# BEFORE THE SCIENCE SUBCOMMITTEE OF THE INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE TO THE

# CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE ORGANIZED PURSUANT TO THE CALIFORNIA STEM CELL RESEARCH AND CURES ACT

#### REGULAR MEETING

LOCATION: AS INDICATED ON THE AGENDA

DATE: JUNE 6, 2011

3 P.M.

REPORTER: BETH C. DRAIN, CSR

CSR. NO. 7152

BRS FILE NO.: 90188

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3. DISCUSSION OF PROCESS FOR OBTAINING SUPPLEMENTAL INFORMATION FROM APPLICANTS FOR CLINICAL TRIAL AND DISEASE TEAM GRANT ROUNDS INCLUDING AN OPPORTUNITY TO OBTAIN INFORMATI DURING PEER REVIEW, SUBJECT TO LATER STAFF CONFIRMATION, OF ADDITIONAL INFORMATION NOT PRESENTED IN THE APPLICATION.	,	4
4. CONSIDERATION OF ADDITIONAL CYCLE OF NEW FACULTY AWARDS PROGRAM.	5	5
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	DARRISTERS REPORTING SERVICE
1	MONDAY, JUNE 6, 2011; 3 P.M.
2	
3	MS. KING: THANKS TO EVERYBODY FOR JOINING
4	THE CALL. I'M GOING TO TURN IT OVER NOW TO JEFF
5	SHEEHY, OUR CHAIR FOR THE SCIENCE SUBCOMMITTEE. MR.
6	SHEEHY.
7	CHAIRMAN SHEEHY: YES. I WANT TO THANK
8	EVERYBODY FOR BEING ON TODAY. I THINK WE'LL GO
9	STRAIGHT TO CALL THE ROLL.
10	MS. KING: SUSAN BRYANT.
11	DR. BRYANT: HERE.
12	MS. KING: MARCY FEIT.
13	MS. FEIT: HERE.
14	MS. KING: MICHAEL FRIEDMAN. ROBERT
15	KLEIN.
16	CHAIRMAN KLEIN: HERE.
17	MS. KING: FRANCISCO PRIETO. PHIL PIZZO.
18	DUANE ROTH.
19	MR. ROTH: HERE.
20	MS. KING: JOAN SAMUELSON. JEFF SHEEHY.
21	CHAIRMAN SHEEHY: HERE.
22	MS. KING: OSWALD STEWARD.
23	DR. STEWARD: HERE.
24	MS. KING: AND ART TORRES.
25	MR. TORRES: HERE.
	3

1072 BRISTOL STREET, COSTA MESA, CALIFORNIA 92626 1-800-622-6092 1-714-444-4100 EMAIL: DEPO@DEPO1.COM

1	UNIDENTIFIED SPEAKER: I DON'T KNOW IF
2	YOU'VE FINISHED WITH THE ROLL CALLING, BUT WE WERE
3	NONE OF THE NAMES THAT YOU JUST MENTIONED. THIS IS
4	FROM STANFORD. WE'RE PART OF IRV WEISSMAN'S GROUP.
5	I GUESS WE'RE IN THE PIZZO SLOT. IRV ASKED US TO
6	COME OVER. THERE ARE THREE OF US HERE RELATED WITH
7	THE CIRM DISEASE TEAM PROJECT.
8	MS. KING: VERY GOOD. THANK YOU SO MUCH
9	FOR LETTING US KNOW. I BELIEVE DR. PIZZO WILL BE
10	JOINING US AS SOON AS HE CAN AS WELL.
11	CHAIRMAN SHEEHY: DO WE EXPECT SHALL WE
12	WAIT?
13	MS. KING: I THINK YOU'RE OKAY GETTING
14	STARTED. WE'RE ALREADY A FEW MINUTES PAST.
15	CHAIRMAN SHEEHY: OKAY. SO I'M GOING TO
16	GO ON INTO THE AGENDA AND START, I THINK, WITH ITEM
17	NO. 3. IS THAT OKAY? DR. FEIGAL, I THINK, WILL BE
18	STARTING US. YOU SHOULD HAVE A DOCUMENT IN YOUR
19	PACKET ABOUT THE PROPOSED PROCESS FOR OBTAINING
20	SUPPLEMENTAL INFORMATION FOR APPLICANTS DURING THE
21	CLINICAL TRIAL AND DISEASE TEAM GRANT ROUNDS.
22	DR. FEIGAL: THANKS FOR THE OPPORTUNITY TO
23	BRING THIS PROPOSED PROCESS TO YOU FOR
24	CONSIDERATION. THE ISSUE THAT WE'RE ACTUALLY TRYING
25	TO ADDRESS IS THAT OF MAKING SURE WE HAVE A COMPLETE

1	PACKAGE OF INFORMATION THAT OUR PEER REVIEW GROUP
2	AND OUR GOVERNING BOARD HAVE IN HAND WHEN THEY MAKE
3	RECOMMENDATIONS AND DECISIONS ABOUT THESE HIGHLY
4	COMPLEX RESEARCH AWARDS FOR DISEASE TEAM GRANTS AND
5	FOR CLINICAL TRIAL AWARDS.
6	SO THE INSTITUTE, AS YOU KNOW, IS CHARGED
7	WITH SUPPORTING THE DEVELOPMENT AND CURES AND
8	THERAPIES THAT ARE BASED ON STEM CELL SCIENCE. AND
9	MOVING THIS TYPE OF TECHNOLOGY TOWARDS AND INTO THE
10	CLINIC INVOLVES YEARS OF DEVELOPMENT, INTENSIVE
11	RESOURCE INVESTMENT, AND ALSO NAVIGATING A CHANGING
12	AND EVOLVING REGULATORY LANDSCAPE.
13	IN ORDER FOR US TO DO THAT, WE'VE
14	DEVELOPED THESE INITIATIVES TO HAVE TEAMS PUT
15	TOGETHER COMPLEX GRANTS THAT INVOLVE THE SCIENCE,
16	THAT INVOLVE REGULATORY ISSUES, THAT INVOLVE
17	OPERATIONAL ISSUES TO ACTUALLY EXECUTE ON HAVING IND
18	ENABLING STUDIES; THAT IS TO SAY, TO GET A FILING
19	FOR A NEW DRUG OR A NEW BIOLOGIC OR A NEW CELL
20	THERAPY AND TO ACTUALLY CONDUCT CLINICAL TRIALS.
21	AND THEY COME INTO THE INSTITUTE FOR REVIEW.
22	AND IN ORDER TO HAVE AN APPROPRIATE
23	REVIEW, WE NEED TO HAVE A VERY BROAD SPECTRUM OF
24	DISCIPLINES AND EXPERTISE REVIEW IT. WE ALSO AS
25	YOU PROBABLY KNOW, THIS IS A NEW TYPE OF RESEARCH
	<u>_</u>

1	AWARD FOR THE INSTITUTE, AND WE HAVE A PROCESS IN
2	PLACE, AND WE THINK IT'S ROBUST AND WE THINK IT'S
3	STRONG, BUT WE THINK IT HAS ROOM FOR IMPROVEMENT.
4	AND THE AREAS WHERE WE THINK IT HAS ROOM
5	FOR IMPROVEMENT IS MAKING SURE THAT WE HAVE COMPLETE
6	INFORMATION IN REAL TIME ABOUT THE RESEARCH GRANT.
7	AND SO WHAT WE'RE SUGGESTING IS A REFINED PROCESS
8	THAT ACTUALLY BUILDS UPON PROCEDURES THAT WE ALREADY
9	HAVE IN PLACE TO MAKE SURE THAT THE PEER REVIEW HAS
10	A COMPLETE PACKET, TO MAKE SURE THAT THE
11	INVESTIGATORS, THE APPLICANT, ACTUALLY FEEL THAT
12	THEY HAVE AN OPPORTUNITY TO ADDRESS SOME OF THE
13	DIFFICULT QUESTIONS THAT COULD ARISE DURING THE
14	REVIEW PROCESS.
15	SO IT'S REALLY TRYING TO STRENGTHEN THAT
16	PROCESS BY ALLOWING THE APPLICANT TO HAVE AN
17	ADDITIONAL AVENUE TO PROVIDE IMPORTANT INFORMATION
18	THAT COULD IMPACT ON FUNDING RECOMMENDATIONS AND
19	DECISIONS.
20	SO WE'RE THINKING OF AT LEAST A TWO-PRONG
21	APPROACH IN ORDER TO DO THAT. ONE, WE WANT TO BE
22	VERY PROACTIVE WITH OUR APPROACH SO THAT PRIOR TO
23	MAJOR DISEASE TEAM OR CLINICAL TRIAL RESEARCH AWARD
24	SUBMISSIONS, AND WE ALREADY DO THIS, BUT WE'RE JUST
25	GOING TO MAKE SURE THAT IT'S REALLY WELL ADVERTISED

1	AND APPLICANTS TAKE ADVANTAGE OF THE OPPORTUNITIES
2	WE'RE OFFERING TO THEM IS THAT WE'LL HOLD A
3	QUESTION-ANSWER SESSION WITH INVESTIGATORS AFTER WE
4	PUT OUT A REQUEST FOR SOLICITATIONS BEFORE THE AWARD
5	ACTUALLY COMES IN. AND THESE COULD BE WEBINIZED, IT
6	COULD BE TELECONS, THEY MIGHT BE IN-PERSON MEETINGS.
7	AND WE'RE GOING TO GO OVER NOT JUST THE
8	LOGISTICS ABOUT THE GRANT REVIEW PROCESS, BUT
9	PROVIDE THE APPLICANT WITH AN OPPORTUNITY TO
10	ACTUALLY ASK US QUESTIONS. AND THEN WE'LL PUT UP
11	MAYBE AN FAQ. IF MAYBE AN APPLICANT WASN'T ABLE TO
12	TAKE ADVANTAGE OF JOINING THAT WEBINAR, WE'LL STILL
13	HAVE THE QUESTION AND OUR PROPOSED RESPONSE
14	AVAILABLE TO THEM.
15	SO THAT'S REALLY GETTING INTO ISSUES OF
16	MAKING SURE THE APPLICANT FEELS COMFORTABLE ABOUT
17	WHAT'S IN OUR MINDS THAT PERHAPS WASN'T AS CLEARLY
18	ARTICULATED AS IT COULD HAVE BEEN IN THE ACTUAL RFA.
19	AND THEN WHAT WE WILL DO IS WE'LL ASK OUR PEER
20	REVIEWERS TO ACTUALLY PROVIDE THEIR REVIEWS TWO
21	WEEKS IN ADVANCE OF WHEN THE PEER REVIEW SESSION IS
22	ACTUALLY PLANNED. RIGHT NOW WE'RE GETTING PEER
23	REVIEW REVIEWS COMING IN VERY CLOSE TO THE TIME THAT
24	WE ACTUALLY HAVE TO HAVE THE PEER REVIEW SESSION.
25	BY PUSHING IT OUT A LITTLE BIT, THIS WILL GIVE US

1	ACTUALLY AN OPPORTUNITY TO FIND OUT IF THE REVIEWERS
2	ARE NOTICING PARTICULAR GAPS OF INFORMATION OR
3	PIVOTAL QUESTIONS THAT WOULD BE HELPFUL FOR THE
4	APPLICANT TO KNOW AND POSSIBLY HAVE AN OPPORTUNITY
5	TO RESPOND TO IN ADVANCE OF PEER REVIEW.
6	SO WHAT WE'RE SUGGESTING IS PUSHING THE
7	REVIEW OUT. NOW, THIS MAY TAKE A LITTLE BIT LONGER,
8	THEN, TO ACTUALLY HAVE THIS PROCESS; BUT TWO WEEKS
9	IN ADVANCE OF A REVIEW MEETING, FOR THEM TO PROVIDE,
10	IF THEY THINK IT'S IMPORTANT, A LIST OF KEY
11	QUESTIONS OR ISSUES. AND IT MAY BE JUST CRITICAL
12	GAPS THAT THEY'RE NOT FINDING IN THE PACKAGE OF
13	INFORMATION, OR THE GRANT APPLICATION ITSELF IS A
14	LITTLE AMBIGUOUS IN HOW THE INFORMATION IS
15	PRESENTED.
16	THIS WILL COME IN. THE SCIENTIFIC STAFF
17	HERE WOULD COMPILE THE DIFFERENT QUESTIONS AND
18	ISSUES. WE WOULD OBVIOUSLY GO BACK TO THE PEER
19	REVIEWERS AND MAKE SURE WE'RE NOT SENDING OUT
20	CONTRADICTORY ISSUES. WE'LL CONSOLIDATE THE ISSUES
21	AND SEND IT OUT TO THE APPLICANT APPROXIMATELY TEN
22	DAYS IN ADVANCE OF A REVIEW MEETING, AND THEN THE
23	APPLICANT WILL HAVE AN OPPORTUNITY TO WRITE WRITTEN
24	RESPONSES TO THE ISSUES THAT COME IN. IT'S NOT
25	MANDATORY, BUT IT'S AN OPPORTUNITY THAT THEY HAVE A

1	CHANCE TO AVAIL THEMSELVES OF.
2	AND THEN WHAT WE WILL DO INSIDE OF CIRM IS
3	DISTRIBUTE THIS TO THE PEER REVIEW IN ADVANCE OF THE
4	REVIEW SESSION. SO THAT'S BEFORE THE PEER REVIEW.
5	AND THEN DURING THE PEER REVIEW, I THINK
6	WE ALL UNDERSTAND THAT THAT'S AN ORGANIC PROCESS,
7	AND THAT ALL QUESTIONS THAT COULD POTENTIALLY BE
8	RAISED WON'T NECESSARILY COME IN BEFORE THE PEER
9	REVIEW. SO DURING THE PEER REVIEW, THERE WILL
10	PROBABLY BE DIFFERENT TYPES OF QUESTIONS. FOR THE
11	TWO KINDS OF QUESTIONS THAT ARISE DURING THE PEER
12	REVIEW FOR WHICH WE THINK THERE MIGHT BE A CONCISE
13	AND SIMPLE ANSWER THAT IF THE APPLICANT HAD AN
14	OPPORTUNITY TO RESPOND TO WOULD BE ABLE TO DO SO.
15	AND THAT ANSWER MAY IMPACT ON WHAT SCORE AND THE
16	FUNDING RECOMMENDATIONS THAT THE PEER REVIEWER
17	MAKES.
18	OR, TWO, THERE MAY BE QUESTIONS THAT ARISE
19	THAT REQUIRE MORE DETAILED RESPONSE. AND WE WANT TO
20	THINK ABOUT A WAY TO GIVE THE APPLICANT A CHANCE TO
21	COME IN TO ADDRESS THOSE ISSUES BEFORE WE DO A FINAL
22	SCORE AND FUNDING RECOMMENDATION.
23	I SENT YOU A WRITTEN PROPOSAL THAT GOES
24	INTO MORE DETAIL ABOUT THE PROCESS AND HOW TO
25	OPERATIONALIZE IT, BUT I THINK THE STEPS THAT I'VE

1	OUTLINED, ONE, BEFORE THE ACTUAL PEER REVIEW AND
2	THEN DURING THE PEER REVIEW OF HOW WE MIGHT MODIFY
3	OUR PROCESS. I BELIEVE THIS WOULD REALLY BE
4	BUILDING UPON THINGS THAT WE'RE ALREADY DOING AND
5	EXPANDING IT. I DON'T SEE THIS AS A RADICAL CHANGE
6	FROM THE WAY WE DO BUSINESS. I THINK IT'S JUST
7	SOMETHING TO HELP STRENGTHEN INFORMATION THAT'S
8	COMING IN, AND THAT WAY IT WOULD MAKE THE SCORING OF
9	THESE APPLICATIONS AND THE FUNDING RECOMMENDATIONS
LO	STRONGER BECAUSE IT TRIES TO ELIMINATE AS MUCH AS
L1	POSSIBLE AMBIGUITIES AND GIVE THE APPLICANT A CHANCE
L2	TO ADDRESS THE QUESTIONS IN REAL TIME.
L3	WE DON'T ENVISION THAT THIS WOULD DELAY
L4	GOING TO THE ICOC. WE WANT TO DO THIS IN A TIME
L5	FRAME THAT IS STILL QUITE EXPEDITED SO THAT WE DON'T
L6	DELAY GETTING FUNDING OUT FOR RESEARCH THAT WE NEED
L7	TO GET DONE. BUT IN ORDER TO DO THIS, THOUGH, IT
L8	WOULD PROBABLY HAVE TO BE A LIMITED NUMBER OF
L9	QUESTIONS OR ISSUES ARISE SO THAT WE ACTUALLY COULD
20	DO THIS. SO THAT'S WHY WE'RE LIMITING THIS TO
21	DISEASE TEAMS AND CLINICAL TRIAL APPLICATIONS AND TO
22	REALLY PRIORITIZING WHAT THE ISSUES ARE. SO THAT'S
23	IN A NUTSHELL WHAT I'M PRESENTING TODAY.
24	CHAIRMAN SHEEHY: THANK YOU, DR. FEIGAL.
25	OBVIOUSLY A LOT OF WORK HAS GONE INTO THIS AND VERY

1	IMPRESSIVE. SO I HAVE THE CHAIR, BOB KLEIN. AND
2	THEN OTHER FOLKS WANT TO COMMENT? MAYBE IF WE
3	CAN
4	DR. BRYANT: I HAVE A QUESTION.
5	CHAIRMAN SHEEHY: OKAY. SO MAYBE BOB AND
6	THEN DR. BRYANT. ARE THERE OTHERS WHO WANT TO MAKE
7	COMMENTS?
8	MS. FEIT: I HAVE JUST ONE QUICK COMMENT
9	TO MAKE.
10	MR. ROTH: AND DUANE.
11	CHAIRMAN SHEEHY: SO BOB.
12	CHAIRMAN KLEIN: SO, DR. FEIGAL, I'D LIKE
13	TO THANK YOU FOR ALL THE TIME YOU PUT INTO THIS. I
14	KNOW DR. TROUNSON PUT A LOT OF EFFORT INTO COMING UP
15	WITH THIS. IT'S VERY HIGHLY RESPONSIVE TO ENHANCING
16	OUR PROCESS.
17	ON WHAT HAPPENS DURING THE SESSION IN REAL
18	TIME, AS YOU SAID, IS VERY ORGANIC. YOU CAN'T
19	PREDICT ALL QUESTIONS. AND OTHER REVIEWERS OTHER
20	THAN THE PRIMARY AND SECONDARY OR OUTSIDE
21	SPECIALISTS ARE GOING TO BE INVOLVED, AND THEY MAY
22	RAISE A QUESTION THAT WAS NOT ANTICIPATED BY THE
23	PRINCIPAL REVIEWERS.
24	THIS WRITE-UP IDENTIFIES THE KEY CONTACT
25	PERSON THAT WOULD BE AVAILABLE. AT THE TEAM'S

1	OPTION, I WOULD SUGGEST THAT THEY COULD HAVE A
2	PERSON AVAILABLE OR A GROUP OF PEOPLE AVAILABLE
3	BECAUSE IT MAY BE A REGULATORY ISSUE OR IT MAY BE A
4	BASIC THE CANDIDATE DESIGNATION ISSUE THAT CAME
5	UP FROM THE ORIGINAL SCIENTIFIC GRANT, OR IT MAY BE
6	A CLINICAL IMPLEMENTATION ISSUE RELATED TO A TRIAL.
7	SO THEY MAY WANT TWO OR THREE PEOPLE AVAILABLE
8	BECAUSE THEY DON'T KNOW WHICH PART OF THE GRANT IS
9	GOING TO BE ADDRESSED BY THE QUESTION. BUT AT THEIR
10	OPTION, IF THEY WANT TO DESIGNATE ONE PERSON, THAT'S
11	FINE. IF THERE'S ONE PERSON WHO HAS COMPREHENSIVE
12	INFORMATION.
13	THE SECOND POINT IS THAT IN TERMS OF THE
14	QUESTIONS THAT ARISE THAT THE CHAIR AND YOU BELIEVE
15	CAN BE ANSWERED OR THE GRANTS WORKING GROUP BELIEVES
16	CAN BE ANSWERED IN REAL TIME, I THINK THAT IT WOULD
17	BE VERY VALUABLE IF WE COULD ATTEMPT TO DO IT
18	TELEPHONICALLY BECAUSE IF WE JUST DO IT BY E-MAILS,
19	THE PERSON RECEIVING IT MAY NOT REALLY UNDERSTAND
20	THE QUESTION AND RESPOND TO AN ISSUE THAT'S NOT A
21	TECHNICAL ISSUE. IF YOU'RE LIVE ON A CALL WITH
22	THEM, AND I UNDERSTAND THAT BEING THE SCIENTIST IN
23	CHARGE OF THIS PROCESS, WE CAN'T HAVE EVERYBODY IN
24	THE PEER REVIEW GROUP TALKING, YOU'RE GOING TO HAVE
25	TO AGGREGATE THESE QUESTIONS, CONSOLIDATE THEM, SEND

THEM TO THEM. IF YOU'RE ON A PHONE CALL WITH THEM,
YOU CAN IMMEDIATELY CLARIFY IN REAL TIME, AND THEN
THEY CAN RESPOND TO THE RIGHT QUESTION INSTEAD OF
GIVING YOU A RESPONSE THAT'S REALLY NOT RESPONSIVE
TO THE CENTRAL THEME OF THE GRANTS WORKING GROUP.
SO I THINK THAT TELEPHONICALLY WOULD BE
PREFERABLE WITH E-MAIL AS A BACKUP BECAUSE IT MAY
HAVE TROUBLE GETTING TO THE RIGHT PEOPLE IN THEIR
TEAM TELEPHONICALLY. IN THAT CASE THEY COULD
RESPOND BY E-MAIL. IT'S NOT AS GOOD A RESPONSE, BUT
YOU SUGGEST THAT IT WOULD BE IN A VERY LIMITED TIME
PERIOD SINCE YOU'RE TRYING TO GET THE RESPONSE
DURING THE GRANTS WORKING GROUP.
SO IT'S A VERY NARROW WINDOW OF TIME, AND
THEY'RE EITHER GOING TO BE AVAILABLE TELEPHONICALLY,
WHICH WOULD BE A PREFERENCE, AND WITH E-MAIL AS A
BACKUP. I THINK THAT THAT COMBINATION OF THE
CLARIFICATIONS OF DATA AHEAD OF TIME AND THE ABILITY
TO RESPOND IN REAL TIME TO THINGS THAT COME UP
DURING THE SESSION WOULD MAKE AN EXTRAORDINARY
CONTRIBUTION QUALITATIVELY TO DECISIONS IN THOSE
SITUATIONS WHERE THERE ARE AMBIGUITIES THAT ARISE.
I JUST WANT TO THANK YOU SO MUCH FOR THE
EFFORT YOU'VE PUT INTO THIS.
DR. FEIGAL: CAN I RESPOND? BEFORE

