# 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 TELEPHONIC MEETING

LOCATION: AS INDICATED ON THE AGENDA

DATE: MARCH 24, 2015

2:30 P.M.

REPORTER: BETH C. DRAIN, CSR

CSR. NO. 7152

BRS FILE NO.: 97380

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2

1	MARCH 24, 2015; 2:30 P.M.
2	
3	CHAIRMAN SHEEHY: SO THIS IS JEFF SHEEHY.
4	I THINK WE'RE READY TO BEGIN. MARIA, COULD YOU CALL
5	THE ROLL, PLEASE.
6	MS. BONNEVILLE: JEFF SHEEHY.
7	MR. SHEEHY: HERE.
8	MS. BONNEVILLE: OS STEWARD.
9	DR. STEWARD: HERE.
10	MS. BONNEVILLE: MICHAEL FRIEDMAN. DAVID
11	HIGGINS.
12	MR. HIGGINS: HERE.
13	MS. BONNEVILLE: BERT LUBIN, SHLOMO
14	MELMED.
15	DR. MELMED: HERE.
16	MS. BONNEVILLE: ART TORRES.
17	MR. TORRES: HERE.
18	MS. BONNEVILLE: JON THOMAS.
19	CHAIRMAN SHEEHY: HERE.
20	MS. BONNEVILLE: KRISTINA VUORI.
21	DR. VUORI: HERE.
22	CHAIRMAN SHEEHY: SO DO WE HAVE ANY
23	MEMBERS OF THE PUBLIC AT ANY OF THE SITES? I'M
24	ASSUMING THAT MEANS NO. SO I THINK WE'LL START OFF
25	WITH THE CONSIDERATION OF ADOPTION OF THE GRANTS
	3
	<u> </u>

1	ADMINISTRATION POLICY FOR CLINICAL STAGE PROGRAMS.
2	GABE, YOU WILL LEAD US THROUGH THAT, RIGHT?
3	MR. THOMPSON: RIGHT.
4	CHAIRMAN SHEEHY: THANK YOU.
5	MR. THOMPSON: THIS IS GABE THOMPSON,
6	DIRECTOR OF GRANTS MANAGEMENT. SO WE ARE HERE TO
7	CONSIDER THE PROPOSED INTERIM GRANTS ADMINISTRATION
8	POLICY REGULATIONS FOR LATE STAGE PROJECTS. SO
9	THESE WILL THE INTERIM REGULATIONS THAT WILL APPLY
10	TO NEW AWARDS FUNDED UNDER THE THREE NEW PROGRAM
11	ANNOUNCEMENTS WE RELEASED A COUPLE MONTHS AGO.
12	SO THE PROPOSED INTERIM GRANTS
13	ADMINISTRATION POLICY FOLLOWS THE SAME BASIC
14	TEMPLATE AS THE EXISTING POLICY, BUT IS REALLY MEANT
15	TO ADOPT ALL THE NEW FEATURES OF THE CLINICAL STAGE
16	PROGRAMS AND THOSE REQUIRED.
17	SO THE GRANTS ADMINISTRATION POLICY IS
18	LISTED IN CHRONOLOGICAL ORDER STARTING AT THE
19	GRANT-MAKING PROCESS ADDRESSING AREAS OF THE
20	APPLICATION AND REVIEW PROCESS, THE PRE-AWARD, AND
21	AWARD REQUIREMENTS, AND RULES GOVERNING PAYMENT AND
22	USE OF FUNDS. THE RESULT IS A POLICY DESIGNED TO
23	ATTRACT HIGH QUALITY APPLICATIONS, REDUCE CYCLE TIME
24	FROM APPLICATION TO PROJECT START, ACCELERATE THE
25	PROGRESSION OF THE FUNDED PROJECTS, AND PROVIDE FOR
	4

