

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: TUESDAY, JANUARY 12, 2016
10 A.M.

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

BRS FILE NO.: 98252

BARRISTERS' REPORTING SERVICE

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I N D E X

ITEM DESCRIPTION	PAGE NO.
1. CALL TO ORDER.	3
2. ROLL CALL.	3
3. CONSIDERATION OF ADOPTION OF INTERIM GRANTS ADMINISTRATION POLICY FOR DISCOVERY, TRANSLATIONAL AND EDUCATION GRANTS.	3
4. PUBLIC COMMENT	NONE

TUESDAY, JANUARY 12, 2016; 10 A.M.

CHAIRMAN SHEEHY: SO I'D LIKE TO CALL THE MEETING TO ORDER. MARIA, WOULD YOU CALL THE ROLL PLEASE.

MS. BONNEVILLE: JEFF SHEEHY.

CHAIRMAN SHEEHY: HERE.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: HERE.

MS. BONNEVILLE: MICHAEL FRIEDMAN.

DR. FRIEDMAN: HERE.

MS. BONNEVILLE: DAVID HIGGINS.

BARRISTERS' REPORTING SERVICE

1 DR. HIGGINS: HERE.

2 MS. BONNEVILLE: BERT LUBIN. SHLOMO
3 MELMED.

4 DR. MELMED: HERE.

5 MS. BONNEVILLE: ART TORRES.

6 MR. TORRES: HERE.

7 MS. BONNEVILLE: JONATHAN THOMAS.

8 CHAIRMAN THOMAS: HERE.

9 MS. BONNEVILLE: KRISTINA VUORI.

10 DR. VUORI: HERE.

11 MS. BONNEVILLE: THANK YOU. WE HAVE A
12 QUORUM.

13 CHAIRMAN SHEEHY: SO WE JUST HAVE ONE ITEM
14 ON THE AGENDA TODAY, CONSIDERATION OF THE ADOPTION
15 OF THE INTERIM GRANTS ADMINISTRATION POLICY FOR
16 DISCOVERY, TRANSLATION, AND EDUCATION. SO I THINK,
17 GABE, ARE YOU PRESENTING THESE? GREAT.

18 MR. THOMPSON: THIS IS GABRIEL THOMPSON,
19 DIRECTOR OF GRANTS MANAGEMENT. JUST TO LET YOU
20 KNOW, THERE'S SLIDES, A COUPLE OF VERY BRIEF SLIDES,
21 FOR THIS THAT ARE IN THE LINK ON THE AGENDA.

22 SO MEMBERS OF THE SUBCOMMITTEE, MEMBERS OF
23 THE PUBLIC, I'M HERE FOR YOUR CONSIDERATION IN THE
24 ADOPTION OF INTERIM GRANTS ADMINISTRATION POLICY FOR
25 DISCOVERY, TRANSLATION, AND EDUCATION PROGRAMS.

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1 WE'RE BRINGING THIS POLICY TO YOU ON AN INTERIM
2 BASIS GIVEN OUR STATUTORY ABILITY. NEXT WEEK THE
3 BOARD PLANS TO APPROVE BRIDGES PROGRAMS AND SPARK
4 PROGRAMS LATER THIS MONTH, AND WE NEED TO HAVE
5 POLICIES IN PLACE TO ENSURE THE PROPER
6 ADMINISTRATION. SO IN LIGHT OF THAT, WE WANT TO
7 HAVE THESE POLICIES ADOPTED ON AN INTERIM BASIS,
8 THAT WILL THEN OPEN THE COMMENT PROCESS FOR THIS
9 NEXT YEAR AND THEN ALLOW ADOPTION OF THE POLICY FROM
10 THERE.

11 SO WE USED THE CLINICAL STAGE GAP, GRANT
12 ADMINISTRATION POLICY, FOR CLINICAL STAGE PROGRAMS
13 AS THE BASIS FOR THEN MAKING THESE ADJUSTMENTS TO
14 THE POLICY TO SUPPORT DISCOVERY, TRANSLATION, AND
15 EDUCATION PROJECTS. THESE WERE THE PROGRAM
16 ANNOUNCEMENTS THAT WERE APPROVED BY THE BOARD IN THE
17 LAST YEAR AND INCLUDE THE (UNINTELLIGIBLE) PROGRAM,
18 THE QUEST PROGRAM, AND SPECIFIC QUESTIONS UNDER THE
19 DISCOVERY STAGE PROJECTS, ALL THE PROGRAMS UNDER
20 TRANSLATIONAL STAGE PROJECTS, AS WELL AS THE
21 BRIDGES, THE SPARK, AND THE CONFERENCE PROGRAMS.

