

BEFORE THE
APPLICATION REVIEW SUBCOMMITTEE AND 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: TUESDAY, JANUARY 19, 2016
11 A.M.

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

BRS FILE NO.: 98253

BARRISTERS' REPORTING SERVICE

I N D E X

ITEM DESCRIPTION	PAGE NO.
REPORTS & DISCUSSION ITEMS	
1. CALL TO ORDER.	3
2. PLEDGE OF ALLEGIANCE.	
3. ROLL CALL.	3
CONSENT CALENDAR ITEMS 4 AND 5:	5
4. CONSIDERATION OF APPOINTMENT OF NEW SCIENTIFIC MEMBERS TO THE GRANTS WORKING GROUP.	
5. CONSIDERATION OF MINUTES FOR SEPTEMBER, OCTOBER, NOVEMBER AND DECEMBER 2015 BOARD MEETINGS.	
ACTION ITEMS	
6. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO PA: EDUC 2 BRIDGES AND PA: EDUC3 SPARK APPLICATIONS.	7
7. CONSIDERATION OF ADOPTION OF INTERIM GRANTS ADMINISTRATION POLICY FOR THE DISCOVERY, TRANSLATIONAL AND EDUCATION PROGRAMS.	20
CLOSED SESSION	NONE
8. DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO APPLICATIONS EDUC 2 (15-05) AND EDUC 3 (15-06). (HEALTH & SAFETY CODE 125290.30(F)(3)(B) AND (C)).	
PUBLIC COMMENT	NONE

BARRISTERS' REPORTING SERVICE

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TUESDAY, JANUARY 19, 2016; 11 A.M.

CHAIRMAN THOMAS: WELCOME, EVERYONE, TO
THE APPLICATION REVIEW SUBCOMMITTEE. WE'RE IN
BEAUTIFUL, RAINY OAKLAND THIS MORNING. AND THANK
YOU ALL FOR PARTICIPATING. SO, AMY, WILL YOU PLEASE
CALL THE ROLL.

MS. CHEUNG: DAVID BRENNER.

DR. BRENNER: HERE.

MS. CHEUNG: LINDA BOXER.

DR. BOXER: HERE.

MS. CHEUNG: KEN BURTIS.

DR. BURTIS: PRESENT.

MS. CHEUNG: ANNE-MARIE DULIEGE.

DR. DULIEGE: PRESENT.

MS. CHEUNG: MICHAEL FRIEDMAN.

DR. FRIEDMAN: HERE.

MS. CHEUNG: JUDY GASSON. SAM HAWGOOD.
DAVID HIGGINS. STEPHEN JUELSGAARD. SHERRY LANSING.
KATHY LAPORTE. BERT LUBIN.

DR. LUBIN: HERE.

MS. CHEUNG: SHLOMO MELMED. LAUREN
MILLER.

MS. MILLER: HERE.

MS. CHEUNG: ADRIANA PADILLA. JOE

BARRISTERS' REPORTING SERVICE

1 PANETTA.

2 MR. PANETTA: HERE.

3 (INTERRUPTION IN PROCEEDINGS.)

4 MS. CHEUNG: ROBERT PRICE.

5 DR. PRICE: HERE.

6 MS. CHEUNG: FRANCISCO PRIETO.

7 DR. PRIETO: HERE.

8 MS. CHEUNG: CARMEN PULIAFITO. ROBERT

9 QUINT. AL ROWLETT.

10 MR. ROWLETT: HERE.

11 MS. CHEUNG: JEFF SHEEHY.

12 MR. SHEEHY: HERE.

13 MS. CHEUNG: OS STEWARD.

14 DR. STEWARD: HERE.

15 MS. CHEUNG: JONATHAN THOMAS.

16 CHAIRMAN THOMAS: HERE.

17 MS. CHEUNG: ART TORRES.

18 MR. TORRES: HERE.

19 MS. CHEUNG: KRISTINA VUORI.

20 DR. VUORI: HERE.

21 MS. CHEUNG: DIANE WINOKUR.

22 MR. JUELSGAARD: ANY, THIS IS STEVE

23 JUELSGAARD. I JOINED A LITTLE WHILE AGO. THIS HAS

24 BEEN ONE OF THE MOST DIFFICULT CALLS TO JOIN. I

25 DON'T KNOW IF YOU CHANGED THE SYSTEM OR WHAT, BUT IT

BARRISTERS' REPORTING SERVICE

1 WAS NOT EASY TO GET THROUGH.

2 MS. CHEUNG: I'LL LOOK INTO THAT FOR THE
3 NEXT CALL.

4 DR. HIGGINS: THIS IS DAVID HIGGINS. I'VE
5 ALSO BEEN HAVING TROUBLE.

6 DR. MELMED: ARE YOU HEARING US.

7 MS. CHEUNG: DR. MELMED, WAS THAT YOU.

8 DR. MELMED: YES, THAT WAS ME. I ANSWERED
9 EARLIER AND YOU NEVER HEARD.

10 MS. BONNEVILLE: NOW WE CAN.

11 CHAIRMAN THOMAS: OKAY. THANK YOU,
12 EVERYBODY. THE FIRST ITEMS ON THE AGENDA ARE
13 CONSENT ITEMS. IF WE DON'T HAVE ANY MEMBERS WHO
14 WANT TO PULL AND DISCUSS SEPARATELY, I WOULD
15 ENTERTAIN A MOTION TO APPROVE ITEMS 4 AND 5.

16 MR. SHEEHY: SO MOVED.

17 DR. JUELGAARD: I SO MOVE.

18 CHAIRMAN THOMAS: MOVED BY MR. SHEEHY,
19 SECONDED BY MR. JUELGAARD. ANY COMMENTS FROM
20 MEMBERS OF THE BOARD? VOICE VOTE ON THIS ONE.

21 MR. HARRISON: YOU NEED TO DO A ROLL CALL.

22 CHAIRMAN THOMAS: AMY, PLEASE CALL THE
23 ROLL.

24 MS. CHEUNG: DAVID BRENNER.

25 DR. BRENNER: YES.

BARRISTERS' REPORTING SERVICE

1 MS. CHEUNG: LINDA BOXER.
2 DR. BOXER: YES.
3 MS. CHEUNG: KEN BURTIS.
4 DR. BURTIS: YES.
5 MS. CHEUNG: ANNE-MARIE DULIEGE.
6 DR. DULIEGE: YES.
7 MS. CHEUNG: MICHAEL FRIEDMAN.
8 DR. FRIEDMAN: YES.
9 MS. CHEUNG: JUDY GASSON.
10 DR. GASSON: YES.
11 MS. CHEUNG: SAM HAWGOOD. DAVID HIGGINS.
12 DR. HIGGINS: YES.
13 MS. CHEUNG: STEPHEN JUELSGAARD.
14 MR. JUELSGAARD: YES.
15 MS. CHEUNG: SHERRY LANSING. KATHY
16 LAPORTE. BERT LUBIN.
17 DR. LUBIN: YES.
18 MS. CHEUNG: SHLOMO MELMED.
19 DR. MELMED: YES.
20 MS. CHEUNG: LAUREN MILLER.
21 MS. MILLER: YES.
22 MS. CHEUNG: ADRIANA PADILLA.
23 DR. PADILLA: YES.
24 MS. CHEUNG: JOE PANETTA.
25 MR. PANETTA: YES.