1	DR. BRYANT ASKS A QUESTION, SHOULD I RESPOND?
2	CHAIRMAN SHEEHY: IF YOU LIKE.
3	DR. FEIGAL: I THINK TWO THINGS. A
4	CONTACT WAS NOT MEANT TO BE RESTRICTIVE. IT WAS
5	ACTUALLY JUST A VERY PRACTICAL THING FOR US. WE
6	WANT ONE POINT OF CONTACT. IT WILL BE UP TO THE
7	TEAM TO DECIDE HOW MANY PEOPLE THEY WANT TO GATHER,
8	BUT WE DON'T WANT TO BE GIVEN SIX DIFFERENT
9	CONTACTS.
10	CHAIRMAN KLEIN: I COMPLETELY UNDERSTAND
11	THE LOGISTICS. THERE OUGHT TO BE ONE POINT OF
12	CONTACT. YOU ALWAYS INTENDED THEM TO BE ABLE TO
13	HAVE AS MANY MEMBERS OF THEIR TEAM AVAILABLE AS THEY
14	THOUGHT WAS ESSENTIAL.
15	DR. FEIGAL: I THINK THE OTHER ISSUE IS,
16	AND I PUT IT IN THE DOCUMENT, ONE OF THE OPTIONS WE
17	GAVE IF FOR WHATEVER REASON DURING THE ACTUAL REVIEW
18	SESSION WE DON'T GET THE IMMEDIATE RESPONSE, MAYBE
19	IT CAN BE SIMPLE AND CONCISE, BUT IT DOES REQUIRE A
20	CONVERSATION, AND THEY WANT TO GET BACK TO US BY
21	E-MAIL. BUT IF THE PEER REVIEW ACTUALLY DECIDES IF
22	THE ANSWER IS X, THEY CAN GO AHEAD AND SCORE AND NOT
23	HAVE TO WAIT.
24	I WAS JUST TRYING TO PROVIDE SOME CAVEATS
25	OF REAL LIFE WHAT COULD HAPPEN AND TO BUILD IT INTO
	14

1	THIS PROPOSAL. SO I DID WANT
2	CHAIRMAN KLEIN: SO IF IT WAS AN A OR B
3	QUESTION, IS THIS THE LINE YOU'RE USING OR IS IT
4	ANOTHER LINE, AND THEY CAN ANSWER BY E-MAIL, YOU
5	COULD AVAIL YOURSELF OF THAT. BUT IF IT'S A MORE
6	COMPLICATED QUESTION, YOU WOULD DO IT
7	TELEPHONICALLY.
8	DR. FEIGAL: THEN IF IT'S REALLY MORE
9	COMPLICATED, IT MIGHT BE GOING TO THE SECOND LEVEL
10	OF QUESTIONS THAT ARE A LITTLE BIT MORE COMPLEX.
11	CHAIRMAN KLEIN: WHAT I'M TRYING TO
12	UNDERSTAND IS ONE OF THE TOOLS YOU'RE GIVING
13	YOURSELF IN THIS AUTHORIZATION THE ABILITY TO HAVE A
14	TELEPHONIC CONVERSATION DURING THE GRANTS REVIEW?
15	MS. SAMUELSON: JOAN HERE.
16	DR. FEIGAL: I THINK WE COULD. AS I SAID,
17	IT'S A LIMITED NUMBER OF ISSUES AND QUESTIONS THAT
18	ARISE SO THAT, PRACTICALLY SPEAKING, BECAUSE
19	PRESUMABLY THE PEER REVIEW NEEDS TO STOP REVIEWING
20	WHILE WE GO OUT AND TRY AND GET SOME OF THESE ISSUES
21	CLARIFIED BECAUSE WE DON'T WANT TO BE OUT OF THE
22	PEER REVIEW EITHER.
23	CHAIRMAN KLEIN: WELL
24	DR. FEIGAL: MAYBE THESE DETAILS
25	CHAIRMAN SHEEHY: MAYBE WE SHOULD HEAR
	15

1	FROM EVERYBODY AND IDENTIFY ALL THE ISSUES THAT WE
2	HAVE AND THEN WE CAN KIND OF WORK THROUGH IT.
3	CHAIRMAN KLEIN: I'LL DEFER A FOLLOW-UP
4	QUESTION BECAUSE I'D LIKE TO HEAR FROM THE OTHER
5	MEMBERS OF THE COMMITTEE AS WELL.
6	CHAIRMAN SHEEHY: JOAN, FOR YOUR
7	INFORMATION, WE'RE ON ITEM 3, WHICH IS THE PROCESS
8	FOR OBTAINING SUPPLEMENTAL INFORMATION FROM
9	APPLICANTS. FOR THE MOST PART, WE'VE JUST GONE
10	THROUGH. DR. FEIGAL DID A PRESENTATION ON THE
11	PROPOSAL BEFORE US THAT SHE'S DONE SUCH A GREAT JOB
12	PULLING TOGETHER.
13	AND THEN THERE'S A COUPLE OF ISSUES THAT
14	BOB HAS RAISED. ONE OF THEM ABOUT HAVING PERHAPS A
15	TELEPHONIC ASPECT TO THE PIVOTAL QUESTION FOR WHICH
16	A CONCISE ANSWER MIGHT BE OBTAINED. BUT RIGHT NOW
17	I'M TAKING COMMENTS. DO YOU WANT ME TO ADD YOUR
18	NAME TO THE LIST?
19	MS. SAMUELSON: OH, YEAH.
20	CHAIRMAN SHEEHY: OKAY. DR. BRYANT IS
21	NEXT, AND THEN MARCY FEIT AND THEN DUANE ROTH, AND
22	I'LL HAVE YOU AFTER THAT.
23	MS. SAMUELSON: OKAY. ONE IS SIMPLY
24	PROCEDURAL ABOUT THE TIMETABLE FOR GETTING THIS
25	STUFF, AND WHETHER IT'S REALISTIC TO THINK WE COULD

1	REALLY BE DELIBERATIVE ABOUT IT. BUT I CAN WAIT AND
2	TALK ABOUT THAT LATER TOO.
3	CHAIRMAN SHEEHY: DR. BRYANT.
4	DR. BRYANT: THIS IS JUST A PROCEDURAL
5	QUESTION. SO I LIKE THE IDEA OF NOT MAKING
6	DECISIONS BASED ON INCOMPLETE INFORMATION AND ASKING
7	A FEW QUESTIONS. IS EVERYONE GOING TO GET THE
8	FEEDBACK AND HAVE THE OPPORTUNITY TO PROVIDE INPUT,
9	ALL THE APPLICANTS?
10	DR. FEIGAL: LET ME EXPLAIN THAT ALL THE
11	APPLICANTS AHEAD OF TIME WILL BE ASKED TO IDENTIFY A
12	CONTACT AND ALL OF THEM CAN PUT TOGETHER THE
13	APPROPRIATE TEAMS THEY WANT, THAT AT X TIME DURING
14	THAT DAY, THEY SHOULD BE ON CALL TO ADDRESS EITHER
15	E-MAIL OR TELEPHONIC ISSUES. AND THE MAJORITY OF
16	THEM, I ANTICIPATE, WILL NEVER BE CALLED OR SENT AN
17	E-MAIL. IT'S ONLY A SUBSET FOR WHICH THERE ARE
18	PIVOTAL QUESTIONS THAT COULD BE ANSWERED CONCISELY
19	AND NOT REQUIRE ADDITIONAL DATA TO BE PROVIDED IN
20	WRITING THAT COULD BE RESPONDED TO.
21	SO I IMAGINE IT'S ONLY A SUBSET OF THE
22	APPLICANTS, AND WE WILL NOT KNOW IN ADVANCE OF THE
23	PEER REVIEW WHICH ONES. BUT ALL THE APPLICANTS WILL
24	BE ADVISED TO PROVIDE US WITH A CONTACT IN CASE WE
25	NEED TO CALL THEM, BUT I ENVISION THE MAJORITY WILL

1	NOT BE ASKED THESE TYPES OF PIVOTAL QUESTIONS.
2	DR. BRYANT: HOW IS THE DECISION GOING TO
3	BE MADE ABOUT WHO GETS CALLED AND WHO DOESN'T? IS
4	IT GOING TO BE THE GRANTS REVIEW COMMITTEE?
5	DR. FEIGAL: AS IN THE PROPOSAL, IT WOULD
6	BE THE CHAIR OF THE GRANTS WORKING GROUP IN COMMAND
7	OF THAT PEER REVIEW SESSION, AND THEN WE WOULD WORK
8	WITH THEM TO CLARIFY WHAT THE ISSUES AND QUESTIONS
9	ARE, AND THEN HAVE SOME SET TIME TO ACTUALLY TRY AND
10	CONTACT THEM EITHER BY E-MAIL OR BY PHONE.
11	DR. BRYANT: OKAY. THANKS.
12	CHAIRMAN KLEIN: JEFF, JUST TO BE CLEAR,
13	ALL APPLICATIONS ON WHICH THE REVIEWERS HAD
14	QUESTIONS 14 DAYS IN ADVANCE, ALL OF THE APPLICANTS
15	WOULD GET A SUMMARY OF WHAT THOSE QUESTIONS ARE AND
16	A CHANCE TO ANSWER THOSE QUESTIONS.
17	DR. FEIGAL: RIGHT. I'M SORRY. I THOUGHT
18	YOU WERE TALKING ABOUT DURING THE PEER REVIEW. BUT
19	IN ADVANCE QUESTIONS ANYTHING THAT WE RECEIVE, WE
20	WOULD CONSOLIDATE THEM AND THEN SEND THEM TO THE
21	APPLICANTS.
22	CHAIRMAN SHEEHY: ALL APPLICANTS WOULD
23	THEN BE GIVEN THE OPPORTUNITY TO RESPOND TO THOSE
24	QUESTIONS THAT WERE IDENTIFIED BY THE REVIEWERS IN
25	THE COURSE OF DOING THEIR INITIAL REVIEWS.

DR. FEIGAL: DOES THAT ANSWER YOUR
QUESTION?
DR. BRYANT: YEAH. THANK YOU.
CHAIRMAN SHEEHY: MARCY FEIT.
MS. FEIT: YES. MY QUESTION GOES ALONG
THE LINES OF BOB'S INQUIRY. AND THAT'S I FAVOR THE
TELEPHONIC PROCESS MYSELF BECAUSE MY CONCERN IS THAT
WE'RE GOING TO GET INTO BUILDING ANOTHER PROCESS OF
REVIEW. AND HOW DO WE LIMIT THE QUESTION AND
ANSWER, QUESTION AND ANSWER? AND THE TELEPHONIC
PROCESS WOULD ALLOW US THEN TO GET VERY CONCISE AND
SPECIFIC ABOUT THIS IS THE QUESTION, THIS IS THE
RESPONSE WE NEED. SO THERE ISN'T A LOT OF TIME
GOING BACK AND FORTH IN E-MAILS AND WHATEVER. SO I
WOULD FAVOR THAT. MY CONCERN IS THAT IT WOULD GET
TOO COMPLICATED.
DR. FEIGAL: WELL, I WAS MAYBE THINKING OF
TOO MANY BACKUP OPTIONS. I SUPPOSE IT COULD BE IF
THAT TEAM IS NOT WE TRY THE CONTACT AND THEY'RE
NOT AVAILABLE, THAT WAS THE OPPORTUNITY. SO THERE
WOULD HAVE TO BE THE ACKNOWLEDGEMENT THAT IF WE
WEREN'T ABLE TO REACH YOU, THAT WAS IT.
MS. FEIT: RIGHT. BECAUSE, AGAIN, MY
CONCERN IS THAT WE'RE GOING TO GET INTO BUILDING YET
ANOTHER PROCESS ON TOP OF THE PROCESS WE ALREADY
19

HAVE. THAT'S JUST GOING TO CREATE A LOT MORE WORK
FOR EVERYBODY. I THINK THE MORE SIMPLER WE HAVE IT,
THE BETTER. AND THANK YOU, DR. FEIGAL. THIS IS A
GREAT DOCUMENT.
CHAIRMAN SHEEHY: OKAY. NEXT I HAVE DUANE
ROTH.
MR. ROTH: YES, ON THE SAME LINE. FIRST,
I LIKE THIS APPROACH. I THINK IT'S NEEDED,
ESPECIALLY IN THESE PARTICULAR REVIEWS. BUT I ALSO
BELIEVE THAT HAVING THE IMMEDIATE ANSWER ON THE
TELEPHONE, THAT DECISION BEING MADE SO IT'S VERY
EFFICIENT BACK AND FORTH, IT CAN'T BE WIDE OPEN,
LET'S HAVE A DIALOGUE, BUT HERE ARE OUR QUESTIONS.
SOMEBODY ON THE OTHER END IS GOING TO BE CALLED,
THEY WILL HAVE TO BE THERE OBVIOUSLY TO TAKE THE
CALL AND BE ALERT THAT IT'S COMING, AND THEN ANSWER
THE QUESTIONS ON THE SPOT SO IT CAN BE PART OF THE
DYNAMIC OF THAT REVIEW PROCESS.
SO I THINK IF YOU WORK TOWARDS THAT, IT
WOULD BE VERY HELPFUL BECAUSE SOME OF THESE THINGS
YOU JUST CAN'T ANTICIPATE AND THEY WEREN'T PART OF
THE RFP. I WOULD EMBELLISH THAT YOU'RE ABLE TO PICK
UP THE PHONE AND CALL AND GET THOSE ANSWERS ON THE
SPOT.
DR. FEIGAL: AND ALSO, JUST TO BE CLEAR,
20

1	ALTHOUGH IT'S ALSO NOTED IN THE DOCUMENT, THERE
2	WOULD BE NO IDENTIFICATION OF REVIEWERS, AND THERE
3	WOULD BE NO DIRECT INTERACTION BETWEEN THE REVIEWERS
4	AND THE APPLICANT. THIS WOULD BE DONE BY SOMEBODY
5	WITHIN CIRM TO ACTUALLY
6	MR. ROTH: THAT'S WHAT I WOULD LIKE TO SEE
7	CHANGED. I'M NOT SURE IT SHOULD BE BETWEEN CIRM AND
8	THE APPLICANT. I THINK IT SHOULD BE ON THE SPOT.
9	YOU'RE HAVING THE REVIEW AND THE DISCUSSION.
10	THERE'S A CONFUSION ABOUT WHAT TESTS WERE DONE AND
11	WHERE. CLEAR THAT UP.
12	DR. FEIGAL: DURING THE ACTUAL
13	CHAIRMAN SHEEHY: I THINK WHAT THEY'RE
14	ENVISIONING IS KIND OF THE WAY THE REVIEW KIND OF
15	WORKS, IT SEEMS LIKE ORGANICALLY IT COMES TO BE A
16	SENSE THAT THERE'S A QUESTION OR TWO THAT PEOPLE
17	THERE'S A REAL DEBATE ON WHAT THE ANSWER IS. THE
18	IDEA IS TO HAVE THAT QUESTION REALLY FIRMLY
19	IDENTIFIED WITHIN THE GROUP, AND THEN THE CHAIR
20	WOULD TAKE THAT TO, PRESUMABLY, DR. FEIGAL OR COULD
21	BE GIL OR DR. OLSON, AND HAVE THAT QUESTION POSED
22	DIRECTLY TO THE GRANTEE.
23	THE REASON FOR THAT SEPARATION IS THAT YOU
24	DON'T WANT TO HAVE THE REVIEWERS IDENTIFIED, AND SO
25	YOU WANT TO MAINTAIN THAT CONFIDENTIALITY FIREWALL.

1	AND YOU ALSO DON'T WANT TO GET INTO THIS TIT FOR TAT
2	BACK AND FORTH. YOU REALLY WANT TO GET TO THE
3	ANSWER IF IT'S NOT A CLEAN, CRISP, CLEAR ANSWER,
4	SOMETHING THAT TAKES EXPLORATION, AND IT'S REALLY
5	CRITICAL TO THE APPLICATION.
6	THEN WE HAVE THE SECOND PART WHERE THERE
7	CAN BE MORE TIME FOR THEM TO GET THE INFORMATION
8	TOGETHER, PRESENT IT AGAIN TO THE FULL WORKING GROUP
9	IN A TELEPHONIC MEETING LATER WHERE THE FULL WORKING
LO	GROUP CAN THEN SCHEDULE CAN THEN SCORE THE
L1	APPLICATION. BUT THE MAIN THING IS TO TRY TO GET IT
L2	REALLY NARROW WITHIN THE IMMEDIACY OF THE WORKING
L3	GROUP WHERE WE'RE TRYING TO GET THROUGH A NUMBER OF
L4	GRANTS, WHICH PRESUMABLY WILL BE 20 OR 25 OR MORE
L5	POTENTIALLY.
L6	DR. FEIGAL: I THINK THE OTHER ISSUE, JUST
L7	TO MAKE ONE COMMENT, IS IT'S HARD TO IT MAY COME
L8	UP GRANT NO. 1, BUT IT MAY ALSO COME UP IN GRANT 36,
L9	A DIFFERENT QUESTION. SO WE DON'T WANT TO BE
20	PAUSING. OTHERWISE WE HAVE TO PUT THE APPLICANTS ON
21	CALL FOR TWO DAYS. WE WANT TO GIVE THEM A DEFINED
22	TIME PERIOD WHEN THEY NEED TO BE AVAILABLE WHEN
23	STAFF CAN CALL THEM. IT'S PARTLY THE PRACTICAL
24	ISSUE.
25	CHAIRMAN KLEIN: JEFF, CAN I COMMENT ON
	22

1	THIS?
2	CHAIRMAN SHEEHY: WE STILL HAVE JOAN WHO'S
3	BEEN WAITING.
4	CHAIRMAN KLEIN: IT'S NOT A NEW QUESTION.
5	I'M TRYING TO CLARIFY WHAT'S BEEN SAID. ONE OF THE
6	THINGS I'M HEARING, DR. FEIGAL, IS THAT DURING THE
7	ACTUAL REVIEW OF THE GRANT, YOU GET ON THE PHONE AND
8	THERE'S A SPEAKER PHONE SO THE WORKING GROUP CAN
9	HEAR THE ANSWER. I THINK THAT'S WHAT DUANE IS
10	GETTING TO. SO THE GRANT REVIEW GROUP CAN HEAR THE
11	QUESTION, SO IT'S REAL-TIME, YOU CALL THEM, HERE'S
12	THE QUESTION, CAN YOU RESPOND? AND THEY HAVE TO
13	RESPOND RIGHT THEN, AND THEN THE WHOLE GRANT WORKING
14	GROUP HEARS THE ANSWER. AND IT'S EITHER
15	SATISFACTORY OR IT ISN'T, BUT AT LEAST THEY GET A
16	CHANCE TO RESPOND TO THE QUESTION IF IT'S A PIVOTAL
17	QUESTION.
18	YOU CAN ONLY DO THAT WITH TWO OR THREE
19	QUESTIONS FOR EACH GRANT ON WHICH THERE ARE
20	QUESTIONS, AND HOPEFULLY THEY'RE NOT PIVOTAL,
21	UNANSWERED QUESTIONS BECAUSE OF THE EARLY PROCESS
22	YOU HAVE, AND IT ONLY COMES DOWN TO FIVE OR SO
23	GRANTS WHERE YOU HAVE THESE OPEN QUESTIONS.
24	DR. FEIGAL: YEAH. I THINK WHAT I'M
25	TRYING TO GET AT IS THE PRACTICAL. WE WANT TO

1	PROVIDE AN OPPORTUNITY, BUT I THINK THIS APPROACH
2	WHERE WE ACTUALLY HAVE A PAUSE EACH AND EVERY GRANT.
3	CHAIRMAN KLEIN: THE ASSUMPTION IS THAT
4	YOUR EARLY PROCESS IS GOING TO ELIMINATE PIVOTAL
5	QUESTIONS ON MOST GRANTS. THIS IS ONLY GOING TO
6	OCCUR WITH A MINORITY OF THE GRANTS IN THE CYCLE.
7	THAT'S THE GOAL.
8	CHAIRMAN SHEEHY: I DON'T KNOW.
9	DR. FEIGAL: IS THAT WHAT YOU'RE THINKING?
10	TAKE A PAUSE AT THAT ACTUAL GRANT AS OPPOSED TO A
11	SET TIME OF THE DAY? BASICALLY THEY'RE ON CALL
12	PRETTY MUCH ALL DAY THEN.
13	CHAIRMAN KLEIN: WE'VE GIVEN THEM YOU
14	CAN GIVE THEM AN HOUR AND A HALF BECAUSE SOMETIMES
15	WE RUN LATE, BUT AN HOUR AND A HALF BLOCK OF TIME.
16	MS. SAMUELSON: THEY ALL HAVE CELL PHONES.
17	DR. FEIGAL: WE SWITCH ORDER OF WHEN WE
18	REVIEW THINGS. MAYBE THIS IS TOO MUCH IN THE WEEDS
19	RIGHT NOW, BUT I'M JUST TRYING TO GIVE US A LITTLE
20	BIT OF FLEXIBILITY BECAUSE SOMETIMES THE ORDER
21	DOESN'T PROCEED EXACTLY BECAUSE OF REVIEWERS CALLING
22	IN. THERE'S JUST THINGS THAT HAPPEN DURING A
23	REVIEW.
24	CHAIRMAN KLEIN: YOU'RE GOING TO HAVE A
25	GOAL TO DO IT IN REAL TIME DURING THAT BLOCK OF
	24

1	TIME. AND IF THAT DOESN'T WORK, YOU HAVE A BACKUP
2	PLAN.
3	DR. TROUNSON: I THINK IT NEEDS TO BE TIME
4	LIMITED. OTHERWISE YOU CAN GET AT THE HALF HOUR
5	VERY QUICKLY. I DO THINK YOU NEED A TIME LIMITED SO
6	THAT YOU GET THE QUESTIONS AND THE RESPONSES.
7	MR. TORRES: MR. CHAIRMAN.
8	MS. SAMUELSON: I'M VERY POLITE.
9	CHAIRMAN SHEEHY: THANK YOU, JOAN.
10	MR. TORRES: YES, YOU HAVE BEEN.
11	MS. SAMUELSON: IT'S NOT A REFLECTION OF
12	MY LACK OF INTEREST.
13	CHAIRMAN SHEEHY: GO AHEAD, JOAN.
14	MS. SAMUELSON: ALL RIGHT. NOW, THIS IS
15	GOING TO FEEL LIKE THE BAD KID AT THE BIRTHDAY
16	PARTY. I THINK WE HAVE TO GO BACK TO THE BEGINNING
17	AND JUST ACKNOWLEDGE THAT WE DIDN'T HAVE TIME TO
18	REFLECT ON THIS STUFF. THE BEGINNINGS OF THE AGENDA
19	CAME ON FRIDAY, AND THERE WASN'T AT THE END OF
20	THE DAY AND THEN WE WERE GETTING STUFF JUST A FEW
21	HOURS AGO. SO I'M HOPING WE'RE NOT GOING TO MAKE
22	ANY PERMANENT DECISIONS OR RECOMMENDATIONS TO THE
23	ICOC UNTIL WE'VE HAD SOME TIME TO REFLECT ON IT.
24	AND IN PART THAT'S BECAUSE IT SEEMS TO ME
25	THERE'S SOME QUESTIONS ABOUT WHETHER THIS CHANGES

1	PROGRAMMATIC REVIEW, WHETHER IT CHANGES THE NATURE
2	OF THE WORKING GROUP, AND THE WAY THAT THE PATIENT
3	ADVOCATES ARE INVOLVED IN IT. IT EXCLUDES THEM FROM
4	PARTICIPATION IN AT LEAST ONE PLACE, I THINK.
5	DR. FEIGAL: NO. ACTUALLY I'M SORRY.
6	GO AHEAD.
7	MS. SAMUELSON: YOU JUST CONTRADICTED ME.
8	SO GO AHEAD.
9	DR. FEIGAL: NO, I INTERRUPTED YOU.
10	MS. SAMUELSON: I HAVE A LOT OF QUESTIONS
11	THAT I DON'T HAVE ANSWERS BECAUSE I DIDN'T HAVE TIME
12	TO THINK ABOUT AND STEW WHAT PROCEDURE MIGHT WORK
13	BETTER, BUT IT SEEMED TO ME THERE WAS SOME PROBLEMS
14	ALONG THOSE LINES.
15	DR. FEIGAL: LET ME CLARIFY. I HAVEN'T
16	CHANGED THE SEQUENCING OF SCIENTIFIC AND
17	PROGRAMMATIC REVIEW. I HAVE NOT DONE THAT. SO
18	MS. SAMUELSON: I DON'T KNOW WHAT THAT
19	MEANS.
20	DR. FEIGAL: IF THAT'S HOW IT'S COME
21	ACROSS, THAT WAS NOT MY INTENT.
22	MS. SAMUELSON: OKAY. I'M NOT SUGGESTING
23	IT IS. I JUST THINK WE'VE GOT TO MAINTAIN THE
24	INTEGRITY OF THAT BECAUSE IT'S WHAT WE'RE GOVERNED
25	BY AND IT'S A GOOD THING.
	26