1	MORE EFFICIENT ADMINISTRATION OF THE PROJECT.
2	THE PRIMARY CHANGES THAT WE MADE TO THE
3	GAP ARE LISTED IN THE IDENTIFIED IN THE MEMO.
4	AND WE SPENT THE LAST MONTH SINCE THE LAST
5	SUBCOMMITTEE MEETING FURTHER CLARIFYING THE
6	LANGUAGE, REFINING IT. AND THOSE CLARIFICATIONS
7	THAT WE SPENT THE LAST MONTH ON INCLUDE LANGUAGE IN
8	THE GAP REGARDING THE NEW SCORING. WE HAD SOME
9	CLARIFYING LANGUAGE AROUND REPORTING REQUIREMENTS
10	WHICH ARE WHEN A GRANT IS REQUIRED TO REPORT TO CIRM
11	WHEN THEY MEET OPERATIONAL MILESTONES, WHEN THEY HIT
12	SUSPENSION EVENTS, AND THEN REGULAR QUARTERLY
13	REPORTING REQUIREMENTS. SO WE'VE CLARIFIED WHAT
14	TYPES OF REPORTS ARE REQUIRED AND WHEN.
15	WE'VE CLARIFIED WHEN PROTOCOL APPROVALS
16	ARE REQUIRED. SO THESE WOULD BE THE IRB APPROVALS,
17	THE IACUC, AND THE SCRO PROTOCOL APPROVALS. SO WE
18	CLARIFIED WHEN WE NEED THOSE DOCUMENTS.
19	AND THEN WE'VE INCLUDED LANGUAGE AROUND A
20	COMMUNICATIONS PLAN. WHAT THIS IS ACTUALLY SPEAKING
21	TO IS THESE ARE CONDITIONS OF THE AWARD WHEN WE'RE
22	FUNDING CLINICAL TRIALS THAT EXPLAIN WHEN THE
23	PROJECT TEAM MUST REPORT TO CIRM WHEN A TRIAL IS TO
24	GO ON CLINICAL HOLD OR WHEN THE PROJECT TEAM IS
25	UNDERGOING AN FDA AUDIT, FOR INSTANCE. SO INSTEAD
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1	OF PUTTING THAT LANGUAGE IN THE NOTICE OF GRANT
2	AWARDS WHERE IT PREVIOUSLY WAS, WE'VE NOW BUILT THAT
3	INTO THE GAP AND WILL APPLY TO ALL AWARDS WHEN WE'RE
4	FUNDING A CLINICAL TRIAL.
5	SO THIS IS BASICALLY WHAT WE SPENT THE
6	LAST MONTH ON, CLARIFYING SOME OF THIS LANGUAGE.
7	AND THIS COMMITTEE HAS REVIEWED AN EARLIER DRAFT IN
8	JANUARY, AND THERE ARE NO SUBSTANTIVE CHANGES
9	BESIDES WHAT I'VE JUST EXPLAINED HERE. AND WE ARE
10	ASKING FOR THE SUBCOMMITTEE'S APPROVAL. THAT WILL
11	THEN GO TO THE BOARD FOR FULL APPROVAL. AND UPON
12	APPROVAL, THESE INTERIM REGS WOULD BECOME EFFECTIVE
13	IMMEDIATELY AND START THE FORMAL OAL, OFFICE OF
14	ADMINISTRATIVE LAW, APPROVAL PROCESS. SO WE HAVE
15	270 DAYS TO THEN MAKE THESE REGULATIONS FORMALLY
16	APPROVED THROUGH THE OAL PROCESS.
17	CHAIRMAN THOMAS: OKAY. COULD YOU JUST
18	DESCRIBE FOR THOSE ON THE COMMITTEE WHO AREN'T
19	FAMILIAR WITH THAT PROCESS EXACTLY WHAT THAT
20	ENTAILS?
21	MR. THOMPSON: RIGHT. SCOTT, WOULD YOU
22	LIKE TO SPEAK TO HOW THAT GOES THROUGH THE OAL
23	PROCESS?
24	MR. TOCHER: SURE. ABSOLUTELY. SO WHILE
25	WE HAVE THE ABILITY TO ADOPT A REGULATION ON OUR OWN

