBUTE THE
4 CELL LINES BECAUSE THE PRIVATE SECTOR WON'T PARTICIPATE
5 IF THEY HAVE TO PUBLICLY ANNOUNCE, AND IT ALSO WOULD
6 HAVE STOCK IMPLICATIONS AND OTHER ISSUES THAT COULD
7 HAPPEN IF YOU MADE THEM PUBLICLY ANNOUNCE WHEN THEY
8 FILE FOR A PROVISIONAL PATENT.

9 THEORETICALLY THE KEY IS THEY WOULD
10 CONFIDENTIALLY COMMUNICATE TO US PURSUANT TO THEIR
11 CONTRACTUAL OBLIGATIONS THAT THEY'VE PROVISIONALLY
12 FILED FOR A PATENT, AND THEY WOULD SHARE THE LINES
13 WITHIN 12 MONTHS AFTER THAT DATE OR SUCH EARLIER DATE
14 AS THEY PUBLISH.

15 DR. CIBELLI: I WANT TO GO BACK TO WHAT WE'RE
16 TALKING HERE IS WHEN WE GOING ASK THEM TO PLEASE
17 TRANSFER THE CELL LINES TO THE BANK. SO IN ACADEMIA WE
18 SORT OF DECIDED THAT IT WILL BE AT THE TIME OF
19 PUBLICATION IN A PEER REVIEW ARTICLE. FOR INDUSTRY NOW
20 YOUR APPLYING COMPLETELY DIFFERENT STANDARD BECAUSE IF
21 YOU THINK YOU HAVE A CELL LINE THAT IS WORTH THE
22 PATENT, THAT KIND OF PUTS YOU AT THE SAME LEVEL OF,
23 OKAY, THIS IS THE TIME TO WRITE A PAPER. THEN YOU'VE
24 GIVEN THEM 12 MONTHS. AND THEN IN 12 MONTHS THAT CELL
25 LINE WILL BE AVAILABLE IN THE BANK, AND IT WILL BE

1 ANNOUNCED TO THE WORLD WE HAVE THIS WONDERFUL CELL LINE
2 THAT GLOWS IN THE DARK, SO EVERYBODY WILL WANT THAT
3 CELL LINE. THAT WILL NOT FLY WELL IN INDUSTRY BECAUSE
4 YOU'RE SUPPOSED TO HAVE MUCH MORE TIME TO DEVELOP A
5 PRODUCT. AND YOU'RE COUNTING ON THE 12 MONTHS OF
6 PROVISIONAL AND THEN THE 18 MONTHS TO DO THE -- UNTIL
7 IT BECOMES PUBLIC WHEN YOU GO INTERNATIONAL.

8 I THINK IT WOULD BE GREAT IF THAT WORKS; BUT
9 IF YOU ARE GOING TO DO IT THAT WAY, IF YOU ARE GOING TO
10 APPLY THE SAME THING YOU'RE APPLYING TO ACADEMIA, THAT
11 IS, AT THE TIME OF THE PUBLICATION OF THE PAPER, IT
12 SHOULD BE THE TIME YOU FILE FOR THE PATENT.

13 MR. KLEIN: WELL, THE PROVISIONAL FILING FOR
14 THE PATENT, YOU MAY NOT HAVE YOUR PAPER WORKED OUT.

15 DR. CIBELLI: THAT'S TRUE.

16 MR. KLEIN: SO I'M TRYING TO GIVE THEM 12
17 MONTHS TO REALLY FILE TO PROTECT THEIR KNOWLEDGE, BUT
18 THEN WORK OUT REPLICATION AND GET TO THE STEPS --

19 DR. CIBELLI: SO WE'RE AT THE FULL PATENT.
20 AT THE TIME OF THE FULL PATENT, SO THAT'S 12 MONTHS
21 AFTER THE PROVISIONAL, THAT WHEN YOU TELL THEM PLEASE
22 BRING IT TO THE BANK.

23 MR. KLEIN: OKAY. SO THAT'S ESSENTIALLY
24 CREATING THE STANDARD. SO IT SOUNDS LIKE WE SHOULD
25 REFERENCE THE TIME THEY APPLY FOR THE FULL PATENT.

1 DR. CIBELLI: SO THEY'LL BE CONCEDING TO CIRM
2 SIX MONTHS OF LEEWAY. OTHERWISE, THEY WILL HAVE SIX
3 MORE MONTHS TO BE QUIET, BUT NOW THEY'RE SAYING, OKAY,
4 WE'LL DO THIS FOR YOU.

5 CO-CHAIR LO: ZACH, AND THEN I WANT TO TRY
6 AND LOOK AT THIS AND SEE IF WE'VE GOT THE GIST OF IT.

7 DR. HALL: JUST GOING TO RAISE THE QUESTION.
8 I ASSUME THAT WHEN WE WORK WITH PRIVATE COMPANIES, WE
9 WILL WRITE -- HAVE SEPARATE CONTRACTS FOR EACH OF
10 THOSE, WHICH THEY WILL NOT FOLLOW UNDER OUR GRANTS
11 ADMINISTRATION POLICY, I DO NOT THINK, JUST BECAUSE
12 THERE WILL BE A LOT OF SPECIAL THINGS THAT WE WANT TO
13 BE SURE ABOUT HAVING TO DO WITH INTELLECTUAL PROPERTY
14 AND HAVING TO DO WITH MAKING REAGENTS AVAILABLE FOR
15 RESEARCH. I THINK WE'LL HAVE TO HAVE SPECIAL LANGUAGE,
16 SPECIAL PROVISIONS, AND ALL THAT FOR IT. I DON'T KNOW.

17 THE QUESTION IS WHETHER WE PUT SOMETHING IN
18 HERE THAT MAY NOT BE NECESSARY AND MIGHT GET IN OUR WAY
19 LATER. I DON'T KNOW ABOUT THAT. I JUST RAISE THAT
20 ISSUE TO SORT OF PUT IT ON THE TABLE.

21 THAT WOULD BE MY ONLY -- IN A WAY THIS IS
22 MORE RELEVANT TO THE INTELLECTUAL PROPERTY PIECE THAN
23 TO BANKING, IS IT NOT? IT'S FOR SHARING. INFORM CIRM
24 IS DIFFERENT. THAT DOESN'T HAVE TO DO WITH SHARING.
25 THAT HAS TO DO WITH OUR OWN THING. BUT THE ISSUE IS

1 YOU WANT THEM TO SHARE REAGENTS AT THAT POINT? SEE, IF
2 THEY DON'T GO THROUGH THE BANK, THEY HAVE TO BE SENT TO
3 THE BANK BY THAT POINT; IS THAT RIGHT?

4 MR. SHEEHY: IT SEEMS TO ME LIKE OUR INTENT
5 HERE IS TO GET THE SHARING OF THE RESOURCE. SO IT
6 SEEMS THAT IT'S NOT -- I THOUGHT THE REGISTRY WOULD
7 REQUIRE THEM -- THE REGISTRATION LANGUAGE SEEMS LIKE
8 THAT WE WOULD ALREADY HAVE A GREAT DEAL OF INFORMATION,
9 ASSUMING THAT THIS STAYS IN, BUT IT SEEMS LIKE OUR
10 REQUIREMENT IS NOT TO INFORM CIRM. IT'S TO INFORM THEM
11 OF THE PATENT APPLICATION AND THEN TO MAKE THE CELL
12 LINE AVAILABLE 12 MONTHS -- WITHIN THE 12 MONTHS THAT
13 THE PATENT APPLICATION HAS BEEN FILED. BECAUSE THEY
14 DON'T HAVE ANY REQUIREMENT RIGHT NOW TO INFORM US WHEN
15 THEY FILE THE PATENT.

16 DR. HALL: THAT WILL BE PART OF THE GRANTS
17 ADMINISTRATIVE POLICY CERTAINLY.

18 CO-CHAIR LO: HOLD ON A MINUTE. LET'S GO
19 BACK TO WHAT WE HAVE ON THE SCREEN JUST TO MAKE SURE WE
20 HAVE CAPTURED WHAT I THOUGHT WE'VE BEEN HEARING. GO TO
21 THE TOP OF THIS. CELLS DERIVED THROUGH CIRM-FUNDED
22 RESEARCH SHALL BE SHARED WITH THE INVESTIGATORS EITHER
23 THROUGH THESE VARIOUS MECHANISMS.

24 CELL LINES DERIVED THROUGH CIRM-FUNDED
25 RESEARCH SHALL BE SHARED WITH OTHER INVESTIGATORS

1 EITHER THROUGH THEIR INSTITUTION, AN ESTABLISHED STEM
2 CELL BANK, OR CIRM-FUNDED STEM CELL BANK. I'M GOING TO
3 SKIP THE NEXT THING, GEOFF. IN ADDITION TO THE STEM
4 CELL LINE, RESEARCHERS MUST ALSO SHARE OR DEPOSIT FULLY
5 ENABLING INFORMATION TO ENABLE OTHER RESEARCHERS TO
6 FUNCTIONALLY REPLICATE THE CELL LINE. FAILURE TO
7 COMPLY WILL BE GROUNDS FOR, AND I ACTUALLY THOUGHT WE
8 SHOULD SAY, NONCONTINUATION OF CIRM FUNDING OR
9 DISQUALIFICATION FROM FUTURE CIRM FUNDING. AND THEN
10 THE INVESTIGATOR SHALL DEPOSIT THE CELL LINES EITHER AT
11 THE DATE OF PUBLICATION OR AT THE TIME OF FILING A FULL
12 PATENT APPLICATION, WHICHEVER COMES FIRST.

13 THAT WOULD COVER, I THINK, BOTH THE ACADEMIC
14 AND THE -- JOSE AND THEN BOB.

15 DR. CIBELLI: I JUST THINK THAT THIS IS GOING
16 TO BE A VERY DIFFICULT ISSUE BECAUSE, IF I UNDERSTAND
17 PROPOSITION 71 WELL, WHAT HAS BEEN TOLD TO THE
18 TAXPAYERS OF CALIFORNIA IS THAT THIS IS GOING TO CREATE
19 A LOT OF OPPORTUNITIES IN BIOTECH AND THINGS OF THAT
20 NATURE, AT THE SAME TIME CURING DISEASES AND THINGS
21 LIKE THAT NATURE TOO. SO I THINK THAT THIS IS GOING TO
22 BE VERY HARD BECAUSE IF YOU ARE SITTING IN THE
23 TECHNOLOGY TRANSFER OFFICE OF STANFORD AND YOU'RE
24 COMING WITH DR. WEISSMAN'S LATEST PAPER, AND SAY, WELL,
25 THIS HAS A CELL LINE THAT COULD REALLY TURN INTO A NICE

1 START-UP BIOTECH COMPANY, DO YOU REALLY WANT TO PUBLISH
2 IT NOW BECAUSE IF YOU DO, THE CELL LINE GOES TO THE
3 BANK. WHY DON'T WE JUST FILE A PATENT AND SIT ON IT
4 FOR ANOTHER YEAR?

5 CO-CHAIR LO: PROVISIONAL PATENT APPLICATION.
6 DR. CIBELLI: FIRST THE PROVISIONAL.

7 MR. KLEIN: GOING BACK, DR. CIBELLI, IF WE
8 WENT BACK AND SAID -- LET'S GO BACK TO THE 18 MONTHS
9 PROVISION BECAUSE NORMALLY THEY'D HAVE 18 MONTHS FROM
10 FILING THE PROVISIONAL PATENT TO FILE A FULL PATENT.

11 DR. CIBELLI: YOU HAVE 12 MONTHS, AND THEN
12 THE PATENT, AND THEN 18 MONTHS UNTIL IT GETS PUBLIC.

13 MR. KLEIN: THAT'S RIGHT. WELL, THIS IS 12
14 MONTHS OF FILING A FULL PATENT.

15 DR. CIBELLI: RIGHT. SO YOU'RE ASKING THEM
16 TO WAIT SIX MONTHS BASICALLY.

17 MR. KLEIN: IN THIS CASE THEY'LL WANT TO FILE
18 A PATENT. WE'RE FORCING THEM, IF THEY WANT TO FILE A
19 PATENT TO PROTECT THE POTENTIAL FOR THIS ECONOMIC
20 OUTCOME, EVEN IF THEY DECIDE NOT TO PUBLISH IT, RIGHT,
21 THEY HAVE TO FILE A PATENT TO PROTECT IT. THEY WOULD
22 NOT WAIT TO A LATER TIME PERIOD. THEY'RE GOING TO TRY
23 AND PUT A PATENT ON THE RECORDS AS SOON AS POSSIBLE.
24 SO DOESN'T THIS COVER YOUR CASE BECAUSE IT'S WHICHEVER
25 IS EARLIER, EITHER 12 MONTHS FROM A FULL PATENT OR

1 PUBLICATION DATE?

2 DR. CIBELLI: IT'S JUST THAT IS GOING TO BE
3 OPEN FOR SPECULATION OF SOME GROUPS THAT ARE LINKED TO
4 BIOTECH. ALMOST EVERY PROFESSOR NOW HAS A BIOTECH
5 COMPANY.

6 DR. KIESSLING: JOSE, WOULD IT BE MORE FAIR
7 IF YOU APPLIED THE SAME STANDARD? WHAT IF IT SAID
8 WITHIN 18 MONTHS OF FILING A FULL PATENT OR
9 PUBLICATION?

10 DR. CIBELLI: EIGHTEEN MONTHS FROM
11 PUBLICATION. SHE'S SAYING THAT.

12 DR. KIESSLING: THAT'S THE SAME STANDARD.
13 THEN YOU'VE GOT THE SAME STANDARD APPLIED TO INDUSTRY.

14 DR. CIBELLI: I THINK THAT WE SHOULD HAVE THE
15 SAME STANDARDS, BUT AT THE SAME TIME I WANT TO HAVE
16 THAT DAMN CELL LINE THAT WAS PUBLISHED LAST WEEK.

17 CO-CHAIR LO: I THINK THAT WHAT ANN IS
18 SUGGESTING, CORRECT ME, IS THAT EITHER YOU GIVE IT TO
19 US WHEN YOU PUBLISH OR WITHIN 18 MONTHS AFTER YOU FILE
20 A FULL PATENT APPLICATION, WHICH IS WHEN YOU WOULD HAVE
21 TO MAKE IT PUBLIC ANYWAY. IT'S NOT 18 MONTHS AFTER
22 PUBLICATION.

23 DR. KIESSLING: WHAT JOSE IS SAYING IS
24 EXACTLY WHAT'S GOING TO HAPPEN. AND IT ISN'T GOING TO
25 BE NECESSARILY THE INVESTIGATOR THAT DOES THAT. IT'S

1 GOING TO BE THE INTELLECTUAL PROPERTY'S OFFICE. THEY
2 COME AROUND LIKE ONCE A MONTH AND SAY WHAT ARE YOU
3 DOING. SO HE'S RIGHT. THEIR RECOMMENDATION WILL BE,
4 LOOK, LET US FILE A PATENT ON THIS. CAN YOU SIT ON A
5 PUBLICATION FOR A WHILE?

6 MR. KLEIN: THAT'S FINE. THEY CAN DO THAT
7 BECAUSE WE'VE GOT A CONTROL HERE.

8 DR. KIESSLING: THAT'S REALLY IMPEDING --
9 YOU'RE NOT GOING TO HAVE THE INFORMATION.

10 DR. HALL: IT'S ACTUALLY PLAYING OFF
11 LONG-TERM VERSUS SHORT-TERM. I THINK ALL OF US REALIZE
12 THAT IN THE CURRENT SYSTEM, IF COMPANIES ARE GOING TO
13 PICK IT UP, THEY'RE GOING TO HAVE TO HAVE PATENTS ON
14 IT. YOU TRADE OFF THE SHORT-TERM GAIN FOR A
15 LONGER-TERM GAIN. IT SEEMS TO ME THAT WHAT WE'D WANT
16 TO DO IS TO NOT MAKE IT IMPOSSIBLE. WE WANT TO MAKE IT
17 POSSIBLE TO PATENT THINGS, BUT WE ALSO WANT TO MAKE
18 SURE THAT CELL LINES ARE AVAILABLE FOR RESEARCH
19 PURPOSES AS QUICKLY AND AS WIDELY AS POSSIBLE.

20 DR. CIBELLI: I UNDERSTAND YOUR INTENTIONS,
21 BUT THE MEMBERS OF THIS INSTITUTE ARE ALSO INDUSTRY,
22 ARE ALSO UNIVERSITIES, SO YOU HAVE TO RECONCILE THAT.
23 I DON'T KNOW HOW YOU ARE GOING TO DO IT. ME AS A
24 RESEARCHER, WEARING MY HAT, I WANT THE CELL LINE
25 TOMORROW. BUT IF I'M THE OWNER OF THE BIOTECH COMPANY,

1 I SAY WAIT A MINUTE. I NEED TO SELL THIS IDEA. I NEED
2 TO GO IN FRONT OF VENTURE CAPITAL AND TELL THEM THAT I
3 GOT THIS BEFORE YOU START DISTRIBUTING THE CELLS TO
4 EVERYBODY.

5 DR. HALL: LET ME SUGGEST IF WE JUST LEAVE
6 THE DEAL WITH THE NONPROFIT SITUATION FOR THE MOMENT.

7 DR. CIBELLI: WHO'S GOING TO PROFIT TODAY?

8 DR. HALL: WELL, IF IT'S IN A BIOTECH
9 COMPANY, IT'S A DIFFERENT MATTER, BUT THE UNIVERSITY
10 HAS CONTROL OF IT UNTIL IT'S LICENSED.

11 CO-CHAIR LO: PLEASE. I WANT TO GIVE
12 EVERYBODY A FAIR CHANCE. BOB AND THEN ANN, JEFF.

13 MR. KLEIN: I JUST WOULD JUST, ZACH, REMIND
14 YOU OF SOMETHING THAT I'M SURE YOU'RE -- I KNOW YOU'RE
15 KEENLY AWARE OF IS THAT SCRIPPS HAS A STANDING
16 AGREEMENT WITH NOVARTIS. AND UC SAN FRANCISCO HAS SOME
17 AGREEMENTS WITH GERON. SO IT'S NOT NECESSARILY A
18 COMPLETELY PURE SITUATION, BUT IT SEEMS THAT THIS --
19 THE ONLY THING THAT THAT DOES IS ESSENTIALLY FORCES
20 YOU, IF YOU'RE A PRIVATE COMPANY, YOU'D BE FORCED TO DO
21 A PUBLICATION OR TO GIVE US THE LINE SIX MONTHS EARLIER
22 THAN YOU OTHERWISE WOULD BE. SO IT SEEMS LIKE A
23 REASONABLE BALANCE BECAUSE A PRIVATE COMPANY WOULD HAVE
24 HAD 12 MONTHS FROM THE PROVISIONAL PATENT TO FILE A
25 FULL PATENT 12 MONTHS AFTER THAT. SO THEY WOULD HAVE

1 HAD 24 MONTHS. AND AT LEAST THIS WAY WE GET TO
2 PUBLICATION SIX MONTHS EARLIER IF YOU'RE TAKING THE
3 PRIVATE SECTOR VIEWPOINT, THAT YOU WANT TO DELAY TO THE
4 LAST MOMENT.

5 DR. CIBELLI: AND YOU ALSO WOULD HAVE IN
6 PLACE A MATERIAL TRANSFER AGREEMENT, SO THE TECHNOLOGY
7 SOMEHOW YOU CAN CLAIM ROYALTIES.

8 MR. KLEIN: YEAH. THEY GET THEIR NORMAL I.P.
9 CO-CHAIR LO: TRY AND KEEP TRACK NOW. ANN.

10 DR. KIESSLING: MAYBE THAT WAS RESOLVED. IT
11 SEEMS TO ME LIKE WHAT YOU NEED TO DO IS PROVIDE
12 PROTECTION FOR THE PERSON WHO DISCOVERED THE CELL LINE
13 AND STILL RELEASE THEM FOR MORE RESEARCH. THAT'S WHAT
14 YOU ARE TRYING TO DO.

15 CO-CHAIR LO: THAT SHOULD BE PART OF OUR
16 STATEMENT OF PURPOSE.

17 DR. CIBELLI: BUT I WANT TO BE -- IF I'M THE
18 PATIENT, I'LL BE REALLY, REALLY MAD BECAUSE OF ALL THIS
19 TECHNICALITY, THE CELL LINE WILL END UP BEING USED
20 WIDELY.

21 DR. KIESSLING: I UNDERSTAND THAT. WHAT YOU
22 ARE TRYING TO DO IS PROTECT THE PERSON WHO DEVELOPED
23 THE CELL LINE. YOU'RE PROTECTING THEIR REVENUE STREAM
24 WHILE PROVIDING THE CELL LINES FOR OTHER REASONS.

25 DR. HALL: I THINK YOU WANT TO PROTECT THE

1 FUTURE PRIVATE USE OF IT. THAT'S WHAT YOU WANT TO
2 PROTECT. ISN'T THAT TRUE, YOU WANT IT TO BE ATTRACTIVE
3 TO COMPANIES TO PICK --

4 DR. CIBELLI: ONCE YOU PUBLISH THE PAPER,
5 YOU'RE FINE.

6 CO-CHAIR LO: GUYS. GUYS, WAIT A MINUTE.

7 DR. CIBELLI: SO YOUR CV AND YOUR TENURE
8 PACKET.

9 DR. KIESSLING: FORGET THAT. FORGET THE
10 PUBLICATION.

11 DR. CIBELLI: THE THING IS WHEN YOU START
12 TALKING ABOUT RAISING MONEY FOR UNIVERSITIES OR FOR
13 PRIVATE INDUSTRY, HOW DO YOU DO THAT?

14 CO-CHAIR LO: PLEASE. PLEASE. PLEASE. I
15 REALLY WANT TO TRY AND MAKE SURE EVERYONE GETS A CHANCE
16 TO SPEAK, AND THAT THOSE WHO PUT THEIR NAMES ON THE
17 LIST AREN'T PENALIZED BY THOSE WHO ARE A LITTLE MORE
18 TALKATIVE. SO TED, JEFF. PROBLEM IS IF EVERYONE IS
19 TALKING, THEN IT'S WHO SHOUTS FIRST, WHICH MAY NOT BE
20 THE BEST WAY TO DO IT.

21 DR. PETERS: I WANT TO TALK ABOUT THE FIRST
22 PHRASE; BUT IF YOU PREFER TO FINISH THIS SUBJECT MATTER
23 AND THEN COME BACK TO ME, IT'S OKAY.

24 MR. SHEEHY: I STILL -- I'M UNCLEAR. I
25 THOUGHT OUR GOAL WITH THIS PARAGRAPH WAS TO MAKE THE

1 CELL LINES AVAILABLE AT THIS POINT, NOT TO INFORM CIRM.

2 CO-CHAIR LO: THAT LAST SHOULD BE -- IT'S NOT
3 INFORM. IT'S ACTUALLY MAKE THEM AVAILABLE TO OTHER
4 INVESTIGATORS AT THOSE TWO TIMES.