1	DR. FEIGAL: SO JUST TO BE CLEAR, ON THE
2	PIVOTAL I THINK THE PRE YOU DON'T HAVE ANY ISSUES
3	WITH BECAUSE THAT'S BEFORE PEER REVIEW EVEN HAPPENS.
4	SO FOR THE PIVOTAL QUESTIONS, THE PATIENT ADVOCATES
5	ARE SITTING IN THE ROOM, AND NOTHING HAS CHANGED
6	ABOUT THE SEQUENCE OF SCIENTIFIC AND PROGRAMMATIC
7	REVIEW.
8	ON THE PIVOTAL QUESTIONS THAT REQUIRE A
9	MORE DETAILED RESPONSE, THERE WERE TWO OPTIONS GIVEN
10	THERE. THE INFORMATION WOULD COME BACK IN WRITING
11	AND BE DISTRIBUTED TO EVERYBODY ON THE PEER REVIEW.
12	THAT INCLUDES PATIENT ADVOCATES.
13	THERE WOULD THEN BE
14	MS. SAMUELSON: BECAUSE PEER REVIEW IS NOT
15	PARTICIPATED IN BY PATIENT ADVOCATES. THAT'S THE
16	WAY THE TERM IS USED.
17	DR. FEIGAL: MAYBE I NEED TO USE A
18	DIFFERENT WORD THEN. BUT WHAT I MEANT TO SAY IS
19	THAT THE DETAIL RESPONSE WOULD BE DISTRIBUTED TO THE
20	SCIENTIFIC AS WELL AS TO THE PATIENT ADVOCATES ON
21	THE GRANT REVIEW.
22	MS. SAMUELSON: DURING THE REVIEW.
23	DR. FEIGAL: AND THEN THERE WOULD BE A
24	TELEPHONIC REVIEW. NOW, IN ONE OPTION WE HAVE
25	EVERYBODY HAS TO BE ON THE TELEPHONIC GRANT REVIEW

GROUP DISCUSSION. ON THE SECOND OPTION, IT WAS MORE
OF A BACKUP IN CASE YOU CAN'T GET EVERYBODY. AND I
LISTED THAT MINIMUM NUMBER THAT WOULD NEED TO BE ON
THE PHONE, AND THEY BOTH INCLUDE PATIENT ADVOCATES.
MS. SAMUELSON: IT'S THE CHAIRS, RIGHT?
DR. FEIGAL: WELL, THE VICE CHAIRS. IT'S
NOT NECESSARILY ALL THE PATIENT ADVOCATES. IN
ADDITION, IT WASN'T ALL THE SCIENTIFIC REVIEW. IT
WAS THE PRIMARY, THE SECONDARY, AND THE KEY
SPECIALISTS. SO THAT WAS REALLY MORE OF A PRACTICAL
ISSUE. JUST IN CASE YOU CAN'T GET EVERYBODY ON THE
PHONE, WE HAVE A BACKUP OPTION.
MS. SAMUELSON: WELL, AND IN THE
IMPLEMENTATION WE WOULD SEE I THINK IF WE'RE
GOING TO CHANGE THE NATURE OF THE GRANTS WORKING
GROUP, WE SHOULD BE INTENTIONAL ABOUT IT AND NOT
HAVE IT JUST SLIDE AWAY.
CHAIRMAN SHEEHY: JOAN, I DON'T THINK
THAT'S WHAT'S HAPPENING HERE. WHAT WE'RE TRYING TO
DO, I THINK, IS NOT BE IN A SITUATION WHERE THERE'S
A QUESTION THAT COMES UP.
MS. SAMUELSON: I SEE THE PROBLEM.
CHAIRMAN SHEEHY: IT'S ALMOST ALWAYS,
WELL, IF IT'S NOT HERE, IT DOESN'T EXIST. THEN WE
LOSE ABOUT 20 POINTS OFF THE SCORE. THE IDEA HERE
28

1	IS TO HAVE, ESPECIALLY WITH THE AMOUNT OF MONEY THAT
2	GRANTS TYPICALLY INVOLVE, IS AN OPPORTUNITY TO GET
3	THE FULLEST RANGE OF INFORMATION. BUT AS FAR AS I
4	CAN SEE, THE WORKING GROUP IS THERE THE WHOLE TIME.
5	THE ONLY THING WHERE IT SEEMS TO BE A
6	LITTLE BIT SHRUNKEN IS THIS SECOND OPTION FOR THE
7	LENGTHY PIVOTAL QUESTIONS. AND, YOU KNOW, IT'S VERY
8	SIMILAR TO WHAT WE DO WHEN WE HAVE IN OTHER
9	RE-REVIEW ISSUES.
10	THE ONLY THING I MIGHT ADD IS BEYOND THE
11	PATIENT ADVOCATE CO-CHAIRS, I MIGHT ADD, IF IT'S
12	DISEASE SPECIFIC, THE PATIENT ADVOCATE WHO IS FROM
13	THAT DISEASE AREA. SO IF THERE WAS, FOR INSTANCE,
14	AN AUTISM GRANT, NOT ONLY THE CO-CHAIRS, BUT JON
15	SHESTACK SHOULD BE ALSO INVITED TO THAT SECOND IF
16	WE END UP DOING THAT OPTION, JUST PUTTING THAT OUT
17	THERE.
18	MS. SAMUELSON: WHAT HAPPENS TO
19	PROGRAMMATIC REVIEW IN THOSE INSTANCES?
20	DR. FEIGAL: YOU DO IT BY PHONE.
21	MS. SAMUELSON: AND WITH A LIMITED NUMBER.
22	CHAIRMAN SHEEHY: IT'S A VERY LIMITED
23	NUMBER, I BELIEVE, JOAN.
24	CHAIRMAN KLEIN: IF I COULD TRY AND
25	CLARIFY HERE. SO, JOAN, IN THE SECOND CASE WHERE
	29
	43

1	THERE IS MORE COMPLICATED INFORMATION THAT CAN'T BE
2	COMPLETELY RESOLVED ON A REAL-TIME PHONE CALL DURING
3	THE GRANTS REVIEW, I THINK IT WOULD BE APPROPRIATE,
4	IT'S BEEN SUGGESTED IN HERE AS AN OPTION, TO HAVE
5	THAT APPROVAL FROM THE GRANTS WORKING GROUP
6	CONDITIONAL UPON THE RESPONSE THAT'S OBTAINED. AND
7	THEN WHEN THE REPORT GOES TO THE BOARD, THAT IS A
8	RECOMMENDATION THAT WAS CONDITIONAL UPON THE
9	RESPONSE. AND IN THE EXECUTIVE SESSION AT THE
10	BOARD, HERE'S THE PROPRIETARY INFORMATION THAT WAS
11	CONVEYED TO CLARIFY THE CONDITIONAL RECOMMENDATION.
12	SO THE PATIENT ADVOCATES ON THE BOARD IN
13	THE PROPRIETARY, THE EXECUTIVE SESSION OF THE BOARD,
14	WILL BE ABLE TO SEE THE MATERIAL THAT WAS RELATED TO
15	IT.
16	CHAIRMAN SHEEHY: YOU'RE ADDING A NEW
17	PROCESS, BOB.
18	MS. SAMUELSON: AND WHEN DID YOU FIRST
19	START THINKING ABOUT THIS? IS IT REALLY AS RECENTLY
20	AS I RECEIVED THE MATERIALS? I HATE TO BE
21	APOLOGETIC ABOUT THIS, BUT THIS IS IMPORTANT STUFF.
22	CHAIRMAN KLEIN: JOAN, WE DISCUSSED THIS
23	IN THE PREPARATORY CALL AND THE BRIEFING CALL FOR
24	THE PATIENT ADVOCATES FOR THE LAST GRANT REVIEW.
25	THIS WHOLE ISSUE WAS BROUGHT UP WITH YOU ON THE

1	PHONE.
2	MS. SAMUELSON: I KNOW THAT. THAT DOESN'T
3	MEAN THE RECOMMENDATION WAS MADE THEN, RIGHT?
4	CHAIRMAN KLEIN: THE PROPOSAL WAS
5	DISCUSSED AT THAT TIME. SO THIS ISSUE HAS BEEN
6	PENDING FOR SOME TIME.
7	DR. FEIGAL: YOU KNOW, ON A
8	CHAIRMAN SHEEHY: I'M SORRY. I STILL HAVE
9	SENATOR TORRES.
10	MR. TORRES: I JUST WANT TO MAKE SURE JOAN
11	WAS FINISHED.
12	MS. SAMUELSON: I'M NOT.
13	MR. TORRES: YOU'LL COME BACK. I WANT TO
14	GET INTO THE WEEDS. AS AN ORGANIC FARMER, I'M
15	CAREFUL ABOUT THE WEEDS. I WANT TO MAKE SURE THAT
16	WE GET BACK IN BECAUSE THE WEEDS SOMETIMES HAVE AN
17	IMPACT ON THE FINAL PRODUCT. AND IN THIS CASE,
18	HAVING BEEN THROUGH ALL OF THESE WORKING GROUPS IN
19	THE PAST, WHAT USUALLY COMES UP IN THE SESSION ARE
20	QUESTIONS BY OTHER SCIENTISTS TO EACH OTHER ABOUT
21	WHAT'S NOT IN THE APPLICATION OR WHAT IS MEANT.
22	SO THE QUESTION FOR ME IS ARE WE GOING TO,
23	AND I'M VERY SENSITIVE TO WHAT ALAN SAID, WAS HOW DO
24	WE KEEP THIS BRIEF AND CONCISE. ARE WE GOING TO
25	MAKE SURE THAT THE NATURE OF THE QUESTIONS ARE

1	LIMITED? WHAT IS GOING TO BE THE NATURE OF THE
2	QUESTIONS THAT ARE ASKED, NOT A FREE FOR ALL BECAUSE
3	AT THAT POINT WE'LL BE AT THE KABUKI HOTEL FOR THE
4	DINNER REVIEW AT THAT POINT.
5	NO. 2, I'M ALSO CONCERNED ABOUT IF THAT'S
6	GOING TO BE THE CASE, WE TRY TO REMAIN ANONYMOUS.
7	THE PEER REVIEWERS TRY TO REMAIN ANONYMOUS. IF YOU
8	HAVE AN APPLICANT ON THE OTHER SIDE OF THE PHONE AND
9	YOU HAVE PEER REVIEWERS MAKING COMMENTS, AREN'T THEY
10	GOING TO BE ABLE TO IDENTIFY THEIR VOICES? HOW DO
11	YOU AVOID THAT? MODULATING THE VOICE?
12	DR. FEIGAL: NO. DO YOU HAVE MORE
13	QUESTIONS?
	MR. TORRES: THOSE ARE THE TWO ISSUES
14	MR. TORRES. THOSE ARE THE TWO 1330ES
14 15	BECAUSE I AM CONCERNED ABOUT MAKING SURE THAT
15	BECAUSE I AM CONCERNED ABOUT MAKING SURE THAT
15 16	BECAUSE I AM CONCERNED ABOUT MAKING SURE THAT THIRDLY, WHO'S GOING TO TRANSCRIBE THE ANSWERS BY
15 16 17	BECAUSE I AM CONCERNED ABOUT MAKING SURE THAT THIRDLY, WHO'S GOING TO TRANSCRIBE THE ANSWERS BY THE APPLICANT TO THE REVIEWER'S QUESTION, WHICH THEN
15 16 17 18	BECAUSE I AM CONCERNED ABOUT MAKING SURE THAT THIRDLY, WHO'S GOING TO TRANSCRIBE THE ANSWERS BY THE APPLICANT TO THE REVIEWER'S QUESTION, WHICH THEN WILL BE IMPORTANT FOR THE BOARD TO REVIEW BEFORE A
15 16 17 18 19	BECAUSE I AM CONCERNED ABOUT MAKING SURE THAT THIRDLY, WHO'S GOING TO TRANSCRIBE THE ANSWERS BY THE APPLICANT TO THE REVIEWER'S QUESTION, WHICH THEN WILL BE IMPORTANT FOR THE BOARD TO REVIEW BEFORE A FINAL VOTE?
15 16 17 18 19	BECAUSE I AM CONCERNED ABOUT MAKING SURE THAT THIRDLY, WHO'S GOING TO TRANSCRIBE THE ANSWERS BY THE APPLICANT TO THE REVIEWER'S QUESTION, WHICH THEN WILL BE IMPORTANT FOR THE BOARD TO REVIEW BEFORE A FINAL VOTE?  DR. FEIGAL: IF I MAY ANSWER THEM, WHAT I
15 16 17 18 19 20	BECAUSE I AM CONCERNED ABOUT MAKING SURE THAT THIRDLY, WHO'S GOING TO TRANSCRIBE THE ANSWERS BY THE APPLICANT TO THE REVIEWER'S QUESTION, WHICH THEN WILL BE IMPORTANT FOR THE BOARD TO REVIEW BEFORE A FINAL VOTE?  DR. FEIGAL: IF I MAY ANSWER THEM, WHAT I WAS THINKING OF. SO THERE'S TWO DIFFERENT TYPES OF
15 16 17 18 19 20 21	BECAUSE I AM CONCERNED ABOUT MAKING SURE THAT THIRDLY, WHO'S GOING TO TRANSCRIBE THE ANSWERS BY THE APPLICANT TO THE REVIEWER'S QUESTION, WHICH THEN WILL BE IMPORTANT FOR THE BOARD TO REVIEW BEFORE A FINAL VOTE?  DR. FEIGAL: IF I MAY ANSWER THEM, WHAT I WAS THINKING OF. SO THERE'S TWO DIFFERENT TYPES OF QUESTIONS. ONE ARE CONCISE AND SIMPLE AND THEY'RE
15 16 17 18 19 20 21 22	BECAUSE I AM CONCERNED ABOUT MAKING SURE THAT THIRDLY, WHO'S GOING TO TRANSCRIBE THE ANSWERS BY THE APPLICANT TO THE REVIEWER'S QUESTION, WHICH THEN WILL BE IMPORTANT FOR THE BOARD TO REVIEW BEFORE A FINAL VOTE?  DR. FEIGAL: IF I MAY ANSWER THEM, WHAT I WAS THINKING OF. SO THERE'S TWO DIFFERENT TYPES OF QUESTIONS. ONE ARE CONCISE AND SIMPLE AND THEY'RE NOT SUBMITTING ADDITIONAL DATA. NOW, I'VE HEARD

1	WHOLE PEER REVIEW, WE'VE IDENTIFIED THOSE
2	PRIORITIZED KEY, CRITICAL QUESTIONS THAT COULD
3	IMPACT ON THE SCORE, BUT IT WOULD HAVE A SIMPLE
4	ANSWER AND A CONCISE ANSWER, AND IT COULD BE
5	ANSWERED TELEPHONICALLY OR IT COULD BE ANSWERED BY
6	E-MAIL, BUT I THINK THE PREFERENCE WAS FOR TELECON.
7	MY SUGGESTION WAS THAT SOMEBODY IN CIRM,
8	NOT SOMEBODY FROM THE PEER REVIEW, ASK THE QUESTIONS
9	SO THAT MY VOICE OR GIL'S COULD BE IDENTIFIED, BUT
10	THERE WOULDN'T BE ANY IDENTIFICATION OF A REVIEWER.
11	AND, FRANKLY, I DON'T THINK THERE SHOULD BE A
12	DIALOGUE WITH THE PEER REVIEWERS EITHER. I
13	PERSONALLY THINK IT SHOULD BE A CALL THAT'S OUTSIDE.
14	IF YOU WANT, IT COULD JUST BE GIL OR I TALKING TO
15	THE PERSON. I DON'T THINK ANYBODY ON THE PEER
16	REVIEW SHOULD BE TALKING.
17	MR. TORRES: I THOUGHT OUR INTENT WAS THAT
18	AFTER THE PEER REVIEW WAS DONE AND THERE ARE
19	QUESTIONS THAT WERE RAISED REGARDING A SPECIFIC
20	APPLICATION, THAT YOU OR SCIENCE STAFF WOULD FOLLOW
21	UP WITH THESE ARE THE QUESTIONS THAT WERE RAISED.
22	DO YOU HAVE ANSWERS?
23	DR. FEIGAL: THAT'S RIGHT.
24	MR. TORRES: RATHER THAN DOING IT
25	TELEPHONICALLY AND LIVE; IN OTHER WORDS, WAITING FOR

THE REVIEW PROCESS TO BE OVER.
DR. TROUNSON: ONLY IF THERE'S SIMPLE
QUESTIONS.
DR. FEIGAL: THE TELEPHONIC OR AS I WOULD
SUGGEST AN E-MAIL TO DOCUMENT IN WRITING WHAT
THEY'VE SAID, BUT TELEPHONIC I CAN UNDERSTAND
BECAUSE THEN THE APPLICANT CAN ASK A QUESTION TO
MAKE SURE THEY UNDERSTOOD WHAT THE QUESTION WAS.
BUT THEN WE COULD COME BACK AND TELL THE
MR. TORRES: IF SOMEONE FROM CIRM IS
ASKING THE QUESTION AND THEN THE APPLICANT HAS A
QUESTION, THE VOICE, THE ARTIFICIAL VOICE OF THE
CIRM PERSON MAY NOT HAVE THE ANSWER TO THAT.
DR. STEWARD: WHEN YOU HAVE A CHANCE, I'D
LIKE TO WEIGH IN ON THIS. I'LL GET ON THE LIST
HERE.
DR. FEIGAL: I REALLY THINK IF THIS IS
GOING TO WORK, IT HAS TO BE PRETTY CLEAR QUESTIONS.
IT CAN'T BE NUANCE. AND SO IT HAS TO BE YOU SAID IN
SECTION 8 THAT YOU WERE USING CELL LINE A AND IN
SECTION 9 IT SAYS YOU'RE USING CELL LINE B. COULD
YOU CLARIFY WHICH ONE ARE YOU USING? OR IT HAS TO
BE IT'S PIVOTAL BECAUSE IT MAKES A DIFFERENCE IN
TERMS OF THE CREDIBILITY YOU MAY HAVE IN TERMS OF
THAT SCORE. I'M JUST MAKING IT UP. BUT THE
34

1	QUESTION HAS TO BE VERY CLEAR.
2	CHAIRMAN SHEEHY: DR. STEWARD.
3	DR. STEWARD: THANKS. SO JUST TO SAY,
4	THIS IS A PROCESS THAT ISN'T ALL THAT DISSIMILAR TO
5	WHAT USED TO GO ON AT NIH. IT WAS CALLED A SITE
6	VISIT, AND BASICALLY REVIEWERS WOULD ACTUALLY COME
7	AND TALK TO THE APPLICANTS FACE TO FACE. AND THAT
8	CHANGED OVER THE YEARS BECAUSE OF REALLY SAVING
9	MONEY BY NIH. AND THEN THEY SWITCHED OVER TO A
10	PROCESS THAT WAS A REVERSE SITE VISIT WHERE THE
11	INVESTIGATORS WENT TO NIH. THE SAME BASIC PROCESS.
12	AND THE POINT IS THAT I THINK WE'RE
13	WORRIED WAY TOO MUCH ABOUT THIS ISSUE OF NOT HAVING
14	A DIRECT COMMUNICATION LINE BETWEEN THE APPLICANT
15	AND THE GRANTS WORKING GROUP. I DON'T THINK YOU
16	NEED TO HAVE THE REVIEWERS TALKING TO THE APPLICANT,
17	BUT THE CHAIR COULD. AND EVERYBODY KNOWS WHO THE
18	CHAIR IS, SO THAT'S NOT A SECRET. POSE THE
19	QUESTIONS, GET THE ANSWERS, DONE DEAL. WE DON'T
20	HAVE TO GO THROUGH THIS TRANSCRIPTION STUFF OR
21	ANYTHING LIKE THAT.
22	AS ALAN SAYS, THIS WOULD BE SOMETHING THAT
23	WOULD APPLY TO SIMPLE QUESTIONS, RELATIVELY
24	SPEAKING, ON PIVOTAL ISSUES. I THINK WE'RE MAKING
25	IT JUST WAY, WAY, WAY TOO COMPLEX.
	25

1	HAVING SAID ALL THAT, I ALSO THINK AND,
2	IN FACT, I HAVE AN APPLICANT SITTING IN THE ROOM
3	WITH ME RIGHT NOW WHO SAID THAT THEY WOULD BE MORE
4	THAN WILLING TO MAKE THEMSELVES AVAILABLE AT ANY
5	TIME THE GRANTS WORKING GROUP CHOSE TO HAVE THEM ON
6	CALL. I DON'T THINK THIS IS MAJOR THRASH FOR
7	APPLICANTS EITHER.
8	CHAIRMAN SHEEHY: OKAY. DO WE HAVE OTHER?
9	YOU KNOW, WE DON'T NECESSARILY HAVE TO GET THIS
10	EXACTLY RIGHT. I THINK, LIKE A LOT OF THINGS, THIS
11	CAN BE EVOLUTIONARY. I THINK WE'RE GOING TO EVOLVE
12	AS WE TRY TO IMPLEMENT THIS. SEE WHAT IT'S LIKE IN
13	REAL TIME. TO KIND OF TRY AND DO SOMETHING THAT IS
14	MOST FEASIBLE. I DO THINK IT'S IMPORTANT THAT WE
15	GET MORE INFORMATION. THESE ARE BIG GRANTS. THE
16	INITIAL STAB AT THIS IS REALLY VERY GOOD. LET'S TRY
17	TO FOCUS MAYBE ON WHATEVER TWEAKS PEOPLE THINK ARE
18	REALLY IMPORTANT, BUT, YOU KNOW, TRYING TO PUT THIS
19	FORWARD AND NOT GET TOO BOGGED DOWN.
20	CHAIRMAN KLEIN: I WOULD JUST THINK THAT,
21	IN LIGHT OF YOUR COMMENT, WHICH I THINK IS VERY
22	APPROPRIATE, JEFF, IS THAT IF WE COULD TRY AS A
23	THIRD APPROACH GETTING THEM ON THE PHONE DURING THE
24	GRANTS WORKING GROUP SO THAT THE MEMBERS OF THE
25	GRANTS WORKING GROUP CAN HEAR THE RESPONSES TO

1	QUESTIONS THAT STAFF POSES, THAT WOULD BE THE
2	PREFERRED APPROACH. BUT, YOU KNOW, IF WE GET OUT OF
3	THEIR TIME SLOT AND THEY CAN'T, HAVE THE STAFF HAVE
4	THE BACKUP CAPACITY TO GET AN E-MAIL RESPONSE THAT
5	THEY CAN BRING TO THE ATTENTION OF THE WORKING GROUP
6	SO THAT YOU HAVE THAT FLEXIBILITY.
7	DR. TROUNSON: I THINK THEY'RE ONLY TRYING
8	TO IMPROVE THE DECISION-MAKING. WE'RE NOT ACTUALLY
9	TRYING TO EXPAND THE AMOUNT OF INFORMATION. WE'RE
10	TRYING TO IMPROVE THE DECISION-MAKING. BECAUSE
11	WE'RE NOW GIVING THREE OPPORTUNITIES TO DO THAT.
12	ONE WHERE WE LOOK IN AND WE CAN SEE THAT THERE ARE
13	QUESTIONS THAT SHOULD BE ASKED, AND THEY HAVE BEEN
14	CLARIFIED THAT QUESTIONS EXIST IN THE REVIEWS.
15	WE'RE GOING TO ASK THOSE QUESTIONS PRIOR TO THE
16	REVIEW, AND THEY WILL HAVE AN OPPORTUNITY TO ANSWER.
17	SO THAT'S ONE CAPACITY TO CLARIFY.
18	SECOND CAPACITY, IF WE HAVEN'T PICKED UP
19	SOMETHING OR THE REVIEWERS HAVEN'T PICKED UP
20	SOMETHING, BUT IT'S STILL AN ISSUE, A QUESTION, AN
21	IMPORTANT QUESTION, BUT SOMETHING THAT THEY CAN
22	ANSWER BY YES, NO, A RELATIVELY SHORT RESPONSE
23	BECAUSE IT'S A CLARIFICATION, DO IT TELEPHONICALLY.
24	THE REASON FOR GOING TO THE THIRD ONE IS
25	IF THE GRANTS REVIEW TEAM, THE WHOLE TEAM, THOUGHT