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1	ON AN INTERIM BASIS, AS GABE INDICATED, THAT IT'S
2	ONLY EFFECTIVE FOR 270 DAYS. SO WE'LL PARALLEL
3	TRACK WITH THAT GOING TO THE OFFICE OF
4	ADMINISTRATIVE LAW, WHICH IS THE STATE AGENCY THAT
5	OVERSEES THE ADOPTION OF REGULATIONS BY OTHER STATE
6	AGENCIES. AND THAT IS A LENGTHY PROCESS DESIGNED TO
7	ELICIT AND INCORPORATE PUBLIC INPUT FROM ALL TYPES
8	OF STAKEHOLDERS IN THE FINAL DEVELOPMENT OF OUR
9	GRANTS ADMINISTRATION POLICY.
10	SO WE BEGIN THAT FORMAL PROCESS AFTER THE
11	BOARD MEETING, ASSUMING THE POLICY IS ADOPTED. AND
12	THAT WILL TAKE US ANYWHERE FROM FOUR TO SIX TO MAYBE
13	EVEN ALL NINE MONTHS TO FINALLY GET THAT IN FINAL
14	SHAPE. AS PART OF THAT PROCESS, THE GAP WILL THEN
15	COME BACK TO THE BOARD FOR A FINAL ADOPTION BEFORE
16	IT CAN BE APPROVED BY THE OFFICE OF ADMINISTRATIVE
17	LAW.
18	SO EVEN WITH YOUR INPUT AND THE BOARD'S
19	HERE TODAY AND THE POST-INPUT THAT FOLLOWS, THE
20	BOARD, IF THIS COMMITTEE CHOOSES TO DO SO, WILL HAVE
21	EVEN ANOTHER OPPORTUNITY TO LOOK AT THE GAP BEFORE
22	IT IS MADE PERMANENT.
23	CHAIRMAN SHEEHY: SO ARE THERE ANY
24	QUESTIONS FROM MEMBERS OF THE COMMITTEE? I THINK WE
25	HIT MOST OF THE HIGH POINTS AT THE LAST MEETING. SO

1	DO I HAVE	A MOTION TO APPROVE?
2		MR. HIGGINS: SO MOVED.
3		CHAIRMAN SHEEHY: DO I HAVE A SECOND?
4		DR. STEWARD: I SECOND.
5		CHAIRMAN SHEEHY: OKAY. NO PUBLIC
6	COMMENT?	ROLL CALL.
7		MS. BONNEVILLE: JEFF SHEEHY.
8		MR. SHEEHY: YES.
9		MS. BONNEVILLE: OS STEWARD.
10		DR. STEWARD: YES.
11		MS. BONNEVILLE: MICHAEL FRIEDMAN. DAVID
12	HIGGINS.	
13		MR. HIGGINS: YES.
14		MS. BONNEVILLE: BERT LUBIN. SHLOMO
15	MELMED.	
16		DR. MELMED: YES.
17		MS. BONNEVILLE: ART TORRES.
18		MR. TORRES: AYE.
19		MS. BONNEVILLE: JON THOMAS.
20		CHAIRMAN THOMAS: YES.
21		MS. BONNEVILLE: KRISTINA VUORI.
22		DR. VUORI: YES.
23		CHAIRMAN SHEEHY: SO NOW TO THE NEXT ITEM
24	ON THE AG	ENDA, CONSIDERATION OF GRANTS WORKING GROUP
25	BYLAWS.	AND I THINK JAMES IS GOING TO LEAD US
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		<b>o</b>