BARRISTERS' REPORTING SERVICE

1 MS. CHEUNG: ROBERT PRICE.

2 DR. PRICE: YES.

3 MS. CHEUNG: FRANCISCO PRIETO.

4 MS. CHEUNG: AYE.

5 MS. CHEUNG: CARMEN PULIAFITO. ROBERT
6 QUINT. AL ROWLETT.

7 MR. ROWLETT: YES.

8 MS. CHEUNG: JEFF SHEEHY.

9 MR. SHEEHY: YES.

10 MS. CHEUNG: OS STEWARD.

11 DR. STEWARD: YES.

12 MS. CHEUNG: JONATHAN THOMAS.

13 CHAIRMAN THOMAS: YES.

14 MS. CHEUNG: ART TORRES.

15 MR. TORRES: AYE.

16 MS. CHEUNG: KRISTINA VUORI.

17 DR. VUORI: YES.

18 MS. CHEUNG: DIANE WINOKUR.

19 CHAIRMAN THOMAS: THANK YOU. WE'RE NOW
20 GOING TO ASK TO GO ON TO ITEM NO. 6, WHICH IS THE
21 BRIDGES AND SPARK PROGRAMS. GOING TO TURN IT OVER
22 TO DR. SAMBRANO.

23 DR. SAMBRANO: THANK YOU, MR. CHAIRMAN.
24 SO I'M GOING TO GO THROUGH THIS PRESENTATION, AND
25 IT'S DIVIDED INTO TWO SEGMENTS. SO WE'RE GOING TO

BARRISTERS' REPORTING SERVICE

1 GO THROUGH THE BRIDGES OVERVIEW AND THEN
2 CONSIDERATION OF THOSE APPLICATIONS, AND THEN WE'LL
3 FOLLOW THAT WITH THE SPARK PROGRAM.

4 SO THAT IS THE ORDER OF THE PRESENTATION
5 TODAY. LET ME GIVE YOU AN OVERVIEW ON THE BRIDGES
6 PROGRAM. SO AS MOST OF YOU KNOW, THE BRIDGES
7 PROGRAM HAS BEEN AROUND FOR A WHILE NOW. SO IT WAS
8 ORIGINALLY A THREE-YEAR PROGRAM THAT WAS RENEWED FOR
9 ANOTHER THREE YEARS, AND THEN ONE THE LAST YEAR OVER
10 THE COURSE OF THIS YEAR FOR A TOTAL OF SEVEN YEARS
11 THAT THIS PROGRAM HAS BEEN IN EXISTENCE WITH A TOTAL
12 OF 16 PROGRAMS, 13 OF THOSE CALIFORNIA STATE
13 UNIVERSITIES AND THREE COMMUNITY COLLEGES.

14 WE HAVE HAD GREATER THAN 700 STUDENTS THAT
15 HAVE COMPLETED THE PROGRAM AND HAVE OVERALL DONE
16 PRETTY WELL IN TERMS OF OUTCOMES. PURSUANT TO A
17 SURVEY THAT WAS DONE A COUPLE OF YEARS AGO, ABOUT 50
18 PERCENT ARE WORKING IN LAB JOBS, 30 PERCENT BECAME
19 ENROLLED IN A GRADUATE OR PROFESSIONAL SCHOOL, AND
20 15 ARE COMPLETING AN EDUCATION PROGRAM OR APPLYING.

21 AND MANY OF THEM HAVE BEEN EMPLOYED FULL
22 TIME IN MANY OF THE LABS. A LOT OF TIMES THE LABS
23 WHERE THEY WERE MENTORED ORIGINALLY. AND THIS
24 COVERS GREATER THAN 20 CALIFORNIA UNIVERSITIES AND
25 RESEARCH INSTITUTES AND GREATER THAN 50 BIOTECH AND

BARRISTERS' REPORTING SERVICE

1 PHARMACEUTICAL COMPANIES.

2 SO THAT WAS THE BRIDGES 1.0, AS WE WOULD
3 CALL IT. BUT AS WE VENTURED INTO CIRM 2.0, WE
4 WANTED TO THINK ABOUT HOW TO RESTRUCTURE THIS
5 PROGRAM TO ALIGN IT WITH OUR MISSION. AND SO THIS
6 IS THE RESULT OF THE CONCEPT THAT WAS PRESENTED TO
7 YOU SEVERAL MONTHS AGO WITH THE OBJECTIVE OF
8 CONTINUING TO FOCUS ON UNDERGRADUATE AND MASTER'S
9 LEVEL STUDENTS AND TO HELP THEM DEVELOP CAREERS IN
10 STEM CELL RESEARCH AND THERAPY DEVELOPMENT.

11 OF COURSE, THERE'S A LOT OF THINGS THAT
12 ARE BEING KEPT AS PART OF THIS PROGRAM, CERTAINLY
13 THE INTERNSHIP COMPONENT, WHICH IS USUALLY ABOUT 12
14 MONTHS, STEM CELL TRAINING COURSE, EDUCATIONAL
15 ENHANCEMENT ACTIVITIES, AND THE BROADENING OF
16 PARTICIPATION FROM UNDERREPRESENTED STUDENT
17 POPULATIONS.

18 THERE ARE SEVERAL THINGS THAT WE ARE
19 ADDING, HOWEVER, TO TRY TO ALIGN WITH THE MISSION.
20 THESE INCLUDE DIRECT PATIENT ENGAGEMENT ACTIVITIES,
21 FORMAL TRAINING ON THE REGULATORY PATHWAY AND
22 DEVELOPMENT PROCESS, COMMUNITY OUTREACH ACTIVITIES,
23 AND CAREER COUNSELING FOR THE TRAINEES AND ALUMNI.
24 SO THESE ARE ALL NEW ELEMENTS; AND ALTHOUGH WE MAY
25 HAVE HAD EXISTING PROGRAMS THAT HAVE REAPPLIED, THEY

BARRISTERS' REPORTING SERVICE

1 ARE IN THE PROCESS OF REAPPLYING TO ADDRESS THESE
2 NEW COMPONENTS.

3 SO WHO CAN APPLY? SO THIS WAS CALIFORNIA
4 UNIVERSITIES AND COLLEGES THAT DON'T HAVE A MAJOR
5 STEM CELL RESEARCH PROGRAM; THAT IS, A MAJOR
6 FACILITIES THE SAME AS IT WAS IN THE ORIGINAL
7 PROGRAM, BUT IS OPEN TO BOTH THESE PREEXISTING
8 BRIDGES PROGRAMS AND POTENTIALLY NEW PROGRAMS.

9 SEVERAL MONTHS AGO THE BOARD APPROVED UP
10 TO 45.7 MILLION TO SUPPORT UP TO ABOUT 15 PROGRAMS,
11 AND EACH AWARD WOULD SUPPORT TEN TRAINEES PER YEAR.
12 THESE PROGRAMS WOULD EXIST, IF APPROVED, FOR UP TO
13 FIVE YEARS EACH.

14 LET ME TELL YOU AND REMIND YOU A LITTLE
15 BIT ABOUT THE SCORING. THIS IS WHAT WE MIGHT REFER
16 TO NOW AS THE OLD SCORING SYSTEM THAT WAS USED IN
17 THIS REVIEW. SO THE SCALE WAS FROM 1 TO 100. AND A
18 SCORE OF 75 TO 100 BEING EXCEPTIONAL MERIT AND
19 WARRANTS FUNDING. IF IT'S A SCORE BETWEEN 65 AND
20 74, THAT'S MODERATE QUALITY OR NO CONSENSUS, BUT
21 SUITABLE FOR PROGRAMMATIC CONSIDERATION, AND 64 AND
22 BELOW MEANS THAT IT IS SUFFICIENTLY FLAWED AND IT
23 DOES NOT WARRANT FUNDING. SO THOSE ARE THE BASIS OF
24 THE SCORES.