5 MR. SHEEHY: THIS IS DOWN THE ROAD, BUT I'LL
6 FORGET. I'M SHORT-TERM MEMORY CHALLENGED. WE DO NEED
7 TO HAVE SOMETHING IN THERE AT SOME POINT ABOUT THE COST
8 BECAUSE YOU CAN ASSIGN PROHIBITIVE COST TO MAKING THE
9 CELL LINE AVAILABLE. YOU CAN SAY, OH, YEAH, I'LL MAKE
10 IT AVAILABLE, BUT IT WILL COST YOU SO MUCH. SO WE NEED
11 TO HAVE SOME SORT OF FORMULA THAT KIND OF CAPTURES.

12 CO-CHAIR LO: CIRM SHALL FUND THE REASONABLE
13 COSTS OF MAKING THESE CELL LINES AVAILABLE TO OTHER
14 RESEARCHERS.

15 CO-CHAIR LANSING: AT CIRM ACCEPTED RATE.

16 DR. EGGAN: THIS IS KEVIN EGGAN. I WOULD
17 URGE YOU NOT TO UNDERESTIMATE THOSE COSTS.

18 CO-CHAIR LO: DON'T UNDERESTIMATE THE COST OF
19 MAKING CELL LINES AVAILABLE, WHICH MAY BE SUBSTANTIAL.

20 CO-CHAIR LANSING: WE WOULD HAVE TO ESTABLISH
21 WHAT'S REASONABLE, WOULDN'T WE?

22 CO-CHAIR LO: ALTHOUGH WE CAN'T SAY
23 REASONABLE IN THE GUIDELINES, RIGHT, WITHOUT THAT RUNS
24 AFOUL OF THE AOL.

25 DR. HALL: JUST PUT A NOTE. WE CAN COME UP

1 WITH SOME LANGUAGE. JUST PUT A FOOTNOTE IN THERE
2 SAYING CIRM WILL BEAR THE COST OR SOMETHING LIKE THAT.

3 CO-CHAIR LO: LET ME MAKE A SUGGESTION. I'M
4 NOT SURE WE HAVE TO WRAP EVERY ISSUE UP TODAY. IT
5 SEEMS LIKE THIS WHAT TO DO WITH THE INVESTIGATORS WHO
6 AREN'T GOING TO PUBLISH AND WHERE IN THE PATENT PROCESS
7 ARE WE GOING TO ASK THEM TO MAKE THEM AVAILABLE IS
8 SOMETHING I DON'T THINK WE HAVE CLOSURE ON HERE. AND
9 WE MAY NEED TO THINK ABOUT IT MORE AND GET SOME
10 FEEDBACK FROM INVESTIGATORS AND BIOTECH COMPANIES OF
11 WHAT THEY THINK IS REASONABLE.

12 BUT ARE THERE BIG ISSUES THAT ARE MISSING
13 HERE? JEFF BROUGHT UP THE COST. ARE THERE OTHER BIG
14 ISSUES? AND WE ALSO WANT TO GET SOME PUBLIC COMMENTS.

15 DR. PETERS: ON THE FIRST CLAUSE, THERE ARE
16 THREE POSSIBLY EXCLUSIVE OPTIONS. I WOULD LIKE TO
17 REDUCE THAT TO ONE AND ONLY ONE AND MANDATE THAT
18 EVERYTHING GO THROUGH THE BANK. I DON'T THINK IT
19 SHOULD BE LEFT TO AMBIGUITY AS TO WHETHER A BANK WILL
20 EXIST OR THAT IT WILL BE THE FOCUS OF BOTH CHANNELING
21 INFORMATION AS WELL AS THE LINES.

22 CO-CHAIR LO: JAMES, IF WE NOW DON'T HAVE A
23 BANK, CAN WE MANDATE THAT THEY --

24 DR. PETERS: I THINK IT'S VERY IMPORTANT,
25 THOUGH, IN OUR VISION THAT WE MAKE A DECISION NOW

1 WHETHER WE'RE GOING TO HAVE A BANK BECAUSE IF WE HAVE
2 LITTLE OPENINGS, SOMEBODY IS GOING TO DRIVE A WEDGE
3 THROUGH THERE. I THINK WE CAN FORECAST THAT THE BANK
4 IS GOING TO TURN OUT TO BE THE TECHNICAL EXPERTISE THAT
5 IS GOING TO REALLY MAINTAIN QUALITY CONTROL AS WE GO, I
6 THINK, ONCE WE DESIGN HOW THAT BANK IS GOING TO
7 FUNCTION. AND RIGHT NOW I THINK THE VAGUENESS HERE
8 MIGHT GET US INTO TROUBLE ON DOWN THE LINE.

9 DR. HALL: COULD WE SAY SOMETHING LIKE
10 THROUGH A CIRM-FUNDED STEM CELL BANK. OR IF THAT'S NOT
11 AVAILABLE OR SOMETHING LIKE THAT BECAUSE IT IS POSSIBLE
12 THAT THESE LINES MAY COME UP BEFORE WE GET THE BANK
13 ROLLING. AND THE THING WE WANT TO EMPHASIZE TO PEOPLE
14 IS THE NEED TO SHARE.

15 DR. PETERS: I THINK GIVEN ALL THE PROBLEMS
16 THAT JOSE HAS BEEN RAISING, WE CAN'T JUST ENCOURAGE
17 THEM TO SHARE. IT'S REALLY GOING TO HAVE TO BE
18 MANDATED, ORCHESTRATED, AND POLICED.

19 CO-CHAIR LO: LET ME SUGGEST THAT IF IT'S THE
20 SENSE OF THIS GROUP THAT OUR STRONG PREFERENCE IS THAT
21 THESE BE PUT INTO A CIRM-FUNDED BANK, BUT THAT IF THAT
22 DOESN'T EXIST, WE ALLOW OTHER OPTIONS, THAT WE TALK
23 WITH JAMES ABOUT HOW TO CRAFT. I DON'T WANT TO TRY AND
24 CRAFT THAT ACTUAL LANGUAGE HERE BECAUSE I THINK THAT'S
25 SOMETHING LEGAL COUNSEL IS GOING TO NEED TO DO. BUT

1 TED'S POINT, WHICH I THINK IS A GOOD ONE, IS THAT WE
2 WANT TO SAY PUT IT IN A CIRM STEM CELL BANK; AND IF
3 THERE IS NOT ONE, HERE ARE SOME OTHER OPTIONS. LET'S
4 WORK OUT HOW TO DO THAT.

5 ARE THERE ANY OTHER BIG ISSUES? IF NOT --
6 JEFF, PLEASE.

7 MR. SHEEHY: CAN I GET SOME CLARIFICATION ON
8 THIS PATENT ISSUE? WE TALKED ABOUT A PROVISIONAL
9 PATENT AND NOW IT SAYS FULL PATENT. I'M REALLY LOST ON
10 THIS. YOU'VE GOT 12 MONTHS FROM PROVISIONAL TO FILING
11 A FULL, AND FROM FULL YOU'VE GOT 18 MONTHS.

12 CO-CHAIR LO: THE OTHER SUGGESTION IS THAT,
13 AGAIN, THIS IS AN ISSUE THAT WE MAY WANT TO GET SOMEONE
14 WHO KNOWS IP -- WHO'S A LAWYER TO HELP WALK US THROUGH
15 THAT. I'M JUST CONCERNED -- I THINK, AS SOMEONE SAID,
16 WE'RE TRYING TO BALANCE CONFLICTING GOODS HERE. ONE IS
17 TO MAKE THIS INFORMATION WIDELY AVAILABLE SO
18 RESEARCHERS CAN BENEFIT SO THAT ULTIMATELY PATIENTS CAN
19 BENEFIT. ON THE OTHER HAND, WE DON'T WANT TO MAKE IT
20 SO -- CREATE SUCH A DISINCENTIVE THAT PEOPLE WILL HAVE
21 PROBLEMS TRYING TO PATENT MATERIALS. SO YOU'RE RIGHT.
22 WHERE EXACTLY IN THAT SEQUENCE, PROVISIONAL VERSUS
23 FULL, 12 VERSUS 18, I'M NOT SURE THAT'S SOMETHING WE
24 WANT TO TRY AND RESOLVE TODAY WITHOUT MORE INFORMATION.

25 BOB AND THEN JOSE.

1 MR. KLEIN: GIVING FULL CREDIT TO MY
2 COLLABORATOR HERE, ANN SUGGESTED WE USE THE TERM "A
3 CIRM-DESIGNATED BANK." THAT DEALS WITH THE ISSUE OF
4 WHETHER OR NOT THERE IS A STATE STEM CELL BANK IN
5 EXISTENCE BECAUSE CIRM, IF THERE IS, CAN DESIGNATE ITS
6 CELL BANK; OR OF THERE ISN'T OR IF IT'S PARTICULARLY
7 COSTLY, IF YOU HAVE FUSION CELLS AND ONLY A UNIVERSITY
8 KNOWS HOW TO MAINTAIN THOSE IN A BANK, THEY CAN
9 DESIGNATE THAT BANK AS THE BANK FOR THOSE TYPE OF CELL
10 LINES. I THINK HER SUGGESTION WAS A VERY EFFECTIVE
11 ONE, TO PERHAPS DEAL WITH THE VARIABLE FACT PATTERNS
12 THAT MAY BE FACED.

13 DR. CIBELLI: I'M GOING TO CLARIFY THE
14 PROVISIONAL. THAT'S WHAT YOU WANTED? I'M NOT A
15 LAWYER. I'M JUST AN INVENTOR, I GUESS. BUT IF YOU
16 HAVE AN IDEA THAT YOU ARE GOING TO CREATE A CELL LINE
17 THAT GLOWS IN THE DARK, YOU WRITE IT IN A BOOK, AND
18 THEN YOU CAN JUST THE NEXT DAY WRITE A PROVISIONAL
19 PATENT. THEN YOU HAVE 12 MONTHS TO WORK VERY, VERY
20 HARD TO CREATE THAT CELL LINE. AND WHEN THE 12 MONTHS
21 PERIOD COMES, AND IF YOU DON'T HAVE THE CELL LINE, YOU
22 JUST DROP THE WHOLE THING. IF YOU DO HAVE THE CELL
23 LINE, THEN IT'S WORTH PATENTING. THAT'S WHAT THE FULL
24 PATENT IS.

25 MR. SHEEHY: SO WE SHOULD DO 12 MONTHS FROM

1 FILING BARRING -- JUST TO GET SOME CLARIFICATION.

2 MR. KLEIN: THE REASON IT'S NOT 12 MONTHS
3 FROM PROVISIONAL PATENT IS IN THE PRIOR DISCUSSION, DR.
4 CIBELLI POINTED OUT QUITE CORRECTLY THAT AFTER YOU HAVE
5 YOUR CELL LINE CREATED, YOU MAY NEED A TIME TO GET
6 OTHER LABS TO REPLICATE IT AND MEET OTHER STANDARDS.
7 SO THE 12 MONTHS IS A COMPROMISE BECAUSE YOU'RE
8 ACTUALLY ALLOWED 18 MONTHS OTHERWISE. AND THIS WOULD
9 ESSENTIALLY CREATE A FASTER STANDARD BECAUSE WE WANT IT
10 OUT THERE FOR BENEFIT OF PATIENTS.

11 MR. SHEEHY: I'M FINE.

12 CO-CHAIR LO: I'M GOING TO ASK THE PUBLIC TO
13 COMMENT. FOR THE RECORD, PLEASE IDENTIFY YOURSELVES.

14 MR. REED: DON REED. I TALKED TO AN ENGLISH
15 SCIENTIST ABOUT THIS ISSUE, AND HE SAID THAT HE FELT IT
16 WAS IMPORTANT THAT THE STEM CELL LINES, WHICH THEY ARE
17 REQUIRED TO DO, BE GIVEN TO A CENTRAL REPOSITORY AS A
18 NEUTRAL TERRITORY RATHER THAN HAVING TO SHARE THEM WITH
19 RIVALS. HE SAID ALSO THAT WAY THERE'S ONLY ONE TIME OF
20 PAINFUL SHARING RATHER THAN MULTIPLES.

21 SECONDLY, I DON'T RECALL HIM SAYING ANYTHING
22 ABOUT WAITING 18 MONTHS. I BELIEVE THAT AS SOON AS THE
23 STEM CELL LINES WERE DERIVED, THEY HAD TO BE DEPOSITED
24 SO THAT THE RESEARCH COULD BE SHARED AND GO ON, BUT THE
25 PROFIT SITUATION COULD BE SEPARATE.

1 CO-CHAIR LO: THANK YOU. WE HAD ANOTHER
2 PUBLIC COMMENT.

3 MR. WONG: JOHN WONG, AND I REPRESENT THE
4 PRIVATE SECTOR. SO I HAVE A SUGGESTION, AND YOU CAN
5 TAKE IT FOR WHAT IT'S WORTH, BUT ALSO THE CELL LINES
6 ARE IMPORTANT. INDEED, THEY ARE IMPORTANT. ONE THING
7 THAT YOU ARE MISSING IS ALSO THE SPECIALTY MEDIA THAT'S
8 REQUIRED TO GROW UP THESE CELL LINES. I THINK THAT ALL
9 SHOULD BE EXPANDED TO BE IN THE DISCLOSURE BECAUSE
10 THERE COULD BE INVENTIONS WITH REGARDS TO NOVEL
11 BIOFACTORS, ETC., THAT ESTABLISHES THESE UNIQUE CELL
12 LINES THAT GLOW IN THE DARK. I THINK YOU ALSO NEED TO
13 CONSIDER THAT AS PART OF THE INTELLECTUAL PROPERTY THAT
14 NEEDS TO BE CONSIDERED IF YOU ARE GOING TO FUND THAT
15 RESEARCH AND THOSE TYPE OF DISCOVERIES COME OUT OF
16 THERE.

17 CO-CHAIR LO: THANK YOU.

18 DR. HALL: CAN I JUST RELATE AN ANECDOTE THAT
19 ACTUALLY TOUCHES ON SOMETHING JOSE SAID, SOMETHING THAT
20 TED SAID, AND SOMETHING THAT DON REED SAID. I SPOKE
21 LAST WEEK WITH AN ENGLISH RESEARCHER WHO'S DERIVED
22 SEVERAL CELL LINES. IT TURNS OUT THAT ALTHOUGH THE UK
23 HAS A STEM CELL BANK, THAT IT IS NOW -- IT'S NOT
24 OPERATING AT FULL CAPACITY, SO THEY CAN'T TAKE NEW
25 LINES. SO HE WANTED TO SHARE HIS LINES WITHIN THE UK

1 COMMUNITY. AND SO WHAT HE DID ACTUALLY WAS TO APPLY TO
2 THE BANK, GO THROUGH ALL THE BANK PAPERWORK, AND THEN
3 HE HIMSELF SENT THE LINES OUT TO THE VARIOUS
4 COLLABORATORS.

5 A, IT IS POSSIBLE TO BE COLLEGIAL IN THE STEM
6 CELL FIELD. B, SOMETIMES WHEN THE BANK ISN'T READY,
7 YOU HAVE TO HAVE ANOTHER MECHANISM THAT FOLLOWS THE
8 BANK PROTOCOL, BUT ALLOWS THEM TO SEND IT OUT. AND
9 THAT, I GUESS, RELATES ALSO TO WHAT YOU SAID AS WELL.
10 INTERESTING LITTLE --

11 MR. KLEIN: IN LIGHT OF THE PUBLIC COMMENT WE
12 JUST HAD, POTENTIALLY WE SHOULD CONSIDER FUNCTIONAL
13 ENABLING INFORMATION, FULLY ENABLING INFORMATION TO
14 FUNCTIONALLY REPLICATE THE CELL LINES AND THE MEDIUM TO
15 MAINTAIN THEM.

16 CO-CHAIR LO: MY SUGGESTION IS THAT WE ASK
17 STAFF TO WORK WITH THIS AND TO FORMULATE THEM IN
18 REGULATORY LANGUAGE, AND THEN LET'S CIRCULATE THIS. WE
19 WILL THEN HAVE AN OPPORTUNITY TO SEE DID WE LEAVE
20 THINGS OUT. DID WE GET THE LANGUAGE QUITE RIGHT? IS
21 12 MONTHS EXACTLY RIGHT? IT SEEMS TO ME THIS IS A GOOD
22 START TOWARDS SETTling -- TO WRITING REGULATIONS WITH
23 REGARD TO THE BANKING. SO IS THAT AGREEABLE TO PEOPLE?
24 I'M GOING TO CHARGE THE STAFF AND JAMES HARRISON AND
25 HIS GROUP TO HELP US MAKE THIS INTO REGULATORY LANGUAGE

1 THAT WILL PASS MUSTER WITH THE OAL.

2 DR. ROWLEY: I JUST WANT TO CLARIFY A POINT,
3 PARTICULARLY WHILE JOSE AND OTHERS ARE HERE. IT SEEMED
4 TO ME THAT WE SAID THAT THE FILING OF A FULL PATENT HAD
5 GIVEN THE COMPANY 12 MONTHS ALREADY TO WORK ON WHATEVER
6 SPECIAL THINGS IT IS. AND SO NOW, IN ESSENCE, WE'RE
7 GIVING THE 12 MONTHS OF THE PROVISIONAL PATENT AND 12
8 MONTHS OF A FULL PATENT; WHEREAS, FOR AN INDIVIDUAL
9 INVESTIGATOR, WHENEVER THEY PUBLISH, THAT'S WHEN THEY
10 HAVE TO SHARE THE LINE. AND I DO NOT THINK THAT THAT'S
11 EQUIVALENT FOR INVESTIGATORS AND FILING PATENTS.

12 SO I THINK THAT WITHIN 12 MONTHS OF FILING A
13 FULL PATENT, I THINK THAT'S WRONG. I THINK AT THE TIME
14 OF FILING OF A FULL PATENT OR PUBLICATION, FROM WHAT I
15 UNDERSTAND, WOULD BE MORE EQUIVALENT.

16 AND THE OTHER THING, WE FOCUSED ON HOW THE
17 CELL LINES GROW AND THINGS THAT ARE IMPORTANT. BUT I
18 WAS FAMILIAR WITH THE UK GUIDELINES. AN IMPORTANT
19 COMPONENT OF THE BANK IS TO MAKE SURE THAT THE CELL
20 LINES WERE OBTAINED WITH FULLY INFORMED CONSENT AND
21 ESTABLISHED WITHIN THAT ETHICAL FRAMEWORK. AND SO THAT
22 WHEN WE SAID THAT LINES THAT YOU WOULD GET FROM THE UK
23 WOULD MEET ALL THE ETHICAL REQUIREMENTS OF THE ESCRO,
24 BECAUSE THEY HAVE BEEN VERY CAREFUL WITH THAT, NOW
25 THAT'S MORE RELATED TO BANKING AND SOME OF THOSE

1 SPECIFIC ASPECTS THAN WE'VE BEEN TALKING ABOUT NOW, BUT
2 THAT REALLY IS ABSOLUTELY CRITICAL.

3 CO-CHAIR LO: GOOD POINT. OKAY. I WOULD
4 SUGGEST WE, FIRST OF ALL, CONGRATULATE OURSELVES AND
5 THEN REWARD OURSELVES WITH A SNACK AND A 15-MINUTE
6 BREAK, AND THEN COME BACK AND TACKLE SOME OF THE OTHER
7 ISSUES. THANKS. I THOUGHT THIS WAS VERY USEFUL.

8 (A RECESS WAS TAKEN.)

9 CO-CHAIR LO: MAY WE RECONVENE HERE. I HOPE
10 EVERYONE WAS ENERGIZED BY OUR BREAK. THERE ARE A
11 COUPLE OF ISSUES I'D LIKE TO DEAL WITH, AND THEN I'D
12 LIKE TO SPEND THE LAST BIT OF OUR MEETING SORT OF
13 PLANNING AHEAD FOR THE FUTURE AND OUR NEXT MEETING AND
14 TO SORT OF SEE WHAT'S A REASONABLE TIMETABLE FOR US TO
15 ACCOMPLISH OUR TASKS.

16 THERE ARE TWO OTHER ISSUES I'D LIKE TO SPEND
17 SOME TIME ON BEFORE WE ADJOURN, AND THEN I'D LIKE TO
18 SPEND THE LAST HALF HOUR OR SO TALKING ABOUT FUTURE
19 PLANS. I WANT TO MAKE SURE WE ADJOURN ON TIME SO WE
20 CAN PREPARE FOR THE DINNER HOSTED BY SHERRY LANSING.

21 ONE ISSUE IS THE SCOPE OF REGULATIONS, TO
22 WHOM AND WHAT ARE THESE REGULATIONS APPLYING. THE
23 OTHER IS DIVERSITY OF DONORS FOR CELL LINES. JUST TO
24 PUT THIS IN CONTEXT, LAST TIME IT WAS POINTED OUT THAT
25 THE NAS GUIDELINES REALLY WERE WRITTEN FOR A NUMBER OF

1 AUDIENCES. AND WHAT WE ARE REALLY DOING IS SETTING THE
2 STANDARDS FOR RECEIVING FUNDING FROM CIRM. AND A LOT
3 OF THE OR SOME OF THE THINGS THE NAS GUIDELINES REALLY
4 PERTAIN TO LIKE HOW TO RUN A STEM CELL BANK AND THINGS,
5 WHICH ARE NOT NECESSARILY DIRECTLY GERMANE TO THE
6 ISSUES WE'RE DEALING WITH.

7 SO STAFF HAS DRAFTED A BRIEF FEW LINES ON THE
8 SCOPE OF REGULATIONS, WHICH ISN'T FOUND IN THE NAS
9 GUIDELINES, BUT IT WOULD BE AN IMPORTANT THING TO PASS
10 REGULATORY MUSTER. AND THEY'VE INCLUDED REFERENCES IN
11 CASE SOMEONE SAYS WHAT DO YOU MEAN BY THAT. THERE ARE
12 ACTUALLY DEFINITIONS THAT ARE AVAILABLE. BUT THE
13 REGULATION SCOPE WOULD BE THE STANDARDS SET FORTH IN
14 THIS CHAPTER, THAT'S ALL THE REGULATIONS, APPLY TO ALL
15 INSTITUTIONS PERFORMING RESEARCH FUNDED BY THE
16 CALIFORNIA INSTITUTE OF REGENERATIVE MEDICINE, AND THE
17 PARENTHESES ARE JUST THE SORT OF WHERE THOSE
18 DEFINITIONS COME FROM. AND WE THOUGHT THIS SORT OF
19 CAPTURED IN MORE REGULATORY LANGUAGE SORT OF THE POINT
20 WE HAD AGREED ON LAST TIME.

21 I WANT TO JUST OFFER THIS TO YOU TO MAKE SURE
22 THAT THIS SEEMED ACCEPTABLE AND CLEAR.

23 JAMES OR GEOFF, DO YOU WANT TO SAY ANYTHING
24 MORE ON THIS?

25 MR. HARRISON: YEAH. THIS LANGUAGE IS FAIRLY

1 TYPICALLY FOUND IN ALL STATE REGULATIONS OF THIS SORT.
2 IT DEFINES TO WHOM THE REGULATIONS APPLY AND WHAT THEIR
3 SCOPE IS. SO IT'S FAIRLY TYPICAL LANGUAGE TO HAVE AT
4 THE START OF REGULATIONS.