1	THAT THIS GRANT HAD SOME MERIT, BUT THERE WAS SOME
2	PARTICULAR ISSUE LIKE, LET'S SAY, A HISTOGRAM OR
3	HISTOLOGY THAT WAS TOTALLY CONFUSED IN THE GRANT
4	APPLICATION, YOU COULDN'T READ IT, COULDN'T SEE INTO
5	IT, YOU COULDN'T SORT OF MAKE HEAD OR TAIL OF IT,
6	WERE THEY ABLE TO PRODUCE A BETTER SPECIMEN FOR US
7	TO BE ABLE TO SEE BECAUSE THE GRANT WAS IMPORTANT,
8	WE WANTED TO CLARIFY THAT WHAT WE WERE SEEING WAS
9	THE REAL THING, WAS THE THING THAT WAS IMPORTANT TO
10	SEE.
11	SO THERE ARE NOW THREE OPPORTUNITIES, I
12	BELIEVE, AND I THINK THEY'RE RELATIVELY
13	STRAIGHTFORWARD, AND I DON'T THINK THEY ACTUALLY
14	ALTER THE REVIEW ITSELF, BUT THEY IMPROVE OUR
15	CAPACITY FOR MAKING A DECISION. THE CLARITY, I
16	THINK, ACROSS THE INFORMATION AND NOT MORE THAN
17	THAT. I WOULDN'T BE ASKING FOR NEW INFORMATION. I
18	THINK THAT'S NOT WHAT WE SHOULD BE DOING. BUT IT
19	SHOULD ABOUT CLARIFYING WHAT INFORMATION IS THERE OR
20	IF, IN FACT, IT WASN'T PUT IN THERE BECAUSE IT WAS
21	SOMEWHERE ELSE AND THEY NEGLECTED TO PUT AN
22	IMPORTANT STATEMENT INTO THEIR APPLICATION.
23	DR. FEIGAL: IS THAT AN AGREEMENT TOO FOR
24	THE PART 2 WHERE WE'RE ASKING PART OF THE ISSUE
25	WAS THERE'S MORE COMPLEX QUESTIONS IN THE PART 2

1	THAT REQUIRE A WRITTEN RESPONSE AND MIGHT REQUIRE
2	SUBMISSION OF MORE DATA.
3	CHAIRMAN SHEEHY: OKAY.
4	MS. SAMUELSON: I HAVE ANOTHER QUESTION.
5	CHAIRMAN SHEEHY: SURE. SO JOAN. ARE
6	THERE OTHERS? LET ME START A NEW LIST. JOAN. IS
7	THERE ANYONE ELSE HAS A QUESTION AFTER JOAN? GO
8	AHEAD, JOAN.
9	MS. SAMUELSON: WHO IS THE CHAIR THAT YOU
10	ARE REFERRING TO?
11	CHAIRMAN SHEEHY: THE CHAIR OF THE WORKING
12	GROUP SESSION.
13	MS. SAMUELSON: SO IT'S THE REVIEW CHAIR?
14	CHAIRMAN SHEEHY: RIGHT.
15	MS. SAMUELSON: SO WE WOULDN'T KNOW IF
16	THAT PERSON HAS EVER EVEN BEEN INVOLVED IN A REVIEW.
17	THEY DON'T NECESSARILY NEED EXPERIENCE WITH OUR
18	PROCESS, RIGHT? THAT'S PROBLEMATIC, I THINK.
19	DR. FEIGAL: I'M A LITTLE BIT CONFUSED BY
20	THE QUESTION.
21	MS. SAMUELSON: WHEN THE CHAIR CHANGES
22	FROM ONE REVIEW TO THE NEXT AND DOESN'T NECESSARILY
23	HAVE ANY HISTORY WITH US. THAT'S A PERSON WITH
24	DIFFERENT EXPERTISE THAN SOMEBODY WHO'S WHEN WE
25	HAD A PERMANENT CHAIR WHO WAS APPOINTED BY THE ICOC.

1	CHAIRMAN SHEEHY: WELL
2	MS. SAMUELSON: IT'S A COMPLETELY
3	DIFFERENT PROCESS.
4	CHAIRMAN SHEEHY: THAT MIGHT BE ANOTHER
5	ISSUE THAT I THINK ISN'T
6	MS. SAMUELSON: I THINK THEY GET RAISED.
7	THAT'S THE PROBLEM. IN THE IMPLEMENTATION, ALL OF
8	THE THINGS THAT HAVE AS I'VE SEEN IT STEP BY STEP
9	CHANGING THE NATURE OF THE WORKING GROUP AND THE
10	WORK PRODUCT WILL BE AT PLAY HERE TOO. THAT'S
11	WHY THOSE THINGS DESERVE DISCUSSION BY
12	THEMSELVES. THAT'S WHAT KEEPS OCCURRING TO ME.
13	DR. STEWARD: COULD I ACTUALLY ADD
14	SOMETHING, OR IS THERE SOMEBODY ELSE ON YOUR LIST.
15	CHAIRMAN SHEEHY: GO AHEAD AND THEN BOB.
16	DR. STEWARD: ACTUALLY JUST TO SPEAK TO
17	JOAN'S IMMEDIATE CONCERN WITH RESPECT TO THIS
18	PROSPECT RIGHT HERE THAT WE'RE DISCUSSING, ONE OF
19	THE OTHER POSSIBILITIES WOULD BE IF THERE ARE ISSUES
20	THAT REQUIRE FOLLOW-UP AND WRITTEN ANSWERS, WE COULD
21	JUST SIMPLY SCHEDULE A CONFERENCE CALL OF THE ENTIRE
22	WORKING GROUP. THAT COULD JUST BE PART OF THE DEAL
23	GOING IN. I DON'T THINK THAT'S ALL THAT DIFFICULT,
24	AND IT WOULD ASSURE THAT THE ENTIRE, IF YOU WANT,
25	ORGANISM OF THE GRANTS WORKING GROUP WAS IN PLAY IN
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1	THIS CONSIDERATION OF THE ADDITIONAL INFORMATION IN
2	THE SAME WAY THAT IT WAS IN PLAY DURING THE REGULAR
3	SESSION OF THE GRANTS WORKING GROUP. IT REALLY
4	WOULDN'T BE THAT HARD TO DO. WE DON'T HAVE TO HAVE
5	THIS SUBGROUP OR ANYTHING ELSE.
6	MY SECOND COMMENT IS THAT JUST THE WHOLE
7	ISSUE OF SOME OF THE THINGS THAT JOAN IS BRINGING UP
8	HERE, I WONDER IF WE SHOULD PUT ON THE AGENDA FOR A
9	SUBSEQUENT MEETING OF THE SCIENCE COMMITTEE.
10	CHAIRMAN SHEEHY: I THINK THAT'S PROBABLY
11	A GOOD IDEA. YOU HAD A QUESTION, BOB? DID YOU HAVE
12	A RESPONSE?
13	DR. FEIGAL: I JUST WANT TO MAKE SURE THAT
14	WHATEVER WE PUT IN PLACE DOESN'T ADD COMPLEXITY TO
15	THE PROCESS. AND I TOO BELIEVE IT'S IMPORTANT. THE
16	DETAILS ARE IMPORTANT, BUT I THINK ALSO THE DETAILS
17	ARE IMPORTANT THAT WE CAN UNDERSTAND THERE'S GOING
18	TO BE ONE PEER REVIEW SESSION, AND THAT THIS IS ONLY
19	FOR THAT SUBSET. FIRST OF ALL, THE THINGS THAT WE
20	HANDLE VERY CONCISELY AND SIMPLY ON A SUBSET FOR
21	QUESTIONS THAT ARE VERY CLEAR, CAN BE ANSWERED
22	CONCISELY WITHOUT NEEDING SUBMISSION OF ADDITIONAL
23	INFORMATION, AND CAN BE ANSWERED IN REAL TIME.
24	THERE'S A VERY SMALL NUMBER, PRESUMABLY,
25	WITH QUESTIONS THAT WILL IMPACT ON THE SCORE, BUT

1	FOR WHICH WE THINK THERE'S A POSSIBILITY THE
2	APPLICANTS CAN ADDRESS THEM IN A VERY SHORT PERIOD
3	OF TIME WITH WRITTEN RESPONSES, AND THEN THERE'S A
4	TELEPHONIC REVIEW. I DON'T THINK WE WANT TO GET
5	INTO ADDITIONAL PROCESSES FOR THE GRANT REVIEW GROUP
6	TO GET TOGETHER TO DECIDE THINGS.
7	I THINK AT THE ACTUAL PEER REVIEW, THAT
8	SESSION, THEY NEED TO DECIDE THE SUBSET THAT CAN BE
9	ANSWERED SIMPLY AND THE SUBSET THAT CAN'T BE
10	ANSWERED SIMPLY, AND DUKE IT OUT AT WHAT THE
11	QUESTIONS ARE AT THAT PEER REVIEW. THAT WOULD BE MY
12	SUGGESTION.
13	DR. STEWARD: AGAIN, I JUST WOULD SAY THAT
14	I DON'T THINK A ONE-HOUR CONFERENCE CALL OF THE
15	GRANTS WORKING GROUP IS ADDING VERY MUCH COMPLEXITY.
16	I REALLY THINK THAT IT'S A RELATIVELY SIMPLE MATTER.
17	OF COURSE, SOME MEMBERS MAY NOT BE ABLE TO ATTEND,
18	SOME MEMBERS ARE OUT OF THE ROOM ANYWAY DURING THE
19	CONSIDERATION OF A SPECIFIC ASPECT OF A GRANT FOR
20	WHATEVER REASON. SO I REALLY DON'T THINK THIS IS
21	THAT HARD TO DO.
22	CHAIRMAN SHEEHY: THAT'S ANTICIPATED, THAT
23	THERE WOULD BE A TELEPHONE
24	DR. FEIGAL: HE'S TALKING ABOUT BEFORE
25	EVEN SENDING QUESTIONS OUT. IS THAT WHAT YOU ARE

1	ASKING, BEFORE WE
2	DR. STEWARD: NO. NO. I'M SAYING THAT IN
3	THIS SITUATION WHERE ON A VERY RARE SITUATION WE
4	WOULD ASK FOR ADDITIONAL INFORMATION FROM THE
5	APPLICANT, THAT WE SCHEDULE A TELEPHONIC CONFERENCE
6	OF THE ENTIRE GRANTS WORKING GROUP.
7	DR. FEIGAL: THAT'S ALREADY IN THERE.
8	CHAIRMAN SHEEHY: I PREFER THAT TO
9	THERE WAS A SMALLER GROUP. I ACTUALLY PERSONALLY
10	WOULD PREFER THE WHOLE WORKING GROUP.
11	CHAIRMAN KLEIN: SO OUR FUNCTIONAL MISSION
12	TOO IS MOVING THESE THERAPIES FORWARD. SO WE'RE
13	TRYING TO ENHANCE OUR PROCESS WITHOUT CREATING TOO
14	MANY ENCUMBRANCES. OS, IF THEY NEED TIME TO GET
15	ANOTHER HISTOGRAM IMAGE AND SO CAN'T BE CONCURRENT
16	WITH THE SESSION, AND YOU'RE GOING TO HAVE A
17	FOLLOW-UP ON A HISTOGRAM IMAGE, I DON'T THINK YOU
18	SHOULD TRY AND CREATE A SITUATION WHERE YOU HAVE TO
19	BY OBLIGATION BRING TOGETHER THE ENTIRE PEER REVIEW
20	GROUP. YOU COULD DO THIS SMALLER GROUP.
21	I DO THINK THE SMALLER GROUP SHOULD
22	INCLUDE THE CHAIR OF THE BOARD SO THAT IF THINGS GET
23	TO THE BOARD, THE CHAIR IS NOT TRYING TO FIGURE OUT
24	WHAT HAPPENED OR WHAT DIDN'T HAPPEN. BUT ALL OF THE
25	PEER REVIEW, ALL OF THE PATIENT ADVOCATES WILL BE IN

1	THE EXECUTIVE SESSION OF THE BOARD WHERE ANY
2	CLARIFICATION OF PROPRIETARY INFORMATION IS
3	EXPLAINED. AND IT WILL BE CLEAR TO EVERYONE THIS
4	WAS A CONDITIONAL APPROVAL, AND EVERYONE THAT IS NOT
5	RECUSED BECAUSE OF A CONFLICT WILL HAVE THE ABILITY
6	TO UNDERSTAND WHAT THAT RESPONSE WAS.
7	MS. SAMUELSON: THAT INFORMATION WOULD
8	ONLY COME UP IF SOMEONE ASKED THAT A GIVEN PROPOSAL
9	BE REVIEWED. IF IT WAS GIVEN A DON'T FUND, IT WON'T
10	COME UP.
11	DR. FEIGAL: JUST TO BE CLEAR, WE HOPE THE
12	MAJORITY OF GRANTS THAT ARE REVIEWED WILL EITHER BE
13	CLEARLY YOU CAN SCORE THEM OR CLEARLY YOU THINK
14	THEY'RE BELOW WHAT YOU WOULD RECOMMEND FOR FUNDING.
15	THIS IS FOR THAT INTERMEDIATE GROUP.
16	MS. SAMUELSON: RIGHT.
17	CHAIRMAN SHEEHY: I THINK WE'VE GOT A
18	PRETTY GOOD FRAMEWORK ON WHICH AT LEAST GET TO AN
19	INITIAL DECISION POINT IF THAT'S OKAY. THIS THING
20	OF DOING THIS ICOC CONFIDENTIAL, THAT'S NOT WHAT
21	I LIKE THIS PROCESS.
22	CHAIRMAN KLEIN: I'M NOT ADDRESSING THAT.
23	CHAIRMAN SHEEHY: I REALLY LIKE THE IDEA
24	THAT WE GET ALL THE QUESTIONS THAT WE HAVE PEER
25	REVIEWED, THE ANSWERS TO QUESTIONS PEER REVIEWED IN

1	SOME FASHION AND SCORED AS OPPOSED TO BRINGING
2	ANYWAY.
3	MS. SAMUELSON: IT'S GOT TO BE DONE.
4	DR. FEIGAL: THAT WAS THE POINT. AND THAT
5	WAY WE BRING ONE PACKAGE OF INFORMATION TO THE ICOC.
6	CHAIRMAN SHEEHY: SO IF YOU'D LIKE TO
7	IF YOU HAVE A MOTION.
8	CHAIRMAN KLEIN: I'D LIKE TO MAKE A MOTION
9	THAT WE PROPOSE IT AS IS WE WOULD PASS THIS AND
10	APPROVE THIS AS PROPOSED EXCEPT THAT THE PREFERRED
11	SOLUTION WOULD BE AS LONG AS THE QUESTION COULD BE
12	ANSWERED SUCCINCTLY IN A TIME LIMIT AS SUGGESTED BY
13	PRESIDENT TROUNSON TELEPHONICALLY IN REAL TIME AS
14	PRESENTED BY THE SCIENTIFIC STAFF BASED UPON
15	QUESTIONS RAISED BY THE ENTIRE PEER REVIEW THEY
16	THOUGHT WERE PIVOTAL TO THE APPLICANT WHERE THE PEER
17	REVIEW MEMBERS CAN HEAR THE RESPONSE.
18	AND NO. 2, THAT IF YOU HAVE TO FALL BACK
19	TO A PIECE OF INFORMATION THAT IS CLARIFIED
20	SUBSEQUENTLY, THAT THE CHAIR OF THE BOARD BE ADDED
21	TO THE GROUP, THIS SMALL GROUP, THAT LOOKS AT THAT
22	INFORMATION FOR CLARIFICATION.
23	CHAIRMAN SHEEHY: I THINK WE WERE GOING TO
24	OPT FOR THE WHOLE WORKING GROUP OPTION.
25	CHAIRMAN KLEIN: THAT'S FINE. IF THE
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1	PRESIDENT IS FINE WITH THAT.
2	DR. FEIGAL: WE WERE
3	DR. TROUNSON: I JUST NEEDED TO ASK THE
4	LAWYERS. WHAT ARE THE KIND OF REQUIREMENTS TO
5	GET WHAT KIND OF NUMBERS DO WE NEED TO GET BACK
6	TO MAKE THIS ACCEPTABLE? THERE ARE 15 SCIENTISTS
7	AND 7 PATIENT ADVOCATES. IS THERE A NUMBER THERE
8	THAT WE NEED?
9	CHAIRMAN KLEIN: WE PREVIOUSLY APPROVED
10	CONDITIONALLY GRANTS OUT OF THE PEER REVIEW GROUP
11	WHO ARE SUBJECT TO A CONFIRMATION IF SOMEONE WAS
12	DROPPING OUT AS A PEER REVIEWER IN ENGLAND OR
13	SOMETHING. SO AS LONG AS THE WHOLE PEER REVIEW
14	GROUP APPROVES IT WITH THIS CONDITION, WE'VE
15	PREVIOUSLY HAD THE AUTHORITY TO DO RECOMMENDATIONS
16	THAT HAVE CONDITIONS ON THEM.
17	CHAIRMAN SHEEHY: WE'RE NOT TALKING ABOUT
18	CONDITIONS. WE'RE TALKING ABOUT WE GET THIS
19	ADDITIONAL INFORMATION, THE GRANT HAS NOT BEEN
20	SCORED YET.
21	DR. FEIGAL: FIRST OF ALL, THERE'S TWO
22	ISSUES. CONCISE ANSWERS, YOU SHOULD SCORE IT DURING
23	THAT PERIOD. LET'S MAKE THAT CLEAR.
24	DR. TROUNSON: GOING TO THIS SECOND. I'M
25	JUST WORRIED THAT IF YOU HAVE TO GET ALL 15 OR CAN

1	YOU ACCEPT 13 OF THE 15?
2	MR. HARRISON: YOU WOULD NEED A QUORUM.
3	DR. TROUNSON: A QUORUM OF THE 15.
4	MR. HARRISON: A QUORUM OF THE GRANTS
5	WORKING GROUP.
6	MS. SAMUELSON: WHICH IS 23.
7	CHAIRMAN KLEIN: QUORUM OF THE 23. YOU
8	HAVE TO HAVE TWO-THIRDS OF THE 23.
9	DR. TROUNSON: THAT'S WHAT WE'VE GOT TO
10	ESTABLISH. WE'VE STILL GOT TO GET THAT.
11	MS. KING: THEN IT'S AN OFFICIAL MEETING
12	OF THE WORKING GROUP.
13	CHAIRMAN KLEIN: FIFTEEN PLUS THE PATIENT
14	ADVOCATES.
15	MS. SAMUELSON: AND THE CHAIR.
16	CHAIRMAN SHEEHY: MAYBE WE CAN SO WHY
17	DON'T WE LET STAFF AND COUNSEL KIND OF NOODLE ON
18	THIS.
19	MS. SAMUELSON: GIVE US A REVISED DRAFT.
20	CHAIRMAN SHEEHY: I THINK THE QUESTION
21	BECOMES
22	MS. SAMUELSON: AND THEN WE CAN FIGURE OUT
23	THINGS LIKE THIS. DOES IT HAVE ANY OTHER IMPACT ON
24	THE GRANT WORKING GROUP FUNCTIONING.
25	CHAIRMAN SHEEHY: THE CHAIR SHOULD
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1	PROBABLY BE INCLUDED TO THE SMALLER GROUP AND ALSO
2	THE DISEASE ADVOCATES, IF IT'S RELEVANT TO THE
3	DISEASE CATEGORY.
4	DR. FEIGAL: I THINK THE LEGAL ISSUE IS
5	JUST THAT IT NEEDS TO BE A QUORUM.
6	CHAIRMAN SHEEHY: IF WE NEED TO HAVE A
7	QUORUM
8	CHAIRMAN KLEIN: I'D LIKE TO BE ABLE TO
9	GET FROM THIS GROUP AT LEAST THEIR SENSE BECAUSE
10	THERE'S A NUMBER OF BOARD MEMBERS THAT ASKED FOR
11	THIS TO COME TO THE BOARD AT THE NEXT SESSION. SO
12	I'D LIKE TO AT LEAST IF YOU HAVE
13	CHAIRMAN SHEEHY: I THINK WE CAN SEND THIS
14	FORWARD TO THE BOARD ACTUALLY. I DON'T THINK
15	BECAUSE THIS IS NOT GOING TO BE PERFECT, I DON'T
16	THINK. WE'RE GOING TO GO AND WE'RE GOING TO USE
17	THIS AND WE'RE GOING TO SAY
18	DR. FEIGAL: THAT WOULD BE MY SUGGESTION,
19	THAT WE GIVE BUY-IN ON SOME OF THE DETAILS TO THE
20	BIGGER CONCEPT. FRANKLY, WE'RE NOT GOING TO BE ABLE
21	TO TRY THIS OUT UNTIL NEXT YEAR.
22	MS. SAMUELSON: THEN, FOR GOODNESS SAKES,
23	LET'S WAIT TILL THE NEXT BOARD MEETING.
24	DR. FEIGAL: WELL, WE DON'T NEED TO WAIT.
25	I THINK

1	MS. SAMUELSON: IF IT WAS IN SUCH A RUSH,
2	WHY DIDN'T WE GET THE MATERIAL EARLIER? WE SHOULD
3	HAVE SOME KIND OF TIMETABLE.
4	DR. FEIGAL: I THINK WHAT WE'RE TRYING TO
5	DO IS BE RESPONSIVE TO THE BOARD AND TO AT OUR
6	LAST REVIEW GROUP MEETING, WE HAD TOLD PEOPLE THAT
7	WE WERE GOING TO DO THIS IN DUE DILIGENCE, AND WE
8	TRIED TO PASS THIS FORWARD. SO JUST LET US KNOW
9	HOW
10	MS. SAMUELSON: I'D LIKE TWO WEEKS NOTICE
11	FOR ANY CHANGES IN THE PROCESS.
12	CHAIRMAN SHEEHY: I HAVE A MOTION ON THE
13	FLOOR, AND I'D LIKE TO GET A SECOND, AND THEN I'M
14	GOING TO TAKE PUBLIC COMMENT.
15	DR. STEWARD: ACTUALLY CAN I JUST SUGGEST
16	THAT WE NOT VOTE ON THIS? I ACTUALLY THINK THERE'S
17	A NUMBER OF ELEMENTS TO THIS THAT, AS JOAN SAID, WE
18	PROBABLY NEED TO THINK ABOUT. I DON'T SEE THE BIG
19	RUSH EITHER. WE HAVE PLENTY OF TIME. WE'RE NOT
20	GOING TO BE ABLE TO ACTUALLY WANT TO USE IT UNTIL
21	NEXT YEAR. WHY DON'T WE REPORT BACK TO THE BOARD
22	THAT WE HAVE HAD A CAREFUL DISCUSSION, THAT THERE
23	ARE POINTS THAT ARE BEING REVISED INTO A NEW DRAFT,
24	AND TAKE IT UP AT THE NEXT MEETING OF THE SCIENCE
25	COMMITTEE HERE, AND THEN GO TO THE BOARD AT ITS