1	THROUGH THAT.
2	MR. HARRISON: YES. THANKS, JEFF.
3	SO WE LAST BROUGHT PROPOSED AMENDMENTS TO
4	THE BYLAWS TO THE BOARD IN 2013, AND WE HAVE NOT
5	AMENDED THE GRANTS WORKING GROUP BYLAWS SINCE THEN.
6	SO TODAY WE PRESENT TO YOU AMENDMENTS TO THE GWG'S
7	BYLAWS THAT ARE INTENDED TO ACCOMPLISH TWO PURPOSES.
8	ONE, TO UPDATE THE BYLAWS TO REFLECT CHANGES IN
9	PRACTICE AND POLICY SINCE THE LAST AMENDMENTS IN
10	2030; SECONDLY, TO CONFORM THE BYLAWS TO THE NEW
11	PROCESSES WE'VE PUT IN PLACE PURSUANT TO CIRM 2.0,
12	ONE OF WHICH GABE MENTIONED IN HIS PRESENTATION
13	INVOLVING THE SCORING OF APPLICATIONS SUBMITTED IN
14	RESPONSE TO PROGRAM ANNOUNCEMENTS 15-01, 15-02, AND
15	15-03.
16	SO I'D LIKE TO BRIEFLY DESCRIBE TO YOU THE
17	SIGNIFICANT CHANGES IN THE AMENDMENT AND THEN SPEND
18	A LITTLE BIT OF EXTRA TIME ON THE PROPOSED SCORING
19	SYSTEM THAT WE WOULD LIKE TO INCORPORATE WITH
20	RESPECT TO CIRM 2.0 APPLICATIONS.
21	SO FIRST, WE HAVE CLARIFIED THE GWG'S ROLE
22	IN OVERSEEING THE PROGRESS OF FUNDED PROJECTS.
23	UNDER PROP 71 THE GWG DOES HAVE AN OVERSIGHT ROLE
24	WITH RESPECT TO ACTIVE APPLICATIONS, AND WE'D LIKE
25	TO MAKE GREATER USE OF THE GWG'S EXPERTISE NOT ONLY

1	REVIEWING APPLICATIONS FOR FUNDING, BUT ALSO HELPING
2	US KEEP TRACK OF THE PROGRESS OF FUNDED PROGRAMS.
3	SO AT PAGE 10 OF THE BYLAWS, WE HAVE AMPLIFIED ON
4	THE GWG OVERSIGHT ROLE.
5	WE'VE ALSO ADDED A PROVISION TO THE BYLAWS
6	TO MORE ACTIVELY ENGAGE THE PATIENT ADVOCATE MEMBERS
7	OF THE GRANTS WORKING GROUP IN THE REVIEW PROCESS.
8	HISTORICALLY SCIENTIFIC REVIEWERS HAVE BEEN ASSIGNED
9	TO EACH OF THE APPLICATIONS, AND PATIENT ADVOCATES
10	HAVE PARTICIPATED IN THE GWG MEETINGS, BUT NOT AS
11	REVIEWERS. WHAT WE PROPOSE TO DO IS INVITE A
12	PATIENT ADVOCATE MEMBER OF THE GWG TO SERVE AS A
13	REVIEWER ON EACH APPLICATION. AND ALTHOUGH THE
14	PATIENT ADVOCATE REVIEWER WILL NOT BE ASKED TO
15	PROVIDE A SCIENTIFIC SCORE, HE OR SHE WOULD BE ASKED
16	TO OFFER HIS OR HER VIEWS REGARDING THE MERITS OF
17	THE APPLICATION DURING THE REVIEW PROCESS ITSELF.
18	AND THEN THE MOST SIGNIFICANT CHANGE, AT
19	LEAST WITH RESPECT TO CIRM 2.0 APPLICATIONS, IS THE
20	NEW SCORING METHODOLOGY THAT WE PROPOSE TO USE. THE
21	GOAL OF THIS SYSTEM IS TO TRY TO OBTAIN CLEAR
22	DIRECTION ABOUT WHETHER TO FUND A PROPOSAL, SEND IT
23	BACK TO THE APPLICANT FOR REFINEMENT AND
24	RESUBMISSION, OR RECOMMEND AGAINST FUNDING. AND
25	REMEMBER UNDER CIRM 2.0 WE NOW HAVE AN OPEN CALL FOR
	10