5 MR. SHEEHY: NOT TO KEEP HARPING ON THE SAME
6 ISSUE, BUT IS INSTITUTIONS A RELATIVELY NARROW WORD?
7 YOU HAVE A DEFINITION.

8 MR. HARRISON: GEOFF HAS A DEFINITION WHICH
9 HE CAN SHARE WITH YOU, BUT MY UNDERSTANDING IS IT DOES
10 APPLY TO PRIVATE ENTITIES AS WELL.

11 MR. SHEEHY: I'M HOPING THAT IT WOULD APPLY
12 TO ANYBODY THAT WE MIGHT FUND.

13 DR. CIBELLI: YOU SAY THAT --

14 MR. LOMAX: HERE'S THE DEFINITION IN RED, BY
15 THE WAY.

16 DR. HALL: INSTITUTION MEANS ANY PUBLIC OR
17 PRIVATE ENTITY.

18 MR. SHEEHY: THAT'S FINE. JUST
19 CLARIFICATION.

20 DR. CIBELLI: JUST SAY THAT IS FOR ANY
21 INSTITUTION THAT HAS FUNDS FROM CIRM.

22 CO-CHAIR LO: PUT BACK THE BLUE SLIDE.
23 INSTITUTIONS FUNDED BY CIRM.

24 ANY PUBLIC COMMENTS ON THIS? BOB HAS A
25 SUGGESTION OR QUESTION. CLINICAL TRIALS FALL UNDER THE

1 DEFINITION OF RESEARCH.

2 MR. LOMAX: SO EVERYONE IS CLEAR, THIS
3 LANGUAGE IS OUT OF THE COMMON RULE, SO IT'S LANGUAGE
4 THAT ALL RESEARCH INSTITUTIONS SHOULD BE VERY FAMILIAR
5 WITH.

6 MR. KLEIN: I WOULD JUST SAY THAT FOR THE
7 PUBLIC TO UNDERSTAND THESE, IT MIGHT BE VERY BENEFICIAL
8 FOR US TO SAY RESEARCH, INCLUDING CLINICAL TRIALS,
9 BECAUSE WE HAVE MORE THAN JUST LEGAL CONSTITUENCIES.
10 WE HAVE PUBLIC CONSTITUENCIES THAT WOULD BETTER
11 UNDERSTAND WHAT WE'RE DOING IF WE REFERENCE CLINICAL
12 TRIALS.

13 CO-CHAIR LO: GOOD. THANK YOU. GEOFF, DO
14 YOU WANT TO PUT UP THE INFORMATION NOW ON DIVERSITY.
15 LAST TIME WE SORT OF AGREED IN PRINCIPLE THAT DIVERSITY
16 OF DONORS TO NEW STEM CELL LINES WAS DESIRABLE FOR A
17 NUMBER OF REASONS. SO STAFF, IN CONSULTATION WITH OUR
18 LEGAL COUNSEL, HAS PROPOSED SOME LANGUAGE. AND HERE
19 THE PROBLEM IS THIS WOULD BE IN THE -- WOULD NOT BE IN
20 REGULATION, BUT WOULD BE IN THE STATEMENT OF PURPOSE.
21 THE REASON IT CAN'T BE REGULATION IS BECAUSE WE'RE NOT
22 SETTING A CLEAR ACTION THAT PEOPLE HAVE TO TAKE TO BE
23 IN COMPLIANCE. SO THAT ONE OF THE THINGS WE'VE
24 STRUGGLED WITH IS CAN WE FRAME THIS IN REGULATORY
25 LANGUAGE. BUT THIS IS A GENERAL STATEMENT OF OUR

1 INTENTION AND THE RATIONALE FOR DIVERSITY OF GENETIC
2 DONORS.

3 AND JAMES HAS A SUGGESTION ON HOW WE MIGHT BE
4 ABLE TO DEVELOP REGULATORY LANGUAGE. DO YOU WANT TO
5 SUGGEST THAT TO US, JAMES?

6 MR. HARRISON: WELL, ONE APPROACH MIGHT BE TO
7 DIRECT THE INSTITUTIONS THAT ARE GOVERNED BY THESE
8 REGULATIONS IN REVIEWING POTENTIAL DONORS TO CONSIDER
9 THE ETHNIC DIVERSITY OF SUCH DONORS.

10 ANOTHER WAY TO DO IT WOULD BE TO MAKE A
11 RECOMMENDATION TO THE GRANTS REVIEW WORKING GROUP IN
12 FUNDING RESEARCH TO CONSIDER AS A CRITERIA THE ETHNIC
13 DIVERSITY OF THE RESEARCH POOL OR SOME OTHER FACTORS.

14 THERE ARE A COUPLE OF DIFFERENT APPROACHES, I
15 THINK, THAT YOU COULD EMPLOY. AS YOU NOTED, THE
16 LANGUAGE AS IT'S CURRENTLY DRAFTED IS ASPIRATIONAL. IT
17 DOESN'T IMPOSE ANY REQUIREMENT ON ANYONE, SO IT'S NOT
18 SOMETHING THAT THE OAL WOULD APPROVE OF IN THE
19 REGULATION ITSELF.

20 CO-CHAIR LO: BUT THE CONSIDER LANGUAGE BEING
21 PROPOSED IN THOSE TWO EXAMPLES WOULD BE ACCEPTABLE AS
22 REGULATION?

23 MR. HARRISON: I THINK SO, YES.

24 CO-CHAIR LO: SO THIS IS SOMETHING WE SHOULD
25 THINK THROUGH.

1 DR. PRIETO: IF WE DIRECT THE GRANTS FUNDING
2 WORKING GROUP --

3 MR. HARRISON: IT SEEMS TO ME THAT THERE ARE
4 TWO DIFFERENT THINGS HERE. ONE IS WHETHER WHAT YOU'RE
5 TALKING ABOUT IS A DIRECTION TO THE INVESTIGATORS
6 THEMSELVES, AND THE OTHER IS WHETHER WHAT YOU'RE DOING
7 IS ASKING THAT THE ICOC, IN AWARDING RESEARCH GRANTS,
8 CONSIDER THIS ISSUE AMONG OTHERS IN ITS AWARD OF
9 GRANTS.

10 DR. CIBELLI: IT'S SOMETHING THAT SHOULD BE
11 CONSIDERED, BUT NOT DISCUSSED TODAY, SO WE HAVE TIME TO
12 GO TO DINNER. BUT I THINK THAT AT SOME POINT IN THE
13 ISSUE OF DIVERSITY, YOU HAVE TO ALSO TALK ABOUT EVEN
14 RUNNING INTO THE SITUATION WHERE YOU ARE GOING TO HAVE
15 MORE GRANTS THAT ARE VERY WELL-WRITTEN GRANTS, THAT ARE
16 TOP ON THE SCORES THAT ARE PROBABLY MORE RELATED TO ONE
17 DISEASE THAN OTHER DISEASES. SO YOU ARE GOING TO HAVE
18 TO ADDRESS THAT ISSUE OF DIVERSITY. SO HOW DO YOU
19 ALLOCATE THE FUNDS TO COVER DISEASES THAT WILL TAKE
20 CARE OF MOST PEOPLE, OR DO YOU HAVE ORPHAN DISEASES
21 THAT YOU HAVE TO TAKE CARE OF. I THINK THAT IS
22 SOMETHING TO CONSIDER IN THE FUTURE.

23 CO-CHAIR LO: THIS IS NOT NECESSARILY, IF I
24 UNDERSTAND YOU RIGHT, SORT OF DIVERSITY AMONG THE
25 DONORS FOR NEW STEM CELL LINES, BUT DIVERSITY IN THE

1 TYPES OF DISEASES THAT ARE TARGETED BY THE GRANTS
2 FUNDED BY CIRM.

3 DR. WILLERSON: NIH, OF COURSE, HAS
4 GUIDELINES FOR THIS. ALL OF US KNOW THAT. I WOULDN'T
5 TRY TO REINVENT THE WHEEL. IT INCLUDES ALL THAT YOU
6 SAID; BUT ALSO WHEN ONE GETS AROUND TO GIVING STEM
7 CELLS TO PATIENTS, ONE ENSURES THAT IT'S MADE AVAILABLE
8 TO A DIVERSE POPULATION. NO ONE IS EXCLUDED.

9 DR. CIBELLI: APPLIED TO THAT, I THINK NIH
10 ALSO HAS DIFFERENT POTS OF MONEY DEPENDING IF YOU HAVE
11 THE CANCER INSTITUTE OR YOU ARE IN THE REPRODUCTIVE
12 AREA. HERE IS ONE POT OF MONEY. YOU DON'T HAVE
13 DIFFERENT INSTITUTES, SO AT SOME POINT YOU ARE GOING TO
14 HAVE TO DECIDE HOW YOU GOING TO DISTRIBUTE THAT MONEY.

15 DR. WILLERSON: I THINK THE EXPECTATION WOULD
16 BE THAT DIVERSITY IS INCLUDED IN ALL THE PROGRAMS.
17 THAT'S ALL. IF ONE FAILED TO DO THAT, IT WOULD BE LIKE
18 NOT SHARING ONE'S STEM CELL LINES.

19 CO-CHAIR LO: I THINK WHAT DR. WILLERSON IS
20 REFERRING TO IS THAT SECTION G OR H, I FORGOT NOW,
21 WHICH TALKS ABOUT ARE YOU INCLUDING CHILDREN, WOMEN,
22 AND DO YOU HAVE ETHNIC DIVERSITY OF PARTICIPANTS
23 ENROLLED IN YOUR STUDY. WE CAN GO BACK AND LOOK AT
24 THAT LANGUAGE AND SEE IF THAT'S APPLICABLE.

25 MR. SHEEHY: I MEAN I SEE WHERE THIS ISN'T

1 NECESSARILY SOMETHING WE WANT TO PUT INTO REGULATIONS,
2 BUT I DO THINK DR. CIBELLI DOES MAKE A POINT, THAT THIS
3 IS SOMETHING WE MIGHT WANT TO CONSIDER AT SOME FUTURE
4 DATE. SO I WONDER IF WE SHOULD START MAYBE TODAY
5 MAKING A LIST OF TOPICS FOR THE POSTREGULATORY,
6 HOPEFULLY FUTURE STANDARDS WORKING GROUP MEETING
7 BECAUSE THIS SEEMS LIKE ONE THAT KEEPS CROPPING UP, AND
8 THIS REALLY ISN'T THE TIME TO TALK ABOUT IT, BUT
9 DIVERSITY OF DISEASE, DIVERSITY OF PATIENT POPULATION.
10 EVEN THOUGH THAT'S SOMETHING THAT MAY BE WORKED OUT
11 THROUGH THE GRANTS WORKING GROUP, I THINK THAT THAT IS
12 A STANDARD THAT WE CAN START TO INFORM FROM THIS
13 STANDARDS WORKING GROUP KIND OF THE COMPLEXION OF THAT.
14 SO I WONDER IF WE MIGHT REQUEST THAT THAT BE PUT ON A
15 FUTURE AGENDA AND GET THAT DIRECTION SET.

16 CO-CHAIR LO: THAT SOUNDS GOOD.

17 MR. KLEIN: WELL, I'D JUST LIKE TO POINT OUT
18 IT'S MY UNDERSTANDING, BUT I'D LIKE A LOT MORE
19 INFORMATION ABOUT IT, THAT ACCORDING TO A DOCTOR COMING
20 FROM AN AFRO-AMERICAN BACKGROUND, HIS POSITION IS THAT
21 BECAUSE THERE'S GREATER GENETIC DIVERSITY AMONG THE
22 AFRO-AMERICAN POPULATION BECAUSE OF THE INTERMARRIAGE
23 BETWEEN LOTS OF DIFFERENT GROUPS THAN IN CERTAIN OTHER
24 POPULATIONS, AND THAT IT TAKES -- THE EMBRYONIC STEM
25 CELLS MIGHT, IN FACT, OFFER A GREATER BENEFIT FOR THAT

1 POPULATION BECAUSE OF THE COMPLEXITY OF GETTING MAJOR
2 HISTOCOMPATIBILITY MATCHES FOR THE AFRO-AMERICAN
3 POPULATION, AND THAT THERE MAY BE CERTAIN POPULATIONS
4 WHO HAVE A PARTICULAR -- WHERE THEIR COMPLEXITY IS SUCH
5 THAT OF THEIR GENETIC BACKGROUND THAT IT IS MORE
6 DIFFICULT FOR THEM TO BENEFIT FROM ADULT STEM CELLS
7 WHERE THEY HAVE MAJOR GENETIC GROUPS SET UP IN
8 CATEGORIES THAT THEY CAN REASONABLY MATCH.

9 NOW, THAT'S A COMPLICATED CONCEPT, BUT IT
10 DEALS WITH ACHIEVING EFFECTIVE DIVERSITY AND EFFECTIVE
11 THERAPIES FOR EACH ETHNIC GROUP IN OUR STATE.

12 DR. PETERS: COULD I ASK FOR CLARIFICATION
13 AMONGST THE RESEARCH GENETICISTS IN THE ROOM? WHEN IT
14 COMES TO DIVERSITY IN STEM CELL LINES, ARE WE TALKING
15 ABOUT THE SAME THING AS ETHNIC AND CULTURAL DIVERSITY?
16 IT SEEMS TO ME THAT WE'RE NOT. ISN'T THE MAIN REASON
17 FOR DIVERSITY IN THE STEM CELL LINE BANK TO APPROXIMATE
18 HISTOCOMPATIBILITY? THAT IS TO SAY YOU REALLY WANT TO
19 COVER THE WATERFRONT OF POSSIBLE GENETIC CODES IN ORDER
20 TO REDUCE IMMUNOREJECTION.

21 SO ON THE ONE HAND, WE WANT TO SAY THAT AS AN
22 INSTITUTION OF THE STATE, WE ARE CONCERNED ABOUT ETHNIC
23 DIVERSITY, BUT SCIENTIFICALLY I MEAN DIVERSITY IS A
24 DIFFERENT THING HERE, ISN'T IT?

25 DR. HALL: THERE IS ANOTHER ISSUE, AND THAT

1 IS THAT ONE OF THE OPPORTUNITIES OFFERED BY SCNT IS TO
2 CREATE CELLULAR MODELS OF DISEASE. AND ONE OF THE
3 ISSUES IN THOSE, THEN, IS TO LOOK AT THE CONTRIBUTIONS
4 OF A VARIETY OF GENES TO PARTICULAR DISEASES. AND THAT
5 IS AN OPPORTUNITY TO DO THAT IN HUMAN CELLS. AND
6 BECAUSE OF THE GENETIC DIVERSITY THE AFRICAN AMERICAN
7 POPULATION, FOR EXAMPLE, THEN YOU WOULD -- THERE ARE
8 DISEASES TO WHICH THEY'RE PARTICULARLY SUSCEPTIBLE, OR
9 AT LEAST GENES THAT ARE REPRESENTED HIGHLY IN THAT
10 POPULATION, PREDISPOSED TO, AND YOU'D LIKE TO FISH
11 THOSE OUT. CORRESPONDINGLY, FOR ASIAN POPULATIONS OR
12 FOR ANY OTHER POPULATIONS, AND SO IN THOSE TERMS, IT
13 ACTUALLY BECOMES A TOOL THAT ALSO INFORMS YOU ABOUT
14 GENETIC SUSCEPTIBILITY IN VARIOUS GROUPS THAT COULD BE
15 VERY HELPFUL.

16 I'M NOT A CARD-CARRYING GENETICIST, SO
17 ANYBODY WHO WANTS TO CORRECT ME, PLEASE GIVE A BETTER
18 VERSION OF THAT. I THINK THAT'S IN ADDITION TO JUST
19 THE HISTOCOMPATIBILITY ISSUE, THE OPPORTUNITY FOR
20 STUDYING A BROAD ARRAY OF ALLELES BASICALLY ON VARIOUS
21 DISEASES WOULD BE IMPORTANT. JANET, DO YOU WANT TO
22 OFFER ANYTHING FROM THAT?

23 DR. ROWLEY: NO. I THINK YOU DID IT VERY
24 WELL.

25 CO-CHAIR LO: SO I'M GOING TO ASK STAFF TO

1 SORT OF REVISE THIS IN LIGHT OF THIS LAST EXCHANGE, AND
2 THEN ASK ANYONE WHO WANTS TO -- I DON'T THINK WE SHOULD
3 TRY AND CRAFT LANGUAGE TODAY, BUT TO SORT OF SUGGEST
4 CHANGES TO THIS. AND THEN ALSO, AS PER DR. WILLERSON'S
5 SUGGESTION, WE WILL ASK STAFF TO LOOK AT THE NIH, THEIR
6 REGULATIONS OR CONDITIONS OF FUNDING OR SOMETHING ABOUT
7 UNDERREPRESENTED POPULATIONS, INCLUDING THEM AS
8 SUBJECTS OF RESEARCH.

9 COULD I INVITE THE PUBLIC IF THEY HAVE
10 COMMENTS ON THIS OR THE PREVIOUS ISSUE ON SCOPE.

11 MS. FOGEL: SUSAN FOGEL OF PRO CHOICE
12 ALLIANCE FOR RESPONSIBLE RESEARCH. AND THESE ELEMENTS
13 DON'T ADDRESS THE OTHER PART OF DIVERSITY, WHICH WAS
14 ENSURING A DIVERSE POPULATION OF RESEARCHERS THAT WAS
15 IN THE ORIGINAL. SO I'M WONDERING WHERE THAT'S GOING.
16 IT'S NOT HERE. THAT'S MY FIRST QUESTION.

17 AND THEN MY SECOND QUESTION IS I GUESS I WANT
18 TO ASK AGAIN WHY IN TERMS OF WE COULDN'T BE CRAFTING A
19 SECTION ON RESEARCH CRITERIA IN WHICH DIVERSITY AND
20 FUNDING CRITERIA IN THE REGULATIONS IN WHICH DIVERSITY
21 WOULD BE ADDRESSED. I THINK IT'S A VERY IMPORTANT
22 ISSUE. AND, YOU KNOW, NOT TO BE A CYNICAL LAWYER, BUT
23 INTENT LANGUAGE MEANS IT LOOKS NICE, BUT IT MEANS NEXT
24 TO NOTHING, AND IT'S CERTAINLY RARELY ENFORCEABLE. AND
25 SO I WOULD ENCOURAGE YOU TO FIND AN INNOVATIVE WAY TO

1 ACTUALLY PUT IT IN THE REGULATIONS.

2 CO-CHAIR LO: THANK YOU.

3 MR. KLEIN: IT MIGHT BE HELPFUL IF STAFF
4 RELATED FOR THE RECORD THAT IN THE INFRASTRUCTURE
5 TRAINING GRANTS THE LANGUAGE WE HAD IN THERE RELATED TO
6 ONE OF THE CRITERIA IN SELECTION TO ACHIEVE DIVERSITY
7 IN THEIR FELLOWSHIP POOL. I THINK IN OUR PRIOR
8 MATERIALS, WE HAD THAT, BUT, GEOFF, I DON'T KNOW IF YOU
9 HAVE IT WITH YOU.

10 DR. PRIETO: WE HAVE THAT IN THESE MATERIALS.

11 MR. KLEIN: YOU MIGHT REFER THE PUBLIC TO
12 THAT.

13 DR. PRIETO: BEHIND TAB 7 IN RFA 05-01, CIRM
14 TRAINING PROGRAM INCLUDED THE FOLLOWING LANGUAGE:
15 BECAUSE OF THE DIVERSITY OF THE CALIFORNIA POPULATION,
16 CIRM IS PARTICULARLY INTERESTED IN TRAINING A DIVERSE
17 POOL OF INVESTIGATORS. WE ENCOURAGE INSTITUTIONS TO
18 MAKE SPECIAL EFFORTS CONSISTENT WITH THE LAW TO RECRUIT
19 AND RETAIN INDIVIDUALS FROM MANY BACKGROUNDS, INCLUDING
20 UNDERREPRESENTED MINORITIES, AS TRAINEES AND AS
21 MENTORS.

22 DR. HALL: I THINK, HOWEVER, IT WOULD ALSO BE
23 FINE TO ADD SOMETHING ABOUT TRAINING IN THIS THING
24 HERE. THAT IS, NOT JUST DEVELOPMENT OF THERAPIES FOR
25 DIVERSE POPULATIONS, BUT ALSO WE COULD PUT --

1 MR. KLEIN: CAN'T YOU PICK UP SOME OF YOUR
2 LANGUAGE.

3 DR. PRIETO: WE WANT TO HAVE THAT LANGUAGE
4 SOMEWHERE. I'M NOT SURE WHERE IT MOST APPROPRIATELY
5 FITS, BUT WE WANT THAT LANGUAGE IN THERE.

6 DR. HALL: WE WANT ALSO TO TRAIN A DIVERSE
7 WORKFORCE.

8 CO-CHAIR LO: GEOFF HAS ALREADY STARTED THIS
9 ON THAT PAGE.

10 MR. KLEIN: SO IT CAN BE ADDED TO THIS
11 SECTION.

12 MS. FOGEL: COULD I JUST ASK YOU TO SAY
13 TRAINING AND FUND A DIVERSE WORKFORCE? NOT JUST ABOUT
14 TRAINING GRANTS, BUT IT'S ALSO THAT YOU WANT TO BE
15 LOOKING AT THE DIVERSITY OF THE WORKFORCE. WE KNOW
16 THERE'S A LOT OF DISCRIMINATION, BOTH GENDER AND
17 RACIAL, AND ETHNIC DISCRIMINATION IN SCIENCE, AND A LOT
18 OF PEOPLE WORKING TO CREATE MORE BALANCE IN TERMS OF
19 THE POPULATION OF SCIENTISTS. IT WOULD BE NICE IF THAT
20 WAS A GOAL OF THIS.

21 DR. HALL: LET US TAKE THAT UNDER ADVISEMENT.
22 IT'S A LITTLE BIT COMPLICATED, I THINK, TO FUND ON THE
23 BASIS OF -- YOU MEAN ETHNIC CONSIDERATIONS OF THE
24 INVESTIGATOR?

25 MS. FOGEL: IT'S VERY ASPIRATIONAL.

1 DR. HALL: I UNDERSTAND THAT, BUT I THINK
2 FUNDING ON THE PART OF THE -- TAKING IT AS A CRITERIA
3 FOR FUNDING, THE ETHNIC BACKGROUND OF THE INVESTIGATOR
4 IS A COMPLICATED ISSUE, AND WE WOULD HAVE TO THINK
5 ABOUT THAT. BUT I THINK WE CERTAINLY SHARE, I HOPE WE
6 SHARE, ASPIRATIONS, AND WE WOULD TRY TO MAKE
7 THAT OPERATIONAL AS MUCH AS WE CAN AND AS MUCH AS WE'RE
8 ALLOWED TO.