1	FOLLOWING MEETING. I THINK THAT THAT'S A GOOD TIME
2	FRAME FOR GETTING IT IN PLACE WHEN WE NEED IT.
3	CHAIRMAN KLEIN: I TRIED TO HANDLE A
4	RESPONSE OR COMMITMENT I MADE TO THE BOARD TO BRING
5	IT TO THE BOARD. AFTER THE CLINICAL TRIAL ROUNDS,
6	THERE WERE SEVERAL BOARD MEMBERS THAT SPECIFICALLY
7	WANTED THIS TO COME TO THE BOARD SO THEY COULD
8	ADDRESS THIS WHILE THIS WAS FRESH IN THEIR MINDS AND
9	THEY COULD DEAL WITH IT. AND SINCE IT HAS BEEN
10	DEVELOPED, AND IMPLEMENTING ANYTHING LIKE THAT TAKES
11	SOME LEAD-TIME AND YOU'RE GOING TO WANT TO LET THE
12	PEOPLE IN THE GRANT ROUNDS KNOW ABOUT IT
13	DR. FEIGAL: I WAS GOING TO SAY THE
14	SOLICITATION WE HAVE TO LET THE THERE'S A
15	PROACTIVE PART. WE ACTUALLY NEED TO LET THEM KNOW
16	BEFORE THE FALL. IF WE DON'T PRESENT IT IN JUNE, WE
17	DON'T HAVE MUCH TIME.
18	CHAIRMAN SHEEHY: HONESTLY, I DON'T SEE
19	WHAT THE ISSUES ARE. I ONLY SEE ONE ISSUE THE
20	TWO ISSUES ARE DO WE HAVE A TELEPHONE OR DO WE HAVE
21	E-MAIL? DO WE DO IT BEFORE THE SESSION OR DURING
22	THE ACTUAL REVIEW? THE OTHER QUESTION I SEE THAT'S
23	HERE IS DO WE USE THE FULL WORKING GROUP OR A
24	SMALLER GROUP. THESE ARE NOT OVERALL THIS POLICY
25	SEEMS TO ME TO BE FAIRLY WELL DEVELOPED TO ADDRESS A
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1	CRITICAL QUESTION AND SOMETHING THAT BOARD MEMBERS
2	HAVE DISCUSSED.
3	BOB'S OFFERED A MOTION THAT KIND OF
4	ADDRESSES THE THREE LIVE QUESTIONS THAT WE'VE
5	IDENTIFIED. I DON'T KNOW WHAT FURTHER REFINEMENT.
6	WE CAN GO AROUND AND AROUND, BUT I DON'T KNOW WHAT
7	FURTHER REFINEMENT PEOPLE WOULD LIKE TO SEE HAPPEN.
8	CHAIRMAN KLEIN: WE HAVE THE ABILITY WE
9	HAVE A THREE-WEEK PERIOD BEFORE THE BOARD MEETING TO
10	FURTHER FIGURE OUT WHAT OUR POSITIONS HERE, READ
11	MATERIALS BECAUSE IT'S GOING TO BE DEBATED AT THE
12	BOARD AS WELL. SO THIS IS NOT OUR ONLY SHOT AT
13	THIS. WE'RE TRYING TO MOVE IT FORWARD WITH
14	ESSENTIALLY WHERE THIS COMMITTEE IS.
15	CHAIRMAN SHEEHY: I THINK IT'S USEFUL. I
16	DON'T THINK WE'RE REVIEWING GRANTS AT THE NEXT BOARD
17	MEETING, SO WE ACTUALLY COULD HAVE TIME TO LOOK AT
18	THIS.
19	SO IS THERE A SECOND FOR MR. KLEIN'S
20	MOTION?
21	MR. TORRES: SECOND.
22	CHAIRMAN SHEEHY: SENATOR TORRES HAS
23	SECONDED IT.
24	MS. SAMUELSON: I'M GOING TO HAVE TO VOTE
25	AGAINST IT, AND I DON'T WANT TO DO THAT. I JUST
	F-1

1	FEEL LIKE IN GOOD CONSCIENCE, I NEED TO FEEL LIKE
2	THE PROCESS WAS DELIBERATIVE ENOUGH, AND I JUST
3	DON'T FEEL THAT WAY.
4	CHAIRMAN SHEEHY: THAT'S FINE. SO IS
5	THERE ANY PUBLIC COMMENT AT ANY OF THE SITES?
6	DR. TROUNSON: I JUST WANTED TO CLARIFY.
7	WAS THE PREFERENCE FOR THE FULL REVIEW IN YOUR
8	PROPOSAL? WAS IT FOR THE SHORTENED?
9	CHAIRMAN KLEIN: I WAS MOVING IT FORWARD
10	WITH PROVIDING THE OPTION. SO IF YOU COULDN'T
11	CONVENE THE ENTIRE GRANTS REVIEW, YOU HAD A BACKUP
12	OPTION THAT WOULDN'T STOP IT GOING TO THE BOARD.
13	AND I WOULD SAY A YEAR AGO THIS WAS I
14	BROUGHT THIS UP, AND THIS HAS BEEN BROUGHT UP IN
15	DISCUSSIONS OF THE BOARD SUBSEQUENTLY ON TWO
16	OCCASIONS, IT WAS BROUGHT UP IN A BRIEFING CALL TO
17	THE PATIENT ADVOCATES BEFORE THE LAST REVIEW AS A
18	PART OF THE PROPRIETARY BRIEFING MATERIALS. AND SO
19	THIS IS NOT A NEW DISCUSSION, AND I THINK WE HAVE AN
20	OBLIGATION, BECAUSE WE'VE BEEN TALKING TO MEMBERS OF
21	THE BOARD ABOUT BRINGING IT TO THEM FOR A LONG TIME,
22	AND WE'RE JUST VERY APPRECIATIVE OF THE WORK THAT'S
23	BEEN DONE, WE'LL HAVE A CHANCE TO FULLY DEBATE IT AT
24	THE BOARD AS WELL.
25	MS. SAMUELSON: THOSE FOLKS SHOULD JOIN
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1	THE SUBCOMMITTEE. THAT WAS SORT OF A JOKE, BOB.
2	CHAIRMAN KLEIN: OKAY. THANKS.
3	CHAIRMAN SHEEHY: CALL THE ROLL.
4	CHAIRMAN KLEIN: DID WE ASK FOR PUBLIC
5	COMMENT?
6	CHAIRMAN SHEEHY: I DID ASK FOR PUBLIC
7	COMMENT AND NONE.
8	MS. KING: SUSAN BRYANT.
9	DR. BRYANT: YES.
10	MS. KING: MARCY FEIT.
11	MS. FEIT: YES.
12	MS. KING: BOB KLEIN.
13	CHAIRMAN KLEIN: YES.
14	MS. KING: DUANE ROTH.
15	MR. ROTH: YES.
16	MS. KING: JOAN SAMUELSON.
17	MS. SAMUELSON: NO.
18	MS. KING: JEFF SHEEHY.
19	CHAIRMAN SHEEHY: YES.
20	MS. KING: OS STEWARD.
21	DR. STEWARD: YES.
22	MS. KING: ART TORRES.
23	MR. TORRES: AYE.
24	CHAIRMAN SHEEHY: OKAY. THAT MOTION
25	CARRIES.
	53

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1	AND THE NEXT ITEM FOR DISCUSSION IS ITEM
2	NO. 4, CONSIDERATION OF AN ADDITIONAL CYCLE OF NEW
3	FACULTY AWARDS.
4	DR. TROUNSON: THERE'S A DOCUMENT.
5	MS. SAMUELSON: JEFF, COULD YOU ADD TO THE
6	AGENDA A DISCUSSION OF THE TIMETABLE FOR BRINGING
7	MATERIALS TO THE SUBCOMMITTEE?
8	CHAIRMAN SHEEHY: I TAKE RESPONSIBILITY
9	FOR THE DELAY IN GETTING MATERIALS FOR IT, JOAN.
10	MS. SAMUELSON: WE'RE GOING TO IN A MINUTE
11	BE VOTING ON SOMETHING THAT I DIDN'T HAVE ANY TIME
12	TO LOOK AT AT ALL BECAUSE IT ARRIVED ABOUT AN HOUR
13	AGO.
14	CHAIRMAN SHEEHY: I UNDERSTAND. I
15	UNDERSTAND. WE'RE TRYING. ALL OF US
16	MS. SAMUELSON: I'M NOT COMPLAINING AS
17	LONG AS I'M NOT OBLIGATED TO MAKE DECISIONS ON IT IN
18	REAL TIME. IT'S CRAZY. IT ISN'T PROFESSIONAL. IT
19	BUGS ME. SO I THINK IF WE CAN'T BE SURE THAT
20	STAFF WILL GET IT TO US, THEN WE'VE GOT TO SET A
21	TIME FRAME.
22	CHAIRMAN SHEEHY: I THINK IT'S SOMETHING
23	WE CAN DISCUSS AT THE NEXT SUBCOMMITTEE MEETING.
24	RIGHT NOW
25	MS. SAMUELSON: SO WE CAN WAIT ON THAT
	5.4

1	ONE. ALL RIGHT. OKAY. GO AHEAD.
2	CHAIRMAN SHEEHY: SO THE NEW FACULTY,
3	WHICH, DR. OLSON, WERE YOU GOING
4	DR. OLSON: WHAT I'D LIKE TO DO IS JUST
5	ASK DR. YAFFE TO SUMMARIZE THE CURRENT NEW FACULTY
6	PROGRAMS WE HAVE, AND THEN I'D LIKE TO TALK A LITTLE
7	BIT ABOUT WHAT A NEW FACULTY PROGRAM GOING FORWARD
8	MIGHT LOOK LIKE. AND, JOAN, I DO APOLOGIZE FOR THE
9	DELAY IN GETTING THE MATERIALS OUT. THAT WAS
10	ACTUALLY MY FAULT. I'M NOT GOING TO LET JEFF TAKE
11	THE BLAME FOR THAT. AND I APOLOGIZE BECAUSE I'VE
12	BEEN WORKING ON GETTING AN RFA OUT. SO THERE IS A
13	LOT OF THINGS GOING ON RIGHT NOW. SO THAT'S WHOLLY
14	MY PROBLEM, AND I TAKE FULL RESPONSIBILITY FOR IT.
15	NONETHELESS, I THINK THAT THE DIALOGUE
16	HERE SHOULD BE HELPFUL IN ESSENTIALLY CLARIFYING
17	THINGS. SO WHAT I'D LIKE TO DO FIRST IS ASK DR.
18	YAFFE TO SUMMARIZE A LITTLE BIT WHAT THE CURRENT NEW
19	FACULTY PROGRAMS ARE.
20	DR. YAFFE: SO AS I'M SURE MOST OF YOU
21	REMEMBER, NEW FACULTY WAS RUNNING TWO ROUNDS, NEW
22	FACULTY I AND II ESSENTIALLY WITH THE SAME PROGRAM
23	GOALS, AWARD FEATURES, AND REVIEW CRITERIA. THE
24	PROGRAM GOALS WERE TO SUPPORT INNOVATIVE RESEARCH
25	PROGRAMS OF NEWLY INDEPENDENT SCIENTISTS AND

1	PHYSICIAN/SCIENTISTS AT A CRUCIAL EARLY STAGE OF
2	THEIR CAREERS AND TO RECRUIT THE TOP YOUNG
3	SCIENTISTS AND PHYSICIAN/SCIENTISTS TO STEM CELL
4	RESEARCH.
5	AND THESE AWARDS PROVIDED SALARY, ACTUALLY
6	ARE PROVIDING SALARY AND RESEARCH SUPPORT FOR UP TO
7	FIVE YEARS, DIRECT PROJECT COSTS OF \$300,000 PER
8	YEAR FOR SCIENTIST AWARD OR \$400,000 PER YEAR FOR
9	PHYSICIAN/SCIENTISTS. I MIGHT MENTION THE ADDED
10	AMOUNT OF PHYSICIAN/SCIENTISTS IS DIRECTED AT BUYING
11	OFF THEIR TIME FROM CLINICAL WORK SO THAT THEY CAN
12	COMMIT MORE TIME TO LABORATORY RESEARCH.
13	AND ADDITIONALLY, THE NEW FACULTY AWARD
14	SUPPORTED RESEARCH USING A BROAD SPECTRUM OF CELL
15	TYPES AND APPROACHES, INCLUDING MODEL SYSTEMS. AND
16	FROM THAT STANDPOINT, IT'S RATHER UNIQUE AMONG OUR
17	RESEARCH GRANTS.
18	CURRENTLY THERE ARE 43 ACTIVE NEW FACULTY
19	AWARDS FROM THE TWO RFA'S. THE TWO RFA'S WERE
20	WITHIN ONE YEAR OF EACH OTHER, SO NEW FACULTY I
21	AWARDS, THE MAJORITY ARE IN YEAR FOUR NOW, YEAR FOUR
22	OF FIVE. NEW FACULTY II AWARDS ARE ALL IN YEAR
23	THREE. OF THOSE 43 AWARDS, 17 WERE
24	PHYSICIAN/SCIENTISTS. HERE PHYSICIAN/SCIENTIST WAS
25	DEFINED AS SOMEONE WITH AN M.D. OR M.D. AND PH.D.

1	DEGREE. THE FACULTY AWARDED REPRESENT 18 DIFFERENT
2	INSTITUTIONS IN CALIFORNIA.
3	AMONG THE FUNDED PROJECTS, IF WE LOOK AT
4	THE AREA OF RESEARCH AND DIVIDE IT AMONG BASIC
5	RESEARCH, CANDIDATE DISCOVERY, WHICH ROUGHLY FALLS
6	INTO MANY OF OUR EARLY TRANSLATION ACTIVITIES, OR
7	PRECLINICAL RESEARCH.
8	THERE ARE 33 GRANTS OR PROJECTS IN BASIC
9	RESEARCH, 10 IN CANDIDATE DISCOVERY, AND ONE
10	THERE'S A MISTAKE ON THE TABLE ONE IN PRECLINICAL
11	RESEARCH.
12	MS. SAMUELSON: COULD YOU
13	DR. YAFFE: AWARDED TO NEW FACULTY. THESE
14	ARE ONLY NEW FACULTY RESEARCH AWARDS.
15	MS. SAMUELSON: COULD YOU REPEAT THOSE
16	NUMBERS?
17	DR. YAFFE: CERTAINLY.
18	MS. SAMUELSON: THANK YOU.
19	DR. YAFFE: THERE ARE 33 IN BASIC
20	RESEARCH, 10 IN CANDIDATE DISCOVERY, AND ONE IN
21	PRECLINICAL RESEARCH.
22	I WANT TO POINT OUT THAT SOME OF THE NEW
23	FACULTY AWARDEES HAVE OTHER GRANTS FROM US. AND SO
24	THERE ARE OTHER SOME OF THESE NEW FACULTY
25	AWARDEES ARE INVOLVED IN OTHER TYPES OF RESEARCH.

1	WHAT I'M GIVING YOU IS THE INFORMATION ABOUT THE
2	PROJECTS SUPPORTED BY THE NEW FACULTY AWARDS.
3	THE NEW FACULTY GRANTEES HAVE BEEN VERY
4	PRODUCTIVE. OF COURSE, THIS IS VERY PRELIMINARY
5	BECAUSE NONE OF THESE AWARDS HAVE BEEN COMPLETED
6	YET, AND MUCH OF THE RESEARCH IS IN A FORMATIVE
7	STAGE. BUT ALREADY WE KNOW OF AT LEAST 133
8	PUBLICATIONS, 59 IN HIGH IMPACT JOURNALS THAT HAVE
9	RESULTED FROM THESE AWARDS, SIX INVENTION
10	DISCLOSURES, AND 5 PATENT APPLICATIONS FILED. AND
11	THERE ARE SIGNIFICANT IMPACTS AND PROGRESS TOWARDS
12	SEVERAL OF THE CIRM STRATEGIC GOALS, INCLUDING NOVEL
13	INSIGHTS INTO SELF-RENEWAL AND ONCOGENICITY OF STEM
14	CELLS AND PROGRESS TOWARDS UNCOVERING KEY MECHANISMS
15	OF STEM CELL DIFFERENTIATION.
16	AND I HAVE A WHOLE FOLDER HERE OF MORE
17	BACKGROUND INFORMATION. IF ANYONE NEEDS THAT OR
18	WANTS THAT, I'M HAPPY TO SUPPLY IT.
19	MS. SAMUELSON: I'D LOVE TO SEE IT FOR
20	ONE.
21	DR. OLSON: I ASKED DR. YAFFE TO GIVE YOU
22	A BIT OF AN OVERVIEW OF THE PROGRAM TO DATE BECAUSE
23	IN DISCUSSIONS THAT HAVE OCCURRED AT THE BOARD, WHAT
24	I THINK HAS BEEN HIGHLIGHTED IS THE FACT THAT WE
25	REALLY NEED TO ENCOURAGE PARTICIPATION OF
	F.O.

1	PHYSICIAN/SCIENTISTS IN STEM CELL RESEARCH AND
2	PARTICULARLY IN THE TRANSLATIONAL ASPECTS OF IT.
3	SO IN KEEPING WITH AND THIS ACTUALLY
4	FOCUSES ON THE MANDATE PUT FORTH BY THE EXTERNAL
5	REVIEW TOO IS TO FOSTER MOVING THINGS INTO THE
6	CLINIC. SO ONE THOUGHT WAS THAT IF WE WANTED TO
7	OFFER A NEW FACULTY AWARD AGAIN, THAT IT MIGHT HAVE
8	A FOCUS ON PHYSICIAN/SCIENTISTS WHO ARE IN THE EARLY
9	STAGES OF THEIR CAREER. SO LET ME REMIND YOU THE
10	EARLY STAGES OF THEIR CAREER REFERS TO THEIR FIRST
11	SIX YEARS AS AN INDEPENDENT FACULTY MEMBER. SO THAT
12	WOULD BE THE IDEA THERE.
13	SO WHAT WE WERE THINKING OF WOULD BE TO
14	ENCOURAGE, IF WE WANTED TO DO A NEW FACULTY AWARD,
15	WE WOULD DO IT FOR PHYSICIAN/SCIENTISTS FOR THE
16	CONDUCT OF EARLY TRANSLATIONAL RESEARCH. THAT,
17	AGAIN, THE KINDS OF ELIGIBILITY WE WERE THINKING OF,
18	THIS IS A PROGRAM FOR ACADEMIC AND NONPROFIT
19	RESEARCH ORGANIZATIONS. SO FACULTY IMPLIES EXACTLY
20	THOSE TWO ORGANIZATIONS. THIS WOULD NOT BE FOR
21	FOR-PROFITS. THERE WOULD OBVIOUSLY NOTHING BE
22	PREVENTING THEM FROM COLLABORATING WITH FOR-PROFIT
23	INSTITUTIONS.
24	WE WOULD USE OUR INSTITUTIONAL LIMIT
25	PROCESS. IN FACT, I WOULD USE THE SAME LIMITS THAT
	F.O.

1	WE PROPOSED BEFORE FOR THE NEW FACULTY EXCEPT IN
2	THIS CASE, RATHER THAN SPLITTING BETWEEN PH.D.
3	SCIENTISTS AND PHYSICIAN/SCIENTISTS, WE WOULD HAVE
4	ALL THE SLOTS WOULD BE FILLED WOULD HAVE THE
5	OPPORTUNITY TO BE FILLED BY PHYSICIAN/SCIENTISTS.
6	MS. SAMUELSON: WHAT DOES THAT MEAN,
7	INSTITUTIONAL LIMITS? I DON'T MEAN TO INTERRUPT.
8	DR. OLSON: AT LEAST WHAT WE DID IN OUR
9	PREVIOUS NEW FACULTY PROGRAM AND, AGAIN, WHAT WE
10	WOULD PROPOSE TO DO WITH THIS ONE WAS THAT LIMITS IN
11	THE SENSE THAT IF AN ORGANIZATION HAD A MEDICAL
12	SCHOOL ASSOCIATED WITH IT, THEY COULD RECOMMEND FOUR
13	PERSONS FOR A NEW FACULTY PROGRAM, FOUR
14	PHYSICIAN/SCIENTISTS. AND, AGAIN, I AM DEFINING
15	PHYSICIAN/SCIENTIST IN THE SAME WAY THAT MICHAEL
16	DID. THEY EITHER HAVE AN M.D. DEGREE OR THEY HAVE
17	AN M.D. DEGREE AND A PH.D. DEGREE. SO FOUR SLOTS
18	FOR INSTITUTIONS THAT HAVE AN ACCREDITED MEDICAL
19	SCHOOL ASSOCIATED WITH THEM AND FOR INSTITUTIONS
20	THAT DO NOT HAVE THAT, TWO SLOTS.
21	WHAT THAT RESULTED IN BEFORE WAS ROUGHLY
22	BETWEEN 50 AND 60 APPLICATIONS, WHICH IS A NUMBER
23	THAT OUR GRANTS WORKING GROUP CAN HANDLE.
24	MS. SAMUELSON: MOST OF THOSE WERE BASIC
25	SCIENTISTS, RIGHT?

1	DR. OLSON: WELL, I THINK WHAT MICHAEL WAS
2	TRYING TO MAKE CLEAR THROUGH HIS PREVIOUS SUMMARY
3	WAS THAT EVEN PHYSICIAN/SCIENTISTS WERE CONDUCTING
4	BASIC RESEARCH.
5	MS. SAMUELSON: THAT'S PART OF THE
6	DAY-TO-DAY JOB, AS I UNDERSTAND IT, OF ALL OF THEM.
7	BUT IF WE'RE TRYING TO INCREASE THE NUMBER THAT ARE
8	DOING TRANSLATIONAL RESEARCH, AND LAST TIME IT WAS
9	33 OR SO BASIC SCIENTISTS AND WHATEVER IT WAS, 10 OR
10	11, TRANSLATIONAL ONES, HOW TO INCREASE THAT NUMBER,
11	I GUESS, IS MY QUESTION.
12	DR. BRYANT: I HAVE A COMMENT ON THAT
13	ALSO. I THINK I COMPLETELY APPROVE OF THE GOAL OF
14	INCREASING THE NUMBER OF TRANSLATIONAL PROJECTS, BUT
15	I THINK LIMITING THE APPLICANTS TO JUST M.D. OR
16	M.D./PH.D. CANDIDATES IS LIMITING THE POOL. THERE
17	ARE PLENTY OF BASIC SCIENTISTS WHO ARE MOVING IN
18	THAT DIRECTION. I THINK IF YOU WANT TO GET THE BEST
19	POOL POSSIBLE, YOU SHOULD NOT LIMIT THE APPLICATIONS
20	THAT WAY.
21	CHAIRMAN SHEEHY: OKAY. SO MAYBE IF WE
22	COULD LET DR. OLSON FINISH MAKING HER PRESENTATION,
23	AND THEN MAYBE WE COULD TAKE QUESTIONS THEN AND KIND
24	OF IDENTIFY THE POINTS WHERE WE WANT TO HAVE
25	DISCUSSION.
	<i>C</i> 1

1	DR. OLSON: I WOULD POINT OUT INSTITUTIONS
2	GET TO NOMINATE THE CANDIDATES. AS YOU INDICATE,
3	IT'S A POINT OF DISCUSSION WITH THIS GROUP AND THEN
4	WITH THE BROADER BOARD AS TO WHO IT SHOULD BE
5	ELIGIBLE FOR. I JUST THINK WE HAVE BEEN HEARING
6	FROM PEOPLE THAT IT IS VERY DIFFICULT TO GET
7	PHYSICIAN/SCIENTISTS. THEY'RE CRITICAL TO
8	TRANSLATIONAL RESEARCH. IT'S IMPORTANT TO GET THEM
9	INVOLVED. WE'RE TRYING TO PROVIDE A WAY FOR
10	INSTITUTIONS TO ENCOURAGE THAT INVOLVEMENT.
11	SO I THINK I WENT THROUGH WHO WE WOULD
12	TARGET, WHO WE WERE SUGGESTING TARGETING IT TOWARDS.
13	AS FAR AS AWARD INFORMATION, I THINK THE
14	PREVIOUS AWARD WAS FIVE YEARS, AND THE RATIONALE FOR
15	THAT IS, AGAIN, IF YOU'RE A NEW FACULTY IN THE EARLY
16	STAGES OF YOUR CAREER, THE IDEA IS SOME OF STABILITY
17	OF FUNDING. AGAIN, THAT MIGHT BE A POINT OF
18	DISCUSSION. OUR TYPICAL AWARD IS THREE YEARS. SO
19	BASICALLY AFTER THE FIRST TWO YEARS, YOU HAVE TO
20	START WRITING THE NEXT AWARD.
21	AGAIN, WE WOULD DO THE TOTAL DIRECT
22	PROJECT COST AT 400,000 A YEAR FIGURE TO ESSENTIALLY
23	BUY TIME. I BELIEVE NIH IS ROUGHLY \$250,000 A YEAR.
24	SO WE ARE PROVIDING CERTAINLY GOOD FUNDING TO HELP
25	WITH THIS.