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1	APPLICATIONS. SO THAT ALLOWS US, WE BELIEVE, TO
2	HAVE A SCORING SYSTEM THAT IS MORE FINE-TUNED TO THE
3	GOAL OF FUNDING THE VERY BEST SCIENTIFIC PROPOSALS,
4	SENDING SOME BACK FOR FURTHER WORK BEFORE THEY'RE
5	RESUBMITTED, AND IN THE CASE OF SOME ESSENTIALLY
6	ADVISING THE APPLICANT NOT TO RESUBMIT THE SAME
7	PROJECT FOR REVIEW.
8	SO RATHER THAN SCORING NUMERICALLY FROM 1
9	TO 100, WHAT WE PROPOSE TO DO IS TO ASK THE
10	SCIENTIFIC MEMBERS TO ASSIGN A SCORE OF ONE, TWO, OR
11	THREE. SO A SCORE OF ONE WOULD SIGNIFY THAT THE
12	APPLICATION HAS EXCEPTIONAL MERIT AND WARRANTS
13	FUNDING. A SCORE OF TWO WOULD MEAN THAT THE
14	APPLICATION NEEDS IMPROVEMENT AND DOESN'T WARRANT
15	FUNDING AT THIS TIME, BUT COULD BE RESUBMITTED IN
16	THE FUTURE TO ADDRESS AREAS OF IMPROVEMENT.
17	FINALLY, A SCORE OF THREE WOULD MEAN THAT THE
18	APPLICATION IS SUFFICIENTLY FLAWED THAT IT DOESN'T
19	WARRANT FUNDING AND THAT THE SAME PROJECT SHOULD NOT
20	BE RESUBMITTED FOR REVIEW.
21	CHAIRMAN THOMAS: CAN I ASK A QUESTION
22	HERE?
23	MR. HARRISON: OF COURSE.
24	CHAIRMAN THOMAS: WITH RESPECT TO TIER
25	THE NUMBER TWO SCORING, DOES THAT ENCOURAGE THE
	11

11

1	APPLICANT TO REAPPLY IN ANY PARTICULAR TIME FRAME,
2	OR IS THERE ANY NUMBER OF TIMES THAT THEY CAN APPLY?
3	ARE WE SETTING A CAP ON THAT? OR WHAT EXACTLY
4	GIL, DO YOU WANT TO ANSWER?
5	DR. SAMBRANO: THERE IS NO CAP ON THE
6	TIMING. I THINK THE EXPECTATION IS THAT IT WILL
7	DEPEND ON WHAT THE RECOMMENDATIONS FROM THE WORKING
8	GROUP ARE. SO IF IT'S A SIMPLE CHANGE OR
9	MODIFICATION THAT THEY CAN MAKE, THEY COULD SUBMIT
10	AS SOON AS THE NEXT CYCLE. IF THEY ARE RECOMMENDING
11	THAT THEY CONDUCT, SAY, ANOTHER ANIMAL STUDY, THAT
12	MIGHT TAKE THEM SIX MONTHS, SO THEY CAN COME BACK IN
13	SIX MONTHS AND REAPPLY THEN. SO IT WILL DEPEND ON
14	WHAT THE RECOMMENDATION IS.
15	AND THEN AT THE TIME, ONCE THEY RESUBMIT,
16	IT WILL GO INTO THAT NEXT CYCLE. IT WILL BE
17	REVIEWED, AND THEN THE GRANTS WORKING GROUP WILL
18	HAVE THE ABILITY TO MAKE ANOTHER RECOMMENDATION
19	BASED ON WHAT THEY SEE, EITHER SCORING ONE BECAUSE
20	THEY THINK THEY'VE ADDRESSED THE CONCERNS AND IT'S A
21	MERITORIOUS APPLICATION, OR THEY FIND OTHER THINGS
22	THAT THEY BELIEVE NEED TO BE FIXED OR CHANGED BEFORE
23	APPROVING.
24	CHAIRMAN THOMAS: AND ON THE QUESTION OF
25	HOW MANY TIMES CAN THEY REAPPLY, THERE'S NO
	12