25 I ALSO WANT TO GIVE YOU A LITTLE BIT OF

BARRISTERS' REPORTING SERVICE

1 CONTEXT WITH THE REVIEW. THIS APPLIES BOTH TO THE
2 BRIDGES AND THE SPARK. DURING THE COURSE OF THE
3 DISCUSSION AND THE REVIEW, MANY OF THE REVIEWERS
4 MADE OBSERVATIONS AND PROVIDED SUGGESTIONS THAT
5 REALLY IMPACT ON ALL THE PROGRAMS, THOUGH SOME OF
6 THEM WERE BROUGHT UP UNDER SPECIFIC PROGRAMS AND
7 THOSE ARE, IN PART, CAPTURED IN THE SUMMARIES, BUT
8 IT WAS ALSO MADE CLEAR TO REVIEWERS THAT UPON
9 LAUNCHING THE NEW AWARDS, WE WOULD BE BRINGING
10 PROGRAM DIRECTORS ON THE APPROVED PROGRAMS TOGETHER
11 TO DISCUSS WAYS OF IMPROVING AND UNIFYING THE
12 PROGRAM. FOR EXAMPLE, THE COLLECTION AND TRACKING
13 OF DATA OF TRAINEES AND THEIR PROGRESS AND WHERE
14 THEY GO. IF WE CAN DO THAT IN A UNIFORM WAY ACROSS
15 ALL THE DIFFERENT PROGRAMS, I THINK THAT WOULD BE
16 HELPFUL TO CIRM IN TERMS OF REPORTING ON SUCCESS OF
17 THESE PROGRAMS. I JUST WANTED TO LET YOU KNOW THAT.

18 AND THEN, FINALLY, HERE'S THE SUMMARY OF
19 RECOMMENDATIONS FROM THE GRANTS WORKING GROUP.
20 THERE WERE A TOTAL OF 14 APPLICATIONS THAT WERE
21 RECOMMENDED FOR FUNDING FOR A FUNDING AMOUNT OF 40.1
22 MILLION. THERE'S ONE APPLICATION THAT IS IN TIER II
23 FOR 30 MILLION, AND THEN THERE ARE TWO NOTED THAT
24 WERE IN TIER III, ALTHOUGH ONE OF THEM WITHDREW
25 YESTERDAY. AND THAT WAS APPLICATION 84-28, THE ONE

BARRISTERS' REPORTING SERVICE

1 LISTED LAST ON THE SPREADSHEET. SO AT THIS POINT WE
2 LOOK FORWARD TO CONSIDERING THESE RECOMMENDATIONS
3 FOR BRIDGES PROGRAM.

4 CHAIRMAN THOMAS: THANK YOU VERY MUCH,
5 DR. SAMBRANO. JEFF, WOULD YOU TAKE IT FROM HERE
6 PLEASE?

7 MR. SHEEHY: SURE. SO I THINK IT'S BEEN
8 AWHILE SINCE WE'VE HAD THE THREE-TIER, BUT FOLLOWING
9 WHAT WE'VE DONE IN THE PAST, THE FIRST QUESTION IS
10 DO WE HAVE ANY MOTIONS TO MOVE ANYTHING FROM TIER
11 III INTO TIER I? OKAY.

12 THEN HEARING NONE, THEN DO WE HAVE ANY
13 MOTIONS TO MOVE THE ITEM IN TIER II INTO TIER I.

14 HEARING NONE, DO WE HAVE A MOTION TO
15 APPROVE FUNDING FOR ALL OF THE APPLICATIONS IN TIER
16 I AND NOT TO FUND ANY OF THE REMAINING APPLICATIONS?

17 MR. ROWLETT: SO MOVED.

18 MR. SHEEHY: DO WE HAVE A SECOND.

19 MR. TORRES: SECOND.

20 MR. SHEEHY: OKAY. DO WE HAVE ANY PUBLIC
21 AT ANY OF THE SITES? NO. DO WE HAVE ANY BOARD
22 COMMENT? THEN, AMY, COULD YOU CALL THE ROLL ON THE
23 MOTION PLEASE.

24 MS. CHEUNG: ANNE-MARIE DULIEGE.

25 DR. DULIEGE: YES.

BARRISTERS' REPORTING SERVICE

1 MS. CHEUNG: DAVID HIGGINS.
2 DR. HIGGINS: YES.
3 MS. CHEUNG: STEPHEN JUELSGAARD. SHERRY
4 LANSING. KATHY LAPORTE. LAUREN MILLER.
5 MS. MILLER: YES.
6 MS. CHEUNG: ADRIANA PADILLA.
7 DR. PADILLA: YES.
8 MS. CHEUNG: JOE PANETTA.
9 MR. PANETTA: YES.
10 MS. CHEUNG: FRANCISCO PRIETO.
11 DR. PRIETO: AYE.
12 MS. CHEUNG: ROBERT QUINT. AL ROWLETT.
13 MR. ROWLETT: YES.
14 MS. CHEUNG: JEFF SHEEHY.
15 MR. SHEEHY: YES.
16 MS. CHEUNG: OS STEWARD.
17 DR. STEWARD: YES.
18 MS. CHEUNG: JONATHAN THOMAS.
19 CHAIRMAN THOMAS: YES.
20 MS. CHEUNG: ART TORRES.
21 MR. TORRES: AYE.
22 MS. CHEUNG: DIANE WINOKUR.
23 MR. HARRISON: OS, YOU SHOULD VOTE YES
24 EXCEPT WITH RESPECT TO THOSE IN WHICH YOU HAVE A
25 CONFLICT.

BARRISTERS' REPORTING SERVICE

1 DR. STEWARD: MY APOLOGY. YES, EXCEPT FOR
2 THOSE WITH WHICH I HAVE A CONFLICT.

3 MR. SHEEHY: ALSO RESPONDING YES, EXCEPT
4 FOR THOSE WHICH I HAVE A CONFLICT.

5 MR. JUELSGAARD: AMY, THIS IS STEVE
6 JUESLGAARD. YES.

7 MR. HARRISON: MOTION PASSES.

8 DR. LUBIN: I WASN'T ASKED, BUT I WOULD
9 SAY YES, EXCEPT FOR THOSE WITH WHICH I HAVE A
10 CONFLICT.

11 MR. HARRISON: WE SHOULD CLARIFY. THIS
12 WAS A MOTION FOR THE APPLICATION REVIEW SUBCOMMITTEE
13 OF WHICH YOU ARE AN EX OFFICIO, NONVOTING MEMBER,
14 DR. LUBIN.

15 DR. LUBIN: THANK YOU.

16 CHAIRMAN THOMAS: GIL, CAN YOU CONTINUE
17 NOW WITH THE SPARK DESCRIPTION PLEASE.

18 DR. SAMBRANO: SO THE SPARKS PROGRAM,
19 FORMERLY KNOWN AS THE CREATIVITY PROGRAM, HAS BEEN
20 RUNNING FOR ABOUT FOUR YEARS. IT ORIGINALLY FUNDED
21 WITH 2.1 MILLION NINE PROGRAMS THAT ARE ABOUT EVENLY
22 SPLIT BETWEEN NORTHERN AND SOUTHERN CALIFORNIA. SO
23 RELATIVELY SPEAKING, THIS IS A MORE INEXPENSIVE
24 PROGRAM RELATIVE TO BRIDGES, BUT IT HAS SUPPORTED
25 MORE THAN 240 HIGH SCHOOL STUDENTS OVER THAT

BARRISTERS' REPORTING SERVICE

1 FOUR-YEAR TIME PERIOD AND MORE THAN 45 HIGH SCHOOLS
2 THROUGHOUT CALIFORNIA FROM WHICH THE STUDENTS HAVE
3 BEEN SELECTED.

4 SIMILAR ON THE BRIDGES PROGRAM, WE THOUGHT
5 ABOUT HOW TO ALIGN THIS WITH THE MISSION OF CIRM
6 2.0. PART OF IT WAS RENAMING IT TO SPARK, SUMMER
7 PROGRAM TO ACCELERATE REGENERATIVE MEDICINE
8 KNOWLEDGE. AND THERE ARE ELEMENTS THAT WE KEPT, OF
9 COURSE, THE INTERNSHIP COMPONENT. IN ALL CASES THE
10 INTERNSHIPS AND THE PROGRAMS ARE A SUPPLEMENT TO AN
11 EXISTING PROGRAM. AND ONE OF THE OTHER THINGS THAT,
12 OF COURSE, WE ARE KEEPING IS BROADENING
13 PARTICIPATION OF UNDERREPRESENTED POPULATIONS, AND
14 THE FAMOUS POSTER DAY WHERE ALL THE STUDENTS COME
15 TOGETHER AT THE VERY END TO PRESENT THEIR FINDINGS
16 TO AN AUDIENCE.