22 SO WITH THAT SAID, I'LL JUST GO OVER THE
23 PROPOSED CHANGES, AND PLEASE LET ME KNOW IF YOU HAVE
24 ANY QUESTIONS.

25 SO THE FIRST CHANGE IS THE CLARIFICATION

BARRISTERS' REPORTING SERVICE

1 OF THE MILESTONES THAT WE'LL BE USING FOR THESE
2 PROGRAMS. SO AS YOU MAY RECALL, CIRM ESTABLISHES
3 MILESTONES ON ITS PROJECTS AS A MARKER OF THE
4 PROJECT'S PROGRESS. FOR CLINICAL STAGE AWARDS, WE
5 USE OPERATIONAL MILESTONES, WHICH ARE OBJECTIVE
6 EVENTS THAT TRIGGER THE DISBURSEMENT OF ADDITIONAL
7 FUNDS. WE'RE CLARIFYING THE POLICY THAT CIRM WILL
8 USE OPERATIONAL MILESTONES FOR ALL ITS TRANSLATION
9 STAGE AWARDS.

10 FOR DISCOVERY AWARDS, WE DEFINED A NEW
11 TERM CALLED PROJECT MILESTONES, WHICH ARE OBJECTIVE
12 EVENTS ESTABLISHED BY CIRM. AND UNLIKE OPERATIONAL
13 MILESTONES, WE'LL DISBURSE FUNDS BASED ON TIME
14 RATHER THAN THE ACCOMPLISHMENT OF PROJECT
15 MILESTONES, BUT STILL RESERVE OUR DISCRETION TO
16 REALLOCATE RESOURCES OR SUSPEND OR TERMINATE A
17 PROJECT IF AN AWARDEE FAILS TO ACCOMPLISH A PROJECT
18 MILESTONE WITHIN A REASONABLE TIME FRAME.

19 AS YOU MIGHT KNOW, THE DISCOVERY PROGRAMS,
20 THE QUEST PROJECT HAS A TWO-YEAR TIME FRAME WITH THE
21 OPTION FOR A SIX-MONTH NO COST EXTENSION. WITH THE
22 QUEST PROGRAM, WE LEARNED THAT THEY WOULDN'T BE ABLE
23 TO ACCOMPLISH ITS GOALS WITHIN A SIX-MONTH TIME
24 FRAME, THEN IT WOULDN'T BE MEETING ITS PROJECT
25 MILESTONES, AND WE COULD DECIDE TO REALLOCATE

BARRISTERS' REPORTING SERVICE

1 RESOURCES, SUSPEND, AND/OR TERMINATE THE PROJECT.

2 SO WE HAVE MADE REVISIONS TO THE
3 APPLICATION REVIEW AND SCORING SECTION TO BASICALLY
4 SIMPLIFY THE DESCRIPTION OF THE SCORING SYSTEM. AS
5 YOU MAY RECALL, THE BOARD APPROVED AMENDMENTS TO THE
6 GWG BYLAWS THAT DEFINE THE SCORING SYSTEM FOR
7 NONCLINICAL PROGRAMS. AND SO WE'VE ALIGNED THE
8 LANGUAGE IN THE GAP TO MATCH THOSE REVISIONS AND
9 ALSO SPECIFIED THE PATIENT ADVOCATE PARTICIPATION IN
10 THE GWG APPLICATION SCORING PROCESS.

11 WE ALSO MADE CHANGES TO UNALLOWABLE COSTS.
12 UNDER MEMBERSHIP DUES, THE MEMBERSHIP DUES HAVE
13 ALWAYS BEEN AN UNALLOWABLE COST. SO THESE WOULD BE
14 COSTS FOR MEMBERSHIPS TO PROFESSIONAL ORGANIZATIONS
15 OR, FOR INSTANCE, ISSCR. AND WE HAD MEMBERSHIP DUES
16 AS UNALLOWABLE BECAUSE OF -- JUST TO ALIGN WITH NIH
17 POLICY, BUT THEN LEARNED (UNINTELLIGIBLE) THAT
18 MEMBERSHIP DUES ACTUALLY PROVIDE MEMBERS BENEFITS
19 THAT COULD BE BENEFICIAL TO OUR PROJECT AND ARE
20 OFTEN TACKED ONTO THE REGISTRATION FOR MEETINGS SUCH
21 AS ISSCR. SO WE ARE MAKING AN ALLOWANCE FOR MAKING
22 MEMBERSHIP DUES AN ALLOWABLE COST AS LONG AS THE
23 AWARDEE CAN REASONABLY ALLOCATE THE COST TO ENSURE
24 THAT THERE'S A BENEFIT TO CIRM PROJECT.