1	DR. SAMBRANO: WE'VE NOT SET A LIMIT.
2	CHAIRMAN THOMAS: SO AS LONG AS THEY KEEP
3	GETTING TWOS, THEY CAN GIVE IT ANOTHER SHOT.
4	MR. HARRISON: SO LET ME BRIEFLY DESCRIBE
5	HOW THE SCORING WOULD WORK AND WHAT THE APPLICATION
6	REVIEW SUBCOMMITTEE WOULD ULTIMATELY SEE. SO AFTER
7	THE SCIENTIFIC MEMBERS SCORE THE APPLICATIONS, THE
8	RESULTS WILL BE PRESENTED TO THE ENTIRE GWG. IF A
9	PLURALITY OF MEMBERS HAVE ASSIGNED A SCORE OF ONE OR
10	TWO, THEN THAT SCORE WOULD CONSTITUTE THE
11	RECOMMENDATION OF THE GWG. SO, FOR EXAMPLE, IF
12	EIGHT MEMBERS ASSIGNED A SCORE OF ONE, SIX MEMBERS
13	ASSIGNED A SCORE OF TWO AND YOU HAD ONE MEMBER
14	ASSIGN A SCORE OF THREE, THAT APPLICATION WOULD BE
15	PLACED IN TIER I, RECOMMENDED FOR FUNDING. AND THAT
16	RECOMMENDATION WOULD BE PRESENTED TO THE APPLICATION
17	REVIEW SUBCOMMITTEE.
18	WITH RESPECT TO A SCORE OF THREE, WE
19	THOUGHT THAT IT WAS IMPORTANT TO HAVE A SLIGHTLY
20	HIGHER THRESHOLD. SO RATHER THAN A PLURALITY OF
21	MEMBERS, IT WOULD TAKE A MAJORITY OF MEMBERS TO
22	PLACE AN APPLICATION IN TIER III. SO, FOR EXAMPLE,
23	IF SIX MEMBERS ASSIGNED A SCORE OF TWO AND NINE
24	MEMBERS ASSIGNED A SCORE OF THREE, THAT APPLICATION
25	WOULD BE PLACED IN TIER III, NOT RECOMMENDED FOR

1	FUNDING, AND THAT PROJECT WOULD NOT BE PERMITTED TO
2	BE SUBMITTED IN THE SAME FORM.
3	ON THE OTHER HAND, IF THERE IS NO
4	PLURALITY AND THERE'S A NUMERICAL TIE BETWEEN TWO OR
5	MORE SCORES, THEN ANY MEMBER OF THE GWG COULD MAKE A
6	MOTION TO BREAK THE TIE BY ASSIGNING THE APPLICATION
7	TO TIER I, II, OR III. SO, FOR EXAMPLE, IF YOU HAD
8	A SPLIT OF SEVEN VOTES EACH IN SCORE ONE AND SCORE
9	TWO AND ONE VOTE FOR SCORE THREE, THEN ANY MEMBER OF
10	THE GWG COULD MOVE THAT THE APPLICATION BE ASSIGNED
11	TO TIER II, FOR EXAMPLE. AND IF THE MAJORITY OF THE
12	GWG MEMBERS, INCLUDING THE PATIENT ADVOCATES,
13	APPROVED THE MOTION, THEN THE APPLICATION WOULD BE
14	ASSIGNED TO TIER II.
15	LIKEWISE, WITH RESPECT TO TIER III, IF A
16	PLURALITY OF SCIENTIFIC MEMBERS BUT FEWER THAN EIGHT
17	ASSIGNED THE APPLICATION A SCORE OF THREE, THEN ANY
18	MEMBER OF THE GWG COULD MAKE A MOTION TO ASSIGN THAT
19	APPLICATION TO TIER II OR TO TIER III. SO, FOR
20	EXAMPLE, IF YOU HAD SEVEN MEMBERS WHO ASSIGNED A
21	SCORE OF THREE, SIX WHO ASSIGNED A SCORE OF TWO, AND
22	TWO WHO ASSIGNED A SCORE OF ONE, THEN ANY MEMBER OF
23	THE GWG COULD MOVE THAT THE APPLICATION BE ASSIGNED
24	TO TIER II, AND, AGAIN, A MAJORITY VOTE WOULD
25	CONTROL WHERE THAT APPLICATION ENDED.
	1.4

