

**BETH C. DRAIN, CA CSR NO. 7152**

BEFORE THE  
APPLICATION REVIEW SUBCOMMITTEE  
OF THE  
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE  
ORGANIZED PURSUANT TO THE  
CALIFORNIA STEM CELL RESEARCH AND CURES ACT  
REGULAR MEETING

LOCATION: VIA ZOOM

DATE: APRIL 20, 2021  
10 A.M.

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

FILE NO.: 2021-09

I N D E X

ITEM DESCRIPTION	PAGE NO.
<b>OPEN SESSION</b>	
1. CALL TO ORDER.	3
2. ROLL CALL	3
<b>ACTION ITEMS</b>	
3. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL STAGE PROJECTS PROGRAM ANNOUNCEMENT (CLIN 1,2 OR 3).	5
<b>CLOSED SESSION</b>	<b>NONE</b>
4. DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO APPLICATIONS SUBMITTED IN RESPONSE TO AGENDA ITEM 3 ABOVE. (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)).	
<b>DISCUSSION ITEMS</b>	
5. PUBLIC COMMENT.	NONE
6. ADJOURNMENT.	46

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APRIL 20, 2021; 10 A.M.

CHAIRMAN THOMAS: OKAY. GOOD MORNING,  
EVERYBODY. WELCOME TO THE APRIL 20TH MEETING OF THE  
ICOC AND THE APPLICATION REVIEW SUBCOMMITTEE. HOPE  
THIS FINDS YOU AND YOUR FAMILY SAFE AND WELL.

MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: YES. DAN BERNAL.

MR. BERNAL: PRESENT.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: PRESENT.

MS. BONNEVILLE: YSABEL DURON.

MS. DURON: HERE.

MS. BONNEVILLE: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: HERE.

MS. BONNEVILLE: ELENA FLOWERS.

DR. FLOWERS: PRESENT.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: STEVE JUELSGAARD.

MR. JUELSGAARD: PRESENT.

MS. BONNEVILLE: DAVE MARTIN.

DR. MARTIN: HERE.

MS. BONNEVILLE: CHRISTINE MIASKOWSKI.

LAUREN MILLER-ROGEN.

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MS. MILLER-ROGEN: HERE.

MS. BONNEVILLE: ADRIANA PADILLA. JOE PANETTA.

MR. PANETTA: HERE.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: HERE.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: HERE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: HERE.

MS. BONNEVILLE: KAROL WATSON.

DR. WATSON: HERE.

MS. BONNEVILLE: DIANE WINOKUR.

THANK YOU.

CHAIRMAN THOMAS: THANK YOU, MARIA. WE'RE GOING TO MOVE INTO THE ACTION ITEMS HERE. FIRST IS, FIRST AND ONLY IS, CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL STAGE PROJECTS PROGRAM ANNOUNCEMENTS, CLINS 1, 2, AND 3. THERE ARE TWO APPLICATIONS TO BE CONSIDERED HERE. OS, AS CHAIR OF THE APPLICATION REVIEW SUBCOMMITTEE, IS GOING TO RUN THE FIRST; BUT AS HE IS CONFLICTED, I WILL RUN THE SECOND. AND SO WITHOUT FURTHER ADO,

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1 LET ME TURN THE MEETING OVER TO OS. THANK YOU, OS.

2 DR. STEWARD: THANK YOU. SO WELCOME,  
3 EVERYBODY. I AM GOING TO ACTUALLY LOG ON WITH MY  
4 PHONE BECAUSE I HAVE SORT OF A WEAK INTERNET  
5 CONNECTION HERE. CAN EVERYBODY HEAR ME?

6 CHAIRMAN THOMAS: YES.

7 MS. BONNEVILLE: YES.

8 DR. STEWARD: OKAY. GOOD. YOU GUYS ARE  
9 FREEZING, SO THAT BOTHERS ME.

10 SO I THINK THAT WE NEED TO START WITH A  
11 PRESENTATION FROM GIL; IS THAT CORRECT, MARIA?

12 MS. BONNEVILLE: THAT IS CORRECT.

13 DR. STEWARD: SO, GIL.

14 DR. SAMBRANO: ALL RIGHT. THANK YOU, OS.  
15 I AM GOING TO SHARE MY PRESENTATION. HOPEFULLY ALL  
16 OF YOU CAN SEE THIS. SO GOOD MORNING TO ALL.