17 THERE ARE THINGS THAT WE ARE ADDING THAT
18 ARE SIMILAR TO THAT IN BRIDGES: DIRECT PATIENT
19 ENGAGEMENT ACTIVITIES, PREPARATORY TRAINING COURSE
20 BEFORE COMMENCEMENT OF THE RESEARCH, AND COMMUNITY
21 OUTREACH ACTIVITIES.

22 SO THIS RFA WAS OPEN TO CALIFORNIA
23 UNIVERSITIES, COLLEGES, OR RESEARCH INSTITUTIONS
24 WITH AN ESTABLISHED HIGH SCHOOL SUMMER INTERNSHIP
25 PROGRAM, AS I MENTIONED PREVIOUSLY. THE ICOC

BARRISTERS' REPORTING SERVICE

1 APPROVED UP TO 4 MILLION TO SUPPORT ABOUT TEN
2 PROGRAMS. EACH WOULD SUPPORT A MINIMUM OF FIVE AND
3 UP TO TEN TRAININGS PER YEAR, AND THIS WOULD BE A
4 PROGRAM THAT WOULD CONTINUE FOR FIVE YEARS.

5 AND HERE ARE THE RECOMMENDATIONS BASED ON
6 THE SAME SCORING SYSTEM DESCRIBED BEFORE. THE
7 APPLICATIONS ARE RECOMMENDED FOR FUNDING IN TIER I.,
8 THERE ARE ZERO IN TIER II, AND ZERO IN TIER III.

9 MR. SHEEHY: THANK YOU, DR. SAMBRANO. SO
10 AT THIS POINT I WOULD EITHER TAKE A MOTION TO MOVE
11 ANY OF THE APPLICATIONS IN TIER I OUT OF THE
12 FUNDABLE CATEGORY OR A MOTION TO FUND ALL THE
13 APPLICATIONS IN TIER I.

14 DR. PRIETO: I'LL MAKE A MOTION TO FUND
15 ALL THE APPLICATIONS IN TIER I.

16 MR. SHEEHY: DO WE HAVE A SECOND?

17 MR. ROWLETT: SECOND.

18 MR. SHEEHY: ANY BOARD DISCUSSION?

19 DR. JUELSGAARD: SO THERE ARE SEVEN
20 PROGRAMS THAT ARE SEEKING FUNDING AS I SEE ON THE
21 AGENDA THAT WAS PROVIDED. BUT WHEN YOU LOOK AT THE
22 PRESENTATION, ESSENTIALLY IT SAYS THAT IN THE PAST
23 WE HAD NINE PARTICIPANTS, IF I'M RIGHT. SO
24 APPARENTLY TWO HAVE DROPPED OUT ALONG THE WAY. DO
25 WE HAVE ANY INSIGHT AS TO WHY THAT HAPPENED?

BARRISTERS' REPORTING SERVICE

1 DR. SAMBRANO: YES. IT'S A LITTLE BIT
2 MISLEADING. SO WHAT HAPPENS IS THERE ARE TWO
3 APPLICANTS THAT WERE IN TIER III, BUT THEY WITHDREW
4 THEIR APPLICATION BEFORE COMING TO THE BOARD. SO
5 OFTEN WHEN WE PROVIDE THE OUTCOMES FROM THE REVIEW
6 TO APPLICANTS, THEY HAVE THE OPTION TO WITHDRAW.
7 TWO OF THEM IN TIER III SELECTED TO DO THAT.

8 DR. JUELSGAARD: JUST TO FOLLOW UP ON THAT
9 THEN, GIL. SO IN THE PAST, THEN, IF I UNDERSTAND IT
10 CORRECTLY, THEY WERE FUNDED. SO THE TWO THAT
11 WITHDREW WERE FUNDED PREVIOUSLY, BUT NOW THEY'VE
12 WITHDRAWN; IS THAT RIGHT?

13 DR. SAMBRANO: I BELIEVE THAT IS THE CASE.
14 WE'RE CHECKING TO BE SURE. WE HAVE HAD, AT LEAST IN
15 THE BRIDGES, I REMEMBER, THERE WERE SOME NEW
16 PROGRAMS THAT CAME INTO THE MIX. I DON'T THINK THAT
17 WAS THE CASE FOR SPARK.

18 MR. JUELSGAARD: IF I'M CORRECT, AND I MAY
19 NOT BE, I APPRECIATE THAT, BUT DO WE KNOW WHY IN THE
20 PAST THEY HAVE BEEN APPROVED BUT NOW THEY HAVE
21 WITHDRAWN? DO WE KNOW WHAT'S CHANGED? AGAIN, IF
22 THESE ARE THE SAME TWO.

23 DR. SAMBRANO: WELL, THE REVIEW WAS A
24 LITTLE BIT DIFFERENT BECAUSE THERE ARE NEW ELEMENTS
25 THAT HAVE BEEN INTRODUCED INTO THE PROGRAM, SO THE

BARRISTERS' REPORTING SERVICE

1 DIRECT PATIENT ACTIVITIES AND OTHER ELEMENTS THAT
2 THEY NEEDED TO BE A PART OF THE PROGRAM. SO AT
3 LEAST A COUPLE THEM DID NOT DO WELL IN REFORMULATING
4 THEIR APPLICATION AND PRESENTING A NEW PROPOSAL THAT
5 WAS BETTER ALIGNED WITH THE PROGRAM THAT WE ENVISION
6 GOING FORWARD.

7 DR. JUELSGAARD: I'M SORRY THIS IS
8 REVISITING HISTORY JUST A LITTLE BIT. IN THE
9 BRIDGES PROGRAMS THERE WAS ONE PROGRAM THAT WAS A
10 TWO RATHER THAN A ONE AND PARTICIPATION WAS A MAJOR
11 CONCERN BY THE GWG REVIEWERS. IS THAT THE SAME
12 SITUATION, THAT IN THE PAST THEY WERE FUNDED, BUT
13 THIS TIME THEY WEREN'T FUNDED BECAUSE THEY BASICALLY
14 DIDN'T STAND OR DIDN'T MEET THE PARTICIPATION
15 REQUIREMENTS THAT WE WOULD HAVE LIKED TO HAVE SEEN?

16 DR. SAMBRANO: RIGHT. THE CRITICISMS
17 RELATED TO NEW ELEMENTS THAT WERE PART OF NOW THE
18 NEW PROGRAM. THIS IS FOR THE PATIENT ENGAGEMENT
19 ACTIVITIES, THE REVIEWERS DID NOT FEEL THEY WERE UP
20 TO PAR ON THAT.

21 DR. JUELSGAARD: ALL RIGHT. THANK YOU.

22 MR. SHEEHY: ANY FURTHER QUESTIONS FROM
23 MEMBERS OF THE BOARD? HEARING NONE, AMY, COULD YOU
24 CALL THE ROLL.

25 MS. CHEUNG: ANNE-MARIE DULIEGE. DAVID

BARRISTERS' REPORTING SERVICE

1 HIGGINS.

2 DR. HIGGINS: YES.

3 MS. CHEUNG: STEPHEN JUELSGAARD.

4 MR. JUELSGAARD: YES.

5 MS. CHEUNG: SHERRY LANSING. KATHY

6 LAPORTE. LAUREN MILLER.

7 MS. MILLER: YES.

8 MS. CHEUNG: ADRIANA PADILLA.

9 DR. PADILLA: YES.

10 MS. CHEUNG: JOE PANETTA.

11 MR. PANETTA: YES.

12 MS. CHEUNG: FRANCISCO PRIETO.

13 DR. PRIETO: AYE.

14 MS. CHEUNG: ROBERT QUINT.

15 DR. QUINT: YES.

16 MS. CHEUNG: AL ROWLETT.

17 MR. ROWLETT: YES.

18 MS. CHEUNG: JEFF SHEEHY.

19 MR. SHEEHY: YES, EXCEPT FOR THOSE WITH

20 WHICH I HAVE A CONFLICT.

21 MS. CHEUNG: OS STEWARD.

22 DR. STEWARD: YES, EXCEPT FOR THOSE WITH

23 WHICH I HAVE A CONFLICT.

24 MS. CHEUNG: JONATHAN THOMAS.

25 CHAIRMAN THOMAS: YES.

BARRISTERS' REPORTING SERVICE

1 MS. CHEUNG: ART TORRES.

2 MR. TORRES: AYE.

3 MS. CHEUNG: DIANE WINOKUR.

4 MR. HARRISON: MOTION PASSES.

5 MR. SHEEHY: SO, CHAIRMAN THOMAS, THAT
6 CONCLUDES THE APPLICATION REVIEW SUBCOMMITTEE.

7 CHAIRMAN THOMAS: THANK YOU VERY MUCH, MR.
8 SHEEHY. ON TO ITEM 7, WHICH IS CONSIDERATION OF
9 AMENDMENTS TO THE GRANTS ADMINISTRATION POLICY.
10 GABE, WILL YOU PLEASE TAKE US THROUGH THOSE.