25 WE HAVE CLARIFIED POST-PROJECT ALLOWABLE

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1 COSTS. SO WE INTRODUCED THIS CONCEPT FOR CLINICAL
2 STAGE PROJECTS WHICH ALLOW THE AWARDEES WHO HAVE
3 REMAINING CIRM FUNDS AT THE END OF THE PROJECT TO
4 USE THOSE FUNDS TO EITHER REDUCE THE CO-FUNDING
5 REQUIRED BY THE AWARD TO A LOWER AMOUNT ORIGINALLY
6 REQUIRED BY THE AWARD, OR TO FUND A PROJECT THAT THE
7 AWARDEE WOULD PROPOSE THAT WOULD FURTHER CIRM'S
8 MISSION SUBJECT TO CIRM'S PRIOR APPROVAL AUDIT, OR
9 TO RETURN THOSE FUNDS TO CIRM WITHIN 30 DAYS OF THE
10 DEADLINE FOR THE FINAL FINANCIAL REPORT. SO WE HAVE
11 THIS FOR CLINICAL STAGE PROJECTS. (UNINTELLIGIBLE)
12 USE OF CIRM FUNDS. AND WE ARE FOLLOWING THIS SAME
13 POLICY FOR (UNINTELLIGIBLE) AS WELL. SO WHAT WOULD
14 HAPPEN IF IT HAD REMAINING FUNDS, AND
15 (UNINTELLIGIBLE...) SHOW STAFF THEY HAD A PRIOR
16 APPROVAL, WE WOULD REVIEW THAT PROJECT AND MAKE A
17 FINAL DETERMINATION. SO WE'RE USING THAT SAME
18 POLICY FOR THE TRANSLATION AND DISCOVERY.

19 THE FINAL EDIT HERE IS UNDER FAILURE OF
20 COMPLIANCE: CONSIDERATION OF PAST PERFORMANCE. SO
21 THIS SECTION SPECIFIES ACTION CIRM MAY TAKE IF AN
22 AWARDEE VIOLATES ONE OF THE TERMS OR CONDITIONS OF A
23 CIRM AWARD, IF THE AWARDEE ENGAGES IN MISCONDUCT, OR
24 THE AWARDEE FAILED TO ACHIEVE A MILESTONE. AND WE
25 PROPOSE TO EXPAND THIS LIST TO INCLUDE PAST

BARRISTERS' REPORTING SERVICE

1 PERFORMANCE OF THE AWARDEE DURING THE
2 (UNINTELLIGIBLE) APPLICATION FOR CIRM FUNDS. SO
3 THIS IS ACTUALLY (UNINTELLIGIBLE), AND WE'RE JUST
4 GETTING THAT LANGUAGE (UNINTELLIGIBLE).

5 SO THAT WAS THE EXTENT OF THE CHANGES
6 WE'VE MADE TO THE INTERIM GAP. IF THE POLICY GETS
7 ADOPTED BY THE SUBCOMMITTEE BOARD, IT WILL BE IN
8 INTERIM STATUS FOR ABOUT A YEAR WHERE WE CAN FURTHER
9 REFINE IT AND MAKE ADDITIONAL COMMENTS, AND THEN BY
10 THE END OF THE YEAR CAN GET TO FINAL ADOPTION. SO
11 WITH THAT, (UNINTELLIGIBLE) THE SUBCOMMITTEE ADOPT
12 THESE INTERIM (UNINTELLIGIBLE).

13 CHAIRMAN SHEEHY: DOES ANYONE HAVE ANY
14 QUESTIONS? SO DO I HEAR A MOTION FOR ADOPTION?

15 MR. TORRES: SO MOVED.

16 DR. FRIEDMAN: SECOND.

17 CHAIRMAN SHEEHY: IF THERE'S NO BOARD
18 COMMENT, IS THERE ANY PUBLIC COMMENT? OKAY. ROLL
19 CALL, PLEASE.

20 MS. BONNEVILLE: JEFF SHEEHY.

21 CHAIRMAN SHEEHY: YES.

22 MS. BONNEVILLE: OS STEWARD.

23 DR. STEWARD: YES.

24 MS. BONNEVILLE: MICHAEL FRIEDMAN.

25 DR. FRIEDMAN: YES.

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MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: BERT LUBIN. SHLOMO
MELMED.

DR. MELMED: YES.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: AYE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: KRISTINA VUORI.

DR. VUORI: YES.

CHAIRMAN SHEEHY: THE MOTION CARRIES. I
THINK THAT CONCLUDES THE BUSINESS FOR TODAY. AND
THE NEXT TIME WE HAVE CONTACT WITH THE JOINT MEETING
WITH THE IP SUBCOMMITTEE WHERE WE'LL TAKE UP THE
VERY CRITICAL (UNINTELLIGIBLE). THANK YOU,
EVERYONE.

(THE MEETING WAS THEN CONCLUDED AT 10:14 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 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 JANUARY 12, 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 PROCEEDINGS. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CSR 7152
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