17 AND SO TODAY I WANT TO GIVE YOU AN  
18 OVERVIEW OF THE RECOMMENDATIONS FROM THE GRANTS  
19 WORKING GROUP, AS MENTIONED, FOR OUR CLINICAL  
20 PROGRAM. JUST AS A REMINDER, OUR CLINICAL PROGRAM  
21 ENCOMPASSES THREE DIFFERENT PROGRAM ANNOUNCEMENTS.  
22 THE TWO APPLICATIONS THAT WE ARE CONSIDERING TODAY  
23 ARE BOTH CLINICAL TRIAL APPLICATIONS.

24 WE ISSUED THE PROGRAM ANNOUNCEMENTS IN  
25 JANUARY, JANUARY 1ST, UNDER PROP 14 AS THE BEGINNING

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1 AND RELAUNCH OF OUR CORE PROGRAMS. AND SO OUR FIRST  
2 DEADLINE WAS AT THE END OF JANUARY. AND SO THIS IS  
3 THE FIRST CYCLE THAT WE ARE THEN SHOWING YOU THE  
4 OUTCOMES AND RECOMMENDATIONS FROM THE GRANTS WORKING  
5 GROUP ON THOSE.

6 AND WE SET AND THE BOARD SET AN ALLOCATION  
7 OF A HUNDRED MILLION FOR THE PERIOD OF JANUARY  
8 THROUGH JUNE OF 2021. THE AMOUNT REQUESTED TODAY BY  
9 BOTH APPLICATIONS WOULD TOTAL TO 14.4 MILLION. AND  
10 SO IF THOSE ARE APPROVED, YOU WOULD HAVE AN UNUSED  
11 BALANCE OF 85.6 MILLION REMAINING UNDER THAT  
12 ALLOCATION.

13 AND SO A REMINDER JUST OF THE CRITERIA  
14 THAT ARE USED BY THE GRANTS WORKING GROUP IN  
15 ASSESSING THE MERIT OF THESE APPLICATIONS. WE IN  
16 THE PAST HAD FOUR KEY QUESTIONS WHICH WE NOW HAVE  
17 FIVE, AND I'LL GO OVER THESE, ESPECIALLY THE FIFTH  
18 ONE IN MORE DETAIL.

19 THE FIRST ONE IS WHETHER THE PROJECT HOLDS  
20 THE NECESSARY SIGNIFICANCE AND POTENTIAL FOR IMPACT,  
21 MEANING WHAT VALUE DOES IT OFFER AND IS IT SOMETHING  
22 WORTH DOING? DOES IT HAVE A SOUND RATIONALE? IS  
23 THE PROJECT WELL-PLANNED AND DESIGNED? IS THE  
24 PROJECT FEASIBLE, INCLUDING, DO THEY HAVE AN  
25 APPROPRIATE AND QUALIFIED TEAM, THE INFRASTRUCTURE,

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1 AND RESOURCES TO CARRY OUT WHAT THEY PROPOSE TO DO?  
2 AND THEN THE NEW AND FIFTH CRITERION, WHICH WAS  
3 ADDED IN THIS CYCLE AND GOING FORWARD, IS DOES THE  
4 PROJECT ADDRESS THE NEEDS OF UNDERSERVED  
5 COMMUNITIES?

6 SO USING THESE CRITERIA, THE GRANTS  
7 WORKING GROUP THEN ASSIGNED A SCIENTIFIC SCORE TO  
8 THESE APPLICATIONS USING A SYSTEM OF 1, 2, OR 3.  
9 GIVING IT A SCORE OF 1 MEANS THAT THIS IS AN  
10 EXCEPTIONAL APPLICATION. IT COULD HAVE SOME MINOR  
11 RECOMMENDATIONS AND ADJUSTMENTS THAT WOULDN'T  
12 REQUIRE FURTHER GWG REVIEW. A SCORE OF 2 MEANS IT  
13 NEEDS IMPROVEMENT. AND SO TYPICALLY THESE  
14 APPLICATIONS GO BACK TO THE APPLICANT TO ADDRESS THE  
15 CONCERNS OF THE REVIEWERS AND THEY RESUBMIT SO THAT  
16 THEY CAN BE REEVALUATED. AND THEN, OF COURSE, A  
17 SCORE OF 3 SUCH THAT IT IS SUFFICIENTLY FLAWED AND  
18 WOULDN'T WARRANT FUNDING AT THIS TIME.