11 MR. THOMPSON: GOOD MORNING. AND THE CIRM
12 TEAM ARE HERE TO PRESENT CONSIDERATION OF ADOPTION
13 OF THE INTERIM GRANTS ADMINISTRATION POLICY FOR
14 DISCOVERY, TRANSLATION, AND EDUCATION PROJECTS.

15 JUST A REMINDER, THE GAP SETS OUT DETAILED
16 RULES FOR BOTH REVIEWING, AWARDING, AND THEN
17 MONITORING AWARDS APPROVED BY THE BOARD. AND IN
18 LIGHT OF THE FACT THAT WE JUST APPROVED TWO
19 EDUCATION PROGRAMS, AND WILL FOLLOW UP SOON WITH
20 TRANSLATION, WE NEED THESE POLICIES TO BE IN PLACE
21 JUST TO SUPPORT THOSE PROGRAMS. GIVEN THE TIMELINES
22 WHERE CIRM IS AVAILING ITSELF OF ITS STATUTORY
23 AUTHORITY TO ADOPT THE POLICY ON AN INTERIM BASIS,
24 WHICH ALLOWS THE POLICIES TO BE EFFECTIVE
25 IMMEDIATELY. AND THEN WE USE THE MAJORITY OF THE

BARRISTERS' REPORTING SERVICE

1 CALENDAR YEAR 2016 TO MAKE ADDITIONAL REVISIONS OR
2 EDITS TO THE POLICY. SO THE BOARD WILL HAVE
3 ADDITIONAL OPPORTUNITIES TO REVIEW THIS AND COMMENT
4 UPON FINAL ADOPTION OF THE POLICY LATER THIS YEAR.

5 SO WITH THAT STATED, I'LL GO OVER THE
6 CHANGES WE MADE. THE BASELINE FOR THE POLICY WAS
7 THE GRANTS ADMINISTRATION POLICY FOR CLINICAL STAGE
8 PROJECTS, AND THEN THE CHANGES ARE EITHER TO ALIGN
9 THE POLICY WITH WHAT WAS SPECIFIED IN THE PROGRAM
10 ANNOUNCEMENTS FOR DISCOVERY, TRANSLATION, AND
11 EDUCATION OR TO JUST SORT OF SIMPLIFY THE LANGUAGE
12 TO MAKE IT MORE CLEAR AND CONCISE.

13 TO GO THROUGH THESE, THE FIRST CHANGE IS
14 TO INTRODUCE THE CONCEPT OF A PROJECT MILESTONE. SO
15 MILESTONES ARE THE MARKER OF A PROJECT'S PROGRESS.
16 FOR CLINICAL STAGE PROJECTS, WE ESTABLISHED
17 OPERATIONAL MILESTONES WHICH WE CALL OBJECTIVE
18 EVENTS THAT, WHEN ACHIEVED, TRIGGER THE DISBURSEMENT
19 OF ADDITIONAL FUNDS. SO WE ARE GOING TO USE THE
20 CONCEPT OF OPERATIONAL MILESTONES FOR TRANSLATION
21 PROJECTS, BUT WE WILL USE THE CONCEPT OF PROJECT
22 MILESTONES FOR DISCOVERY AWARDS.

23 SO A PROJECT MILESTONE WOULD BE AN
24 OBJECTIVE EVENT ESTABLISHED BY CIRM. AND THOUGH ALL
25 THE FUNDS WOULD BE DISBURSED ON BASED ON TIME RATHER

BARRISTERS' REPORTING SERVICE

1 THAN THE ACCOMPLISHMENT OF A PROJECT MILESTONE,
2 CIRM, AT ITS SOLE DISCRETION, COULD REVISE PROJECT
3 ACTIVITIES, REALLOCATED RESOURCES, SUSPEND AND/OR
4 TERMINATE THE PROJECT IF AN AWARDEE FAILS TO
5 ACCOMPLISH A PROJECT MILESTONE WITHIN A REASONABLE
6 TIME.

7 SO WE ALSO REMOVED THE TERM "SUSPENSION
8 EVENT" GIVEN THAT THOSE WERE MAINLY FOR CLINICAL
9 STAGE PROGRAMS AND DON'T REALLY APPLY TO THE OTHER
10 PROGRAMS.

11 DR. JUELSGAARD: CAN I INTERRUPT YOU AT
12 THIS POINT. THIS IS STEVE JUELSGAARD. SO CAN YOU
13 EXPLAIN WHY YOU DECIDED TO INTRODUCE THE TERM
14 "PROJECT MILESTONES" INTO THE PROCESS RATHER THAN
15 THE WAY WE HAD IT BEFORE? WHAT WAS WRONG WITH WHAT
16 WE DID BEFORE WHICH WAS SIMPLY BASED ON TIME? WHAT
17 WAS WRONG WITH THAT APPROACH AS TO THE APPROACH THAT
18 YOU'RE PROPOSING NOW?

19 MR. THOMPSON: SO OUR THINKING HERE WAS
20 THAT IN EARLIER STAGE PROJECTS, THAT THERE WOULD BE
21 SOME ALLOWANCE OF THE CRITICAL PATH THAT THE
22 PROJECTS ARE GOING ON AND TO TRY TO GET TO THEIR
23 GOAL WITHIN A REASONABLE TIME PERIOD. AND SO WE
24 THOUGHT PROJECT MILESTONES WOULD BE MORE APPROPRIATE
25 IN THAT CASE AND BECAUSE THERE'S LESS OBJECTIVE

BARRISTERS' REPORTING SERVICE

1 EVENTS THAT ARE IN CRITICAL STAGE PROGRAMS. FOR
2 INSTANCE, WE BASE OPERATIONAL MILESTONES ON PERCENT
3 OF PATIENTS INVOLVED IN THE TRIAL. SO 50 PERCENT OF
4 PATIENTS ENROLLED WOULD BE ONE EXAMPLE, BUT TRYING
5 TO FIND A SIMILAR TYPE OF MILESTONE FOR TRANSLATION
6 AND DISCOVERY WHERE THE PATH WOULD BE DIFFERENT WE
7 FELT WARRANTED A DIFFERENT DEFINITION.

8 MR. HARRISON: IF I COULD JUST ELABORATE
9 BRIEFLY. THE FUNDS FOR THE DISCOVERY PROGRAMS,
10 WHICH ARE SMALLER, SHORTER AWARDS, WILL BE DISBURSED
11 ON A TIME BASIS, BUT WANTED TO ENSURE THAT WE HAD
12 SOME MECHANISM TO TERMINATE AN AWARD IF WE
13 DETERMINED THAT THE PROJECT HAD SIMPLY GONE OFF THE
14 TRACK. SO THE PROJECT MILESTONE, THE NEW DEFINITION
15 WE PROPOSE WOULD GIVE US THAT ABILITY.