9 I THINK ALSO THE POINT THAT DR. WILLERSON
10 RAISED ABOUT NIH, I THINK WHEN WE COME TO THE TIME OF
11 CLINICAL TRIALS, WE CERTAINLY WILL WANT TO LOOK
12 PARTICULARLY CAREFULLY AT THAT. AND I THINK WE NEED TO
13 THINK ABOUT HOW WE PUT IT IN. WE DON'T NEED TO
14 REINVENT THE WHEEL THERE, BUT WE'LL THINK ABOUT WHETHER
15 WE OUGHT TO INCLUDE THAT AT THIS STAGE OR NOT, I THINK,
16 WOULD BE ANOTHER THING. JUST FOOTNOTE IF YOU WOULD.

17 CO-CHAIR LO: I THINK THAT OUR LEGAL COUNSEL
18 AND THE OAL HAVE POINTED OUT THAT ASPIRATIONS ARE FINE.
19 IT'S JUST THEY CAN'T GO INTO REGULATORY LANGUAGE. SO
20 THE ISSUE IS, AS WE'RE STRUGGLING WITH TRYING TO
21 DEVELOP REGULATORY LANGUAGE, DO WE WANT TO SAY
22 SOMETHING ASPIRATIONAL JUST TO SORT OF REASSURE THE
23 PUBLIC THAT IT HASN'T DROPPED OFF OUR RADAR.

24 OKAY. I WOULD LIKE ACTUALLY NOW MOVE ON TO
25 SORT OF FUTURE PLANNING AND PARTICULARLY ASK YOU TO

1 THINK THROUGH WHAT I THINK WILL BE THE NEXT BIG TOPIC
2 THAT WE NEED TO DEAL WITH, WHICH WE HAD SLATED TO TRY
3 AND DISCUSS IN DECEMBER, WHICH IS INFORMED CONSENT.

4 LET ME SORT OF TRY AND PUT THIS IN CONTEXT.
5 IF YOU TALK TO MANY STAKEHOLDERS, RESEARCHERS, RESEARCH
6 INSTITUTIONS, IRB'S, PARTICIPANTS IN HUMAN RESEARCH,
7 MANY OF THEM HAVE CONCERNS ABOUT WHAT'S HAPPENED WITH
8 INFORMED CONSENT. NAMELY, THAT YOU GET GIVEN A VERY,
9 VERY LONG CONSENT FORM, WHICH KEEPS GETTING LONGER
10 EVERY MONTH. THE IRB SPENDS AN INORDINATE AMOUNT OF
11 TIME SORT OF REWRITING CONSENT FORMS FOR INVESTIGATORS.
12 AND IN A MULTICENTER TRIAL, EVERY IRB WANTS TO TAKE
13 THEIR OWN CRACK. AND IT'S NOT QUITE CLEAR HOW THAT
14 COMPLICATED CONSENT DOCUMENT REALLY FURTHERS THE GOAL
15 OF HELPING TO ASSURE THAT THE PARTICIPANTS IN RESEARCH
16 GIVE VOLUNTARY CONSENT AND INFORMED CONSENT.

17 AND EARLIER WE WERE SORT OF CHALLENGED TO
18 SORT OF BE WILLING TO SORT OF THINK IMAGINATIVELY AND
19 INNOVATIVELY. AND IT STRIKES ME THIS IS A SITUATION
20 WHERE THE STANDARD THING PEOPLE DO, WHICH IS TO MAKE
21 CONSENT FORMS MORE AND MORE COMPLICATED AND HAVE THE
22 REGULATIONS BE MORE AND MORE DETAILED, MAY NOT BE THE
23 APPROACH WE WANT TO TAKE.

24 SO I JUST WANT TO SORT OF CALL YOUR ATTENTION
25 TO UNDER TAB 6, PAGE 5 THE DRAFT RECOMMENDED

1 REGULATIONS, SECTION 100007, WHICH IS REALLY TAKEN FROM
2 THE NAS GUIDELINES AND ALSO MAKES REFERENCE TO EXISTING
3 CALIFORNIA LAW ON INFORMED CONSENT. AS YOU CAN SEE,
4 THERE'S A LOT OF SPECIFICS AS TO WHAT INFORMATION NEEDS
5 TO BE PRESENTED TO PEOPLE WHO MIGHT BE THE SUBJECTS OF
6 RESEARCH, PARTICULARLY DONORS. AND ACTUALLY SINCE THIS
7 WAS SUGGESTED IN MAY BY THE NAS, TWO OTHER ISSUES HAVE
8 COME UP. ONE IS THAT THIS ONLY TALKS ABOUT INFORMED
9 CONSENT, DOESN'T ADDRESS THE VOLUNTARY NATURE OF
10 CONSENT, AND THAT WAS RAISED.

11 AND OTHER ISSUES HAVE COME UP REGARDING THE
12 WAY NAS PHRASED SORT OF THE RECONTACT OF DONORS OF
13 MATERIALS FOR STEM CELL LINES. IT WAS PHRASED IN TERMS
14 OF INFORMATION -- RECONTACT FOR GIVING THEM INFORMATION
15 THAT MIGHT BE OF USE TO THEM, BUT DIDN'T THINK OF
16 RECONTACT FOR THE PURPOSES OF GATHERING MORE
17 INFORMATION ABOUT THE SAFETY OF USING THE MATERIALS
18 DERIVED FROM THEIR DONATION FOR TRANSPLANTATION TRIALS.

19 SO I GUESS I WANT TO SORT OF JUST PLACE
20 BEFORE YOU SORT OF THAT SORT OF CONTEXT AND THEN TRY
21 AND SORT OF THINK THROUGH HOW BEFORE DECEMBER WE CAN
22 ACTUALLY WORK ON THESE ISSUES TO SEE IF THIS IS THE
23 APPROACH WE WANT TO TAKE.

24 MR. KLEIN: TWO ITEMS. ONE IS THE GOVERNOR
25 VETOED SB 18, THE ORTIZ BILL, WHICH ADDRESSED INFORMED

1 CONSENT ALONG WITH LEGISLATIVE AUDITS AND OTHER
2 SUBJECTS. AND I THINK IT WOULD BE APPROPRIATE FOR US
3 TO SEE IF THE ORTIZ INFORMED CONSENT LANGUAGE COULD BE
4 HARMONIZED WITH THE LANGUAGE WE HAVE ON INFORMED
5 CONSENT FROM THE NATIONAL ACADEMY TO THE EXTENT THAT
6 THERE ARE VALUABLE THOUGHTS AND CONSIDERATIONS THERE.
7 IT WOULD OBTAIN THE NEED FOR FUTURE LEGISLATION
8 DEALING WITH THAT AND AVOID TWO DIFFERENT STANDARDS.
9 CERTAINLY WE DON'T NEED CONFLICTING STANDARDS.

10 SECONDLY, AS A RELATED ITEM TO INFORMED
11 CONSENT, BECAUSE IT DEALS WITH PATIENTS' RIGHTS AND
12 INFORMATIONAL CONTROLS, IS THE ISSUE OF
13 CONFIDENTIALITY. AND I THINK FOR IMMEDIATE CONCERN IS
14 THE QUESTION DID THE NATIONAL ACADEMY FOCUS MORE ON
15 CONFIDENTIALITY RELATED TO RESEARCH AS VERSUS CLINICAL
16 WORK. IN OTHER WORDS, NOW THAT THERE IS NUCLEAR
17 TRANSFER TECHNOLOGY AVAILABLE THAT MAY BE USED
18 IMMEDIATELY DEALING WITH IDENTIFYING SPECIFIC DISEASES
19 WITH GENETIC MARKERS WHERE WITH SMALL POPULATIONS YOU
20 NEED TO BE ABLE TO FIND A WAY TO UNLOCK THAT
21 INFORMATION FOR DIRECT CUSTOMIZED THERAPIES, DO WE NEED
22 A DIFFERENT STANDARD FOR CONFIDENTIALITY RELATED TO
23 NUCLEAR TRANSFER?

24 AND JUST AS AN EXAMPLE, THE KOREANS ARE USING
25 A DOUBLE ENCRYPTION SYSTEM WITH THREE DIFFERENT

1 PHYSICIANS HAVING TO INPUT CONCURRENTLY A CODE TO
2 UNLOCK INFORMATION NECESSARY FOR NUCLEAR TRANSFER FOR
3 THERAPY. MAYBE THERE APPROPRIATE CONFIDENTIALITY
4 MECHANISMS THAT ALLOW US TO USE THERAPIES THAT ARE
5 CUSTOMIZED WHERE WE NEED THE IDENTITY AT THE OTHER END
6 OF THE PATIENT IN ORDER TO REALLY USE THESE NEW
7 BREAKTHROUGHS THAT ARE COMING THROUGH THAT HAVE
8 CLINICAL APPLICATIONS.

9 DR. ROWLEY: I JUST WANT TO SAY IN TERMS OF
10 THE ACADEMY, WE CERTAINLY CONSIDERED MANY OF THESE
11 ISSUES. AND, OF COURSE, JUST AS OUR DISCUSSION IS
12 DISTILLED DOWN INTO A VERY SMALL FRACTION OF WHAT
13 ACTUALLY WENT ON, WE WERE MINDFUL OF THE PROBLEM OF
14 CONFIDENTIALITY. WE ALSO WERE AWARE THAT IN THE UK
15 CELL LINE BANK THAT THEY INSISTED THAT THEY KNOW WHO
16 THE DONOR OF THE EMBRYO WAS OR THE OOCYTES, THOUGH THAT
17 IS IN A SEPARATE BANK FROM ALL THE OTHER INFORMATION,
18 BUT THAT THERE WAS A WAY TO RELATE IT.

19 ALSO, ALTA IS FOND OF REMINDING US THAT FOR
20 ANYTHING THAT'S GOING TO BE USED IN PATIENTS, THE FOOD
21 AND DRUG ADMINISTRATION REQUIRES THAT YOU KNOW THE
22 DONOR OF THE EMBRYOS OR THE OOCYTES. SO IF YOU'RE
23 THINKING THAT FAR DOWN THE LINE, YOU HAVE TO HAVE IT,
24 SO WHY NOT START WITH THAT INFORMATION, BUT MAKE
25 CERTAIN, JUST AS YOU'RE DESCRIBING THE KOREANS'

1 EFFORTS, TO MAKE SURE THAT THAT INFORMATION IS
2 CONFIDENTIAL.

3 AND THE OTHER ISSUE, IN UK AND EUROPE, IT IS
4 REQUIRED THAT IF AN INVESTIGATOR FINDS SOMETHING, SOME
5 GENETIC VARIANT OR ABNORMALITY IN THE CELLS IN THE
6 COURSE OF THAT INDIVIDUAL'S INVESTIGATION, THAT THAT
7 INFORMATION IS SENT BACK TO THE PATIENT'S PHYSICIAN,
8 AND THEN IT'S UP TO THE PHYSICIAN TO DEAL WITH THE
9 PATIENT IN TERMS OF INFORMING THEM THAT THIS -- WE
10 DISCOVERED YOU'VE GOT THIS GENETIC ABNORMALITY.

11 NOW, THE PHYSICIAN -- THE PATIENT CAN SAY I
12 DON'T WANT TO KNOW, JUST AS PATIENTS WHO ARE AT RISK OF
13 PARKINSON'S SAYING, NO, I DON'T WANT TO BE TESTED
14 BECAUSE I DON'T WANT TO KNOW, BUT AT LEAST THERE IS
15 THAT CHANNEL BACK. AND THE STATES WITH OUR POOR HEALTH
16 SYSTEM, WE DON'T HAVE -- IT'S MUCH MORE DIFFICULT.

17 CO-CHAIR LO: JEFF AND THEN ANN.

18 MR. SHEEHY: CONFIDENTIALITY ISSUE. I'M
19 WONDERING IF THIS MIGHT BE SOMETHING IF WE MIGHT CHANGE
20 OUR MODEL A LITTLE BIT FOR THIS AND MAYBE BRING IN
21 SOMEONE TO PRESENT ESPECIALLY ON THE COMPLICATED ISSUE
22 LIKE INFORMED CONSENT BECAUSE FOR ME REALLY PUTTING
23 MYSELF -- TRYING TO VISUALIZE MYSELF AS A PERSON WHO'S
24 SIGNING THIS INFORMED CONSENT AND LOOKING AT ALL THIS
25 INFORMATION. I WONDER, AS JONATHAN WAS SUGGESTING

1 EARLIER, WE MIGHT HAVE SOMEONE ACTUALLY COME UP AND
2 PRESENT SOME OPTIONS, KIND OF WORK US THROUGH THIS.
3 MAYBE SOMEONE FROM SENATOR ORTIZ' OFFICE SO THAT WE
4 COULD GET SOME MEETING OF MINDS AS WE GO FORWARD.

5 BUT RATHER THAN WORDS ON THE WALL, SOME
6 SUGGESTED LANGUAGE, AND THEN WE KIND OF THROW DARTS AT
7 IT AND HOPE WE GET IT RIGHT, MAYBE BRINGING A LITTLE --
8 I THINK THIS IS ONE OF OUR BIG ISSUES. I JUST WANTED
9 TO SUGGEST THAT.

10 DR. KIESSLING: I WANTED TO ASK DR. ROWLEY,
11 ARE THE DELIBERATIONS THAT YOU WENT THROUGH AVAILABLE?

12 DR. ROWLEY: NO.

13 DR. KIESSLING: WAS THERE A TRANSCRIPT OF
14 THAT?

15 DR. ROWLEY: NO. BECAUSE WE JUST SAT AROUND
16 THE ROOM.

17 DR. KIESSLING: BECAUSE WE HAVE A TRANSCRIPT
18 RIGHT, OF OUR MEETING. THAT WASN'T AVAILABLE?

19 DR. ROWLEY: NO. WE DIDN'T HAVE THAT KIND
20 OF --

21 MR. KLEIN: THEY HAVE THE MATERIALS. THEY
22 AGGREGATED A TREASURY OF MATERIALS THAT MIGHT BE
23 VALUABLE.

24 DR. ROWLEY: BUT THE INDIVIDUAL DISCUSSIONS,
25 WE DIDN'T HAVE, AND A LOT OF THIS WAS CONFERENCE CALLS.

1 MR. KLEIN: IN LIGHT OF YOUR POINT, CAN WE --
2 WE TALKED ABOUT AT THE FIRST MEETING POTENTIALLY
3 GETTING ACCESS TO MATERIALS, AND POTENTIALLY WE CAN GET
4 ACCESS, FOR EXAMPLE, ON THE CONFIDENTIALITY ISSUE, SO
5 WE COULD HAVE THE BENEFIT OF WRITTEN MATERIALS THAT
6 WERE COLLECTED TO INFORM US.

7 CO-CHAIR LO: ONE THRUST OF THAT MIGHT BE TO
8 HAVE A DIFFERENT KIND OF BRIEFING BOOK, WHICH ACTUALLY
9 HAS ARTICLES OR WHATEVER PERTINENT TO THESE ISSUES OF
10 CONSENT AND CONFIDENTIALITY. THIS IS AN OPTION.
11 SHERRY AND JON.

12 DR. KIESSLING: BERNIE, I HAVE ONE MORE
13 THING. THERE WAS A VERY INTERESTING ARTICLE IN SCIENCE
14 MAYBE THREE OR FOUR MONTHS AGO ABOUT THE RISKS OF
15 VOLUNTEERING FOR STUDIES. WAS ANYBODY AWARE OF THAT?
16 VOLUNTEERING FOR A STUDY. AND IT WAS A VERY
17 INTERESTING -- THIS IS NOT SOMETHING I HAD EVER THOUGHT
18 OF, BUT I THINK WE NEED TO THINK ABOUT IT IN THIS
19 CONTEXT.

20 IT WAS SOMEBODY WHO HAD VOLUNTEERED FOR A
21 STUDY TO DISCOVER THAT -- AND IT WAS AN IMAGING
22 STUDY -- THEY DISCOVERED THEY HAD A BRAIN TUMOR AND
23 THEIR INSURANCE COMPANY DROPPED THEM. NOW, THEY HAD NO
24 SYMPTOMS OF A BRAIN TUMOR. THEY WEREN'T SICK. AND IT
25 WASN'T EVEN CLEAR THAT THIS WAS A TUMOR THAT WAS GOING

1 TO GROW. THERE'S A REAL RISK TO BEING A -- WE TOUCHED
2 ON THIS A LITTLE BIT. WHAT ARE WE GOING TO DO WITH THE
3 INFORMATION THAT WE FIND OUT? I THINK THAT'S REALLY
4 IMPORTANT IN THE CONTEXT OF OUR CURRENT HEALTH
5 INSURANCE.

6 CO-CHAIR LANSING: IT HAS TO BE CONFIDENTIAL.
7 DOESN'T ALLOW IT.

8 MR. SHESTACK: WHAT DID SHERRY SAY?

9 CO-CHAIR LANSING: I THINK IT'S CONFIDENTIAL.
10 CALIFORNIA LAW DOESN'T ALLOW IT TO EVEN BE DISCLOSED,
11 AND AN INSURANCE CAN'T DROP YOU. SO THAT WOULD BE A
12 MAJOR SUIT THAT THIS PERSON WOULD HAVE IN CALIFORNIA.
13 YOU CAN'T BE DROPPED. THEY MAY TRY TO. UNLESS I'M
14 REMEMBERING EVERYTHING WRONG.

15 ANYWAYS, THE POINT IS -- WHAT I WANTED TO SAY
16 IS THAT THIS ISSUE, WHICH IS AN ENORMOUS ISSUE, IT
17 SEEMS TO ME IT KIND OF BOILS DOWN TO THREE AREAS TO ME
18 AND HOW MUCH WE WANT TO SAY IN OUR GUIDELINES BECAUSE
19 IT'S LIKE OPENING UP A WHOLE LOT, AND WHAT WE'RE
20 SUPPOSED TO SAY AS COMPARED TO WHAT BECOMES
21 PRESCRIPTIVE, WHATEVER. CONFIDENTIALITY IS EXTREMELY
22 IMPORTANT FOR ALL THE REASONS THAT WE'VE ALL BEEN
23 TALKING ABOUT. AND HOW WE MAINTAIN THAT BECOMES THE
24 MECHANICS WHICH INSTITUTIONS HAVE TO DO.

25 AND, AGAIN, AS MUCH AS I'D LOVE TO DIG INTO

1 IT, I DON'T KNOW THAT THAT'S OUR MANDATE. WE JUST HAVE
2 TO SAY THE UTMOST CONFIDENTIALITY.

3 THEN WHAT CONSTITUTES INFORMED CONSENT? THIS
4 IS REALLY A BIG ISSUE. HOW MUCH INFORMATION IS ENOUGH?
5 AND THIS IS SOMETHING THAT WE HAVE TO -- SOMEBODY HAS
6 TO SET A STANDARD FOR SO THAT A PERSON WHO'S
7 VOLUNTEERING KNOWS ALL THE RISKS THAT COULD HAPPEN AND
8 WHAT IS ENOUGH INFORMATION.

9 AND THEN THE THIRD THING THAT EVERY GROUP
10 THAT I TALK TO IS CONCERNED ABOUT IS THAT THESE
11 PATIENTS, WOMEN IN PARTICULAR, BE PRESSURED TO
12 PARTICIPATE IN THESE TRIALS. AND WE HAVE TO MAKE SURE
13 THAT NOBODY CAN BE PRESSURED UNDER ANY CIRCUMSTANCES TO
14 PARTICIPATE IN ANY OF THESE TRIALS. THAT'S THE BIG
15 FEAR, THAT, YOU KNOW, NO MATTER WHAT WE SAY, THE
16 DOCTORS WILL START PRESSURING PEOPLE.

17 CO-CHAIR LO: JON AND JOSE AND FRANCISCO.

18 MR. SHESTACK: I'D LIKE TO JUST MAKE MY
19 COMMENTS PART OF A DIALOGUE WITH YOU, SO I WANT YOU TO
20 BE BACK ON THE SAME DOCKET SINCE YOU PREPARED PART OF
21 THIS. YOUR AREA OF EXPERTISE IS INFORMED CONSENT?

22 CO-CHAIR LO: I SHARE THE GLORY AND THE
23 RESPONSIBILITY WITH THE STAFF, BUT WE'VE WORKED.

24 MR. SHESTACK: I'M JUST WONDERING IS IT
25 NECESSARILY THAT COMPLICATED? THE NAS GUIDELINES AND

1 THESE GIVE A LOT OF SPECIFIED REALLY PRETTY
2 SPECIFICALLY THINGS THAT YOU SHOULD PUT IN YOUR
3 INFORMED CONSENT FORM. AND WHY NOT, AT LEAST FOR THE
4 FIRST PART OF INFORMED CONSENT, WHICH THIS IS FOR
5 RESEARCH INVOLVING PROCUREMENT OR DERIVATION OF CELLS,
6 NOT CLINICAL TRIALS AFTERWARDS, BUT JUST FOR THAT, WHY
7 CAN'T WE JUST HAVE STAFF PRODUCE A SAMPLE INFORMED
8 CONSENT FORM AND EVERYBODY LOOK AT IT AND MAKE SURE
9 WE'VE GOT EVERYTHING ON IT? IT'S NOT THAT LONG A LIST.

10 AND THERE ARE A HUNDRED OF THESE BOILERPLATE
11 INFORMED CONSENT FOR GENETIC STUDIES, FOR IMAGING
12 STUDIES. BUT PARTICULARLY FOR STUFF WHERE YOU
13 DERIVE -- YOU GET BIOMATERIALS FROM SOMEBODY AND YOU
14 THEN HAVE ISSUES OF SOMETIMES WHAT YOU DISCOVER IS
15 PATERNITY OR SOMETHING. THERE ARE PROTOCOLS. IT'S NOT
16 THAT HARD TO DO TO GET TEN OF THEM, REDACT THEM, AND
17 PUT THIS IN, AND JUST SHOW IT TO THE GROUP, AND MAKE
18 THIS -- THIS PART COULD BE A LITTLE BIT MORE PAINLESS
19 FOR MOST OF IT, IT SEEMS TO ME. DOES THAT SEEM
20 REASONABLE TO YOU?

21 CO-CHAIR LO: THAT'S CERTAINLY POSSIBLE TO
22 DO. ONE APPROACH IS TO DEVELOP IN A SENSE A MODEL
23 CONSENT FORM.

24 MR. SHESTACK: ISN'T THAT WHAT THEY'RE ASKING
25 THIS COMMITTEE TO DO, TO BASICALLY SAY WE AGREE -- WE

1 HAVE VETTED THE CONSENT PROCESS?

2 CO-CHAIR LO: ON THE OTHER HAND, THERE ARE --
3 ANN KIESSLING GAVE US A PRESENTATION AT OUR FIRST
4 MEETING, THAT THE CONSENT FORM IS ONLY ONE PART OF A
5 WHOLE PROCESS FOR OOCYTE DONORS INVOLVING COUNSELING,
6 ASSESSMENT OF COMPREHENSION OF WHAT WAS DISCLOSED. A
7 LOT OF SORT OF PROCEDURAL THINGS TO MINIMIZE OR
8 ELIMINATE THE RISK OF UNDUE INFLUENCE, THAT THEY ALWAYS
9 HAD TO KEEP CONTACTING THE INVESTIGATORS.
10 INVESTIGATORS COULDN'T -- SO I THINK ONE ISSUE IS A
11 CRITICISM THAT BY FOCUSING AGAIN ON A MODEL CONSENT
12 FORM, INVESTIGATORS SAY SHOULD I JUST COPY IT, KIND OF
13 PUT IN THE LOCAL DETAILS, AND DON'T ATTEND TO ALL THESE
14 OTHER ASPECTS, WHICH MAY, IN FACT, BE AS IMPORTANT OR
15 MORE IMPORTANT. BUT I THINK YOU'RE RIGHT. WE
16 CERTAINLY COULD TRY AND DO MORE WITH SAYING WHAT ARE
17 THE CONSENT FORMS USED BY PEOPLE WHO NOW ARE DOING
18 OOCYTE DONATION. TRY AND LOOK AT THE BEST FEATURES AND
19 GO FROM THERE. THAT WOULD CERTAINLY BE A CONTRIBUTION.