1	THESE PROGRAMS ARE NOT INEXPENSIVE. A
2	FIVE-YEAR PROGRAM, ASSUMING A ROUGHLY EQUIVALENT
3	INDIRECT AND OTHER RATES, FACILITIES RATE, YOU END
4	UP BEING ABOUT AN \$80 MILLION PROGRAM FOR ABOUT 20
5	AWARDS.
6	THE TIMELINE, AND THIS IS GIVEN THE
7	CURRENT SCHEDULE AND TAKING INTO CONSIDERATION THAT
8	WE WOULD NOT HAVE TO DO A PREAP REVIEW OR ANYTHING
9	LIKE THAT, WE CAN POST THIS RFA NEXT SPRING, AND WE
10	COULD REVIEW IT IN THE LATE FALL OF NEXT YEAR. SO
11	THAT'S WHEN WE HAVE OPEN REVIEW SLOTS. I WOULD JUST
12	POINT OUT WE HAVE WHAT WAS THE INTRODUCTION OF THE
13	CLINICAL ADVISORY PANEL, WE ARE DOING A LOT OF
14	EXTERNAL OR GROUP REVIEWS OF VARIOUS TYPES. SO THIS
15	IS A BIG DEAL FOR THE REVIEW OFFICE AND I THINK THE
16	SCIENCE OFFICE IN GENERAL. THAT'S WHAT THE PROPOSAL
17	IS. I'M HAPPY TO ANSWER ANY QUESTIONS OR HEAR ANY
18	DISCUSSION ABOUT IT.
19	CHAIRMAN SHEEHY: SO I HAVE SENATOR
20	TORRES. DR. BRYANT, I ASSUME I STILL HAVE YOU.
21	DR. BRYANT: I'M HERE.
22	CHAIRMAN SHEEHY: JOAN.
23	MS. SAMUELSON: YEP.
24	CHAIRMAN SHEEHY: ARE THERE OTHERS WHO
25	WOULD LIKE TO MAKE COMMENTS? BOB. THAT'S IT. DR.
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1	TROUNSON. SO I THINK, DR. BRYANT, YOU HAD ALREADY
2	RAISED QUESTIONS, AND THEN I'M GOING TO TAKE ART.
3	AND THEN DO YOU NEED TO SAY SOMETHING OR WE CAN WAIT
4	TILL WE GET YOU ON THE LIST. DR. BRYANT, GO AHEAD.
5	DR. BRYANT: IT'S JUST THAT I COMPLETELY
6	APPLAUD THE GOAL. I THINK IT KIND OF SAYS BY
7	ELIMINATING BASIC SCIENTISTS, THAT SOMEHOW THE
8	PHYSICIAN/SCIENTISTS AREN'T AS COMPETITIVE IF
9	THEY'RE IN THE SAME POOL. SO I DON'T THINK WE WANT
10	TO GIVE THAT IMPRESSION, AND I DON'T THINK THAT
11	THAT'S NECESSARILY TRUE. BUT THERE ARE M.D.
12	SCIENTISTS WHO HAVEN'T HAD RESEARCH EXPERIENCE TO
13	ANY GREAT DEGREE.
	ONE WAY TO ENCOURAGE THEM TO SET TANGLIVED
14	ONE WAY TO ENCOURAGE THEM TO GET INVOLVED
14 15	WOULD BE TO HAVE THEM PARTICIPATE WITH BASIC
15	WOULD BE TO HAVE THEM PARTICIPATE WITH BASIC
15 16	WOULD BE TO HAVE THEM PARTICIPATE WITH BASIC SCIENTISTS IN A PROJECT. SO YOU GET BOTH THE SOLID
15 16 17	WOULD BE TO HAVE THEM PARTICIPATE WITH BASIC  SCIENTISTS IN A PROJECT. SO YOU GET BOTH THE SOLID  BASIC SCIENCE AND THE PHYSICIAN EXPERIENCE, AND IT
15 16 17 18	WOULD BE TO HAVE THEM PARTICIPATE WITH BASIC  SCIENTISTS IN A PROJECT. SO YOU GET BOTH THE SOLID  BASIC SCIENCE AND THE PHYSICIAN EXPERIENCE, AND IT  WOULD BE A TRAINING OPPORTUNITY FOR THE YOUNG
15 16 17 18 19	WOULD BE TO HAVE THEM PARTICIPATE WITH BASIC  SCIENTISTS IN A PROJECT. SO YOU GET BOTH THE SOLID  BASIC SCIENCE AND THE PHYSICIAN EXPERIENCE, AND IT  WOULD BE A TRAINING OPPORTUNITY FOR THE YOUNG  PHYSICIAN/SCIENTISTS TO COLLABORATE IN THAT WAY.
15 16 17 18 19 20	WOULD BE TO HAVE THEM PARTICIPATE WITH BASIC  SCIENTISTS IN A PROJECT. SO YOU GET BOTH THE SOLID  BASIC SCIENCE AND THE PHYSICIAN EXPERIENCE, AND IT  WOULD BE A TRAINING OPPORTUNITY FOR THE YOUNG  PHYSICIAN/SCIENTISTS TO COLLABORATE IN THAT WAY.  BUT I THINK LIMITING YOU'VE GOT THIS WHOLE GROUP
15 16 17 18 19 20 21	WOULD BE TO HAVE THEM PARTICIPATE WITH BASIC  SCIENTISTS IN A PROJECT. SO YOU GET BOTH THE SOLID  BASIC SCIENCE AND THE PHYSICIAN EXPERIENCE, AND IT  WOULD BE A TRAINING OPPORTUNITY FOR THE YOUNG  PHYSICIAN/SCIENTISTS TO COLLABORATE IN THAT WAY.  BUT I THINK LIMITING YOU'VE GOT THIS WHOLE GROUP  OF PEOPLE OUT THERE WHO ARE ENTERING BASIC SCIENCE
15 16 17 18 19 20 21	WOULD BE TO HAVE THEM PARTICIPATE WITH BASIC  SCIENTISTS IN A PROJECT. SO YOU GET BOTH THE SOLID  BASIC SCIENCE AND THE PHYSICIAN EXPERIENCE, AND IT  WOULD BE A TRAINING OPPORTUNITY FOR THE YOUNG  PHYSICIAN/SCIENTISTS TO COLLABORATE IN THAT WAY.  BUT I THINK LIMITING YOU'VE GOT THIS WHOLE GROUP  OF PEOPLE OUT THERE WHO ARE ENTERING BASIC SCIENCE  OF STEM CELL RESEARCH IN THE HOPE OF ALSO MAKING IT
15 16 17 18 19 20 21 22	WOULD BE TO HAVE THEM PARTICIPATE WITH BASIC  SCIENTISTS IN A PROJECT. SO YOU GET BOTH THE SOLID  BASIC SCIENCE AND THE PHYSICIAN EXPERIENCE, AND IT  WOULD BE A TRAINING OPPORTUNITY FOR THE YOUNG  PHYSICIAN/SCIENTISTS TO COLLABORATE IN THAT WAY.  BUT I THINK LIMITING YOU'VE GOT THIS WHOLE GROUP  OF PEOPLE OUT THERE WHO ARE ENTERING BASIC SCIENCE  OF STEM CELL RESEARCH IN THE HOPE OF ALSO MAKING IT  TRANSLATIONAL. THEY JUST DON'T HAPPEN TO HAVE AN

1	THAT'S VERY APPROPRIATE AT THIS STAGE IN THE GAME.
2	DR. OLSON: LET ME RESPOND A LITTLE BIT.
3	I APPRECIATE THE COMMENT THAT BASIC SCIENTISTS MAY
4	BE INTERESTED IN TRANSLATIONAL ACTIVITIES. I WILL
5	SAY THAT FROM OUR LIMITED FROM OUR EXPERIENCE
6	HERE, IT'S A LITTLE DIFFERENT. THEY COME AT IT FROM
7	A VERY DIFFERENT PERSPECTIVE. I'M NOT SAYING THAT
8	THERE AREN'T A LOT OF VERY GOOD BASIC SCIENTISTS WHO
9	CAN DO TRANSLATIONAL RESEARCH. I THINK THE POINT
10	HERE AND THEY HAVE PLENTY OF OPPORTUNITIES TO
11	PARTICIPATE IN THAT, BY THE WAY. WE HAVE AN EARLY
12	TRANSLATIONAL RESEARCH PROGRAM, WHICH WE'RE ACTUALLY
13	WITHIN A COUPLE OF WEEKS. OF THE NEXT RFA IS GOING
14	TO BE OUT FOR IT. WE PROVIDE OPPORTUNITIES TO
15	EITHER ADDRESS SOME OF THE EARLY PROOF OF CONCEPT
16	THROUGH A DEVELOPMENT CANDIDATE FEASIBILITY AWARD.
17	WE PROVIDE OPPORTUNITIES TO TRY AND GO THE WHOLE WAY
18	THROUGH A DEVELOPMENT CANDIDATE AWARD.
19	WHAT WE ARE SPECIFICALLY TRYING TO DO HERE
20	IS FOR THOSE PHYSICIAN/SCIENTISTS TO STEP BACK TO
21	BRING THEIR PERSPECTIVE TO RESEARCH AND TO ENCOURAGE
22	THEIR PARTICIPATION IN TRANSLATIONAL RESEARCH WHERE
23	THEY CAN BRING THE PERSPECTIVE THAT IS NOT SO
24	READILY AVAILABLE. AND I THINK THAT THAT IS AN
25	IMPORTANT ASPECT OF THIS.

1	DR. BRYANT: I UNDERSTAND THAT, BUT YOU
2	CAN DO THAT IN THE REVIEW PROCESS BECAUSE IF WHAT
3	YOU'RE LOOKING FOR IS THE BEST GRANT OF A CERTAIN
4	TYPE AND APPEARANCE THAT COME THROUGH, YOU SHOULDN'T
5	NEED TO LIMIT WHO CAN APPLY FOR THEM.
6	CHAIRMAN SHEEHY: I THINK, DR. BRYANT, IF
7	YOU LOOK AT OUR INITIAL NEW FACULTY AWARD, WE SPLIT
8	IT INTO PH.D. SCIENTISTS AND THEN M.D./PH.D.
9	SCIENTISTS. AND THERE IS LIKE, AS DR. PIZZO SAID AT
10	THE LAST ICOC MEETING, THAT THERE IS A NATIONAL
11	PROBLEM. I'VE SEEN IT IN HIV WITH THE DECLINING
12	NUMBER OF PHYSICIAN/SCIENTISTS DECIDING TO DO
13	RESEARCH. IT'S JUST SO ONEROUS FOR THEM TO DO SO.
14	AND THE QUESTION WE'RE TRYING TO ADDRESS
15	IS A VERY NARROW INFRASTRUCTURE ISSUE IN TERMS OF
16	MOVING OUR SCIENCE FORWARD.
17	SO THE REALITY IS THAT, AS DR. PIZZO SAID,
18	A DECADE AGO THERE WERE 25,000 CLINICIAN/SCIENTISTS
19	IN THE U.S. AND NOW WE'RE DOWN TO 14,000. SOME OF
20	THE PROBLEMS THAT EXIST ARE WHAT WE'RE TRYING TO
21	ADDRESS WITH THIS RFA, WHICH IS PROVIDE SECURE
22	FUNDING THAT INCLUDES BUYING THEIR CLINIC TIME, BUT
23	THEY CAN ACTUALLY LAUNCH A CAREER AS A RESEARCHER AS
24	WELL AS AN M.D.
25	SO WE'RE NOT TRYING TO ANSWER A BROAD
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1	PROBLEM HERE. WE'RE TRYING TO ADDRESS A VERY NARROW
2	ONE. AND IT DOES SEEM REASONABLE TO ASSUME THAT IF
3	WE ARE GOING TO BE SUCCESSFUL IN GETTING PRODUCTS IN
4	THE CLINIC, WE NEED TO HAVE A CADRE OF
5	PHYSICIAN/SCIENTISTS WITHIN THE STATE IN ORDER TO
6	TAKE THAT RESEARCH FORWARD.
7	DR. BRYANT: I COMPLETELY AGREE. I JUST
8	THINK THAT THE MECHANISM DOESN'T HAVE TO BE
9	EXCLUSION OF BASIC SCIENTISTS. MAYBE COOPERATION
10	BETWEEN THEM WOULD BE THE THING TO GO FOR SO THAT
11	THEY CAN CROSS TRAIN EACH OTHER.
12	CHAIRMAN SHEEHY: OKAY. SENATOR TORRES.
13	MR. TORRES: I AGREE WITH DR. BRYANT, AND
14	I THINK THAT BY LIMITING THIS PROCESS, WE MIGHT
15	BASICALLY EXCLUDE SOME REAL STARS THAT WE MAY NOT
16	KNOW ABOUT.
17	MY OTHER CONCERN IS HOW DO WE COME UP WITH
18	THE 300,000 AND WHAT DOES THAT COVER? LAST TIME I
19	CHECKED A BASIC STEM CELL SCIENTIST AT UCSF IS
20	EARNING MAYBE 45, 46,000 A YEAR. WHAT DOES THE
21	300,000 COVER?
22	DR. OLSON: THE RESEARCH.
23	MR. TORRES: THAT'S WHY I'M ASKING THE
24	QUESTION.
25	DR. OLSON: SORRY. WE FORGET YOU DON'T
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1	WORK WITH THIS ON A DAILY BASIS.
2	MR. TORRES: NO, I DON'T.
3	DR. OLSON: I'LL LET DR. YAFFE RESPOND.
4	DR. YAFFE: ONE PORTION OF THAT WOULD BE
5	SALARY AT A THE PERCENTAGE. THE VAST MAJORITY OF
6	THAT WOULD BE THE ACTUAL COST OF THE RESEARCH FOR
7	PERSONNEL AND SUPPLIES AND SOME MONEY FOR EQUIPMENT.
8	SO OUT OF THE 400,000, YOU'RE ABSOLUTELY RIGHT. THE
9	SALARY WOULD BE WELL, IT DEPENDS ON WHAT LEVEL
10	THEY ARE, BUT THE SALARY WOULD BE 50 TO \$100,000.
11	MR. TORRES: I THINK THAT'S IMPORTANT TO
12	PUT OUT THERE BECAUSE OTHERWISE THE PUBLIC THINKS
13	WE'RE PAYING THESE SCIENTISTS AS MUCH AS SOME PEOPLE
14	WANT TO PAY THE NEXT CHAIR.
15	DR. OLSON: THIS IS IN EVERY CONCEPT
16	PROPOSAL THAT COMES TO YOU. WE TALK ABOUT THE
17	DIRECT PROJECT COST, AND THAT DOESN'T IT'S
18	USUALLY ONLY A FRACTION OF THE PI SALARY, THE
19	PRINCIPAL INVESTIGATOR'S SALARY.
20	DR. STEWARD: COULD I JUST RAISE ONE
21	ISSUE? I ACTUALLY AM VERY STRONGLY SUPPORTIVE OF
22	PROGRAMS TO PROVIDE WAYS FOR CLINICALLY TRAINED
23	INDIVIDUALS TO GET INTO RESEARCH AND TO GET GOING.
24	AND ALL OTHER THINGS BEING EQUAL, I THINK I WOULD
25	
	ACTUALLY AGREE THAT THIS SHOULD BE LIMITED TO THOSE

1	SORTS OF INDIVIDUALS.
2	BUT THERE'S ONE ISSUE HERE THAT MIGHT BE
3	JUST WORTH MENTIONING. AND IT IS THAT ALTHOUGH IT
4	IS AN OPEN COMPETITION, THE FACT OF THE MATTER IS
5	THAT THERE'S ESSENTIALLY ZERO CHANCE THAT YOU'RE
6	GOING TO HAVE AN M.D. AT AN INSTITUTION THAT DOES
7	NOT HAVE A MEDICAL SCHOOL. SO DE FACTO YOU'RE
8	LIMITING THIS TO CERTAIN INSTITUTIONS, AND I'M
9	WORRIED ABOUT THAT.
10	CHAIRMAN SHEEHY: OKAY. THEN I HAVE JOAN
11	NEXT AND THEN BOB AND THEN DR. TROUNSON.
12	MS. SAMUELSON: I'VE GOT A COUPLE
13	QUESTIONS, BUT FIRST I WANT TO UNDERSTAND OS' POINT
14	BETTER.
15	CHAIRMAN SHEEHY: DR. FEIGAL HAS A COMMENT
16	TOWARDS THAT.
17	MS. SAMUELSON: I'D LIKE OS TO EXPLAIN
18	WHAT HE MEANT FIRST.
19	DR. STEWARD: JUST THAT REALLY PEOPLE WHO
20	HAVE M.D. DEGREES END UP AT PLACES WHERE THERE ARE
21	MEDICAL SCHOOLS. I DON'T KNOW OF A SINGLE PERSON
22	WHO'S RECEIVED AN M.D. WHO ENDS UP AT AN INSTITUTION
23	THAT DOESN'T HAVE A MEDICAL SCHOOL ASSOCIATED WITH
24	IT. NOW, THERE ARE SOME OUT THERE THAT I DON'T KNOW
25	ABOUT, BUT I THINK IT'S REALLY, REALLY RARE.

1	DR. FEIGAL: RESEARCH INSTITUTE. THERE'S
2	SOME AS INDEPENDENT RESEARCH.
3	DR. YAFFE: DR. STEWARD, THERE ARE
4	CERTAINLY M.D.'S AT THE BURNHAM INSTITUTE. THERE
5	ARE M.D.'S AT SCRIPPS CLINIC THAT DOESN'T HAVE A
6	MEDICAL SCHOOL. THERE ARE M.D.'S AT THE GLADSTONE.
7	THESE ARE ALL GRANTEES.
8	DR. STEWARD: WAIT A MINUTE. LET ME MAKE
9	MYSELF VERY CLEAR. I DON'T MEAN INSTITUTIONS THAT
10	ARE CLINICAL. OF COURSE, THERE ARE M.D.'S THERE.
11	AND THOSE ARE M.D.'S WITH BASIC SCIENCE DEGREES.
12	I'M TALKING ABOUT PLACES LIKE UC BERKELEY OR UC
13	MERCED OR PLACES LIKE THAT WHERE THEY MIGHT HAVE
14	SOMEONE WHO IS AN UP AND COMING STEM CELL STAR. AND
15	BY LIMITING IT TO M.D.'S, WE WOULD BE, AGAIN, DE
16	FACTO EXCLUDING THEM.
17	CHAIRMAN SHEEHY: WE'VE IDENTIFIED THAT AS
18	AN ISSUE. DR. BRYANT RAISED IT TOO. SO THAT CAN BE
19	PART OF WHAT WE PROPOSE. AND I JUST WANT TO REMIND
20	PEOPLE THAT WE'RE WORKING OFF A TEMPLATE. SO WE'RE
21	NOT DESIGNING A COMPLETELY NEW RFA. WE'RE WORKING
22	OFF THE IDEA HERE WAS TO REPEAT A ROUND THAT
23	ALREADY HAPPENED. THE FIRST ROUND HAD PH.D. FACULTY
24	AND M.D./PH.D. FACULTY, AND M.D. FACULTY. IF THE
25	DECISION HERE IS TO RESPOND THIS TO ENCOMPASS A
	70

1	BROADER RANGE OF INDIVIDUALS, I THINK THAT THAT DOES
2	HAVE TO BE PLACED IN SOME SORT OF CONTEXT OF WHAT
3	OUR STRATEGIC PLAN IS GOING FORWARD.
4	WE DO FUND A LOT OF BASIC SCIENCE RIGHT
5	NOW. BUT HAVING SAID THAT, THIS IS REALLY A
6	DECISION FOR THIS COMMITTEE AND FOR THE BOARD TO
7	MAKE.
8	THE NEXT PERSON, JOAN, YOU WERE MAKING
9	COMMENTS. AND SO I DON'T THINK THAT YOU HAD AN
10	OPPORTUNITY TO FINISH WHAT YOU ARE SAYING. WOULD
11	YOU LIKE TO GO AHEAD?
12	MS. SAMUELSON: YOU BET. THANKS. IT
13	SOUNDS LIKE TO ME WHAT WE'RE TRYING TO DO IS WE'RE
14	LOOKING AT A SPECIFIC TYPE OF RFA THAT WAS USED
15	BEFORE, BUT TALKING AT THE SAME TIME IN THE WIDER
16	CONTEXT OF HOW DO WE INCREASE TRANSLATIONAL RESEARCH
17	IN OUR RESEARCH PORTFOLIO. AND THERE MAY BE I'M
18	HEARING THAT THERE ARE A VARIETY OF WAYS TO DO THAT.
19	I'M WONDERING IF THAT DOESN'T DESERVE ITS OWN
20	SPECIAL ATTENTION. MAYBE WITH THIS RFA A PIECE OF
21	THAT DISCUSSION, THAT WE WOULD HAVE ANOTHER DATE
22	WHERE WE'RE REALLY FOCUSED ON IT AND HAVE THE
23	ABILITY TO LOOK AT ALL THE VARIOUS MECHANISMS THAT
24	HAVE BEEN SUCCESSFUL ANYWHERE ELSE.
25	CHAIRMAN SHEEHY: THEN I HAVE BOB.