16 DR. JUELSGAARD: ALL RIGHT. JAMES, I CAN
17 UNDERSTAND THAT, AND I CAN UNDERSTAND THAT GO OFF
18 THE TRACKS APPROACH, BUT THAT LANGUAGE IS NOT USED
19 IN WHAT I'M LOOKING AT RIGHT HERE. RATHER, IT'S
20 CIRM AT ITS DISCRETION CAN DO THIS.

21 SO CLINICAL MILESTONES TO ME ARE A VERY;
22 COMMON AND ACCEPTABLE APPROACH FOR DETERMINING
23 CONTINUED (UNINTELLIGIBLE) ALMOST ALL THE TIME IN
24 INDUSTRY AS A WAY OF -- WHEN ONE COMPANY OR
25 ORGANIZATION FINDS ANOTHER CLINICAL RESOURCE, BUT

BARRISTERS' REPORTING SERVICE

1 REALLY AREN'T USED SO MUCH IN THE DISCOVERY,
2 TRANSLATIONAL PHASE BECAUSE THERE'S SO MANY
3 POSSIBILITIES THAT CAN TURN UP ALONG THE WAY OF WHY
4 IT MIGHT BE MORE DIFFICULT, WHY ONE THING MIGHT LEAD
5 TO ANOTHER. SO I'M STILL STRUGGLING A LITTLE BIT
6 WITH THE NEED FOR CHANGING AT THIS POINT.

7 I UNDERSTAND THAT A MILESTONE IS MORE
8 OBJECTIVE AND THAT YOU HAVE A DATE IN MIND BY WHICH
9 SOMETHING HAS TO BE DONE. BUT AT THIS VERY, VERY
10 EARLY STAGE, TRYING TO PREDICT WHEN THINGS MIGHT
11 COME TO FRUITION IS JUST A LOT HARDER.

12 AND LET ME JUST SAY THIS. IN ADDITION TO
13 THIS, I FIND THAT IT'S JUST A LITTLE AWKWARD TO
14 DISCUSS THIS WITHOUT HAVING SOME OF OUR ACADEMIC OR
15 RESEARCH-ORIENTED COLLEAGUES ABLE TO ENGAGE IN THE
16 DISCUSSION BECAUSE THEY OBVIOUSLY HAVE A LOT OF
17 INSIGHT INTO THIS OR EXPERIENCE IN THIS. SO THOSE
18 OF US THAT ARE DISCUSSING THIS ARE LESS EXPERIENCED
19 POTENTIALLY IN THAT REGARD.

20 MY CONCERN IS JUST I DON'T KNOW HOW
21 MILESTONE ORIENTED THIS KIND OF ACTIVITY SHOULD
22 REALLY BE.

23 MR. HARRISON: STEVE, IF I COULD JUST
24 RESPOND BRIEFLY FIRST TO YOUR LAST POINT. ALL THE
25 MEMBERS OF THE BOARD CAN PARTICIPATE IN THIS

BARRISTERS' REPORTING SERVICE

1 DISCUSSION BECAUSE IT'S DISCUSSION ABOUT A STANDARD.
2 THEY'RE FREE TO WEIGH IN WITH THEIR EXPERIENCE. OUR
3 INTENT HERE REALLY WASN'T TO PUT CIRM IN A POSITION
4 WHERE IT WOULD TERMINATE AN AWARD SIMPLY BECAUSE IT
5 WAS TAKING MORE TIME OR WAS LEADING TO AN OUTCOME
6 OTHER THAN WHAT WE HAD HOPED FOR. WE RECOGNIZE THAT
7 THESE PROGRAMS ARE SMALL, THEY'RE SHORT IN TIME, AND
8 THEY'RE BASIC DISCOVERY. SO WE ANTICIPATE THAT
9 THERE WILL BE CHANGES IN DIRECTION.

10 WHAT WE'RE LOOKING FOR HERE IS A MEANS TO
11 TERMINATE A PROJECT WHERE THE GRANTEE HAS
12 EFFECTIVELY DECIDED TO TURN IN A WHOLE NEW DIRECTION
13 AND, IN EFFECT, A NEW PROJECT. WE WANT TO MAKE SURE
14 WE HAVE THE DISCRETION AT THAT POINT IN TIME TO PUT
15 A STOP TO IT. SO THIS IS NOT A POWER WE WOULD
16 ANTICIPATE USING FREQUENTLY. IT'S MORE A MEANS OF
17 TRYING TO KEEP THE PROGRAMS IN PROGRESS AND IN
18 CHECK.

19 MR. JUELSGAARD: THANKS. I YIELD THE
20 FLOOR.

21 DR. BOXER: I AM REALLY UNCLEAR ON HOW ONE
22 DEFINES A PROJECT MILESTONE AND HOW THAT RELATES TO
23 BASIC RESEARCH. SO I GUESS I WOULD AGREE WITH THE
24 PREVIOUS COMMENTS, THAT I DON'T REALLY UNDERSTAND
25 WHAT WAS WRONG WITH THE PREVIOUS PROCESS.

BARRISTERS' REPORTING SERVICE

1 AND I GUESS -- SO LET ME ASK. LET'S SAY
2 THERE'S AN UNFORESEEN RESULT OR DISCOVERY THAT
3 POTENTIALLY OPENS UP SOMETHING VERY INTERESTING. I
4 PRESUME THAT MUST HAVE HAPPENED IN THE PAST AND THAT
5 INVOLVES A DISCUSSION WITH CIRM SCIENTIFIC STAFF. I
6 MEAN HOW WOULD THAT HAVE BEEN HANDLED IN THE PAST.

7 DR. MILLS: SO THE PROBLEM WE HAVE IS WHAT
8 HAPPENS WHEN TWISTS OF FATE TAKE AN AWARD INTO A
9 SCOPE THAT IS NOT -- IS NO LONGER THE PROJECT THAT
10 THE GWG REVIEWED AND IS NO LONGER THE PROJECT THAT
11 THE ICOC FUNDED. AND THAT HAPPENS FAIRLY OFTEN. SO
12 WE HAVE, AND I'LL LET JAMES TALK MORE ABOUT IT, BUT
13 WE HAVE SORT OF CONTRACTUAL OBLIGATIONS TO MAKE SURE
14 WE FUND THE RESEARCH THAT YOU AS THE BOARD APPROVED
15 AND THE GWG RECOMMENDED. AND WHAT WE CAN'T HAVE ARE
16 PEOPLE PUTTING IN ONE APPLICATION, STARTING ON A
17 PROJECT, DECIDE THEY WANT TO DO SOMETHING COMPLETELY
18 DIFFERENT, AND THEN USE OUR FUNDS TO DO THAT IN AN
19 UNREVIEWED FASHION.

20 THIS IS A MECHANISM BY WHICH WE WOULD BE
21 ABLE TO CONTROL THAT. BUT I WOULD SAY THE FIRST
22 THING WE DID, BECAUSE OUR GOAL IS TO TRY TO GET
23 THESE THERAPIES ACCELERATED TO THE PATIENT, THE
24 FIRST THING WE DID, AS YOU GUYS WILL ALL RECALL AND
25 TOOK PART IN, WAS SETTING UP MECHANISMS WHEREBY A

BARRISTERS' REPORTING SERVICE

1 NEW DISCOVERY POPPED UP, YOU WEREN'T WONDERING WHEN
2 YOU COULD REAPPLY OR IF YOU COULD REAPPLY IN A
3 TIMELY FASHION. SINCE WE PUT BOTH THE DISCOVERY AND
4 THE TRANSLATIONAL PROGRAMS ON REVIEW CYCLES EVERY
5 SIX MONTHS, WHILE ONE PROGRAM MAY NEED TO BE WINDED
6 DOWN BECAUSE THE DIRECTION HAS CHANGED BASED ON THE
7 MECHANISMS THAT JAMES AND GABE PROPOSED TODAY, THE
8 OTHER ONE, IF FOUND TO BE MERITORIOUS BY THE GWG AND
9 THE BOARD, ARE CONTINUOUSLY AND COMPLETELY AVAILABLE
10 WITHOUT ANY DELAY OR TIME GAP IN FUNDING.