20 WE ALSO HAVE TO KEEP IN MIND THAT ALMOST
21 CERTAINLY WILL CHANGE SO THAT WHATEVER WE PUT IN THE
22 REGULATIONS HERE, SOMEONE WILL BE ABLE TO DO IT BETTER
23 IN ONE MONTH, SIX MONTHS, AND SO FORTH. THAT'S
24 CERTAINLY SOMETHING THAT WE COULD -- I MEAN WE'RE
25 ASKING OUR STAFF TO DO A LOT.

1 MR. SHESTACK: JUST TO HAVE A DOCUMENT THAT
2 HAS IT ALL ON ONE PLACE AND EVERYONE CAN SAY, YES, THIS
3 IS PRETTY GOOD. THERE ARE OBVIOUSLY OTHER PARTS OF IT.

4 DR. KIESSLING: DO YOU WANT TO GO INTO THAT
5 DETAIL -- I MEAN DO YOU WANT LEVEL OF DETAIL IN THE
6 REGULATIONS, THE LEVEL OF DETAIL LIKE THE CONSENTING
7 PROCESS THAT WE HAVE FOR DONORS?

8 MR. SHESTACK: THERE WILL ULTIMATELY BE A
9 CIRM-APPROVED CONSENT FORM; IS THAT NOT TRUE, OR WILL
10 YOU LEAVE IT TO EVERY INSTITUTION TO DO THEIR OWN BASED
11 ON THE STANDARDS WE SET HERE?

12 CO-CHAIR LO: I THINK THAT'S EXACTLY THE SORT
13 OF ISSUE THAT WE NEED TO THINK ABOUT. DO WE SAY THIS
14 IS THE CIRM FORM WHICH YOU MUST USE, OR DO WE GIVE MORE
15 FLEXIBILITY TO INSTITUTIONS? IS IT A --

16 MR. SHESTACK: FLEXIBILITY. YOU'RE DOING
17 THEM A BIG FAVOR IF YOU DID IT FOR THEM, CREATED THE
18 FORM FOR THEM.

19 DR. HALL: I THINK THE QUESTION IS, MAYBE
20 OTHERS --

21 CO-CHAIR LO: GOT A COUPLE OF PEOPLE IN LINE.
22 JOSE, FRANCISCO, AND THEN ZACH.

23 DR. CIBELLI: I JUST WANT TO ECHO WHAT JON
24 WAS SAYING. WE HAVE TO SET THE STANDARD, THE HIGHEST
25 STANDARD WE CAN, AND THEN ENFORCE IT. SO IF WE CAN

1 GRANDFATHER THE BEDFORD RESEARCH FOUNDATION GUIDELINES,
2 THAT WILL BE GREAT BECAUSE I HAVE THE PRIVILEGE TO SEE
3 A FEW CONSENT FORMS FROM DIFFERENT PLACES ON THIS
4 SPECIFIC, MAKING EMBRYONIC STEM CELLS, AND THEY'RE ALL
5 VERY DIFFERENT.

6 I MEAN I HAVE, FOR EXAMPLE, BEDFORD WILL PUT
7 TWO OR THREE PAGES ON THE RISKS, AND I'VE SEEN ANOTHER
8 GROUP PUT IN HALF A PARAGRAPH ON THE RISKS. SO WE'VE
9 GOT TO BE THE BEST WE CAN. AS FAR AS I CAN TELL, THE
10 BEST I'VE SEEN ARE THE BEDFORD, ANN KIESSLING'S
11 GUIDELINES. ACTUALLY ANN KIESSLING'S PROCESS. IF WE
12 CAN ENFORCE THAT, THAT WOULD BE GREAT.

13 DR. PRIETO: I'M A LITTLE WARY OF THAT,
14 ALTHOUGH I UNDERSTAND THE BENEFITS, BUT I THINK THE KEY
15 POINTS ARE THE THINGS THAT SHERRY BROUGHT UP, IS
16 ENSURING THAT EVERYONE ENFORCES CONFIDENTIALITY, THAT
17 THE BASIC PRINCIPLES ARE ADHERED TO. AND I WOULD ADD
18 INTELLIGIBILITY BECAUSE I THINK I'VE SEEN A LOT OF
19 CONSENT FORMS ALSO, AND I USE CONSENT FORMS. AND THE
20 DISCUSSION THAT I HAVE WITH PATIENTS I THINK REALLY
21 CONVEYS A LOT MORE INFORMATION THAN THE FORM EVER DOES.
22 AND THE LEVEL AT WHICH FORMS ARE WRITTEN IS FREQUENTLY
23 REALLY INACCESSIBLE TO MOST OF THE PEOPLE WHO HAVE TO
24 SIGN THEM. AND WE NEED TO KEEP THAT IN MIND, THAT
25 PEOPLE NEED TO REALLY UNDERSTAND WHAT THEY'RE SIGNING

1 AND AGREEING TO.

2 DR. TAYLOR: I WAS JUST GOING TO MAKE KIND OF
3 A COMMENT ABOUT THIS FROM SORT OF AN IRB, GCRC TYPE OF
4 A POINT OF VIEW. I'VE REVIEWED A LOT OF MULTISITE SORT
5 OF COMMERCIAL STUDIES WHERE YOU REALIZE AS A REVIEWER
6 YOU HAVE VERY LITTLE CONTROL OVER THE BODY OF THE
7 PROTOCOL OR THE APPLICATION, BUT MANY OF US SORT OF
8 HAVE, I THINK, SITTING ON BODIES LIKE THAT, REVIEW
9 BOARDS, LIKE TO BE ABLE TO AT LEAST HAVE SOME CONTROL
10 OVER THE WAY THE CONSENT FORMS ARE WRITTEN. AND WHILE
11 IT DOESN'T SEEM LIKE THERE WOULD BE THAT MUCH
12 INTERINSTITUTIONAL VARIATION IN TERMS OF CULTURAL
13 SENSITIVITY AND THIS AND THAT, I THINK THAT WE WOULD BE
14 BETTER SERVED, EVEN WITHIN THE STATE OF CALIFORNIA, TO
15 PROVIDE GUIDELINES RATHER THAN A KIND OF BOILERPLATE
16 CONSENT FORM JUST BECAUSE THAT SEEMS TO BE ONE OF THE
17 AREAS IN WHICH INSTITUTIONS LIKE TO HAVE SOME MORE
18 FLEXIBILITY. I'M NOT SURE WHETHER IT'S RIGHT OR WRONG,
19 BUT THAT'S CLEARLY BEEN THE PRACTICE.

20 CO-CHAIR LO: THESE ARE THE DILEMMAS. THOSE
21 OF YOU WHO HAVE DONE NIH-FUNDED RESEARCH KNOW THAT THE
22 NIH HAS PUT UP, FOR INSTANCE, HEART LUNG AND NCI HAVE
23 TEMPLATES FOR INFORMED CONSENT, AND THE NCI HAS A FORM
24 WHICH IS IN A FREQUENTLY ASKED QUESTIONS FORMAT AS
25 OPPOSED TO THE USUAL SORT OF INFORMED CONSENT PROCESS.

1 AND THEY'VE DONE THAT, FOR EXAMPLE, ON THE ISSUE OF
2 GIVING CONSENT TO HAVE YOUR STORED SPECIMENS USED FOR
3 FUTURE RESEARCH AND THIS TIERED OR LAYERED CONSENT.
4 NIH HAS -- DIFFERENT INSTITUTES HAVE GIVEN SORT OF
5 DIFFERENT SAMPLE CONSENT FORMS. AND A LOT OF IRB'S, AS
6 YOU KNOW, HAVE THEIR OWN TEMPLATE FORMS FOR DIFFERENT
7 TYPES OF RESEARCH.

8 SO IT'S CERTAINLY POSSIBLE TO DO THAT. I
9 THINK THE QUESTION WE MAY WANT TO THINK ABOUT IS
10 WHETHER THAT'S A FRUITFUL DIRECTION FOR CIRM TO TAKE,
11 OR IS THERE SOME OTHER APPROACH THAT WE MIGHT WANT TO
12 DO IN ADDITION OR INSTEAD THAT REALLY FURTHER OUR
13 GOALS, WHICH I THINK SHERRY VERY NICELY OUTLINED.

14 SO I THINK IT WOULD BE NICE TO GET A SENSE OF
15 HOW WE WANT THIS TO SORT OUT AND WHETHER WE WANT TO
16 BRING IN SOME MORE EXPERTISE ON DIFFERENT APPROACHES TO
17 SORT OF IMPROVING THE CONSENT PROCESS. I THINK THESE
18 ARE OPTIONS WE SHOULD THINK ABOUT.

19 MR. LOMAX: TO OFFER ONE OTHER TECHNICAL
20 POINT AS WELL, AND WE CAN CIRCULATE THIS SO FOLKS CAN
21 GET A LITTLE BIT OF A FLAVOR OF HOW THIS HAS BEEN
22 HANDLED IN CALIFORNIA, BUT THERE IS AN EXPERIMENTAL
23 SUBJECTS BILL OF RIGHTS WHICH ACTUALLY WOULD COVER THE
24 CLINICAL TRIAL PHASE. THEY'RE IN EXISTING LAW. AND
25 WHAT THAT WILL DO -- WE'LL CIRCULATE THIS -- AT LEAST

1 GIVE YOU KIND OF A SENSE OF HOW REGULATION, HOW THE
2 ISSUE OF INFORMED CONSENT HAS BEEN SCOPED IN A
3 REGULATORY DOCUMENT. YOU CAN SEE THAT, AND WE'LL
4 CIRCULATE THAT SOMETIME AFTER THIS MEETING.

5 CO-CHAIR LO: IN ADDITION, WHAT GEOFF IS
6 REFERRING TO IS STATE REGULATION ON SUBJECTS BILL OF
7 RIGHTS. THERE'S ALSO COMPARABLE STATE LAW ON THE
8 CONSENT FORM. AND, OF COURSE, THE COMMON RULE OF THE
9 FEDERAL REGULATIONS ON HUMAN SUBJECTS RESEARCH ALSO HAS
10 A LIST OF WHAT YOU NEED TO DISCLOSE TO THE PATIENT AND
11 NEEDS TO BE INCLUDED IN THE CONSENT FORM. THERE'S THE
12 NAS GUIDELINES WITH PARTICULAR REGARD TO STEM CELL
13 RESEARCH. SO, AGAIN, THESE ARE ALL KIND OF THE
14 APPROACH OF THESE ARE THINGS THAT YOU MUST DO IN EVERY
15 CONSENT FORM. AND IT'S CERTAINLY POSSIBLE FOR US TO
16 TAKE THAT APPROACH AS WELL. AS SOMEONE SUGGESTED, WE
17 COULD LOOK AT CURRENT CONSENT FORMS AND PROCESSES AND
18 SEE IF THERE'S SOMETHING THERE THAT WE WANT TO ENDORSE
19 AS BEING --

20 DR. HALL: IF YOU WERE TO PUT DOWN THE SORT
21 OF GENERAL PRINCIPLES THAT YOU WOULD WANT TO BE
22 INVOLVED IN A CONSENT FORM, WHAT WOULD THEY BE IF WE
23 WERE TO SORT OF LAY THEM OUT? ONE IS THE THING WE'VE
24 SEEN ALREADY, RIGHT? I GUESS IT ISN'T. I'M SORRY. IT
25 WAS CONNECTED TO SOMETHING THAT GEOFF SHOWED EARLIER.

1 THAT IS THAT PEOPLE SHOULD BE INFORMED OF ALL THE USES
2 THAT -- INSOFAR AS POSSIBLE THE USES TO WHICH THEIR
3 CELLS MIGHT BE PUT. THAT MAY BE A CHANGING LIST, SO
4 YOU DON'T WANT TO SPECIFY THERE. ALSO, WHATEVER
5 MEDICAL RISKS THERE ARE ALSO MAY BE A CHANGING LIST.
6 IT SEEMS TO ME YOU DO NOT WANT TO SPECIFY THERE. BUT
7 YOU WANT BOTH OF THOSE ITEMS TO BE COVERED IN A GENERAL
8 WAY. YOU WANT IT TO HAVE SOME, HOWEVER YOU COVER THE
9 INTELLIGIBILITY OR THE ISSUE THAT PEOPLE NEED TO SHOW
10 THAT THEY'VE UNDERSTOOD WHAT THIS IS ABOUT, AND WHAT
11 OTHER KINDS OF THINGS WOULD THERE BE?

12 CO-CHAIR LO: ON THAT LEVEL ZACH IS
13 ABSOLUTELY RIGHT. THE MOST GENERAL THING IS THAT
14 INFORMED AND VOLUNTARY CONSENT IS ESSENTIAL. WHAT DOES
15 THAT MEAN? THE NEXT LEVEL DOWN IS THE PATIENTS NEED TO
16 BE INFORMED WHAT'S BEING PROPOSED, THE RISKS, ANY
17 BENEFITS TO THEM. THEY HAVE TO BE GIVEN THE
18 OPPORTUNITY TO ASK QUESTIONS. THEY HAVE TO BE TOLD
19 THAT THEY ARE FREE -- ALTERNATIVES TO PARTICIPATING.
20 THEY NEED TO BE TOLD THAT THEY MAY DECLINE TO
21 PARTICIPATE WITHOUT ANY JEOPARDY TO THEIR HEALTHCARE.
22 THEY MAY WITHDRAW FROM RESEARCH AT ANY TIME. THEY NEED
23 TO BE TOLD OF ANY PAYMENT, ANY AVAILABILITY OF
24 COMPENSATION FOR RESEARCH-RELATED INJURIES.

25 SO THAT LIST ONE MIGHT ADD, AND ALSO I THINK

1 ONE COULD SAY THAT THE DISCUSSION NEEDS TO BE HELD IN
2 LANGUAGE THAT IS INTELLIGIBLE. I FORGET WHAT THE EXACT
3 LANGUAGE IS.

4 NOW, IN ADDITION TO THAT, I THINK WE MIGHT
5 ALSO WANT TO SAY SOMETHING ABOUT COMPREHENSION AS
6 OPPOSED TO DISCLOSURE OF INFORMATION. I THINK ZACH
7 RAISED A VERY IMPORTANT POINT ABOUT TRYING TO
8 ANTICIPATE THE FACT THAT THERE WILL BE FUTURE USES,
9 SOME OF WHICH WE MAY NOT NOW BE ABLE TO SPECIFY.

10 SO THAT'S A LEVEL THAT'S NOT QUITE AS
11 SPECIFIC AS THE ACTUAL LANGUAGE, BUT DOES, I THINK,
12 GIVE THE ISSUES THAT NEED TO BE ADDRESSED IN THE
13 CONSENT PROCESS. AND GEOFF IS LOOKING DOWN. THERE ARE
14 OTHER ITEMS THAT HAVE APPEARED ON THESE KINDS OF LISTS.

15 DR. HALL: ONE THING I WOULD ADD, I THINK IT
16 WAS IMPLICIT IN WHAT YOU SAID, BUT MAYBE IT SHOULD BE
17 MADE EXPLICIT; THAT IS, THAT THEY'RE BEING DONATED FOR
18 RESEARCH.

19 CO-CHAIR LO: YES. THE DISTINCTION BETWEEN
20 RESEARCH AND CLINICAL CARE. SO THAT'S ONE APPROACH
21 WHICH HAS BEEN FOLLOWED IN REGULATIONS.

22 THE OTHER APPROACH THAT HAS ALSO BEEN
23 FOLLOWED IS TO ACTUALLY HAVE TEMPLATE FORMS. SO I
24 THINK THERE'S -- I THINK -- I SENSE SOME SORT OF
25 DISAGREEMENT AS TO WHETHER TEMPLATE FORMS ARE GOING TO

1 BE THE WAY TO GO HERE OR NOT, SO I THINK THAT'S
2 SOMETHING WE NEED TO THINK THROUGH.

3 CO-CHAIR LANSING: I DEFINITELY THINK WE NEED
4 TO THINK THROUGH IT, BUT MY NATURAL INSTINCT, AS MUCH
5 AS I WOULD LIKE TEMPLATE FORMS, BECAUSE THEY'RE VERY
6 SPECIFIC, THAT THAT IS NOT WHAT WE'RE SUPPOSED TO DO.
7 AND THAT ALSO, THE MINUTE WE HAVE A TEMPLATE FORM, IT
8 WILL BE DIFFERENT THE NEXT DAY. DO YOU KNOW? BECAUSE
9 THE SCIENCE IS MOVING SO FAST, WE CAN'T KEEP UP WITH
10 IT. I REALLY THINK THAT WE NEED TO HAVE A VERY STRONG
11 MISSION STATEMENT OF ALL THE THINGS THAT INFORMED
12 CONSENT APPLIES TO AND SHOULD HAVE IN -- THEY SHOULD
13 HAVE IN THIS IS WHAT INFORMED CONSENT IS, WHAT YOU JUST
14 SAID, ALL THESE THINGS, AND AS ZACH WAS SAYING THEM,
15 AND MAYBE THERE'S A COUPLE MORE, DO YOU KNOW, IN THERE.

16 I REALLY WOULD WANT SOME SENTENCE THAT NO ONE
17 COULD BE PRESSURED, WHATEVER, BUT I DON'T THINK WE CAN
18 DO MUCH MORE THAN THAT BECAUSE IF WE REALLY GET INTO
19 HERE'S A TEMPLATE FORM, HERE'S THE INFORMATION EVERY
20 WOMAN NEEDS TO KNOW, WELL, I CAN TELL YOU THAT BY THE
21 TIME IT'S DONE TYPING THERE WILL BE SOMETHING ELSE THAT
22 WE NEED TO KNOW. I JUST THINK IT'S DANGEROUS.

23 HOW WE ARE GOING -- THIS IS THE QUESTION
24 WHICH I DON'T KNOW. HOW WE'RE GOING TO MONITOR THAT
25 EVERY DOCTOR ADHERES TO THIS AND THAT EVERY INSTITUTION

1 ADHERES TO THIS, THAT I HAVEN'T A CLUE, BUT WE'RE GOING
2 TO HAVE TO FIGURE THAT OUT.

3 DR. KIESSLING: AREN'T WE GOING TO HAVE TO
4 TAKE IT SORT OF PIECE BY PIECE? NOT IN TERMS OF --
5 CONSENTING A SIX-MONTH OLD NUCLEAR TRANSFER OR NUCLEAR
6 TRANSFER DONOR WHO DONATES NUCLEUS IS VERY DIFFERENT
7 FROM CONSENTING A WOMAN TO DONATE EGGS. IT SEEMS LIKE
8 IT'S GOING TO HAVE TO BE SORT OF TOPIC BY TOPIC, NOT
9 JUST A GLOBAL.

10 CO-CHAIR LO: I THINK CLEARLY THE CONCERN IS
11 ABOUT OOCYTE DONORS WHERE I THINK THERE'S BEEN CONCERNS
12 RAISED ABOUT BOTH RISK, FAILURE TO APPRECIATE --
13 FAILURE TO BE TOLD OR APPRECIATE RISK AND THE COERCION
14 ISSUE.

15 DR. KIESSLING: THAT ONE WE CAN HANDLE.

16 CO-CHAIR LO: LOT OF PEOPLE HAD THEIR HANDS
17 UP. LET ME MAKE SURE. I'VE GOT ROB TAYLOR, FRANCISCO,
18 AND JEFF. ANYONE ELSE I MISSED HERE?

19 DR. TAYLOR: I WAS GOING TO MENTION THAT I
20 THINK ONE OF THE THORNIEST MOVING TARGETS IS GOING TO
21 BE THE CONFIDENTIALITY ISSUE BECAUSE THAT, AS WE EVOLVE
22 IN OUR THINKING, WE'RE GOING TO WANT TO GO BACK TO
23 SUBJECTS WHO HAVE PARTICIPATED IN THE PAST. I THINK
24 WE'RE GOING TO HAVE MECHANISMS. PEOPLE COULD SAY I
25 NEVER WANT TO BE CONTACTED AGAIN. YOU CAN HAVE MY

1 GAMETES, BUT THAT'S THE END OF THE ROAD. BUT THIS IS
2 GOING TO HAVE TO CHANGE A LITTLE BIT AS WE MOVE
3 FORWARD. I THINK THAT IN AND OF ITSELF IS GOING TO BE
4 ALMOST IMPOSSIBLE UP FRONT TO PREDICT AND SORT OF
5 ESTABLISH IN A TEMPLATE FORMAT.

6 DR. PRIETO: I THINK SHERRY MADE MOST OF THE
7 POINTS I WANTED TO. IT'S VERY TEMPTING TO HAVE THE
8 IDEAL INFORMED CONSENT FORM AND INFORMED CONSENT
9 PROCESS, BUT I DO AGREE. I THINK IT GETS OUT OF DATE
10 IMMEDIATELY, AND I'VE SEEN FORMS THAT LOOK VERY GOOD TO
11 ME. FIVE YEARS FROM NOW THE SOCIAL SCIENTISTS MAY TELL
12 US NO, NO, NO. THIS IS NOT REALLY HOW PEOPLE LEARN AND
13 UNDERSTAND THINGS, AND YOU'VE BEEN DOING IT ALL WRONG.
14 WE DON'T -- WE WILL HAVE CREATED SOMETHING, IF WE LOCK
15 DOWN ONTO THAT, THAT WILL TEND TO BE CAST IN STONE. I
16 THINK IT'S BETTER FOR US IN OUR ROLE TO FOCUS ON THE
17 PRINCIPLES THAT PEOPLE SHOULD ADHERE TO AND THEN LEAVE
18 IT AT THAT.

19 MR. SHEEHY: JUST A QUESTION. DO WE CONSIDER
20 AT ALL VENUE IN THIS? VENUE, FOR INSTANCE, WHAT'S THE
21 RELATIONSHIP BETWEEN A FERTILITY CLINIC AND RESEARCH
22 DONATIONS? DO WE JUST KIND OF NOT ADDRESS THAT AT ALL?
23 IS THAT SOMETHING -- I KNOW EARLY ON WHEN WE WERE
24 DISCUSSING THIS, IT SEEMED TO BE SOME FOLKS WHO FELT
25 LIKE THERE SHOULD BE A SEPARATION. BUT IT'S NOT CLEAR

1 TO ME THAT THAT'S NECESSARILY GOING TO HAPPEN. AND OUR
2 INFORMED CONSENT PROCESSES REALLY DON'T ADDRESS THAT
3 AND ACTUALLY LEAVE THAT POSSIBILITY OPEN, BUT SOME OF
4 THESE MORE STRUCTURAL KIND OF CONSIDERATIONS, SUCH AS
5 VENUE, WHAT AN APPROPRIATE VENUE MIGHT BE WHERE CONSENT
6 CAN BE GIVEN.