1	CHAIRMAN KLEIN: SO GIVEN THE POINTS THAT
2	HAVE BEEN RAISED, A BLENDED APPROACH COULD BE
3	POSSIBLE HERE. THE ORIGINAL ROUND I AND ROUND II
4	WERE SET UP WITH ESSENTIALLY PRODUCED 60 PERCENT
5	IN THE BASIC SCIENCE AWARDS AND 40 PERCENT OF
6	PHYSICIAN/SCIENTISTS, IN FACT EXCUSE ME. THAT'S
7	NOT TRUE. THERE'S 43 AWARDS IN THE ORIGINAL TWO
8	ROUNDS. SEVENTEEN OF THOSE AND ACTUALLY IT COMES
9	OUT JUST UNDER 40 PERCENT, 38 PERCENT OR SOMETHING.
10	WE COULD POTENTIALLY, KNOWING THAT THERE'S
11	THIS REAL SHORTAGE OF CLINICALLY TRAINED INDIVIDUALS
12	IN STEM CELL RESEARCH THAT ARE CRITICAL FOR THE
13	TRANSLATIONAL PROCESS, THAT WE COULD DO A 70-30
14	ROUND WITH 70 PERCENT GOING TO PHYSICIAN/SCIENTISTS
15	AND 30 PERCENT GOING TO NONPHYSICIAN/SCIENTISTS.
16	AND THAT WOULD HAVE THE EFFECT THAT IT WOULD ALMOST
17	EQUALIZE, BASED ON OUR PRIOR ROUND. IN OUR PRIOR
18	ROUNDS WE HAD 26 NONPHYSICIAN/SCIENTISTS AND 17
19	PHYSICIAN/SCIENTISTS, SO YOU COULD REBALANCE A SMALL
20	ROUND HERE 70-30 IN FAVOR OF THIS REAL DEFICIT OF
21	PHYSICIAN/SCIENTISTS. YOU BRING IT UP TO 31
22	PHYSICIAN/SCIENTISTS AND 32 BASIC SCIENTISTS ON A
23	CUMULATIVE BASE.
24	IT MAY ALSO ADDRESS OS' POINT THAT THERE
25	MAY BE SOME INSTITUTIONS IN THE STATE THAT HAVE

1	GREAT TALENT THAT DON'T REALLY HAVE A
2	PHYSICIAN/SCIENTIST TO NOMINATE OR A CANDIDATE FOR
3	THIS PHYSICIAN/SCIENTIST AWARD TO NOMINATE, SO IT
4	KEEPS THEM IN THE PROCESS. SO NOT HAVING IT IT
5	DOES ALSO ADDRESS DR. BRYANT'S POINT THAT IT DOESN'T
6	FULLY EXCLUDE. IT JUST CREATES A PREFERENCE TO
7	REBALANCE OUR PROCESS AND DEAL WITH THE DEFICIT
8	THAT'S IDENTIFIED. SO SOME REAL SHINING STARS THAT
9	ARE STILL OUT THERE THAT DIDN'T GET ROUND I AND
10	ROUND II COULD BE PICKED UP. IT'S A SMALL
11	ALLOCATION AFFIXED TO THAT CATEGORY, BUT IT MEANS
12	THAT WE STILL CAN GET SOME EXTREMELY BRIGHT
13	CANDIDATES AND HELP US REBALANCE OUR PORTFOLIO WHILE
14	PICKING UP A FEW IN THAT MINOR CATEGORY.
15	DR. TROUNSON: I HAVE THE VIEW THAT THESE
16	PHYSICIAN/SCIENTISTS ARE BECOMING EXOTIC. THEY'RE,
17	IN FACT, AN ENDANGERED SPECIES REALLY. REALLY THIS
18	IS WORLDWIDE. THE PROBLEM IS THAT THERE'S PLENTY OF
19	DEMANDS TO ACTUALLY HAVE DOCTORS GO INTO CLINICS.
20	BUT TO GET THEM TO COME INTO THE RESEARCH AND COME
21	FROM TO DISCOVERY THROUGH TRANSLATION AND HEAD UP
22	SOME OF THESE PROGRAMS IS REALLY WHAT I THINK WE
23	NEED TO DO. WE'RE HOPING TO GET 20.
24	AND I TELL YOU WHAT. IF WE GOT FIVE OF
25	THEM AT THE QUALITY OF CATRIONA JAMIESON, AND YOU

1	COULD CHOOSE ANY OTHER TYPE OF PERSON. FOR EXAMPLE,
2	SOMEBODY WHO CAN ACTUALLY DELIVER AT THE KIND OF
3	RATE THESE YOUNG PEOPLE DELIVER. THIS WILL
4	ACCELERATE WHAT WE CAN DO ABSOLUTELY, ABSOLUTELY.
5	I THINK IF YOU SORT SPIN IT BACK TO 15 AND
6	5, OKAY, IT SAYS WE'VE GOT FAR MORE PH.D.'S IN
7	THERE. I'M A PH.D. IN A SENSE I THINK THERE ARE
8	PLENTY OF OPPORTUNITIES FOR PH.D.'S GOING IN THE
9	CURRENT PROGRAM. I THINK THEY'VE DONE WELL. I
10	DON'T SEE THAT WE WOULD HAVE THE SAME IMPACT IF WE
11	HAD ANOTHER FIVE M.D./PH.D.'S. THESE PEOPLE HAVE
12	BEEN LOST EVERYWHERE ALL AROUND THE WORLD AND
13	PARTICULARLY BEING LOST IN THE U.S., BEING LOST OUT
14	OF NIH FUNDING, LOST OUT OF NIH.
15	WE ACTUALLY NEED THEM. THIS IS WHAT OUR
16	BUSINESS IS. THIS IS WHAT OUR CORE BUSINESS IS NOW,
17	AND WE'VE GOT TO ACTUALLY DRIVE REALLY HARD FOR THIS
18	PROGRAM. SO IF I HAVE A PREFERENCE, GIVE ME 20
19	M.D./PH.D.'S, AND WE'LL MAKE UP 5 PH.D. SCIENTISTS
20	IN SOME OTHER PROGRAM, BUT GIVE THEM TO ME PLEASE
21	BECAUSE WE'VE GOT AN OPPORTUNITY HERE TO REALLY GO
22	THROUGH THIS SPACE WITH THESE YOUNG PEOPLE. THEY'RE
23	ACTUALLY LOOKING AROUND, BUT THEY'RE NOT FINDING THE
24	SORT OF OPPORTUNITY THAT'S THERE. AND PHIL PIZZO IS
25	RIGHT. EVEN DEAN AND EVERY FACULTY CAN KNOW THIS.

1	AND IT'S WORLDWIDE. IT'S RIGHT ACROSS THE BOARD.
2	WE WANT THESE REALLY TOP PEOPLE, THE TOP
3	PEOPLE, THE TOP INTELLECT IN THIS WHOLE BUSINESS IS
4	IN THE MEDICAL FIELD. IT REALLY IS. YOU HAVE A
5	LOOK AT THE TOP PEOPLE IN STEM CELLS, AND IT'S
6	CROWDED WITH THESE M.D./PH.D. PEOPLE. IT'S REALLY
7	CROWDED WITH THEM. AND SO IF WE CAN GET THESE
8	PEOPLE AND GIVE THEM A CHANCE, THEN I THINK IT'S
9	TERRIFIC. I THINK WE'VE GOT THIS IS WHAT EXACTLY
10	WHAT WE SHOULD BE DOING.
11	SO I'M NOT REALLY I CAN SEE WHERE THAT
12	YOUR PROPOSAL THERE, BOB, IS EFFECTIVE AS AN
13	ARGUMENT. BUT THE SENSE OF IT IS IF WE WANT TO GO
14	REALLY HARD FOR THIS OPPORTUNITY, I'M GOING TO SORT
15	OF SIDE WITH JEFF HERE BECAUSE I THINK WE WANT AS
16	MANY OF THESE PEOPLE AS WE CAN TO DRIVE THIS
17	OPPORTUNITY BECAUSE THAT'S WHERE BASICALLY OUR FEET
18	ARE GOING, AND WE NEED TO BE THUNDERING DOWN THAT
19	TREK RIGHT NOW. WE'RE THE LAST OPPORTUNITY IN TOWN.
20	THERE ARE NOT MANY OTHER OPPORTUNITIES FOR THESE
21	PEOPLE WORLDWIDE.
22	CHAIRMAN SHEEHY: I WOULD JUST MAKE ONE
23	COMMENT MYSELF. HOW BROAD DO YOU MEAN EARLY
24	TRANSLATION? DOES THAT GO INTO EARLY STAGE CLINICAL
25	WORK TOO?

1	DR. OLSON: ACTUALLY NOT AT THE MOMENT.
2	THAT'S SOMETHING THAT WE NEED TO DISCUSS. THEY'RE
3	TYPICALLY VERY DIFFERENT REVIEW GROUPS BECAUSE THE
4	ONE, YOU START GETTING IN THE REGULATED SPACE. I
5	CALLED IT EARLY TRANSLATION PURPOSELY AT THIS POINT,
6	SO IT'S KIND OF RIGHT BEFORE REGULATED SPACE. SO WE
7	HAVE TO COMPENSATE THAT BECAUSE IF IT'S A CLINICAL
8	PROGRAM, FIRST, THE DOLLARS WON'T COVER IT. THE
9	DOLLARS WON'T EVEN COVER DEVELOPMENT PROGRAMS. THE
10	DOLLARS WILL COVER A PRETTY GOOD RESEARCH PROGRAM.
11	CHAIRMAN SHEEHY: SO DOES ANYONE ELSE HAVE
12	ANY COMMENTS? SHOULD WE
13	CHAIRMAN KLEIN: I'D LIKE TO UNDERSTAND
14	WHAT DR. OLSON JUST SAID. SO IN ORDER WHAT KIND
15	OF BUDGET WOULD WE NEED TO GIVE THEM TO BE ABLE TO
16	CARRY OUT GETTING THEM IN EARLY TRANSLATION
17	PROGRAMS?
18	DR. OLSON: LET ME SO OUR EARLY
19	TRANSLATIONAL AWARDS, WHICH GET THEM UP TO GOING
20	INTO IND ENABLING PRECLINICAL DEVELOPMENT, WE HAVE
21	TWO TYPES OF AWARDS. ONE AWARD IS ROUGHLY THE
22	\$300,000 A YEAR DIRECT PROJECT COST. THAT JUST GETS
23	THEM SO IT'S ABOUT A \$1.2 MILLION AWARD OR A
24	LITTLE HIGHER, 1.5. THAT GETS THEM TO A PROOF OF
25	CONCEPT IS THE END GAME WE'RE ASKING FOR THERE.

1	THE OTHER TYPE OF AWARD, THE DEVELOPMENT
2	CANDIDATE AWARD, AGAIN, THIS IS ONLY A THREE-YEAR
3	AWARD. THIS IS THE ONE WITH MILESTONES, FAIRLY
4	ACTIVE MANAGEMENT. THAT IS UP TO ROUGHLY FIVE TO \$6
5	MILLION. IT'S ROUGHLY \$1.2 MILLION OVER THREE YEARS
6	IN DIRECT COST.
7	CHAIRMAN KLEIN: SO THEN COULD CARRY THE
8	EARLY TRANSLATION UP TO FINALLY A CANDIDATE?
9	DR. OLSON: YEAH. BUT THE QUESTION IS
10	YOU HAVE TO THIS IS WHAT I WAS WRESTLING WITH
11	WHEN WE TALKED ABOUT THIS IS WHEN YOU'RE TRYING TO
12	GIVE PEOPLE THE FREEDOM TO DEVELOP THEIR RESEARCH,
13	TO DO A TRANSLATIONAL RESEARCH, I WOULD ASK THEM TO
14	DO A TRANSLATIONAL PROGRAM. AND I WOULD COME UP
15	WITH SOME SORT OF CRITERIA. BUT I'M NOT SURE THAT
16	I'D WANT TO BE AS PRESCRIPTIVE AND AS MONITORING AS
17	WE MIGHT NEED TO BE IF WE WERE DOING OUR VERY GOAL
18	ORIENTED.
19	DR. TROUNSON: WELL
20	DR. OLSON: THIS HASN'T BEEN WHOLLY WORKED
21	OUT YET.
22	DR. TROUNSON: I SLIGHTLY DISAGREE. IT
23	SHOWS YOU ESSENTIALLY WE HAVEN'T SORT OF COME TO ANY
24	FIRM VIEW. I ACTUALLY THINK THAT STOPPING THESE
25	PEOPLE WANTING TO GO DOWN INTO THAT PRECLINICAL PART

1	OF THE PROGRAM WOULD BE CRAZY. THIS IS WHAT THEY'RE
2	GENERATED FOR. THIS IS WHAT THEY'RE HYPER AT. THEY
3	WANT TO ACTUALLY DO THAT, AND THEY WANT TO GET CLOSE
4	TO PATIENTS.
5	SO I ACTUALLY WOULDN'T BE TOO PRESCRIPTIVE
6	ABOUT WHERE THEY ARE IN THAT SPACE, BUT I'D LIKE
7	THEM TO COME FROM SOME SORT OF DISCOVERY COMPONENT
8	AND DRIVE IT THROUGH. THAT WOULD BE GREAT. I
9	WOULDN'T BE AGAINST THEM STARTING FURTHER UP THE
10	TRAIL.
11	DR. OLSON: THEY'RE VERY DIFFERENT
12	DOLLARS.
13	CHAIRMAN KLEIN: MY QUESTION IS JUST IN
14	TRYING TO STAY IN THE SAME BUDGET, IS IT VALUABLE TO
15	DO FOUR YEARS AT 500,000 INSTEAD OF FIVE YEARS AT
16	400,000, TO GIVE THEM MORE DOLLARS TO MEANINGFULLY
17	DEAL WITH THE EARLY TRANSLATION?
18	DR. TROUNSON: IT'S POSSIBLE.
19	DR. OLSON: THAT'S A POSSIBILITY. AND I
20	THINK WE'D HAVE TO THINK ABOUT HOW TO DO A REVIEW
21	BECAUSE WELL, WE COULD PROBABLY MANAGE TO DO
22	DEPENDS ON IF THEY GOT IN THE CLINIC TOO.
23	DR. FEIGAL: FRANKLY, WE HAVE AN ISSUE
24	CHAIRMAN KLEIN: WOULD IT BE POSSIBLE TO
25	DO A RECOMMENDATION THAT GAVE THEM THE OPTION OF
	7.0

1	APPLYING FOR FIVE YEARS AND 400 OR FOUR YEARS AT
2	500,000?
3	DR. OLSON: IT'S THE OUTCOMES THAT ONE
4	NEEDS TO DETERMINE. IF THERE ARE SPECIFIED
5	OUTCOMES, THE SPAN OF RESEARCH, AND I THINK THAT'S
6	WHAT I'M HEARING IS THAT THE GROUP WOULD BE
7	INTERESTED IN INCLUDING THINGS NOW, I'M NOT SURE
8	IF SAYING IN THE CLINICAL AS WELL.
9	DR. TROUNSON: I'M NOT SPECIFICALLY,
10	BUT
11	DR. OLSON: I UNDERSTAND.
12	DR. TROUNSON: IT'S A TOTALLY DIFFERENT
13	WAYS TO DO THAT. SOME OF THESE PEOPLE WILL ACTUALLY
14	GO THERE VERY QUICKLY. IT'S BEEN SEEN SOME
15	EXAMPLES, THAT THEY'VE GONE FROM THE BASIC SCIENCE
16	STRAIGHT TO THE CLINIC. THEY HAVE GONE.
17	DR. OLSON: THEY'VE HAD PROJECTS THAT
18	WENT.
19	DR. TROUNSON: THAT'S RIGHT. THAT DOESN'T
20	DISTURB ME TOO MUCH.
21	CHAIRMAN KLEIN: YOU'RE SAYING WRITE THE
22	RFA TO BE PERMISSIVE AND INCLUSIVE OF A BROADER
23	SCOPE.
24	DR. OLSON: OF THROUGH PRECLINICAL
25	DEVELOPMENT IS WHAT I'M HEARING.
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1	MS. SAMUELSON: I HAVE A QUESTION.
2	DR. TROUNSON: THIS WOULD BE A MAJOR SHOT
3	AT THESE PEOPLE. THIS WOULD PROBABLY BE OUR LAST
4	MAJOR SHOT AT THESE SORTS OF PEOPLE.
5	DR. OLSON: I THINK THAT YOUR POINT ABOUT
6	CHANGING, FOUR YEARS, 500,000, I THINK THAT WOULD
7	GIVE THEM MORE FLEXIBILITY.
8	MS. SAMUELSON: I HAVE A QUESTION, MR.
9	CHAIR.
10	CHAIRMAN SHEEHY: SURE.
11	MS. SAMUELSON: OKAY. WE'VE FUNDED A LOT
12	OF BASIC SCIENCE, AND THE THEORY OF IT HAS BEEN THAT
13	WE FUND A GREAT OF BASIC SCIENCE AND FROM IT WILL
14	COME IDEAS THAT THEN TRANSLATE INTO A CLINICAL
15	RESULT. SO ARE WE FUNDING WHAT THAT SUGGESTS IN
16	THIS RFA, OR IS THAT ANOTHER ONE? IN OTHER WORDS,
17	WOULD THIS FUND THE BASIC SCIENCE RESEARCHER WHO'S
18	BEEN WORKING HARD AT SOME ASPECT OF BASIC SCIENCE IN
19	THE REALM OF REGENERATIVE MEDICINE AND THEN HAS GOT
20	A GREAT IDEA HE OR SHE WOULD LIKE TO LOOK CAREFULLY
21	AT AND TRY TO MOVE IT ALONG TO A THERAPEUTIC RESULT?
22	IS THAT SORT OF PROJECT FUNDABLE HERE?
23	AND ALSO WOULD IT BE COMPETITIVE? WE'VE WATCHED A
24	LOT OF PROJECTS IN THE TRANSLATIONAL REALM WITH
25	GREAT IDEAS, BUT THEY GOT SHOT DOWN AT THE

1	IMPLEMENTATION LEVEL IN THE FINE-TUNING OF THE
2	DETAILS IN PEER REVIEW.
3	CHAIRMAN SHEEHY: I THINK YOU'RE TALKING
4	ABOUT A DIFFERENT RFA. SO THIS ONE IS MUCH MORE
5	FOCUSED.
6	MS. SAMUELSON: THIS IS JUST PH.D., M.D.
7	CHAIRMAN SHEEHY: THIS IS TO DEVELOP
8	CLINICIAN/SCIENTISTS SPECIFICALLY.
9	MS. SAMUELSON: AS OPPOSED TO
10	TRANSLATIONAL RESEARCHERS? IS THAT SO SEPARATE?
11	CHAIRMAN SHEEHY: THEY'RE PUTTING THEM ON
12	TOP.
13	DR. OLSON: I THINK WHAT WE'RE TRYING TO
14	DO, JOAN, IS TO ADDRESS A REAL GAP IN THE TYPES OF
15	EXPERTISE AND PERSONNEL WHO ARE AVAILABLE TO DO
16	TRANSLATIONAL RESEARCH. WE ACKNOWLEDGE THAT THERE
17	MAY BE CERTAINLY PH.D. SCIENTISTS WHO DO IT, BUT
18	WHERE THE REAL GAP IN THE FIELD LIES IS WITH THOSE
19	PHYSICIAN/SCIENTISTS, BRINGING THEM BACK FROM JUST
20	THE CLINICAL WORK, BRINGING THEM BACK SO THAT THEY
21	CAN BRING THEIR KNOWLEDGE OF WHAT PATIENTS NEED AND
22	WHAT WORKS FOR PATIENTS INTO TRANSLATIONAL RESEARCH.
23	WE'RE TRYING TO ADDRESS A GAP.
24	MS. SAMUELSON: AND I'M NOT OPPOSED IN THE
25	SLIGHTEST. I'M JUST NOT HEARING THAT WE KNOW WHAT

1	THE OVERALL PROGRAMMATIC CONTEXT OF THIS WOULD BE.
2	I CAN THINK OF OTHER THINGS THAT MIGHT INCREASE THAT
3	POPULATION AS WELL. LET'S SAY ANOTHER RESEARCH
4	LEADER AWARD OR SOMETHING TO THAT EFFECT I THINK
5	WE'VE BEEN FUNDING LATELY.
6	CHAIRMAN SHEEHY: WELL, YOU KNOW, IN ANY
7	EVENT
8	MS. SAMUELSON: TRAIN THEM. AND I'D JUST
9	LIKE TO BE SURE THAT WE'RE BEING DELIBERATIVE ABOUT
10	HOW WE'RE SPENDING OUR MONEY.
11	CHAIRMAN SHEEHY: I HEAR YOU. I DON'T
12	I JUST DON'T KNOW WHAT PROCESS YOU WOULD LIKE TO GO
13	THROUGH IN ORDER TO GET TO THE TYPE OF QUESTION THAT
14	YOU WANT TO ASK THAT GET YOU THE TYPES OF ANSWERS.
15	FROM MY PERSPECTIVE, THE GENESIS OF THIS WAS
16	COMMENTS BY REVIEWERS THAT, GOSH, THAT WAS A GREAT
17	ROUND, SOME ANALYSIS BY STAFF, AND JUST LOOKING AT
18	PERSONALLY SOME CONVERSATIONS WITH DR. TROUNSON,
19	THAT HAD ACTUALLY HAD BEEN A VERY PRODUCTIVE ROUND
20	AND THAT PERHAPS THIS IS SOMETHING WE OUGHT TO
21	CONSIDER REPEATING; THAT IS, DOING SOMETHING WE'VE
22	DONE OVER AGAIN.
23	WHAT YOU ARE TRYING TO ASK IS A MUCH
24	BROADER QUESTION THAT TAKES A LOT MORE ANALYSIS. SO
25	IF YOU THINK THAT THAT PRECLUDES MOVING FORWARD ON

1	THIS, THEN YOU MAY NOT WANT TO SUPPORT MOVING
2	FORWARD ON THIS. TO ME PERSONALLY I WOULD PREFER TO
3	FORWARD ON THIS.
4	MS. SAMUELSON: I'D LIKE TO MOVE FORWARD
5	ON THIS, BUT I WOULD PREFER THAT THE FEEDBACK BE A
6	LITTLE LESS WORD OF MOUTH, THAT WE'RE BASING OUR
7	JUDGMENT DECISIONS
8	CHAIRMAN SHEEHY: WHAT WE DID IS WE ASKED
9	STAFF TO ANALYZE THE PRODUCTIVITY OF THE INDIVIDUALS
10	IN THIS ROUND. AND SO DR. YAFFE GAVE US A VERY
11	NICE, AND I THINK HE'S GOT ADDITIONAL INFORMATION HE
12	CAN GET TO YOU THAT KIND OF SHOWS THE PRODUCTIVITY
13	OF THIS PARTICULAR ROUND. SO I UNDERSTAND WE HAVE
14	LIKE 700 PUBLICATIONS ROUGHLY 788, SO 133 ARE
15	FROM THIS ROUND ALONE, WHICH SEEMS LIKE THAT THIS,
16	IN TERMS OF PRODUCTIVITY, THIS PARTICULAR ROUND WAS
17	EXTREMELY PRODUCTIVE JUST AS A QUICK SHORTHAND
18	MEASURE.
19	MS. SAMUELSON: BUT THEY ALL SAY
20	PUBLICATIONS ALONE AREN'T THE MEASURE.
21	CHAIRMAN SHEEHY: I THINK SIX INVENTION
22	DISCLOSURES AND FIVE PATENTS IS ALSO FAIRLY
23	IMPRESSIVE TOO.
24	WHAT WOULD BE NICE AT THIS POINT IS MAYBE
25	TO GET A MOTION, IF THERE IS ONE, TO GO FORWARD.