11 SO THAT'S THE BALANCE WE'RE TRYING TO
12 STRIKE HERE, MAKING SURE THAT CIRM IS ABLE TO DO
13 BUSINESS IN A TIMELY FASHION THAT DOESN'T DELAY THE
14 RESEARCH, BUT ALSO GIVING US THE PROPER GOVERNANCE
15 OVERSIGHT TO MAKE SURE THAT WHAT WE ACTUALLY
16 APPROVED FOR FUNDING GOES ON AND IS ACTUALLY THE
17 WORK THAT'S GETTING DONE.

18 DR. STEWARD: THIS IS OS. COULD I
19 COMMENT?

20 CHAIRMAN THOMAS: ABSOLUTELY.

21 DR. STEWARD: JUST TO MAYBE ALLAY SOME OF
22 CONCERNS, THIS IS REALLY NOT ALL THAT MUCH DIFFERENT
23 THAN WHAT GOES ON AT NIH. EVERY YEAR NIH GRANTEEES
24 SUBMIT PROGRESS REPORTS THAT ARE REVIEWED BY THE
25 PROGRAM OFFICERS. AND NIH HAS THE OPTION AT THAT

BARRISTERS' REPORTING SERVICE

1 POINT IN TIME TO LOOK AT WHAT'S BEEN DONE AND WHAT'S
2 PLANNED AND MAKE A DETERMINATION OF WHETHER THE
3 RESEARCH IS OUT OF SCOPE FOR THE ORIGINAL PROPOSAL.
4 AND THERE ARE OCCASIONALLY DECISIONS MADE ALONG
5 THOSE LINES.

6 NOW, I WOULD SAY THAT I THINK THAT MAYBE
7 CIRM IS A LITTLE BIT MORE FOCUSED IN ITS ATTACK ON
8 THE PROBLEMS AND MIGHT BE MORE LIKELY TO DETERMINE
9 SOMETHING AS BEING OUT OF SCOPE THAN NIH MIGHT BE,
10 BUT I DON'T THINK INVESTIGATORS WILL FIND THAT ALL
11 THAT DIFFERENT OR PARTICULARLY CONCERNING. THANK
12 YOU.

13 DR. JUELSGAARD: ONE LAST QUESTION. I'VE
14 HEARD EXACTLY THE TERM YOU USED WHEN YOU DESCRIBED
15 THIS, BUT YOU INDICATED THAT ALONG THE WAY WE'VE HAD
16 SOME ISSUES WITH SOME NUMBER, WHICH I ASSUME IS MORE
17 LIKELY THE CASE BASED ON WHAT OS JUST SAID WITH THE
18 NIH. WHAT PERCENTAGE OF TIME OR WHAT SPECIFICALLY
19 HAPPENED OR WHAT PERCENTAGE OF TIME DID THESE THINGS
20 HAPPEN THAT CAUSED THIS ISSUE TO COME ON THE FORE
21 WITH THE DESIRE TO CHANGE THE APPROACH? SO WHAT
22 LIES BEHIND THIS?

23 DR. MILLS: SO THEY COME IN ALL DIFFERENT
24 SORT OF VARIETIES OR SEVERITY, BUT THERE WAS A
25 NUMBER THROWN OUT, I WANT TO SAY, 80 PERCENT RANGE.

BARRISTERS' REPORTING SERVICE

1 SO APPROXIMATELY 80 PERCENT OF THIS STAGE
2 APPLICATION THAT COMES BEFORE US HAS ONE OR MULTIPLE
3 CHANGE REQUESTS, WHICH ARE IRONICALLY CALLED PRIOR
4 APPROVAL REQUESTS, SOMETHING OF WHICH LIKE 90
5 PERCENT ARE GIVEN TO US AFTER THE FACT.

6 DR. JUELSGAARD: SO, AGAIN, THOSE 90
7 PERCENT OF THE CASES CIRM WOULD EVALUATE WHETHER TO
8 CONTINUE THE FUNDING OR TO STOP IS. THAT WHAT
9 YOU'RE SAYING?

10 DR. MILLS: YES, BECAUSE IT'S A CHANGE.
11 NOW, TO TAKE THAT EVEN FURTHER, MOST OF THE TIME,
12 THE VAST MAJORITY OF THE TIME, EVEN IF THEY'RE
13 SUBMITTED AFTER THE FACT, THE PRIOR APPROVAL REQUEST
14 IS APPROVED.

15 DR. JUELSGAARD: OKAY.

16 CHAIRMAN THOMAS: ANY OTHER QUESTIONS
17 ALONG THESE LINES? OKAY. CAN YOU CONTINUE?

18 MR. THOMPSON: SO THE NEXT REVISION WE
19 MADE WAS UNDER APPLICATION REVIEW AND SCORING
20 SECTION. WE'RE SIMPLIFYING THIS LANGUAGE TO JUST
21 DESIGNATE WHETHER AN APPLICATION IS EITHER
22 RECOMMENDED FOR FUNDING OR NOT RECOMMENDED FOR
23 FUNDING. WE PREVIOUSLY HAD A MUCH MORE DETAILED
24 SECTION DESCRIBING THE FUNDING. BUT GIVEN THE BOARD
25 APPROVED AMENDMENT TO THE GWG BYLAWS THAT DEFINE THE

BARRISTERS' REPORTING SERVICE

1 SCORING FOR NONCLINICAL PROGRAMS, WE DIDN'T NEED TO
2 INCLUDE THAT MUCH DETAIL WITHIN THE GAP ITSELF.

3 THE NEXT SECTION IS UNDER UNALLOWABLE
4 COSTS. CIRM IS PROPOSING TO ALLOW MEMBERSHIP DUES
5 TO BE CHARGED TO CIRM AWARDS WHEN REASONABLY
6 ALLOCATED TO THE PROJECT. MEMBERSHIP DUES HAD BEEN
7 PREVIOUSLY UNALLOWABLE TO ALIGN WITH NIH POLICY, BUT
8 OUR COMPLIANCE SECTION HAS REVEALED THERE COULD BE
9 ACTUALLY JUSTIFIABLE REASONS TO CHARGE MEMBERSHIP TO
10 A CIRM AWARD FOR PROJECT PERSONNEL WHO ARE WORKING
11 ON A PROJECT. SO THE DUES ARE OFTEN ASSOCIATED WITH
12 REGISTRATION AT A CONFERENCE, WHICH IS AN
13 UNALLOWABLE (INTERRUPTION BY A CELL PHONE).
14 MEMBERSHIP DUES SHOULD BE ALLOWABLE WHEN THE PROJECT
15 ITSELF CAN REASONABLY ALLOCATE THE COST TO CIRM
16 PROJECTS.

17 MR. SHEEHY: JUST FOR FOLKS MAKE SURE
18 EVERYBODY IS CLEAR. THE SCORING SYSTEM WILL BE 85
19 AND ABOVE IS FUNDABLE, 84 AND BELOW IS NOT
20 RECOMMENDED FOR FUNDING, RIGHT. SO WE MOVED TO TWO
21 TIERS. SO WHAT WE HAD TODAY WE WILL NEVER SEE
22 AGAIN. THIS WOULD BE SEPARATE FOR THE ONE, TWO,
23 THREE SCORING THAT WE DO IN THE CLINICAL PROGRAMS.
24 JUST SO EVERYBODY IS CLEAR ABOUT THE CHANGE OF THE
25 SCORING SYSTEM (UNINTELLIGIBLE).