7 CO-CHAIR LO: JEFF, DID YOU MEAN DONATION OF
8 OOCYTES IN FERTILITY CLINIC?

9 MR. SHEEHY: OOCYTES. YEAH. YEAH. AND
10 THERE MIGHT BE A DIFFERENT -- YOU COULD IMAGINE A
11 DIFFERENT -- YOU KNOW, THERE WAS A SUGGESTION MADE AT
12 ONE OF THE PUBLIC MEETINGS OF HAVING A DISCUSSION OF --
13 DONATION DISCUSSION AT THE TIME WHEN PEOPLE GO IN FOR
14 IVF. ONE PERSON IN L. A. SUGGESTED IT MIGHT NOT BE BAD
15 TO ALLOW PEOPLE TO HAVE, IF THERE ARE EXTRA EMBRYOS, I
16 DON'T MIND HAVING THEM DONATED AT A CERTAIN POINT. I
17 THINK SOME OF THESE VENUE DISCUSSIONS MIGHT BE
18 PERTINENT.

19 CO-CHAIR LO: IF WE DECIDE TO TAKE THAT UP,
20 WE REALLY, I THINK, NEED TO HEAR FROM ROB OR SOMEONE
21 ELSE WHO DOES IVF IN TERMS OF THE PROCESS AND THE
22 PSYCHOLOGY OF WHAT IS GOING ON THERE BECAUSE WHEN OUR
23 INSTITUTION CONSIDERED THAT, THE NOTION OF TRYING TO
24 SORT OUT WHAT THE RISKS WERE TO THE WOMAN OR COUPLE IN
25 IVF IN TERMS OF IF WE TAKE OOCYTES THAT WE OTHERWISE

1 COULD HAVE USED FOR YOUR INFERTILITY TREATMENT AND GIVE
2 THEM TO RESEARCHERS AND YOU'RE UNABLE TO CONCEIVE WITH
3 THE OOCYTES THAT WERE RETRIEVED, CAN YOU REALLY -- HOW
4 CAN YOU REALLY ANTICIPATE WHAT THAT MIGHT BE LIKE?
5 THAT'S A HUGE ISSUE.

6 MR. SHEEHY: THAT'S WHAT I'M RAISING.

7 DR. ROWLEY: THESE ARE QUESTIONS THAT ALSO
8 CAME UP IN THE ACADEMY'S DISCUSSION. AND WE DID STATE
9 THAT TO THE EXTENT THAT IT WAS POSSIBLE TO HAVE THE
10 RESEARCH SEPARATED FROM THE CLINICAL CARE OF THE
11 PATIENT, WE THOUGHT THAT PUT IN AN ADDED PROTECTION.
12 BUT I ALSO UNDERSTAND THAT MANY RESEARCHERS HAVE MADE
13 CLOSE ASSOCIATIONS WITH CLINICS TO GET A RELIABLE
14 SOURCE, IF YOU WILL, OF MATERIAL. SO THAT'S VERY HARD
15 TO DO. BUT ONE OF THE STATEMENTS IN THIS, WHICH IS YOU
16 HAVE TO REALLY EMPHASIZE TO PATIENTS THAT THEIR CARE
17 WILL NOT BE CHANGED AT ALL AS TO WHETHER THEY DO OR
18 DON'T PROVIDE EMBRYOS.

19 AND THE OTHER ISSUE, WHICH GOES TO YOUR LAST
20 POINT, WAS THAT THE ACADEMY RECOMMENDS THAT EVEN IF A
21 COUPLE COMES IN AND SAYS WHEN WE'RE FINISHED WITH OUR
22 FAMILY, YOU CAN HAVE THE EMBRYOS, THAT, IN FACT, ALL OF
23 THE DONORS BE RECONSENTED AT THE TIME THAT IT IS CLEAR
24 THAT THERE ARE EMBRYOS AVAILABLE FOR RESEARCH PURPOSES.
25 AND JUST BECAUSE THEY SAID THAT DAY ONE, YOU HAVE TO GO

1 BACK AND GET A PROPER RECONSENT.

2 CO-CHAIR LO: JANET, COULD I ASK YOU A
3 QUESTION? DID YOUR NAS PANEL ADDRESS THE ISSUE OF
4 OOCYTE DONATION IN IVF PRACTICES AS OPPOSED TO EMBRYO
5 DONATION IN IVF PRACTICES?

6 DR. ROWLEY: WE DIDN'T DO IT IN ANY GREAT
7 DETAIL. IT WAS RAISED JUST EXACTLY IN THE CONTEXT THAT
8 YOU JUST DID IT, THAT IF YOU -- BECAUSE FRESH OOCYTES
9 ARE SO MUCH MORE PREFERABLE, BUT WE DID THINK THAT IT
10 WAS PROBABLY IMPROPER TO DONATE EXTRA OOCYTES AT THAT
11 TIME. FROZEN OOCYTES YOU DON'T NEED, THEN YOU CAN
12 DONATE, BUT FRESH OOCYTES, THAT WOULD BE IMPROPER.

13 DR. PETERS: COULD YOU JUST SAY WHY IT'S
14 IMPROPER?

15 DR. ROWLEY: WELL, BECAUSE YOU DON'T KNOW AT
16 THE TIME YOU'RE OBTAINING THESE OOCYTES WHICH ONES WILL
17 ACTUALLY BE ABLE TO BE FERTILIZED AND LEAD TO VIABLE
18 EMBRYOS.

19 DR. PETERS: PUT TOGETHER TO ME, ON THE ONE
20 HAND, A FRESH OOCYTE IS BETTER; ON THE OTHER HAND, YOU
21 HAVE THIS DOUBT BECAUSE I WAS WONDERING ABOUT THE WORD
22 "IMPROPER" BECAUSE I THOUGHT YOU WERE SAYING,
23 SCIENTIFICALLY SPEAKING, THE FRESH OOCYTE IS SUPERIOR.

24 DR. ROWLEY: YES. I THINK THE KOREAN WORK
25 HAS SHOWN THAT FRESH OOCYTES ARE MUCH MORE EFFICIENT

1 FOR SOMATIC CELL NUCLEAR TRANSFER AND OTHER THINGS.

2 DR. PETERS: I JUST WANT TO KNOW WHY IT'S
3 IMPROPER. I'M NOT GOING TO DISAGREE WITH YOU; BUT IF
4 WE'RE GOING TO SAY IT'S IMPROPER AND SCIENTISTS OUGHT
5 NOT TO DO IT, WE OUGHT TO HAVE A REASON. AND WHAT'S
6 THE REASON?

7 DR. ROWLEY: WELL, YOU WANT TO -- IF YOU
8 GET -- WELL, ACTUALLY ROBERT IS THE ONE WHO SHOULD BE
9 SPEAKING TO THIS BECAUSE HE DOES THIS AND I DON'T. MY
10 VIEW IS THAT IF YOU GET TEN OOCYTES FROM A WOMAN AT THE
11 TIME OF SUPEROVULATION, THEN VERY OFTEN YOU WILL TRY TO
12 MAKE EMBRYOS OUT OF ALL TEN OOCYTES. IF YOU SAY LET'S
13 SEE IF WE COULD MAKE EMBRYOS OUT OF SIX OF THE OOCYTES,
14 YOU CAN HAVE FOUR FOR RESEARCH, WELL, IF THE SIX DON'T
15 WORK, YOU'VE GIVEN AWAY OTHER OPPORTUNITIES RIGHT AT
16 THAT TIME TO MAKE EMBRYOS, BUT YOU SHOULD BE SPEAKING.

17 DR. TAYLOR: THERE ARE A COUPLE OF ISSUES.
18 ONE IS I THINK THE IVF PROCEDURE WITH EACH INDIVIDUAL
19 PUNCTURE OF THE OVARY PROBABLY CARRIES SOME THEORETICAL
20 INCREMENTAL RISK. FRANKLY, ONCE YOU MAKE THE DECISION
21 TO DO A PROCEDURE, YOU PROBABLY ARE HAVING MOST OF THE
22 RISK UP FRONT. BUT WITH EACH EXTRA OOCYTE THAT YOU TRY
23 TO PUNCTURE, PARTICULARLY AS YOU GET TO SMALLER AND
24 SMALLER OOCYTES THAT HAVE -- SMALLER AND SMALLER
25 FOLLICLES WHICH HAVE LESS OF AN OPPORTUNITY OF REALLY

1 GIVING YOU A CLINICALLY USEFUL OOCYTE, THEN YOU' RE
2 REALLY SUBJECTING SOMEONE TO A MORE PROLONGED
3 PROCEDURE, INCREASED RISKS OF BLEEDING, MAYBE INCREASED
4 RISK OF INFECTION, SOME OTHER KIND OF SUBTLE RISK. SO
5 I THINK THAT THAT'S ONE SIDE OF THE EQUATION.

6 THE OTHER IS BECAUSE OF OUR REAL INABILITY TO
7 FREEZE OOCYTES IN AN EFFECTIVE FASHION, ANY OOCYTE THAT
8 YOU COLLECT REALLY NEEDS TO THEN BE DEVELOPED INTO AN
9 EMBRYO. THEN WE CAN FREEZE THOSE EMBRYOS, BUT YOU CAN
10 END UP WITH A LOT OF BANKED AND FROZEN EMBRYOS THAT MAY
11 ULTIMATELY BE USEFUL TO THE COUPLE, BUT MAY BE IN
12 EXCESS OF WHAT THAT COUPLE IS SORT OF INTERESTED IN
13 USING CLINICALLY.

14 I THINK THOSE ARE THE TRADE-OFFS A LITTLE
15 BIT. ON THE OTHER SIDE OF THAT IS INCREASING EVIDENCE
16 THAT FAIRLY MATURE OOCYTES CAN BE OBTAINED FROM SORT OF
17 SMALLISH FOLLICLES AND THE IDEA THAT WE ORIGINALLY HAD
18 THAT THE BIGGER THE FOLLICLE, THE MORE LIKELY THAT WAS
19 GOING TO BE A MATURE OOCYTE AND LIKELY TO GIVE RISE TO
20 A HEALTHY PREGNANCY, I'M NOT SURE THAT WE CAN PREDICT
21 THAT AS WELL AS WE KIND OF THOUGHT WE COULD PREVIOUSLY.
22 SO THERE MAY BE SOME VALUE IN TAKING WHAT SEEM TO BE
23 KIND OF SMALL FOLLICLES THAT MIGHT HAVE OOCYTES OF SORT
24 OF WHAT WE PREVIOUSLY WOULD HAVE SUGGESTED MIGHT NOT BE
25 OF THE HIGHEST QUALITY.

1 SO IT'S A MULTILAYERED KIND OF A SITUATION.
2 I THINK THOSE ARE REALLY THE ISSUES. WHAT'S THE RISK
3 TO THE WOMAN TO SORT OF ASPIRATE MULTIPLE OOCYTES WHEN
4 YOU'RE ONLY USING A CERTAIN NUMBER TO TRY TO GENERATE
5 EMBRYOS.

6 CO-CHAIR LO: ROB, COULD YOU ALSO JUST REVIEW
7 FOR US THE STATISTICAL LIKELIHOOD OF ACHIEVING
8 PREGNANCY WITH ONE SUPEROVULATION CYCLE IN TERMS OF IF
9 YOU GET TEN OOCYTES FROM THE RETRIEVAL, HOW MANY
10 TYPICALLY, IF YOU TRY AND FERTILIZE ALL, HOW MANY
11 TYPICALLY FERTILIZE, HOW MANY TYPICALLY DEVELOP ENOUGH
12 TO BE IMPLANTED, AND OF THOSE, HOW MANY ARE WHAT'S
13 LIKELY FOR CARRYING OUT A SUCCESSFUL PREGNANCY? IT
14 SEEMS TO ME ONE OF THE TRADE-OFFS IS HOW DO YOU SAY TO
15 THE WOMAN WHO MIGHT BE DONATING FRESH OOCYTES FOR
16 RESEARCH, WHAT IS THE IMPACT GOING TO BE ON YOUR
17 PRIMARY GOAL IN FERTILITY TREATMENT?

18 DR. TAYLOR: I GUESS THE BIGGEST CHALLENGE
19 WITH THAT QUESTION IS I THINK THE WOMEN THAT WE CAN
20 PREDICT THE BEST IN TERMS OF HOW THEY'RE LIKELY TO
21 RESPOND TO GONADOTROPIN TREATMENT, HOW MANY EGGS WE'RE
22 LIKELY TO RECOVER, WHAT THE FERTILIZATION POTENTIAL OF
23 THOSE EGGS IS. AND SORT OF WHAT THE ULTIMATE
24 IMPLANTATION SUCCESS IS GOING TO BE PROBABLY COMES FROM
25 OUR DONOR POPULATION OF YOUNG, HEALTHY WOMEN, MANY

1 ALMOST -- MANY OF WHOM HAVE BEEN PREGNANT PREVIOUSLY
2 AND ESTABLISHED ALL OF THOSE KIND OF END POINTS.

3 IT GETS HARDER AND HARDER AS WOMEN HAVE MORE
4 UNEXPLAINED FORMS OF INFERTILITY THAT WE DON'T REALLY
5 UNDERSTAND, POOR OVARIAN RESPONSES TO GONADOTROPIN
6 STIMULATION, AND SORT OF OTHER REALLY KIND OF
7 MYSTERIOUS EFFECTS THAT I THINK WE CAN'T PREDICT SO
8 WELL. UNFORTUNATELY THOSE ARE THE WOMEN THAT WE'RE
9 KIND OF CLINICALLY ATTENDING TO THE MOST. AND I THINK
10 THEY'RE THE HARDEST TO BE ABLE TO PREDICT, PARTICULARLY
11 IF THEY'VE NEVER BEEN PREGNANT. IF YOU'RE TAKING THEM
12 THROUGH THEIR FIRST CYCLE OF OVULATION INDUCTION, IT
13 COULD BE HARD TO REALLY ANTICIPATE UP FRONT WHAT THE
14 OUTCOME IS GOING TO BE.

15 IF WE WERE TO TAKE A YOUNG, HEALTHY DONOR
16 MAYBE IN HER SORT OF MID TO LATE TWENTIES, WE COULD
17 CERTAINLY EXPECT WITH KIND OF A FAIRLY NOT SO
18 AGGRESSIVE STIMULATION PROTOCOL TO BE ABLE TO GET 10 TO
19 20 EGGS AND TO EXPECT THAT 70 PERCENT OF THOSE WILL
20 ACTUALLY FERTILIZE. AND THAT THE MAJORITY OF THOSE,
21 MAYBE 70 TO 80 PERCENT, WILL GO ON TO FORM WHAT LOOK
22 LIKE GOOD EMBRYOS OVER THE FIRST THREE DAYS.

23 IN THE PRACTICES THAT I'VE BEEN INVOLVED IN
24 HAVEN'T GONE OUT TO BLASTOCYST CULTURE, SO THE NUMBERS
25 DROP OFF QUITE A BIT AT THAT STAGE. WE KIND OF DECIDED

1 THAT THAT WASN'T SO HELPFUL TO GO TO THAT POINT. SO
2 THOSE ARE WHAT THE NUMBERS ARE KIND OF LOOKING LIKE IN
3 A HEALTHY YOUNG WOMAN. UNFORTUNATELY IT'S KIND OF MORE
4 COMPLEX, TYPICALLY OLDER PATIENT WHO IS HARDER TO
5 PREDICT ON.

6 CO-CHAIR LO: TO SORT OF SAY ANOTHER THING IN
7 RESPONSE TO TED'S VERY IMPORTANT QUESTION, THE OTHER
8 SORT OF THING THAT'S VERY HARD TO PREDICT IS THAT IT'S
9 NOT UNCOMMON, MY UNDERSTANDING, IF A WOMAN HAS AN
10 OOCYTE DONOR WHO'S SORT OF THE YOUNG, HEALTHY DONOR
11 THAT ROB WAS TALKING ABOUT, AND THEY SAY I JUST WANT
12 ONE CHILD, THAT'S IT, AND THEN THEY HAVE THE CHILD, AND
13 THEY SAY, OH, NOW I'VE CHANGED MY MIND. I WOULD
14 ACTUALLY LIKE TO HAVE A SECOND CHILD, AND I'D LIKE THAT
15 TO BE A GENETIC SIBLING OF THE FIRST CHILD, WHICH MEANS
16 OOCYTES FROM THE FIRST DONOR. THEN IF YOU WANT TO DO
17 THAT, YOU WOULD HAVE TO GO BACK TO A SECOND DONATION
18 CYCLE FROM THAT DONOR, WHICH THAT DONOR MAY OR MAY NOT
19 WANT TO DO. SO HAVING THE OOCYTES ALL FERTILIZED AND
20 FROZEN GIVES YOU THAT OPTION.

21 AND THERE'S CONSIDERABLE EVIDENCE THAT THOSE
22 KINDS OF REPRODUCTIVE DECISIONS ARE VERY HARD TO SORT
23 OF MAKE AT ONE POINT WITHOUT CHANGING YOUR MIND. IT'S
24 THAT SORT OF RESPECT FOR THE FACT THAT EVEN THOUGH YOU
25 SAY THAT YOU DON'T WANT TO HAVE MORE THAN ONE CHILD

1 NOW, WE WANT TO NOT TAKE AWAY THE POSSIBILITY THAT YOU
2 MAY CHANGE YOUR MIND. THAT MAKES IT HARD TO SORT OF
3 TAKE FRESH OOCYTES FROM AN IVF TREATMENT CENTER.

4 I THINK THE OTHER THING, CORRECT ME IF I'M
5 WRONG, ANN, BUT I THOUGHT FROM YOUR PRESENTATION AT THE
6 FIRST SESSION, YOU SAID THAT THE WOMEN WHO TYPICALLY
7 COME TO YOUR ORGANIZATION TO DONATE OOCYTES FOR
8 RESEARCH ARE DIFFERENT FROM THE WOMAN WHO TYPICALLY
9 WILL COME TO AN IVF CLINIC TO DONATE FOR REPRODUCTIVE
10 PURPOSES.

11 DR. KIESSLING: RIGHT. IN SOME WAYS IT'S A
12 LITTLE UNFORTUNATE THAT THE EGG DONORS FOR STEM CELL
13 RESEARCH HAVE BEEN LUMPED INTO THE FERTILITY CLINIC
14 VENUE BECAUSE I THINK THAT PUTS A LOT OF PRESSURE ON
15 FERTILITY CLINICS, AND I THINK IT FLIES IN THE FACE OF
16 A COUPLE OF PANELS PRIOR TO THIS THAT REALLY
17 RECOMMENDED THAT WOMEN GOING THROUGH INFERTILITY
18 TREATMENT NOT BE ASKED TO IN ANY WAY PARTICIPATE IN
19 THIS. AND THERE'S A BUNCH OF CAVEATS THAT YOU CAN PUT
20 UP. IT SHOULD BE -- WOMEN DONATING EGGS FOR STEM CELL
21 RESEARCH SHOULD BE RECRUITED FOR RESEARCH, PERIOD.
22 IT'S A RESEARCH PROJECT.

23 AND THE FACT THAT THEY'RE LUMPED INTO
24 FERTILITY CLINICS IS BECAUSE THAT'S WHERE THE EXPERTISE
25 IS FOR HANDLING THE HORMONES. IT'S VERY POSSIBLE THAT

1 FERTILITY CLINICS SHOULD NOT BE INVOLVED IN THAT
2 RECRUITMENT.

3 CO-CHAIR LANSING: THIS IS WHAT I DON'T
4 UNDERSTAND. AREN'T THERE LIKE TONS OF EGGS THAT AREN'T
5 GOING TO BE USED?

6 DR. KIESSLING: NO.

7 CO-CHAIR LANSING: WHY DO WE HAVE THAT
8 INFORMATION?

9 DR. KIESSLING: THAT'S VERY DIFFERENT. THE
10 FERTILITY CLINIC HAS GOTTEN INVOLVED BECAUSE OF THE
11 EMBRYOS. THAT'S WHERE THE EXPERTISE IS, BUT IT'S
12 POSSIBLE THAT -- THE AAAS CAME OUT WITH A DOCUMENT TWO
13 OR THREE YEARS AGO THAT RECOMMENDS THAT THIS WORK NOT
14 GO FORWARD IN FERTILITY CLINICS. AND THEY MADE THAT
15 RECOMMENDATION FOR TWO REASONS. IT'S REALLY DIFFICULT
16 TO FIGURE OUT HOW YOU WOULD RECRUIT AND CONSENT WOMEN
17 FOR DONATING EGGS FOR RESEARCH IF THEY WENT TO A
18 FERTILITY CLINIC TO BEGIN WITH. IT'S TWO DIFFERENT
19 THINGS. IT'S A BAIT AND SWITCH. IT'S LIKE WE'D LIKE
20 YOU TO DONATE YOUR KIDNEY, BUT YOU DON'T QUALIFY. CAN
21 WE HAVE YOUR LIVER? IT'S A REAL PROBLEM IN THE WORLD
22 OF INFORMED CONSENT. THAT WAS ONE.

23 AND THE OTHER WAS THE REASON TO NOT HAVE THE
24 RESEARCH GO FORWARD IN FERTILITY CLINICS WAS BECAUSE IT
25 WOULD ALLEVIATE FEARS OF CLONING A HUMAN. NOW, I THINK

1 THOSE FEARS ARE BEING DEALT WITH AT THE LEVEL OF
2 LEGISLATION. I THINK THE FEARS ABOUT -- CERTAINLY IN
3 CALIFORNIA THAT'S BEEN DEEMED A DRACONIAN OFFENSE. I
4 DON'T THINK ANYBODY IS GOING TO DO THAT, BUT THOSE ARE
5 THE TWO REASONS THAT THE AMERICAN ASSOCIATION FOR THE
6 ADVANCEMENT OF SCIENCE PANEL DECIDED THAT THIS WORK
7 SHOULD NOT GO FORWARD IN A FERTILITY CLINIC.

8 DR. ROWLEY: LET ME JUST ANSWER YOUR
9 QUESTION. SHERMAN ELIAS, WHO'S AT NORTHWESTERN, SAID
10 THAT HE HAD SEVERAL THOUSAND FROZEN OOCYTES.

11 CO-CHAIR LANSING: I REMEMBER READING THIS,
12 SO I'M NOT MAKING THIS UP.

13 DR. ROWLEY: CLINICS HAVE A FAIR NUMBER.

14 CO-CHAIR LANSING: THERE ARE.

15 MR. KLEIN: DR. ROWLEY, ISN'T ONE OF THE
16 ISSUES THE FLASH FREEZING, THE VITRIFICATION TECHNIQUE,
17 THEY'VE USED THAT TO PRODUCE CHILDREN AND THINK THAT
18 THEY CAN BE USED FOR NUCLEAR TRANSFER, BUT THERE'S SOME
19 DOUBT OVER THE PREVIOUS FREEZING TECHNIQUES THAT WERE
20 SLOWER FREEZING TECHNIQUES, WHETHER THEY CAN BE USED
21 FOR NUCLEAR TRANSFER.