1	SOMEONE LIKE TO MAKE THAT.
2	MR. TORRES: SO MOVED.
3	CHAIRMAN SHEEHY: SENATOR TORRES. IS
4	THERE A SECOND?
5	MS. FEIT: SECOND.
6	CHAIRMAN SHEEHY: IS THERE ANY PUBLIC
7	COMMENT? WE HAVE DON REED HERE IN SAN FRANCISCO.
8	MR. REED: THIS WAS A PERFECT EXAMPLE OF A
9	PUBLIC INSTITUTION WORKING THINGS OUT, FIGHTING BACK
10	AND FORTH. I STARTED OUT THINKING THAT THIS WAS
11	MAYBE NOT NECESSARY BECAUSE WHY SHOULD WE EXCLUDE
12	PEOPLE. AT THE END, I FEEL THERE IS A GAP AND THAT
13	THESE PEOPLE ARE NEEDED. IT'S JUST LIKE WHAT WE DID
14	WITH PROPOSITION 71 IN THE BEGINNING. WE SAW A GAP
15	AND WE'RE FILLING IT. SO I'M IN FAVOR OF THIS. I
16	THINK THIS IS A GOOD IDEA.
17	CHAIRMAN SHEEHY: IS THERE ADDITIONAL
18	PUBLIC COMMENT? MELISSA, COULD YOU CALL THE ROLL.
19	DR. BRYANT: COULD YOU RESTATE THE MOTION.
20	CHAIRMAN SHEEHY: IT IS TO MOVE THIS
21	FORWARD AS PRESENTED. THERE WERE A COUPLE OF I
22	THINK STAFF HAS TAKEN A COUPLE WE EXPECT STAFF TO
23	BRING SOME OF THIS STUFF THAT WAS DISCUSSED TODAY,
24	TO TOGGLE BETWEEN FOUR AND FIVE AND FIVE AND FOUR,
25	BUT THE BASIC MOTION, SENATOR TORRES AND MARCY

	DARRISTERS REPORTING SERVICE
1	AGREE, IS TO BASICALLY MOVE THIS CONCEPT FORWARD
2	WITH THE COMMENTS THAT WERE MADE TODAY BASICALLY.
3	AGAIN, THIS WOULD BE PHYSICIAN/SCIENTIST LIMITED. I
4	THINK THAT'S WHERE WE ARE.
5	DR. BRYANT: NOT A BALANCE LIKE YOU JUST
6	SAID?
7	CHAIRMAN SHEEHY: NO. I THINK WOULD BE
8	PHYSICIAN/SCIENTIST LIMITED.
9	DR. BRYANT: I'M JUST GOING TO SAY NO
10	THEN.
11	MS. KING: MARCY FEIT.
12	MS. FEIT: YES.
13	MS. KING: ROBERT KLEIN.
14	CHAIRMAN KLEIN: YES.
15	MS. KING: DUANE ROTH. JOAN SAMUELSON.
16	MS. SAMUELSON: I'M GOING TO ABSTAIN FOR
17	NOW. I'D LIKE TO SEE THE EXTRA INFORMATION, AND I
18	HOPE TO FEEL ENTHUSIASTIC BY THE TIME OF THE ICOC
19	VOTE.
20	MS. KING: JEFF SHEEHY.
21	CHAIRMAN SHEEHY: YES.
22	MS. KING: OSWALD STEWARD.
23	DR. STEWARD: YES.
24	MS. KING: ART TORRES.
25	MR. TORRES: AYE.
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1	MS. KING: I WILL CIRCLE BACK TO DUANE
2	ROTH. SO WE DON'T HAVE A QUORUM, BUT WE CAN JUST
3	TAKE THIS ONE AS A SENSE OF THE SUBCOMMITTEE.
4	CHAIRMAN SHEEHY: REALLY TRYING TO GIVE
5	DIRECTION TO STAFF.
6	MS. SAMUELSON: WE NEED A QUORUM. WE
7	CAN'T BE OPERATING THAT WAY. WE JUST CAN'T. WE
8	DON'T HAVE A QUORUM, WE DON'T HAVE A QUORUM.
9	CHAIRMAN KLEIN: JOAN, WE HAVE ACCEPTED AS
10	PART OF OUR OPERATING PROCEDURES HAVING A SENSE OF
11	THE COMMITTEE.
12	MS. SAMUELSON: I KNOW IN EXTREMIS, BUT
13	THAT DIDN'T MEAN TO BECOMES STATUS QUO. I JUST
14	DON'T APPROVE OF THIS.
15	CHAIRMAN KLEIN: WELL, JOAN, WE RESPECT
16	YOUR OPINION AS AN INDIVIDUAL.
17	MS. SAMUELSON: ALL RIGHT. AND CO-VICE
18	CHAIR. ALL RIGHT.
19	CHAIRMAN SHEEHY: THANK YOU. WE HAVE ONE
20	MORE ITEM, A DISCUSSION OF THE OPPORTUNITY FUND.
21	FRANKLY, THE FINAL APPROVAL YOU GUYS AREN'T GOING
22	TO BRING THIS CONCEPT FORWARD TO BE APPROVED AT THIS
23	POINT. SO THE ICOC WILL HAVE AT LEAST TWO MORE
24	BITES AT THIS APPLE. SO WHAT WE'RE JUST TRYING TO
25	DO IS PROVIDE SOME DIRECTION, AND I DON'T THINK THE
	96

1	CONCEPT WILL COME FORWARD. WHAT DO YOU THINK?
2	DR. OLSON: IT WILL NOT NEED TO COME
3	FORWARD UNTIL QUITE LATER THIS YEAR. THERE'S NO
4	NEED.
5	CHAIRMAN SHEEHY: WE COULD TAKE THIS
6	FORWARD WITH A SENSE OF THE COMMITTEE TO HAVE A
7	DISCUSSION ABOUT THIS AT THE BOARD, BUT THIS IS
8	WE'RE NOT ON THIS NEW FACULTY THING ANYWHERE NEAR A
9	FINAL DECISION POINT.
10	DR. OLSON: IT BASICALLY PUTS IT ON A
11	CALENDAR AND GIVES US SOME SENSE OF WHAT THE
12	COMMITTEE AND WHAT THE BOARD MAY BE INTERESTED IN.
13	CHAIRMAN KLEIN: I THINK IT IS ALSO
14	VALUABLE, OS, BETWEEN NOW AND THE BOARD MEETING, IF
15	YOU COULD IDENTIFY SOME INSTITUTIONS THAT ARE
16	CRITICAL CONTRIBUTORS OF THIS PROCESS THAT MAY NOT
17	BE ABLE TO PARTICIPATE BECAUSE OF A LACK OF
18	PHYSICIAN/SCIENTIST CANDIDATES. MAYBE THEY'RE
19	GETTING PHYSICIAN/SCIENTISTS WHO HAVE BEEN NURTURED
20	IN THE FIELD FOR SOME TIME, BUT DON'T HAVE ANY YOUNG
21	PHYSICIAN/SCIENTISTS THAT WOULD COMPETE. THAT WOULD
22	BE VALUABLE INFORMATION.
23	DR. STEWARD: BOB, I HAVE TO SAY I'VE
24	RETHOUGHT THIS A LITTLE BIT. AND ONE OF THE REASONS
25	THAT I DID END UP VOTING YES IS THAT IT OCCURRED TO
	0.7

ME THAT IF THERE IS A PHYSICIAN/SCIENTIST WHO
HAPPENS TO BE AT UC MERCED, IT'S ACTUALLY PRETTY
UNLIKELY THAT THEY'RE GOING TO END UP DOING THE KIND
OF THING THAT WE'RE REALLY WANTING THEM TO DO, WHICH
IS TO REALLY MOVE FORWARD IN A WAY THAT HAS ONE FOOT
IN THE CLINIC AND ONE FOOT IN RESEARCH. PEOPLE WHO
HAVE MADE THAT DECISION HAVE MADE A DECISION REALLY
TO FOCUS ON RESEARCH EXCLUSIVELY.
SO THAT WAS ONE OF THE REASONS I ACTUALLY
FELT COMFORTABLE ABOUT VOTING YES. I DO THINK THAT
FROM THE LET'S CALL IT JUST POINT OF VIEW OF
FAIRNESS, WE NEED TO JUST REMEMBER THIS. AND IF
THERE ARE ISSUES THAT ARISE BECAUSE SOME
INSTITUTIONS FEEL LEFT OUT, THEN MAYBE THERE WOULD
BE A WAY TO ADJUST THINGS AROUND THE EDGES. I WAS
TRYING TO THINK OF A WAY TO DO THAT, AND I HONESTLY
COULDN'T THINK OF IT. JUST TO HAVE THAT ON THE
TABLE.
CHAIRMAN KLEIN: DR. BRYANT, WE WILL BY
RAISING IT FOR DISCUSSION AT THE BOARD WILL GET YOUR
INPUT AT THE BOARD MEETING. AND SO THAT WOULD GIVE
THE STAFF A SENSE OF WHAT THE BOARD IS DOING IN
TERMS OF COMING BACK WITH THEIR LATER CONCEPT
APPROVAL.
DR. BRYANT: OKAY. I'M NOT SURE I'M GOING
88

1	TO BE AT THE BOARD MEETING, BUT I'LL CHECK CAREFULLY
2	ON MY CALENDAR.
3	CHAIRMAN SHEEHY: WE HAVE THE OPPORTUNITY
4	FUND. I DON'T KNOW IF WE HAVE TIME. YOU GUYS MAYBE
5	WANT
6	DR. TROUNSON: IT'S IN THREE PARTS, JEFF.
7	WE KIND OF WE WERE GOING TO BRING THE FIRST PART
8	HERE FOR DISCUSSION, BUT I THINK, GIVEN THE TIME, TO
9	BE HONEST, IT PROBABLY WOULDN'T DO JUSTICE TO IT.
10	AND THIS IS FAIRLY IMPORTANT. PAT OLSON WAS GOING
11	TO ROLL OUT THE FIRST ONE. THE OTHER TWO PARTS OF
12	THIS WE'RE STILL WORKING ON, AND I THINK THEY'RE
13	IMPORTANT PARTS AS WELL. BUT PAT'S PART HAS BEEN
14	COMPLETED. PERHAPS WE COULD TAKE ANOTHER SCIENCE
15	SUBCOMMITTEE. I'M NOT ANTICIPATING WE SHOULD BRING
16	THIS TO THE BOARD AT THIS STAGE UNLESS YOU FEEL AT
17	LEAST, OKAY, WE'RE MATURE IN ONE PART OF IT.
18	CHAIRMAN KLEIN: LET'S TRY AND MOVE WITH
19	THE PART THAT PAT HAS BECAUSE PROVIDING SOME
20	OPPORTUNITIES FOR SOME THINGS THAT MAY BE STUFF
21	RIGHT NOW THAT COULD BE MOVING FORWARD MIGHT BE VERY
22	IMPORTANT.
23	DR. TROUNSON: TO BE HONEST, BOB, WE DON'T
24	THINK THAT THERE'S AN URGENCY YET FOR THAT PART OF
25	IT. SHE'S TALKING ENABLING PROJECTS TO GO FROM ONE

1	PLACE TO ANOTHER. WE'RE NOT IN A SORT OF
2	DESPERATION TIME SPOT RIGHT AT THE PRESENT TIME.
3	MS. SAMUELSON: I'M GOING TO GET OFF.
4	WE'VE LOST A QUORUM.
5	(SIMULTANEOUS DISCUSSION.)
6	CHAIRMAN KLEIN: MAYBE DR. OLSON COULD
7	JUST GIVE US THE CONCEPT SO THAT IT HELPS PEOPLE.
8	DR. FEIGAL: IF I COULD JUST ADD, THERE
9	ARE IF YOU COULD JUST ALSO SCOPE OUT THE THREE
10	COMPONENTS BECAUSE I THINK THEY'RE IMPORTANT, BUT
11	WE'RE NOT GOING TO GO INTO DETAIL ON TWO OR THREE.
12	CHAIRMAN SHEEHY: THIS IS IN YOUR PACKET.
13	CHAIRMAN KLEIN: LET'S JUST TAKE A FEW
14	MINUTES.
15	CHAIRMAN SHEEHY: JUST A QUICK OVERVIEW.
16	IF SOMETHING JUMPS OUT, MAYBE YOU CAN SEND COMMENTS
17	TO PAT OR DR. FEIGAL TO LOOK AT THIS BECAUSE WE'RE
18	STILL EARLY IN THIS, BUT I THINK THIS IS FAIRLY
19	IMPORTANT.
20	DR. FEIGAL: I THINK DON CAME SPECIFICALLY
21	TO HEAR SOME OF THIS.
22	DR. OLSON: SO I THINK WHAT WE'RE TRYING
23	TO DO IS RESPOND TO SOME OF THE RECOMMENDATIONS OF
24	THE EXTERNAL BOARD, WHICH IS BASICALLY TO PUSH
25	TRANSLATIONAL RESEARCH FORWARD, TO BE MORE FRIENDLY
	90

1	TO INDUSTRY TIMELINES OR TO TIMELINES, TO BE MORE
2	POROUS. AND ESSENTIALLY WHAT WE'RE PROPOSING IS
3	ESSENTIALLY A FUND THAT WOULD PROVIDE SOME WELL,
4	IT WOULD WORK FOR A NUMBER OF OPPORTUNITIES.
5	AND ONE OF THEM WOULD BE A BRIDGE FUNDING
6	PROGRAM. AND THE IDEA BEHIND THE BRIDGE FUNDING
7	PROGRAM IS THAT WE MAY HAVE SOME VERY GOOD PROJECTS
8	IN, SAY, EARLY TRANSLATION, IN DISEASE TEAM, IN
9	TARGETED CLINICAL DEVELOPMENT, AND THEY GET TO THE
10	END OF THEIR PERIOD. AND I KNOW THAT WE'RE
11	OPTIMISTIC IN DISEASE TEAM, AND THE BOARD HAS
12	ADDRESSED THIS SITUATION WHEREBY IF THEY HAVE FUNDS
13	LEFT OVER, THEY CAN CONTINUE TO MOVE FORWARD, BUT I
14	THINK THE MORE LIKELY SITUATION IS THEY GET TO THE
15	END OF THEIR TERM AND THEY DON'T HAVE FUNDS.
16	AND RATHER THAN JUST STOP, BECAUSE OUR RFA
17	ROUNDS ARE ALWAYS NOT PRECISELY TIMED TO MOVING ON,
18	SO THE IDEA HERE IS FOR EXISTING TRANSLATIONAL OR
19	CLINICAL OR PRECLINICAL DEVELOPMENT PROGRAMS IS THAT
20	THE BOARD WOULD AUTHORIZE A FUND, WHICH THE
21	PRESIDENT, THROUGH A PROCESS, COULD USE TO AUTHORIZE
22	BRIDGE FUNDING FOR NO MORE THAN A YEAR TO GET THEM
23	TO THE NEXT STAGE.
24	AND THERE WOULD BE A PROCESS THAT WOULD
25	INCLUDE A DISCUSSION WITH THE, OKAY, CLINICAL
	0.1

1	DEVELOPMENT ADVISORY PANEL, JUST TO RUN IT ACROSS
2	THEM, SO THEY PROVIDE SOME ADVICE TO ALAN AND ALAN
3	TO ENABLE HIS DECISION ON A RECOMMENDATION TO
4	ACTUALLY AUTHORIZE FUNDING. WE WOULD KEEP THE BOARD
5	APPRAISED OF HOW THE FUNDS WERE ALLOCATED FROM THE
6	PROGRAM. SO THAT'S THE FIRST OF THREE
7	OPPORTUNITIES.
8	MR. TORRES: QUESTION ON THAT. DOES THE
9	PRESIDENT CURRENTLY HAVE THAT AUTHORITY TO DO THAT?
10	DR. OLSON: NO, HE DOES NOT.
11	MR. TORRES: EVEN FROM EXISTING FUNDS THAT
12	MAY BE LEFT OVER?
13	DR. FEIGAL: FOR EXISTING, HE COULD, IF IT
14	ALREADY EXISTS.
15	MR. TORRES: IF A GRANT WAS ALREADY
16	ONGOING AND IT RAN OUT OF TIME.
17	DR. OLSON: I BELIEVE THAT THE ICOC
18	AUTHORIZED APPROVAL TO IF THERE WERE LEFTOVER FUNDS
19	FOR THE PRESIDENT ALLOW THEM TO MOVE TO A STAGE NOT
20	CONTEMPLATED BY THE ORIGINAL APPLICATION. LEFT OVER
21	WITHIN THE AWARD.
22	MR. TORRES: WITHIN THE AWARD ITSELF. HE
23	HAS THAT AUTHORITY NOW?
24	DR. OLSON: YES. JUST THAT LIMITED
25	AUTHORITY. AS I SAY, THERE AREN'T TOO MANY. THAT'S

1	JUST FOR DISEASE TEAM I. THAT WAS A VERY LIMITED
2	AUTHORIZATION.
3	MR. TORRES: COULD WE SHIFT THAT FROM
4	LEFTOVER FUNDS IN ONE DISEASE TEAM TO ANOTHER
5	DISEASE TEAM?
6	DR. OLSON: NO, NOT CURRENTLY. SO THAT'S
7	THE BRIDGE FUNDING PROGRAM.
8	THERE WERE TWO OTHER TYPES OF PROGRAMS
9	THAT WE'VE BEEN WORKING ON THAT ALSO WOULD MAKE
10	SENSE TO PERHAPS TALK ABOUT IN THE CONTEXT OF AN
11	OPPORTUNITY FUND. ONE OF THEM IS WHAT WE'RE CALLING
12	A CALIFORNIA EXTERNAL INNOVATION FUND PROGRAM. AND
13	THE IDEA HERE IS THAT YOU WILL RECALL THAT THE
14	EXTERNAL REVIEW POINTED OUT THAT THERE ARE MANY
15	GREAT DISCOVERIES GOING ON THROUGHOUT THE WORLD, NOT
16	JUST IN CALIFORNIA, AND WE WOULD LIKE, IF WE WERE
17	ABLE TO IDENTIFY SOME OF THOSE OPPORTUNITIES,
18	PARTNER THEM WITH A CALIFORNIAN AND THEN PROVIDE
19	THEM SOME FUNDING TO GET THEM TO THE NEXT APPLICABLE
20	REVIEW. WE THINK THAT COULD BE A VERY POWERFUL TOOL
21	TO BRING SOME OF THESE KEY INNOVATIONS INTO
22	CALIFORNIA.
23	SO THAT'S ONE IDEA BEHIND THAT, AND ALAN
24	AND OTHERS OF US ARE WORKING TO FLESH THAT OUT A BIT
25	MORE. THAT WAS A SPECIFIC RECOMMENDATION.

1	THEN THE OTHER ONE IS THE INDUSTRY
2	STRATEGIC PARTNERSHIP PROGRAM. AND I THINK I'LL
3	JUST DEFER TO ELONA ON THIS TO SAY A FEW WORDS ABOUT
4	THAT BECAUSE SHE'S SPENT A LOT OF TIME WORKING AND
5	THINKING ABOUT THIS.
6	MS. BAUM: OKAY. LET ME START BY SAYING
7	THAT I WOULD CALL IT MORE APPROPRIATELY THE
8	STRATEGIC PARTNERSHIP PROGRAM BECAUSE IT WON'T BE
9	RESERVED FOR, AT LEAST THIS IS THE CONCEPT, IT
10	WOULDN'T BE RESERVED FOR INDUSTRY ONLY, BUT ALSO,
11	FOR INSTANCE, FOUNDATIONS. BUT THE GOAL WITH
12	RESPECT TO THIS PROGRAM IS TO ALLOW US TO ENGAGE
13	BIOPHARMA, FOR INSTANCE, FOUNDATIONS MORE READILY.
14	AND THE PROGRAM IS IN ITS INFANCY STAGES EVEN IN
15	CONCEPT. NOTHING WOULD BE PRESENTED EVEN UNTIL WE
16	HAD AMPLE PUBLIC INPUT, BUT THE VISION IS THAT WE
17	UNDERSTAND BIOPHARMA IS CRITICAL TO OUR SUCCESS.
18	IT WAS RECOGNIZED BY, IN FACT, SOME OF THE
19	NOMINEES FOR CHAIR AS WELL AS THOSE ON THE EXTERNAL
20	ADVISORY PANEL. THEY BRING A TREMENDOUS AMOUNT OF
21	EXPERIENCE IN MANUFACTURING, REGULATORY, AND
22	CLINICAL DEVELOPMENT THAT WE WOULD LIKE TO BE ABLE
23	TO TAP IN EARLY, BUT WE ALSO BELIEVE THAT THROUGH
24	THESE PARTNERSHIPS WITH BIOPHARMA AND FOUNDATIONS,
25	WE CAN ACTUALLY GREATLY LEVERAGE TAXPAYER MONEY,
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1	CIRM FINANCES.
2	AND SO WE WANT TO EXPLORE DIFFERENT WAYS
3	ABOUT RAISING A PROGRAM THAT WILL ALLOW US TO DO
4	THIS, FOSTER THIS TYPE OF DEVELOPMENT, AND
5	ULTIMATELY BRING THERAPIES TO PATIENTS. BUT, AGAIN,
6	IT'S IN ITS INFANCY STAGES, AND THERE WILL BE A LOT
7	OF PUBLIC INPUT BEFORE WE MOVE FORWARD ON THAT.
8	CHAIRMAN KLEIN: CAN I COMMENT ON THAT?
9	EMPHASIZING THE FACT THERE'S GOING TO BE A NUMBER OF
10	PUBLIC MEETINGS TO DISCUSS THIS AND DEVELOP THIS,
11	THE FACT THAT WE'VE DEVELOPED THE LEVERAGE PROGRAMS
12	WELL FOR FACILITIES IS AN INDICATION OF THE KIND OF
13	DEPTH THAT'S OUT THERE. AND AS ELONA HAS STATED,
14	WHETHER IT'S THE WELLDON TRUST OR THE GATES
15	FOUNDATION OR OTHER FOUNDATIONS, THEY CAN
16	PARTICIPATE AS WELL AS THE BIOTECH AND PHARMA
17	COMMUNITY IN BRINGING FUNDS THAT PROVIDE LEVERAGE,
18	FINANCIAL LEVERAGE, FOR WHAT WE'RE DOING, BUT IT
19	SHOULD BE REALLY IMPORTANT FOR US TO FOCUS ON MINING
20	THE CAPACITY HERE FOR PHARMA AND BIOTECH TO NOT JUST
21	BRING FUNDS, BUT REALLY PARTICIPATE IN THE
22	REGULATORY PROCESS WITH THEIR REGULATORY EXPERTISE
23	IN THE DEVELOPMENTAL PROCESS WITH THEIR DEVELOPMENT
24	EXPERTISE BECAUSE IN HONORING OUR MANDATE TO
25	PATIENTS, IT'S NOT MONEY ALONE THAT'S GOING TO GET

1	US THERE. THAT'S LEVERAGE THAT'S GOING TO BE
2	HELPFUL. THEIR SCIENTIFIC CONTRIBUTION ARE HELPFUL,
3	BUT WE'LL ALSO POTENTIALLY PULL IN SOME OF THEIR
4	CRITICAL IP, WHICH WE REALLY NEED TO MAKE THEM
5	VESTED, PARTICIPATING PLAYERS IN THIS PROCESS. SO
6	WE BRING ALL OF THEIR ASSETS IN HERE IF WE'RE REALLY
7	GOING TO STREAMLINE GETTING DOWNSTREAM TO PATIENTS.
8	SO YOU'RE GOING TO HAVE A LOT OF THINGS TO
9	DEVELOP IN PUBLIC HEARINGS. I MAY ATTEND JUST TO
10	LEARN, BUT I WON'T BE A PARTICIPANT, BUT I THINK
11	THIS IS A VERY, VERY RICH POTENTIAL TO BRING IN MORE
12	ASSETS TO SERVE OUR CRITICAL MISSION OF GETTING TO
13	PATIENTS, WHICH IS WHAT THIS IS ALL ABOUT. SO VERY
14	SUPPORTIVE OF THE BREADTH OF THIS AND THE
15	OPPORTUNITIES THAT THIS CAN BRING TO PATIENTS.
16	CHAIRMAN SHEEHY: ARE THERE OTHER
17	COMMENTS? OKAY. WELL, I JUST WANT TO SAY I THINK
18	THIS IS VERY FULLY DEVELOPED. I LOOK FORWARD TO
19	WHAT ELSE MAY BE COMING. UNLESS THERE'S ANY PUBLIC
20	COMMENT?
21	MR. TORRES: DOES THE BOARD WANT TO LOOK
22	AT THIS AS WELL?
23	CHAIRMAN SHEEHY: I THINK IT WILL COME
24	BACK TO THE SCIENCE SUBCOMMITTEE AGAIN AND THEN IT
25	WILL COME TO THE BOARD. THIS IS STILL EARLY. IF

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THERE'S NOT, THEN I'M GOING TO ADJOURN THE MEETING.
 1
 2
      THANK YOU.
 3
                      (THE MEETING WAS THEN CONCLUDED AT
      05:07 P.M.)
 4
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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 TELEPHONIC PROCEEDINGS BEFORE THE SCIENCE SUBCOMMITTEE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON JUNE 6, 2011, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CSR 7152 BARRISTER'S REPORTING SERVICE 1072 BRISTOL STREET SUITE 100 COSTA MESA, CALIFORNIA (714) 444-4100