19 SO WHEN BEGINNING OUR REVIEW CYCLE THIS  
20 YEAR, THERE WERE SOME NEW ELEMENTS THAT WE  
21 INTRODUCED INTO THE APPLICATIONS. AND SO WE  
22 PRESENTED THESE NEW ELEMENTS TO THE GRANTS WORKING  
23 GROUP AS PART OF OUR INSTRUCTIONS. SO AMONG THEM  
24 WERE THE INCREASE IN SCOPE JUST SO THAT THEY WERE  
25 AWARE THAT GENE THERAPY IS NOW PART OF WHAT CIRM CAN

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1     FUND; THE INCLUSION OF A DATA SHARING PLAN, WHICH IS  
2     PART OF THE APPLICATION AND SOMETHING THAT CAN AND  
3     SHOULD BE EVALUATED; ADDRESSING THE NEEDS OF  
4     UNDERSERVED COMMUNITIES; AND THE ADDITION OF THIS AS  
5     A REVIEW CRITERION, ALTHOUGH WE ALREADY HAD THIS  
6     SECTION AND HAVE ACTUALLY BEEN ADDRESSING IT FOR  
7     QUITE A WHILE, THE REVIEW CRITERION ITSELF IS NEW;  
8     AND THEN, LASTLY, A SECTION ON DIVERSITY, EQUITY,  
9     AND INCLUSION. AND SO I WANT TO JUST SPEND A LITTLE  
10    TIME ON THESE LAST NEW ELEMENTS. THE FIRST ONE OF  
11    ADDRESSING THE NEEDS OF THE UNDERSERVED AND JUST  
12    DISTINGUISHING IT FROM THE DIVERSITY, EQUITY, AND  
13    INCLUSION SECTIONS BECAUSE THERE IS CERTAINLY  
14    SOMETIMES CONFUSION ABOUT THESE TWO.

15            SO THE FIRST SECTION ON ADDRESSING THE  
16    NEEDS OF UNDERSERVED COMMUNITIES IS A SECTION THAT  
17    DESCRIBES THE APPLICANT'S PLAN FOR OUTREACH AND  
18    ENROLLMENT OF A DIVERSE PATIENT COHORT THAT ACCOUNTS  
19    FOR RACIAL, ETHNIC, AND GENDER DIVERSITY IN THE  
20    CLINICAL TRIAL. AND SO THIS IS A COMPONENT THAT HAS  
21    EXISTED IN THE APPLICATIONS FOR QUITE A WHILE. AND  
22    I'LL EXPLAIN THAT FURTHER IN THAT IT IS EVALUATED AS  
23    PART OF THE OVERALL PROJECT AND INCORPORATED INTO  
24    THE SCIENTIFIC MERIT SCORE OF THE 1, 2, OR 3.

25            SEPARATELY, WE ADDED A SECTION ON



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1 DIVERSITY, EQUITY, AND INCLUSION IN RESEARCH. AND  
2 SO THIS SECTION DESCRIBES HOW THE APPLICANT TEAM  
3 WOULD INCORPORATE PERSPECTIVES AND EXPERIENCES TO  
4 IMPROVE THE PROJECT THROUGH THE COMPOSITION OF THE  
5 TEAM OR ANY OTHER APPROACHES THAT THE APPLICANT  
6 WOULD PRESENT. AND THIS SECTION IS EVALUATED AND  
7 SCORED BY PATIENT ADVOCATE MEMBERS AND IS  
8 REPRESENTED BY THE DEI SCORE, WHICH IS ON A SCALE OF  
9 ZERO TO TEN.

10 NOW, THIS SECTION IS NOT ONLY NEW, IT IS  
11 STILL UNDER DEVELOPMENT, AND SO IT IS A SECTION THAT  
12 WE WOULD ADVISE, AND I'LL GO INTO IT IN A LITTLE  
13 MORE DETAIL, THAT WE CONSIDER IT SORT OF A TEST RUN  
14 IN TERMS OF HOW IT IS USED IN MAKING A FINAL FUNDING  
15 DECISION ON ANY OF THESE APPLICATIONS.