22 DR. KIESSLING: WHETHER THE EGGS ARE FRESH OR
23 FROZEN, IT'S THE CONSENT PROCESS BEHIND WHICH THEY WERE
24 OBTAINED THAT'S IMPORTANT.

25 MR. KLEIN: I'M JUST SAYING THERE MAY BE

1 CERTAIN FROZEN EGGS THAT ARE NOT EFFECTIVE FOR THIS
2 PURPOSE.

3 DR. KIESSLING: BUT EVEN IF THEY WERE, YOU
4 NEED TO KNOW HOW THEY WERE -- UNDER WHAT GUIDELINES
5 THEY ARE OBTAINED.

6 MR. KLEIN: RIGHT. THE OTHER QUESTION IS
7 THERE'S A COUNTERVAILING GROUP DEALING WITH PATIENT
8 GROUPS WHERE PATIENT GROUPS WHERE THERE ARE WOMEN WHO
9 ARE GOING UNDER FERTILITY TREATMENT WHERE THEY MAY BE
10 YOUNGER WOMEN AND THEY'RE GOING TO USE 12 EGGS OR 15
11 EGGS FOR THE IN VITRO PROCESS WHERE THEY CONSENT TO --
12 THEY WANT TO ACCOMPLISH TWO GOALS. THEY WANT TO GO
13 THROUGH IN VITRO PROCESS, BUT THEY DON'T WANT TO GO
14 THROUGH A SEPARATE PROCESS FOR EGG DONATION. SO THEY
15 HAVE 20 EGGS THAT ARE EXTRACTED WITH THE INTENTION THAT
16 THEY USE 12 OR 15 FOR THE IN VITRO AND FIVE EGGS
17 BECAUSE THEY'RE INTERESTED IN THIS PATIENT-DIRECTED
18 RESEARCH RELATED TO A PATIENT GROUP THEY'RE A PART OF
19 OR THEIR FAMILY IS A PART OF.

20 IN THAT SITUATION, THERE IS AN OVERLAP WITH
21 FERTILITY CLINICS RELATED TO AN OTHERWISE
22 PATIENT-DIRECTED MOTIVATION.

23 CO-CHAIR LO: JEFF AND THEN SHERRY.

24 MR. SHEEHY: THIS KIND OF BRINGS ME BACK. I
25 REALLY THINK WE NEED TO MAKE SOME STATEMENT ABOUT VENUE

1 BECAUSE IT'S NOT CLEAR, AS I LISTEN TO THIS DISCUSSION,
2 THAT INFORMED CONSENT IS POSSIBLE, ESPECIALLY FOR
3 OOCYTE DONATION WITHIN THE CONTEXT OF A FERTILITY
4 CLINIC. IT SEEMS TO ME, TOO, THAT FERTILITY CLINICS
5 PAY FOR OOCYTE DONATION. SO I DON'T KNOW -- I JUST
6 THINK THIS IS OUR MOST ETHICALLY CHALLENGING MINEFIELD,
7 AND I THINK THAT WE SHOULD REALLY BE VERY CAREFUL ABOUT
8 HOW WE GO ABOUT THIS.

9 CO-CHAIR LANSING: I AGREE WITH WHAT YOU'RE
10 SAYING, THAT IT IS ONE OF OUR BIGGEST CHALLENGES. I
11 DON'T THINK THAT WE SHOULD GET INTO WHETHER IT'S AT A
12 FERTILITY CLINIC OR WHETHER IT'S FOR RESEARCH OR
13 WHATEVER. I DON'T THINK THAT IS OUR MISSION. OUR
14 MISSION IS TO MAKE, AND I HAVE A GREAT DEAL OF FAITH IN
15 THE INTELLIGENCE OF THE PEOPLE THAT DECIDE TO DO THIS,
16 AND SO, YOU KNOW, YES, IT IS DIFFICULT TO DECIDE IF
17 YOU'RE AT A FERTILITY CLINIC. I UNDERSTAND THAT, AND
18 IT'S DIFFICULT TO DECIDE TO GO INTO ANY RESEARCH
19 PROJECT.

20 TO ME THE MOST IMPORTANT, IMPORTANT THING IS
21 THAT ANY WOMAN WHO DECIDES THAT SHE IS VOLUNTARILY
22 INTERESTED IN THIS HAS AN UNBELIEVABLE AMOUNT OF
23 INFORMATION BEFORE SHE MAKES THAT DECISION AS TO ALL
24 THE RISKS THAT ARE THERE AND, YOU KNOW, ISN'T IN ANY
25 WAY COERCED TO DO THIS, ISN'T IN ANY WAY PRESSURED.

1 AND IT CAN BE MANY VENUES, AS FAR AS I'M CONCERNED. IT
2 JUST -- I DON'T THINK THAT'S OUR DUTY IN THIS GROUP. I
3 THINK IN THIS GROUP OUR DUTY IS TO MAKE SURE THAT IT IS
4 REALLY INFORMED CONSENT, AND THAT THERE'S MAYBE A TIME,
5 YOU DON'T HAVE TO SIGN IN 10 MINUTES AND MAKE AN
6 ANSWER, WHATEVER, AND THAT THE CONFIDENTIALITY IS
7 MAINTAINED. I THINK THAT'S WHAT WE'RE ABOUT, YOU KNOW.

8 DR. PETERS: IF WE DO HAVE THE KIND OF
9 INFORMED CONSENT YOU'RE TALKING ABOUT, WOULD A FRESH
10 OOCYTE STILL BE IMPROPER OR WOULD IT BE PROPER?

11 CO-CHAIR LANSING: I THINK IT'S PROPER. I
12 THINK IT'S PROPER.

13 MR. SHEEHY: FOR ME THE QUESTION ISN'T FRESH
14 OOCYTES. I CAN IMAGINE A SCENARIO WHERE SOMEONE'S GONE
15 IVF ONCE, DIDN'T TAKE, SPEND 15, 20,000, THEY GO IN
16 AGAIN. GEEZ, ALL I GOT IS TEN, DOC. THEY SAY, WELL,
17 YOU KNOW, IF YOU'LL LET ME HAVE A COUPLE OF EGGS FOR
18 RESEARCH --

19 CO-CHAIR LANSING: THAT'S NOT INFORMED
20 CONSENT.

21 MR. SHEEHY: HOW DO YOU ENFORCE THAT?

22 CO-CHAIR LANSING: BECAUSE IF THAT'S THE
23 CONVERSATION, THEN THAT PATIENT IS NOT GETTING THE
24 INFORMATION THAT THEY NEED.

25 MR. SHEEHY: HOW DO YOU ENFORCE? TWO PEOPLE

1 WALK INTO A CLINIC TO DONATE EGGS, A FERTILITY CLINIC,
2 ONE GETS 5, 10, 15, 20,000 BECAUSE IT'S FOR
3 REPRODUCTIVE REASONS, THE OTHER PERSON THAT GOES
4 UNCOMPENSATED BECAUSE IT'S FOR RESEARCH REASONS, AND
5 THEY'RE SITTING NEXT TO EACH OTHER IN THE WAITING ROOM.
6 I JUST -- SOMETHING TELLS ME IN THE REAL WORLD THAT
7 THIS WILL NOT WORK.

8 CO-CHAIR LANSING: I DON'T WANT TO LIMIT A
9 PATIENT'S ABILITY OR WOMAN'S ABILITY TO HAVE CHOICE AS
10 TO WHAT SHE WANTS TO DO. WHAT I WANT IS TO MAKE
11 SURE -- THIS IS A HEALTHY DISCUSSION. WHAT I WANT TO
12 DO IS TO MAKE SURE THAT THIS INDIVIDUAL KNOWS
13 EVERYTHING BEFORE THEY GO AHEAD. IT'S THEIR CHOICE.

14 MR. SHEEHY: THAT'S WHY WE HAVE RULES.
15 COMPENSATION DISRUPTS CHOICE, AND ECONOMIC PRESSURE CAN
16 INTERFERE WITH THE INFORMED CONSENT PROCESS, WHICH IS
17 KIND OF WHY --

18 DR. KIESSLING: ONE OF THE THINGS THAT WE'VE
19 THOUGHT ABOUT IN OUR EGG DONOR PROGRAM IS OFFERING IT
20 AS A LITTLE COURSE WHERE YOU HAVE TO HAVE A CERTIFICATE
21 BECAUSE THE DONORS COME AND, YOU KNOW, YOU COULD SPEND
22 SIX OR SEVEN HOURS WITH THEM. THEY'RE REALLY
23 INTERESTED IN THE SCIENCE, AND THEY GENERALLY HAVE A
24 PERSONAL INTEREST TO BE INTERESTED IN THE SCIENCE AND
25 WHAT'S BEHIND IT. AND ONE OF THE THINGS THAT -- I

1 HAVEN'T DONE THIS AND I HAVEN'T REALLY PROPOSED IT
2 BECAUSE I DON'T KNOW WHO WOULD DO IT, BUT ONE OF THE
3 THINGS IS YOU COULD ASK WOMEN DONATING EGGS FOR
4 RESEARCH TO SHOW THAT THEY HAVE A LITTLE CERTIFICATE
5 THAT THEY'VE HAD X NUMBER OF HOURS AND THEY PASSED A
6 LITTLE EXAM AT THE END OR SOMETHING LIKE THAT. IT
7 WOULDN'T HAVE TO BE OVERBURDENING SO THAT IT WOULD BE
8 DIFFICULT, BUT IT WOULD CERTAINLY MAKE THE INFORMED
9 CONSENT PART OF IT CLEARER.

10 CO-CHAIR LANSING: I BELIEVE THAT WE'RE GOING
11 TO HAVE TO DO SOMETHING LIKE THAT, BUT I DON'T KNOW
12 THAT THAT DOESN'T COME UNDER WHAT YOU CALL PRESCRIPTIVE
13 AND THAT THAT'S NOT THE MECHANICS OF HOW YOU DO THIS.
14 I AGREE WITH YOU. THEY REALLY NEED A LOT OF
15 INFORMATION. AND HOW WE'RE GOING TO MONITOR THAT
16 EVERYBODY GETS THE FAIR AMOUNT OF INFORMATION, NO
17 MATTER WHAT CLINIC YOU GO TO OR HOSPITAL YOU GO TO OR
18 RESEARCH INSTITUTE, THAT IS THE CHALLENGE OF THE
19 EXECUTION. THAT'S NOT OUR AREA. AS MUCH AS I WOULD
20 LOVE TO GET INTO IT, THAT'S NOT OUR AREA.

21 CO-CHAIR LO: IF I CAN JUST SORT OF ASK JAMES
22 TO COMMENT ON SOMETHING SHERRY JUST SAID IN TERMS OF
23 THE IDEA THAT JANET PRESENTED OF SORT OF HAVING A --
24 ASKING THE WOMAN WHO'S DONATING OOCYTES TO DEMONSTRATE
25 SHE UNDERSTOOD THE MATERIALS DISCLOSED. I THINK IT'S

1 OKAY TO BE PRESCRIPTIVE AS LONG AS WE MAKE IT CLEAR
2 WHAT THE INSTITUTION OR RESEARCHER NEEDS TO DO TO
3 SATISFY THAT SORT OF PRESCRIPTIVE ELEMENT; IS THAT
4 CORRECT?

5 MR. HARRISON: THAT IS CORRECT. ONE OF THE
6 INTERESTING QUESTIONS THAT DR. KIESSLING'S SUGGESTION
7 RAISES IS WHETHER WE'RE REGULATING THE DONORS
8 THEMSELVES; THAT IS, REQUIRING A DONOR TO OBTAIN TWO
9 HOURS OF EDUCATION REGARDING THE SCIENCE AND THE RISKS
10 ASSOCIATED WITH CONSENT BEFORE THE DONOR MAY DONATE
11 BIOLOGICAL MATERIALS OR WHETHER WE'RE REGULATING THE
12 INSTITUTIONS WHO ARE CONDUCTING THE RESEARCH OR BOTH.
13 BUT WE, AS A THRESHOLD MATTER, NEED TO ANSWER THAT
14 QUESTION BECAUSE WE NEED TO KNOW WHO'S GOING TO BE
15 GOVERNED BY THESE REGULATIONS.

16 DR. KIESSLING: IT TAKES MORE THAN TWO HOURS.

17 CO-CHAIR LO: I'D LIKE TO TRY AND SORT OF
18 MOVE US ALONG HERE. THIS HAS BEEN, I THINK, A VERY
19 GOOD DISCUSSION, BUT I'M THINKING ABOUT WHAT WE NEED TO
20 DO BEFORE NEXT MEETING TO TRY AND REACH CLOSURE
21 EVENTUALLY.

22 A NUMBER OF SUGGESTIONS WERE MADE, AND LET ME
23 SORT OF TRY AND SPELL THEM OUT AND SEE WHETHER THERE'S
24 AGREEMENT ON THEM. ONE WAS SUGGESTED THAT WE GATHER
25 CONSENT FORMS AND CONSENT PROCEDURES CURRENTLY BEING

1 USED AT SITES THAT OBTAIN FRESH OOCYTES FOR RESEARCH
2 PURPOSES JUST TO GET A SENSE OF WHAT ACTUALLY IS GOING
3 ON OUT THERE.

4 NOW, THERE'S A SUGGESTION MADE THAT WE
5 ACTUALLY CONSIDER DRAWING UP A CIRM SAMPLE CONSENT FORM
6 OR TEMPLATE, NOT AGREEMENT ON THAT, IN FACT, SOME
7 STRONG DISAGREEMENT WITH THAT, BUT A SENSE THAT WE
8 SHOULD AT LEAST TRY AND ARTICULATE THE GENERAL
9 PRINCIPLES OR ELEMENTS OF INFORMED CONSENT, SORT OF
10 WHAT SHERRY TALKED ABOUT, AND THERE'S PROBABLY OTHERS
11 TO ADD TO THAT. AND, AGAIN, THERE ARE EXISTING
12 STATUTES, LAWS, REGULATIONS THAT WE CAN GO TO TO SORT
13 OF MAKE SURE WE HAVEN'T OVERLOOKED ANYTHING.

14 MY SENSE IS WE SHOULD DEFINITELY DO THAT.
15 THAT'S AT LEAST THE LEVEL WE WANT TO INCLUDE IN OUR
16 FINAL REGULATIONS.

17 THEN THE OTHER ISSUE, I GUESS, IS WOULD IT BE
18 USEFUL TO OUR DELIBERATIONS FOR THE DECEMBER MEETING TO
19 GET ADDITIONAL INFORMATION FROM OTHER PEOPLE. SO SOME
20 OF THE SUGGESTIONS THAT I HEARD, AND I MAY BE
21 OVERREADING WHAT PEOPLE SAID, TO NOT JUST GET WHAT WAS
22 IN THE ORTIZ BILL THAT THE GOVERNOR VETOED, BUT MAYBE
23 TO HAVE SOMEONE FROM SENATOR ORTIZ' OFFICE SORT OF GIVE
24 US SORT OF THE BACKGROUND, THE REASONING OF THE BILL,
25 AND THE REACTIONS TO SORT OF THE GENERAL PRINCIPLES WE

1 MAY BE ENUNCIATING IN ORDER TO TRY AND PROMOTE HARMONY
2 AND OBIVATE THE NEED FOR ADDITIONAL LEGISLATION.

3 A LOT OF WHAT WE'RE TALKING ABOUT IS SORT OF
4 BASED ON HOW WE THINK WOMEN WHO MIGHT BE OOCYTE DONORS
5 IN EITHER RESEARCH OR IVF CONTEXT MIGHT REACT. I DON'T
6 KNOW IF IT'S WORTH TRYING TO GET INFORMATION FROM THAT
7 OR REPRESENTATIVES OF SUCH WOMEN, ADVOCATES FOR SUCH
8 WOMEN. IT STRIKES ME NO MATTER WHAT WE DO, WE SHOULD
9 TRY AND DO SOME WORK BETWEEN NOW AND THE NEXT MEETING.
10 I THINK WE SHOULD CERTAINLY CIRCULATE THESE MATERIALS
11 THAT STAFF AND I WILL HELP TO DRAW UP. I THINK WE
12 SHOULD PROBABLY SCHEDULE A COUPLE OF CONFERENCE CALLS.
13 I THINK WE MAY ACTUALLY WANT TO SORT OF FORM
14 SUBCOMMITTEES AND ASK PEOPLE TO SORT OF THINK THROUGH
15 CERTAIN ISSUES AND START A DISCUSSION TO SORT OF,
16 AGAIN, LEAD US -- HELP US TO MOVE FORWARDS TOWARDS
17 MAKING SOME RECOMMENDATIONS FOR REGULATIONS NEXT
18 MEETING.

19 I JUST WANTED TO SORT OF GET A SENSE OF ARE
20 THERE ANY OTHER THINGS PEOPLE THINK WE SHOULD DO BEFORE
21 THE NEXT MEETING AND AT THE NEXT MEETING TO ENSURE THAT
22 OUR DELIBERATIONS ON THIS ISSUE ARE AS THOUGHTFUL AND
23 AS EFFECTIVE AS POSSIBLE.

24 DR. KIESSLING: I WOULD LIKE A REVIEW OF
25 HIPAA GUIDELINES. ALTHOUGH I'VE HAD TO TAKE A CLASS AT

1 MY OWN INSTITUTION, AND I THINK I UNDERSTAND THE HIPAA
2 GUIDELINES, I WAS VERY SURPRISED WHEN THE UNIVERSITY OF
3 PITTSBURGH DECIDED THAT THEY DIDN'T NEED TO REVIEW THE
4 KOREAN PROGRAM AND THEY HID BEHIND A HIPAA GUIDELINE.
5 AND I DON'T QUITE UNDERSTAND -- I'D LIKE TO KNOW WHERE
6 THAT FITS INTO THIS BECAUSE IT'S POSSIBLE THAT IF WE
7 WANT TO ADOPT THOSE FEDERAL GUIDELINES AS PART OF THESE
8 GUIDELINES, THAT IT WILL REALLY MAKE SOME OF THE
9 CONSENT PROCESSING A LOT SIMPLER. DO YOU UNDERSTAND
10 WHAT I MEAN? THERE'S A DIFFERENCE BETWEEN HUMAN
11 SUBJECTS CONSENT IN THE HIPAA GUIDELINES, AND THEY HAVE
12 TO DO WITH CONFIDENTIALITY. AND BECAUSE THE KOREAN
13 STEM CELL LINES WERE GOING TO BE BLINDED TO THE
14 UNIVERSITY OF PITTSBURGH RESEARCHERS, THE UNIVERSITY OF
15 PITTSBURGH DECIDED THEY DIDN'T NEED TO KNOW ANYTHING
16 ABOUT HOW THE DONORS WERE RECRUITED.

17 I DIDN'T UNDERSTAND THAT DECISION. WE HAD
18 THIS CONVERSATION. I DID NOT UNDERSTAND WHY THE
19 UNIVERSITY OF PITTSBURGH TOOK THAT POSITION, BUT IT'S
20 POSSIBLY BECAUSE I DON'T QUITE UNDERSTAND THE INTENT OF
21 THE SCOPE OF THE HIPAA GUIDELINES.

22 CO-CHAIR LO: OKAY. THAT'S AN IMPORTANT AND
23 EXTREMELY DIFFICULT, BUT I THINK THAT WOULD BE A GOOD
24 REASON FOR GETTING SOME ENLIGHTENMENT. THAT'S A GOOD
25 TOPIC. ANYTHING ELSE THAT WE SHOULD --

1 DR. HALL: I JUST WANTED TO ASK DR. ROWLEY.
2 IN TERMS OF THE PREVIOUS DISCUSSION ABOUT NUCLEAR
3 TRANSFER AND THE HIPAA GUIDELINES AND THE NATIONAL
4 ACADEMY'S GUIDELINES, I DIDN'T REALLY UNDERSTAND IN
5 WHAT WAY THE NATIONAL ACADEMY GUIDELINES -- I DON'T
6 REMEMBER. I WONDERED IF YOU HAD A COMMENT ON THAT, IN
7 WHAT WAY THEY WERE NOT ADEQUATE TO THE QUESTION OF --

8 DR. ROWLEY: WELL, YOU'RE ASKING ME A
9 QUESTION I CAN'T REMEMBER IN GREAT DETAIL. I THINK I
10 FALL BACK TO SAYING ALTA SAID THAT, AT LEAST RIGHT NOW
11 FOR HIPAA, OOCYTES AND EMBRYOS ARE NOT HUMAN SUBJECTS.
12 AND SO WE DIDN'T HAVE TO -- THAT WAS NOT AN ISSUE
13 WITHIN THE TIME FRAME THAT OUR GUIDELINES WOULD BE
14 APPLICABLE.

15 DR. HALL: SO THEY DON'T FALL WITHIN HIPAA
16 GUIDELINES UNLESS --

17 DR. KIESSLING: I THINK THIS IS REALLY A
18 TOPIC -- I MUST SAY THAT IF I DON'T UNDERSTAND IT, I'M
19 ASSUMING OTHERS DON'T UNDERSTAND IT BECAUSE I'VE REALLY
20 THOUGHT ABOUT THIS A LOT. I DON'T UNDERSTAND THE
21 OVERLAP IN THIS CONTEXT BETWEEN HIPAA GUIDELINES AND
22 IRB GUIDELINES.

23 CO-CHAIR LO: WE CAN TRY AND GET SOME
24 CLARIFICATION ON THAT. PROBABLY BE WORTH CONTACTING
25 SOMEONE WHO'S A HIPAA SORT OF EXPERT.

1 DR. ROWLEY: BUT ALSO ASKING ALTA IF SHE
2 WOULD EITHER PRESENT OR PREPARE --

3 CO-CHAIR LO: ALTA MAY BE ABLE TO DO THAT.

4 DR. ROWLEY: -- A POSITION PAPER OR GIVE US
5 GUIDANCE AS TO WHO MIGHT BE USEFUL IN THIS AREA. IF WE
6 GO INTO HIPAA TOTALLY, WE'LL BE HERE ALL DAY JUST
7 TALKING ABOUT HIPAA GUIDELINES, WHICH DON'T REALLY HAVE
8 RELEVANCE TO HUMAN EMBRYONIC STEM CELL RESEARCH.

9 CO-CHAIR LO: I THINK WHERE THEY DO HAVE --
10 THEY ARE PERTINENT IS THAT WE'RE KEEPING THE IDENTITIES
11 OF THE DONORS TO TRACK BACK FOR FDA SORT OF PURPOSES.
12 THEN THAT'S IDENTIFIABLE INFORMATION. HOW THAT'S
13 PROTECTED, DEPENDING ON HOW THAT'S SET UP, THAT'S
14 CLEARLY IDENTIFIABLE INFORMATION AND IT'S A
15 TECHNICALITY AS TO WHETHER IT'S PERSONALLY IDENTIFIABLE
16 HEALTH INFORMATION ALL GATHERED IN A RESEARCH CONTEXT.
17 IT'S COMPLICATED.