1	ONCE THIS PROCESS IS COMPLETE, THE CIRM
2	TEAM WOULD PRESENT THE GWG RECOMMENDATIONS TO THE
3	BOARD ALONG WITH THE DISTRIBUTION OF SCORES AMONG
4	THE THREE TIERS. SO THE BOARD WOULD HAVE
5	TRANSPARENCY BOTH AS TO THE SCORING AS WELL AS ANY
6	MOTIONS THAT WERE NECESSARY IN ORDER TO PRESENT THE
7	FINAL SLATE OF APPLICATIONS TO THE APPLICATION
8	REVIEW SUBCOMMITTEE FOR ITS CONSIDERATION.
9	SO THAT'S A THUMBNAIL SKETCH OF THE
10	PROCESS AND THE OTHER SIGNIFICANT CHANGES TO THE
11	BYLAWS. AND I'D BE HAPPY TO ANSWER ANY QUESTIONS.
12	MR. HIGGINS: I HAVE A QUESTION FOR YOU,
13	JAMES. IN THE CASE YOU JUST DESCRIBED WHERE THERE'S
14	AMBIGUITY IN THE SCORES AND THERE'S A MOTION MADE TO
15	MOVE TO A PARTICULAR TIER SCORE, IF THE MOTION
16	DOESN'T PASS, WHAT'S THE RESULT?
17	MR. HARRISON: THE MOTION DOESN'T PASS,
18	THEN PRESUMABLY ANOTHER MOTION WOULD BE MADE. SO IN
19	THE SCENARIO THAT I JUST PRESENTED, IF A MEMBER HAD
20	MOVED TO HAVE THAT APPLICATION ASSIGNED TO TIER II,
21	AND A MAJORITY VOTED AGAINST THAT MOTION, THEN
22	ANOTHER MOTION COULD BE MADE TO ASSIGN THE
23	APPLICATION TO TIER III. AND IF A MAJORITY VOTE
24	CARRIED, THE APPLICATION WOULD BE ASSIGNED TO TIER
25	III AND THAT WOULD BE PRESENTED TO THE APPLICATION
	15

,	DEVITEL CURCOMMITTEE AC THE DECOMMENDATION OF THE
1	REVIEW SUBCOMMITTEE AS THE RECOMMENDATION OF THE
2	GWG.
3	MR. HIGGINS: THANK YOU.
4	CHAIRMAN SHEEHY: ARE THERE ADDITIONAL
5	QUESTIONS?
6	CHAIRMAN THOMAS: I HAVE ANOTHER QUESTION,
7	JEFF. JAMES, UNDER THE PRE-CIRM 2.0 PROTOCOL, THERE
8	WERE AVENUES TO APPEAL SCORES. DOES THIS CHANGE IN
9	THE SCORING AFFECT THOSE PROTOCOLS IN ANY WAY?
10	MR. HARRISON: IT DOES NOT, ALTHOUGH UNDER
11	THE INTERIM GRANTS ADMINISTRATION POLICY THAT GABE
12	JUST PRESENTED, THE ONLY AVENUE FOR APPEAL FOR
13	APPLICATIONS SUBMITTED IN RESPONSE TO THE THREE
14	PROGRAM ANNOUNCEMENTS ADOPTED AS CIRM 2.0 WOULD BE
15	FOR CONFLICTS OF INTEREST. IN OTHER WORDS,
16	CURRENTLY WE PERMIT APPEALS BASED ON A DISPUTE OF
17	MATERIAL FACT OR MATERIAL NEW INFORMATION. BECAUSE
18	APPLICATIONS WILL NOW BE ACCEPTED ON A MONTHLY
19	BASIS, THERE REALLY IS NO NEED FOR THAT KIND OF
20	PROCESS. TO THE EXTENT THERE IS ANY ISSUE LIKE
21	THAT, THE APPLICANT CAN COME BACK AND IT CAN BE
22	ADDRESSED THERE, A REVISED SUBMISSION.
23	CHAIRMAN THOMAS: THANK YOU.
24	CHAIRMAN SHEEHY: JAMES, SO I HAD A
25	QUESTION, BUT I DON'T KNOW IF THIS HAS ALL BEEN
	16