BARRISTERS' REPORTING SERVICE

1 MR. HARRISON: ONE POINT TO ADD TO THAT,
2 JEFF. ONE OF THE REASONS WE DIDN'T WANT TO INCLUDE
3 THAT LEVEL OF DETAIL IN THE GAP IS IT'S ALREADY SET
4 FORTH IN THE BYLAWS. THE BYLAWS ARE AN INTERNAL
5 SORT OF DOCUMENT, AND THE BOARD CAN CHANGE THE
6 BYLAWS AND THOSE CHANGES GO INTO EFFECT IMMEDIATELY.
7 ONCE WE PUT IT INTO THE GRANTS ADMINISTRATION
8 POLICY, IT BECOMES SUBJECT TO THE ADMINISTRATIVE
9 PROCEDURE ACT, WHICH WOULD MEAN WE'D NEED TO GO
10 THROUGH A LENGTHY PROCESS TO CHANGE WHAT IS
11 EFFECTIVELY AN INTERNAL POLICY.

12 MR. SHEEHY: THANK YOU.

13 MR. THOMPSON: THE NEXT SECTION IS
14 POST-PROJECT ALLOWABLE COSTS. THIS WAS A CONCEPT WE
15 INTRODUCED FOR CLINICAL STAGE PROGRAMS TO
16 INCENTIVIZE THE EFFICIENT USE OF CIRM FUNDS WHICH
17 ALLOWED, OF THE PROJECTS HAD REMAINING CIRM FUNDS AT
18 THE END OF THEIR PROJECT, TO EITHER REDUCE THE
19 ACTUAL CO-FUNDING TO AN AMOUNT THAT WAS LOWER THAN
20 WHAT WAS ORIGINALLY REQUIRED ON THE AWARD OR TO FUND
21 A PROJECT AT THE AWARDEE INSTITUTION THAT FURTHERS
22 CIRM'S MISSION SUBJECT TO CIRM'S PRIOR APPROVAL AND
23 SUBJECT TO CIRM REGULATIONS AND AUDIT, OR TO RETURN
24 THE FUNDS TO CIRM WITHIN 30 DAYS OF THE DEADLINE FOR
25 FINAL FINANCIAL REPORTS.

BARRISTERS' REPORTING SERVICE

1 WE'RE GOING TO EXTEND THE POLICY FOR
2 POST-PROJECT ALLOWABLE COSTS FOR ALL TRANSLATION AND
3 DISCOVERY PROJECTS. SO IF ANY OF THOSE PROJECTS
4 HAVE AVAILABLE FUNDING, THEY CAN SUBMIT TO CIRM A
5 PRIOR APPROVAL TO USE THAT FUNDING FOR CIRM MISSION
6 CRITICAL PROJECTS SUBJECT TO REVIEW.

7 THE FINAL SECTION IS UNDER FAILURE OF
8 COMPLIANCE. SO UNDER THE FAILURE OF COMPLIANCE
9 SECTION, WE SET FORTH THE ACTIONS CIRM CAN TAKE IF
10 ONE OR MORE OF THE CONDITIONS OF THE AWARD ARE
11 VIOLATED. AND IN THIS SECTION WE PROPOSE TO EXPAND
12 THE LIST TO INCLUDE CONSIDERATION OF PAST
13 PERFORMANCE. AND WE ADDED THIS LANGUAGE TO ALIGN
14 WITH THE POLICY MODIFICATIONS UNDER CIRM 2.0
15 APPROVED BY THE BOARD IN DECEMBER.

16 THAT'S THE EXTENT OF THE CHANGES WE'D LIKE
17 TO MAKE. AGAIN, IF YOU WERE TO ADOPT THE POLICY
18 TODAY, IT WOULD GO INTO INTERIM STATUS, AND YOU HAVE
19 ADDITIONAL TIME IN 2016 TO PROVIDE COMMENTS AND
20 REVIEW THE POLICY.

21 CHAIRMAN THOMAS: THANK YOU VERY MUCH,
22 GABE. DO I HEAR A MOTION TO APPROVE THESE INTERIM
23 AMENDMENTS?

24 DR. FRIEDMAN: I MAKE THE MOTION.

25 CHAIRMAN THOMAS: THANK YOU, DR. FRIEDMAN.

BARRISTERS' REPORTING SERVICE

1 DO I HEAR A SECOND?

2 MR. TORRES: SECOND DR. FRIEDMAN'S MOTION.

3 CHAIRMAN THOMAS: SECONDED MORE OR LESS

4 SIMULTANEOUSLY BY MR. SHEEHY AND SENATOR TORRES.

5 ANY FURTHER DISCUSSION ON THIS ITEM? AMY, PLEASE

6 CALL THE ROLL.

7 MS. CHEUNG: DAVID BRENNER.

8 DR. BRENNER: YES.

9 MS. CHEUNG: LINDA BOXER.

10 DR. BOXER: YES.

11 MS. CHEUNG: KEN BURTIS.

12 DR. BURTIS: YES.

13 MS. CHEUNG: ANNE-MARIE DULIEGE.

14 DR. DULIEGE: YES.

15 MS. CHEUNG: MICHAEL FRIEDMAN.

16 DR. FRIEDMAN: YES.

17 MS. CHEUNG: JUDY GASSON.

18 DR. GASSON: YES.

19 MS. CHEUNG: SAM HAWGOOD. DAVID HIGGINS.

20 DR. HIGGINS: YES.

21 MS. CHEUNG: STEPHEN JUELGAARD.

22 MR. JUELGAARD: YES.

23 MS. CHEUNG: SHERRY LANSING. KATHY

24 LAPORTE. BERT LUBIN.

25 DR. LUBIN: YES.

BARRISTERS' REPORTING SERVICE

1 MS. CHEUNG: SHLOMO MELMED.
2 DR. MELMED: YES.
3 MS. CHEUNG: LAUREN MILLER.
4 MS. MILLER: YES.
5 MS. CHEUNG: ADRIANA PADILLA.
6 DR. PADILLA: YES.
7 MS. CHEUNG: JOE PANETTA.
8 MR. PANETTA: YES.
9 MS. CHEUNG: ROBERT PRICE.
10 DR. PRICE: YES.
11 MS. CHEUNG: FRANCISCO PRIETO.
12 MS. CHEUNG: AYE.
13 MS. CHEUNG: CARMEN PULIAFITO. ROBERT
14 QUINT.
15 DR. QUINT: YES.
16 MS. CHEUNG: AL ROWLETT.
17 MR. ROWLETT: YES.
18 MS. CHEUNG: JEFF SHEEHY.
19 MR. SHEEHY: YES.
20 MS. CHEUNG: OS STEWARD.
21 DR. STEWARD: YES.
22 MS. CHEUNG: JONATHAN THOMAS.
23 CHAIRMAN THOMAS: YES.
24 MS. CHEUNG: ART TORRES.
25 MR. TORRES: AYE.

BARRISTERS' REPORTING SERVICE

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MS. CHEUNG: KRISTINA VUORI.

DR. VUORI: YES.

MS. CHEUNG: DIANE WINOKUR.

MR. HARRISON: MOTION PASSES.

CHAIRMAN THOMAS: THANK YOU. THAT
CONCLUDES THE ACTION ITEMS ON THE AGENDA. I WILL
ASK. I BELIEVE THERE ARE NO MEMBERS OF THE PUBLIC
AT ANY OF THE SITES, BUT JUST FOR THE SAKE OF
COMPLETENESS, ASK IF THERE IS ANYBODY WHO WANTS TO
COMMENT AMONGST THE MEMBERS OF THE PUBLIC AT THIS
TIME. HEARING NONE, THAT CONCLUDES TODAY'S MEETING.
THANK YOU VERY MUCH, EVERYBODY. HAVE A WONDERFUL
REST OF THE DAY.

(THE MEETING WAS THEN CONCLUDED AT 11:52 A.M.)

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE TELEPHONIC PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE AND THE APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON JANUARY 19, 2016, 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 TO THE BEST OF MY ABILITY TO HEAR AND UNDERSTAND THE TELEPHONIC TRANSMISSION. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CSR 7152
BARRISTERS' REPORTING SERVICE
160 S. OLD SPRINGS ROAD
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ANAHEIM, CALIFORNIA
(714) 444-4100

BARRISTERS' REPORTING SERVICE

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