18 OKAY. SO I'M GOING TO SORT OF CALL ON STAFF
19 TO SORT OF HELP THINK THIS THROUGH AND THEN TRY AND SET
20 UP SORT OF SOME INTERIM WORK FOR US ALL TO DO TO BE
21 BETTER PREPARED FOR DECEMBER.

22 I THOUGHT IT MIGHT BE USEFUL TRYING TO RECAP
23 WHAT HAPPENED TODAY. FIRST OF ALL, WE HAVE PENDING --

24 DR. ROWLEY: A PUBLIC COMMENT.

25 CO-CHAIR LO: PUBLIC COMMENTS ON THE OOCYTE

1 DONATION ISSUE. THANK YOU FOR REMINDING ME.

2 MR. REED: DON REED. I WOULD JUST LIKE TO
3 ASK THAT -- I THINK HER NAME IS SUZY LEATHER, AND SHE'S
4 THE HEAD OF THE ENGLISH HFEA PROGRAM. AND SHE DESIGNED
5 A PROGRAM TO GIVE TO POTENTIAL EGG DONORS WITH THE IDEA
6 OF BEING LIKE A COURSE, AND IT'S A SEVERAL-DAY COURSE.
7 AND YOU HAVE TO PASS A TEST TO PROVE THAT YOU
8 UNDERSTAND THE ISSUES INVOLVED. AND THEY SAID THEIR
9 BIGGEST FEAR WOULD BE THAT SOMEBODY DOWN THE ROAD MIGHT
10 SAY, GEE, IF ONLY I HAD UNDERSTOOD. THEY DIDN'T MAKE
11 IT CLEAR.

12 CO-CHAIR LO: GOOD POINT. ANOTHER PUBLIC
13 COMMENT?

14 MS. FOGEL: THANK YOU. SUSAN FOGEL. FIRST
15 OF ALL, THIS IS AN AREA WHICH IS VERY IMPORTANT TO THE
16 PRO CHOICE ALLIANCE. IT'S AN AREA THAT WE SPEARHEADED
17 WITH SENATOR ORTIZ. I WANT TO, FIRST OF ALL, SAY SB 18
18 IS OF LIMITED USEFULNESS BECAUSE MUCH TOO MUCH MODELED
19 ON A FERTILITY CLINIC ASPECT. SO IT'S WONDERFUL TO
20 BRING SENATOR ORTIZ IN. SHE'S CERTAINLY INTERESTED IN
21 MOVING THIS ISSUE FORWARD, BUT IT WASN'T SUCH A GOOD
22 BILL.

23 THERE ARE A COUPLE OF ISSUES I WANT TO RAISE.
24 FIRST OF ALL, I'LL SAY OVER AND OVER AGAIN, SEPARATING
25 FERTILITY FROM RESEARCH IS INCREDIBLY IMPORTANT. THERE

1 IS NO WAY FOR YOU TO SEPARATE OUT THE CONFLICTS OF
2 INTEREST WHEN YOU HAVE A FERTILITY CLINIC WHOSE FIRST
3 RESPONSIBILITY IS SUPPOSED TO BE TO THAT PERSON WHO'S
4 TRYING TO GET PREGNANT AND SORT OUT HOW ARE YOU
5 GOING -- HOW ARE THEY GOING TO BOTH HAVE A NO. 1
6 PRIORITY TO THIS WOMAN WHO'S TRYING TO GET PREGNANT AND
7 THEN SELLING -- LET'S FACE IT. THERE'S MONEY IN THIS
8 FOR FERTILITY CLINICS. EVEN THOUGH THE WOMAN MAY NOT
9 GET COMPENSATED, PROP 71 ALLOWS THEM TO RECOUP EXPENSES
10 OF STORAGE AND EXTRACTION. AND WHAT WE DON'T WANT THIS
11 TO TURN OUT TO BE IS A BIG BOON FOR THE FERTILITY
12 INDUSTRY WHICH, WITH ALL DUE RESPECT TO THOSE OF YOU
13 WHO MAY BE INVOLVED IN IT, IS BARELY REGULATED. IT'S
14 LIKE THE LEAST REGULATED MEDICAL PROCEDURES. SO I
15 THINK WE HAVE TO BE REALLY CAUTIOUS ABOUT THAT.

16 THE OTHER THING I WANT TO RAISE THAT'S NOT --
17 WASN'T ON YOUR LIST OF PRINCIPLES IS MEDICAL CARE FOR
18 WOMEN WHO MAY SUFFER SIDE EFFECTS FROM THE EGG
19 EXTRACTION PROCEDURES. THE DRUGS CARRY ALL KINDS OF
20 RISKS. UP TO 30 PERCENT OF WOMEN GET SICK WITHIN THE
21 FIRST TWO WEEKS. AND YOU HAVE AN OPPORTUNITY TO SET
22 SOME VERY HIGH STANDARDS AND MAKE SURE THAT THERE'S
23 SOME PROVISION FOR THEIR MEDICAL CARE. JUST
24 COMPENSATION FOR INJURY ISN'T SUFFICIENT. THEY NEED TO
25 GET MEDICAL CARE RIGHT AWAY.

1 AND THE OTHER -- I GUESS I WANT TO ALSO GO
2 BACK TO THE IDEA OF THE TERMS OF THE CONFLICT. THE
3 IDEA THAT SOMEHOW YOU CAN GET MORE EGGS LATER IS IN
4 MANY CASES OBVIOUSLY, NOT ONLY BECAUSE THE WOMEN WHO
5 ARE AGING, BUT IS BECOMING MORE AND MORE A STANDARD OF
6 CARE FOR WOMEN WHO ARE UNDERGOING CANCER TREATMENTS OR
7 OTHER KINDS OF TREATMENTS THAT MAY FOREVER DESTROY
8 THEIR ABILITY TO PRODUCE EGGS TO HARVEST THEIR OWN EGGS
9 FOR THEIR OWN FERTILITY LATER. AND OBVIOUSLY IT WOULD
10 BE IRRESPONSIBLE FOR ANY DOCTOR TO SUGGEST THAT WOMEN
11 IN THOSE SITUATIONS BE ASKED TO GIVE SOME FOR RESEARCH.

12 THERE NEEDS TO BE A DIFFERENT MODEL, AND YOU
13 HAVE, AGAIN, I THINK, AN OPPORTUNITY AND A
14 RESPONSIBILITY TO FIND A BETTER, DIFFERENT WAY OF DOING
15 IT. SO THANK YOU FOR THIS INTERESTING DISCUSSION. WE
16 WOULD BE VERY HAPPY. WE HAVE EXPERTISE WITHIN OUR
17 COALITION ON THIS ISSUE. WE'D BE VERY HAPPY TO WORK
18 WITH THE WORKING GROUP OR A SUBCOMMITTEE ON THIS TO
19 COME OUT WITH THE BEST RESULT.

20 CO-CHAIR LO: THANK YOU VERY MUCH. OKAY.
21 LET'S TRY AND RECAP WHERE WE ARE. I'M SORT OF LOOKING
22 UNDER TAB 8 AT THIS VERY NICE LITTLE CHART THAT STAFF
23 HAD PREPARED FOR US IN TERMS OF OUR TIMETABLE. SO WE
24 DID TALK ABOUT DIVERSITY AND SCOPE, ESCRO, AND BANKING
25 AT TODAY'S MEETING. I THINK WITH REGARD TO DIVERSITY

1 AND SCOPE, MY SENSE IS WE HAVE A GENERAL SENSE OF WHAT
2 WE WANT TO SAY. NOW WE NEED TO WORK WITH STAFF AND
3 WITH LEGAL COUNSEL TO TRANSLATE THAT INTO SORT OF
4 REGULATORY LANGUAGE THAT WILL COME BACK TO US FOR
5 APPROVAL.

6 WITH REGARD TO ESCRO, WE HAD AN EXTENDED
7 DISCUSSION THIS MORNING, WHICH I THINK WE REACHED SOME
8 CLOSURE ON SOME OF THE ASPECTS OF ESCRO, BUT IF YOU
9 LOOK UNDER TAB 6 AT THIS CHART, WHICH SORT OF IS THE
10 DIFFERENT CHUNKS OF OUR DRAFT RECOMMENDED REGULATIONS,
11 THERE ARE OTHER ESCRO ISSUES THAT WE ACTUALLY DID NOT
12 GET A CHANCE TO TALK ABOUT TODAY IN TERMS OF WE TALKED
13 ABOUT WHAT WE WANT THEM TO DO AND SORT OF HOW THEY
14 MIGHT BE SET UP AND THE OPTIONS FOR SETTING THEM UP,
15 BUT WE ACTUALLY DIDN'T GO THROUGH THE OTHER SECTIONS
16 WHICH TALKED ABOUT WHAT THEY WOULD REVIEW, WHAT THEY
17 NEEDED TO BE NOTIFIED OF, WHAT THEY NEED TO REVIEW, AND
18 APPROVE. I THINK THAT'S SOMETHING WE'RE GOING TO HAVE
19 TO FIT INTO OUR AGENDA OBVIOUSLY BEFORE WE CAN FINISH
20 OUR WORK HERE.

21 WITH REGARD TO BANKING, AFTER LUNCH WE DID, I
22 THINK, REACH CLOSURE ON SOME LANGUAGE ABOUT BANKING
23 WHICH I ACTUALLY THOUGHT HAD SOME INNOVATIVE IDEAS. I
24 HOPE THAT WE CAN TRANSLATE. AGAIN, THAT NEEDS TO BE
25 TRANSLATED INTO REGULATORY LANGUAGE.

1 MY SENSE IS THAT BEFORE THE NEXT MEETING, WE
2 WILL BE IN TOUCH WITH YOU BOTH ELECTRONICALLY AND MAYBE
3 TRYING TO ARRANGE SOME SMALL CONFERENCE CALLS TO GET
4 YOUR FEEDBACK ON THE LANGUAGE THAT STAFF WITH LEGAL
5 COUNSEL PROPOSED FOR THE REGULATORY LANGUAGE.

6 DR. PETERS: BERNIE, COULD I ADD SOMETHING AT
7 THIS PARTICULAR POINT? WE MIGHT HAVE COME TO CLOSURE
8 WITH REGARD TO THAT PARTICULAR PROVISION. I MYSELF
9 HAVE GOT A LOT MORE I WANT TO SAY ABOUT BANKING, AND I
10 WOULD LIKE US NOT TO DROP THIS PARTICULAR TOPIC. IF
11 WE'RE NOT GOING TO DO IT TODAY, I'D LIKE TO HAVE IT ON
12 THE DECEMBER LIST OF ISSUES.

13 I THINK BANKING IS ONE OF THE KEY ELEMENTS IN
14 GETTING THE WHOLE OF PROP 71 TO ACCOMPLISH WHAT ITS
15 GOALS ARE. AND I FEEL THAT IT DESERVES MORE DISCUSSION
16 THAN MERELY COMING UP WITH A REGULATION. I THINK THE
17 REGULATIONS NEED TO BE PUT INTO THE CONTEXT OF WHAT WE
18 HOPE THE CIRM BANK WILL ACCOMPLISH.

19 CO-CHAIR LO: OKAY. I THINK WE HAVE SEVERAL
20 AGENDAS WITH DIFFERENT TIME FRAMES. I THINK CLEARLY
21 OVER THE DURATION OF CIRM, WE'LL HAVE A LOT MORE --
22 THERE WILL BE A LOT OF THE BANKING ISSUES THAT WILL
23 NEED TO BE ADDRESSED BOTH BY US AND ELSEWHERE IN CIRM.

24 WE ALSO HAVE A REGULATORY REQUIREMENT THAT
25 THE CLOCK WILL START TICKING WHEN THE ICOC APPROVES THE

1 INTERIM GUIDELINES SO THAT WE DO HAVE A REGULATORY TASK
2 AS WELL AS, I THINK, A MORE IN-DEPTH DISCUSSION OF
3 OTHER ISSUES THAT HAVE CROSS LINKAGES. I THINK ONE OF
4 THE THINGS WE WILL STRUGGLE WITH IS HOW TO TAKE THINGS
5 WHICH ARE CURRENTLY ASPIRATIONAL AND PUT THEM IN THE
6 REGULATIONS IN A WAY THAT WILL BE ACCEPTABLE TO THE
7 OAL. BUT I THINK, TED, YOU ARE ABSOLUTELY RIGHT.
8 THERE ARE OTHER ISSUES THAT WE DID NOT TALK ABOUT TODAY
9 WHICH PROBABLY WE'RE NOT GOING TO BE ABLE TO SETTLE
10 BEFORE WE RECOMMEND FINAL REGULATIONS BECAUSE A LOT OF
11 IT IS CONTINGENT ON OTHER PLANS CIRM MAY DEVELOP AS TO
12 SETTING UP A BANK.

13 FOR INSTANCE, IF CIRM ACTUALLY DECIDES TO
14 FUND A BANK OR A COUPLE OF BANKS AND WE GET MORE
15 EXPERTISE, WE CLEARLY WILL NEED TO DO -- WELL,
16 SOMEBODY, AND I HOPE THIS GROUP WILL HAVE INPUT BECAUSE
17 OF ITS ETHICAL EXPERTISE ON HOW YOU SET THAT BANK UP IN
18 THE MOST THOUGHTFUL WAY. AND SO I THINK YOU'RE RIGHT.
19 WE NEED TO COME BACK TO THINGS.

20 BUT, TED, IF YOU HAVE SPECIFIC THINGS THAT
21 YOU FEEL NEED TO BE PUT INTO THE REGULATIONS, THE TIME
22 FRAME ON THAT IS SHORTER IN THE SENSE WE NEED TO DEAL
23 WITH THOSE ISSUES UP FRONT. PLEASE DON'T LET US MISS
24 ANYTHING AS WE SEND AROUND THESE SUGGESTED FINAL
25 GUIDELINES. IF YOU THINK THERE'S SOMETHING IMPORTANT

1 THAT'S MISSING THAT NEED TO GO IN AS REGULATION, THAT
2 NEEDS TO BE PICKED UP SOON. BUT THIS IS NOT THE LAST
3 WORD WE WILL SAY, AT LEAST I HOPE NOT, THIS IS NOT BY
4 ANY MEANS THE LAST THING WE'LL SAY ABOUT BANKING.

5 AND I THINK WE DID GET SOME GOOD IDEAS ON
6 CONSENT. I THINK WE MAY BE A LITTLE CLEARER ON THE
7 APPROACH WE'RE GOING TO TAKE TO CONSENT. AND WE ALSO,
8 I THINK, HAVE SOME INFORMATION NEEDS THAT WE NEED TO
9 FILL BEFORE THE NEXT MEETING, WHICH YOU ALL SUGGESTED
10 WHICH I THINK WILL KEEP US BUSY BEFOREHAND.

11 SO ANY OTHER THOUGHTS ON SORT OF WHERE WE GO
12 FROM HERE FOR THE NEXT COUPLE OF MEETINGS?

13 INTELLECTUAL PROPERTY IS ANOTHER ONE OF THESE
14 HUGE, VITAL ISSUES THAT'S CROSSCUTTING BETWEEN OUR
15 GROUP AND OTHER ACTIVITIES AT CIRM. ZACH, PLEASE.

16 DR. HALL: JUST TO BRING THIS GROUP UP TO
17 DATE BECAUSE THE SORT OF MAJOR THRUST OF THE IP IS
18 UNDER THE INTELLECTUAL PROPERTY TASK FORCE, WHICH IS
19 CHAIRED BY ED PENHOET. AND IT WILL BE HAVING ITS FIRST
20 MEETING TOMORROW IN SACRAMENTO. AND SOME OF YOU WILL
21 BE PARTICIPATING IN THAT.

22 THEN ON FRIDAY, I THINK IT IS, THERE'S ON THE
23 31ST A SENATE JOINT COMMITTEE HEARING ON INTELLECTUAL
24 PROPERTY. AND I THINK ED WILL BE TESTIFYING AT THAT
25 COMMITTEE HEARING, AND A NUMBER OF US WILL BE THERE.

1 SENATOR ORTIZ AND, I THINK, SENATOR RUNNER, BUT I'M NOT
2 SURE OF THAT. AT ANY RATE, SENATOR ORTIZ WILL BE
3 CHAIRING THAT.

4 AND THEN WE NEED TO HAVE, AS WE'VE SAID, OUR
5 INTERIM GRANTS ADMINISTRATIVE POLICY. AND THE KEY
6 POINT OF THAT IS WE NEED TO HAVE AN INTERIM
7 INTELLECTUAL PROPERTY POLICY. AND SO AFTER THE VARIOUS
8 INPUT, THE IP TASK FORCE PLANS TO MEET IN NOVEMBER AND
9 TO MAKE A RECOMMENDATION TO THE ICOC FOR AN IP POLICY
10 THAT WOULD FORM PART OF OUR -- AN INTERIM IP POLICY
11 THAT WOULD FORM PART OF THE INTERIM GRANTS
12 ADMINISTRATION POLICY THAT WILL BE -- ALL OF THIS WE
13 NEED TO DO BEFORE WE CAN SEND OUT RESEARCH GRANTS.

14 AND SO THAT REPORT WILL THEN BE BROUGHT HERE
15 AT THE DECEMBER 1ST MEETING, WHICH IS SHORTLY BEFORE
16 THE ICOC MEETING. AND YOU WILL HAVE A CHANCE, THEN, TO
17 EITHER COMMENT ON THAT OR TO MODIFY IT. I GUESS THE
18 CURRENT STRATEGY IS, BECAUSE OF OUR TIGHT TIMELINE, IF
19 YOU HAVE MODIFICATIONS, THEN WE WOULD SEND BOTH THE IP
20 TASK FORCE AND WHATEVER MODIFICATIONS OR CHANGES THIS
21 GROUP MIGHT WISH TO MAKE ON TO THE ICOC, WHICH WILL
22 MEET ON DECEMBER 6TH.

23 SO AT ANY RATE, THIS IS, ONCE AGAIN, ONE OF
24 THOSE AREAS IN WHICH WE HAVE TWO GROUPS WHO ARE
25 CONCERNED. IT'S AN AREA IN WHICH THERE ARE OBVIOUS

1 ETHICAL IMPLICATIONS. THERE ARE ALSO POLITICAL
2 OVERTONES AND STRATEGIC OVERTONES IN THE SENSE THAT WE
3 NEED TO END UP WITH AN IP POLICY, AS WE SAID EARLIER,
4 THAT MAKES WHAT WE DO ATTRACTIVE TO BE PICKED UP BY THE
5 PRIVATE SECTOR AND DEVELOPED INTO AVAILABLE THERAPIES
6 FOR CALIFORNIANS. SO, AT ANY RATE, IT WILL BE HERE AS
7 ONE OF THE ITEMS NEXT TIME, BUT WE WILL HAVE A PROPOSAL
8 AT LEAST TO SERVE AS A STARTING POINT FOR THE
9 CONVERSATION.

10 MR. KLEIN: ON INTELLECTUAL PROPERTY AS WELL,
11 WHILE WE ESTABLISH AN INTERIM POLICY ON WHAT TO USE THE
12 FUNDS FOR, THERE ARE CERTAIN USES OF THE FUNDS, ONE
13 THAT I PARTICULARLY BELIEVE WOULD BE APPROPRIATE, WHICH
14 IS USING FUNDS FOR COMPASSIONATE CARE OR SETTING UP
15 MODELS FOR ACCESS FOR LOW AND MODERATE INCOME PERSONS
16 TO THESE NEW THERAPIES, WHERE IT MAY TAKE US MONTHS OR
17 A YEAR TO FIGURE OUT HOW TO IMPLEMENT THOSE
18 MODIFICATIONS. BUT WE NEED TO ESTABLISH UP FRONT WHAT
19 PORTION OF THE FUNDS GO TO SPECIFIC USES, SO WE HAVE A
20 POLICY IN PLACE, AND THEN THE IMPLEMENTATION OF THAT
21 POLICY MAY TAKE A SIGNIFICANT LENGTH OF TIME.

22 CO-CHAIR LO: I THINK THIS WAS EXTREMELY
23 HELPFUL BECAUSE IT'S IMPORTANT THAT WE PUT OUR WORK IN
24 THE CONTEXT OF EVERYTHING ELSE THAT CIRM IS DOING. AND
25 I THINK THE ISSUES, ZACH, THAT YOU AND BOB JUST RAISED,

1 I THINK, ARE ISSUES OF INTEREST TO THIS GROUP. AND SO
2 I THINK IT'S VERY REASSURING TO KNOW THESE ARE VERY
3 ACTIVE ITEMS ON THE CIRM AGENDA.

4 ONE OF THE THINGS WE'LL NEED TO SORT OF TRY
5 AND CLARIFY WITH YOU IS WHAT WOULD BE THE ROLE OF THIS
6 GROUP IN, FOR EXAMPLE, THE COMPASSIONATE ACCESS AS
7 THAT'S WORKED OUT IN THE FUTURE, HOW THIS GROUP CAN
8 PLAY A CONSTRUCTIVE ROLE IN THAT BECAUSE I THINK IT'S
9 SOMETHING THAT IS OF -- I KNOW THERE ARE A NUMBER OF
10 PEOPLE IN THE COMMUNITY WHO HAVE SAID THAT'S A KEY PART
11 OF THEIR VISION FOR CIRM. AND I THINK THERE'S
12 EXPERTISE ON THIS GROUP FROM THE PEOPLE WITH ETHICS
13 BACKGROUND AND ADVOCACY BACKGROUND. SO THAT'S GREAT.

14 NOW, LET ME JUST ASK A VERY IMPORTANT
15 ADMINISTRATIVE DETAIL, WHICH IS DO WE ALL KNOW HOW TO
16 GET TO SHERRY LANSING'S HOUSE FOR DINNER?

17 CO-CHAIR LANSING: LET ME JUST TELL IT TO
18 YOU. GO DOWN SUNSET, AND IT'S TWO MINUTES FROM HERE,
19 FIVE MINUTES. GO DOWN SUNSET. WHEN YOU SEE -- BEFORE
20 BEVERLY GLEN THERE'S A LIKE A FIRE STATION ON SUNSET,
21 TURN LEFT AND MAKE AN IMMEDIATE RIGHT ON BELLAGIO. I'M
22 GOING HOME TO COOK NOW.

23 CO-CHAIR LO: I WANT TO THANK ALL OF YOU FOR
24 MEETING, AND I WOULD BE GLAD TO ENTERTAIN A MOTION TO
25 ADJOURN.

1 CO-CHAIR LANSING: YOU WERE GREAT. I THINK
2 WE SHOULD APPLAUD BERNIE.

3 (APPLAUSE.)

4 CO-CHAIR LO: HAVING HEARD A MOTION MADE,
5 SECONDED, AND APPROVED UNANIMOUSLY, I DECLARE THE
6 MEETING ADJOURNED.

7 (THE MEETING WAS THEN ADJOURNED AT 5:28 P.M.)

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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE PROCEEDINGS BEFORE THE SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS WORKING GROUP OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATON INDICATED BELOW

LUXE HOTEL SUNSET BOULEVARD
11461 SUNSET BOULEVARD
LOS ANGELES, CALIFORNIA
ON
MONDAY, OCTOBER 24, 2005

WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CSR 7152
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