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1	THOUGHT THROUGH YET. SO HOW DID THE OVERSIGHT
2	REVIEW WORK? DO WE KNOW THAT YET? I THINK THAT'S
3	LOOKING AT PROJECTS THAT ARE CURRENTLY IN OUR
4	PORTFOLIO.
5	MR. HARRISON: THAT'S CORRECT. AND YOU
6	PUT YOUR FINGER ON IT, JEFF. WE'RE STILL EXAMINING
7	WHAT THE SCOPE OF THAT OVERSIGHT WILL LOOK LIKE. AS
8	YOU KNOW, THE PRESIDENT PLANS TO APPOINT A CLINICAL
9	ADVISORY PANEL FOR EACH CLINICAL STAGE PROJECT THAT
10	WE FUND. AND EACH OF THOSE CAP'S WILL MAKE PROGRESS
11	REPORTS TO THE GWG, AND THE GWG WILL HAVE THE
12	ABILITY TO CONSIDER THOSE REPORTS. IN TERMS OF THE
13	TYPES OF DECISIONS OR RECOMMENDATIONS THAT WE WOULD
14	ASK THE GWG TO MAKE PURSUANT TO THAT REVIEW, THAT'S
15	STILL IN THE WORKING PROCESS.
16	CHAIRMAN SHEEHY: AND JUST TO BE CLEAR,
17	AND THE RECOMMENDATIONS THAT THE GWG WOULD MAKE
18	WHERE WOULD THOSE END UP?
19	MR. HARRISON: THAT DEPENDS ON THE NATURE
20	OF THE RECOMMENDATION. AGAIN, THIS IS SOMETHING
21	THAT WE'RE STILL WORKING OUR WAY THROUGH. SOME
22	WOULD COME TO THE BOARD. SOME COULD GO TO THE CIRM
23	PRESIDENT DEPENDING UPON THE SCOPE OF THE
24	RECOMMENDATION.
25	CHAIRMAN SHEEHY: THANK YOU. ARE THERE
	17

1	ANY OTHER QUESTIONS? SO COULD I GET A MOTION TO
2	ADOPT?
3	MR. HIGGINS: SO MOVED.
4	CHAIRMAN SHEEHY: AND A SECOND?
5	DR. STEWARD: SECOND.
6	CHAIRMAN SHEEHY: THANK YOU, OS. NO
7	FURTHER COMMENT? CAN WE CALL THE ROLL THEN, PLEASE,
8	MARIA.
9	MS. BONNEVILLE: JEFF SHEEHY.
10	MR. SHEEHY: YES.
11	MS. BONNEVILLE: OS STEWARD.
12	DR. STEWARD: YES.
13	MS. BONNEVILLE: MICHAEL FRIEDMAN. DAVID
14	HIGGINS.
15	MR. HIGGINS: YES.
16	MS. BONNEVILLE: BERT LUBIN. SHLOMO
17	MELMED.
18	DR. MELMED: YES.
19	MS. BONNEVILLE: ART TORRES.
20	MR. TORRES: AYE.
21	MS. BONNEVILLE: JON THOMAS.
22	CHAIRMAN THOMAS: YES.
23	MS. BONNEVILLE: KRISTINA VUORI.
24	DR. VUORI: YES.
25	CHAIRMAN SHEEHY: SO THE MOTION CARRIES.
	18

160 S. OLD SPRINGS ROAD, SUITE 270, ANAHEIM, CALIFORNIA 92808 1-800-622-6092 1-714-444-4100 EMAIL: DEPO@DEPO1.COM

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1
      IF THERE'S ANYTHING ANYONE ELSE WANTS TO ADD,
 2
      OTHERWISE WE CAN ADJOURN. WE'RE ADJOURNED. THANK
 3
      YOU.
 4
                      (MEETING WAS THEN CONCLUDED AT 2:54
 5
      P.M.)
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#### REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE 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 ON MARCH 24, 2015, 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 BARRISTERS' REPORTING SERVICE 160 S. OLD SPRINGS ROAD SUITE 270 ANAHEIM, CALIFORNIA (714) 444-4100