16 SO LET ME JUST GO AND ADDRESS THE NEEDS OF  
17 THE UNDERSERVED FIRST. SO WHEN IT COMES TO CLINICAL  
18 TRIALS, ALL PROJECTS THAT ARE FUNDED THROUGH STATE  
19 FUNDS OR EVEN THROUGH FEDERAL FUNDS, THERE ARE  
20 EXISTING LAWS THAT REQUIRE WOMEN AND MINORITIES BE  
21 INCLUDED IN CLINICAL STUDIES. SO THIS HAS BEEN THE  
22 CASE EVEN SINCE CIRM'S ORIGINAL FOUNDING, AND SO  
23 THIS IS PART OF OUR REGULATIONS. AND SO THIS  
24 SECTION REALLY DRAWS OUT WHAT THE PLANS BY THE  
25 APPLICANT WOULD BE IN ORDER TO ADDRESS THIS. AND SO

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1 GIVEN IT'S IMPORTANCE, WE CREATED THAT NEW FIFTH  
2 REVIEW CRITERION IN ORDER TO INCORPORATE IT INTO THE  
3 SCORING OF CLINICAL TRIAL APPLICATIONS.

4 AND SO THE INSTRUCTIONS TO THE APPLICANT,  
5 BASICALLY JUST TO SUMMARIZE, ARE FOR THEM TO PRESENT  
6 THEIR PLAN FOR OUTREACH AND STUDY PARTICIPATION BY  
7 UNDERSERVED AND DISPROPORTIONATELY AFFECTED  
8 POPULATIONS, TO PRESENT ANY JUSTIFICATION FOR THE  
9 EXCLUSION OF ANY GROUPS THAT ARE AT RISK FOR THE  
10 DISEASE, AND BASICALLY HAVE AN OVERALL PRESENTATION  
11 OF WHAT THEY INTEND TO DO, AND NOTING THAT THE  
12 GRANTS WORKING GROUP AND GOVERNING BOARD WILL  
13 EVALUATE THOSE PLANS.

14 THE FIFTH REVIEW CRITERION THEN LAYS OUT  
15 THESE SUBQUESTIONS OF WHETHER THE PROPOSAL  
16 ADEQUATELY ADDRESSES ALL OF THIS. DOES THE PROPOSAL  
17 PROVIDE A CLEAR AND ROBUST PLAN FOR OUTREACH AND  
18 STUDY PARTICIPATION? DOES THE PROPOSAL ADDRESS THE  
19 PLAN DISTRIBUTION OF SUBJECTS ACCORDING TO RACE,  
20 SEX, GENDER, AND ETHNICITY? AND DO THEY HAVE AN  
21 APPROPRIATE RATIONALE FOR THE STUDY POPULATION THAT  
22 THEY ARE ADDRESSING? AND IF THERE IS ANY GROUP THAT  
23 IS EXCLUDED, WHETHER THERE IS ADEQUATE  
24 JUSTIFICATION? SO THIS IS WHAT THE GRANTS WORKING  
25 GROUP GUIDANCE IS AND PROVIDES ON THAT SECTION.

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1 NOW, DISTINCT FROM THAT IS A VERY SEPARATE  
2 SECTION ON THE DIVERSITY, EQUITY, AND INCLUSION, AS  
3 I MENTIONED BEFORE, WHICH IS THE NEW ELEMENT TO BE  
4 EVALUATED BY PATIENT ADVOCATE MEMBERS. THIS IS  
5 INTENDED TO BE A MORE HOLISTIC VIEW OF DIVERSITY AND  
6 INCLUSION IN THE COMPOSITION OF THE RESEARCH TEAM  
7 AND OTHER APPROACHES. AND SO THESE INSTRUCTIONS TO  
8 THE APPLICANT ARE STILL A LITTLE BIT VAGUE. SO I  
9 THINK THIS IS CERTAINLY WHERE WE NEED TO DEVELOP OUR  
10 GUIDANCE BOTH TO THE APPLICANTS AS WELL AS TO  
11 REVIEWERS IN TERMS OF WHAT IS EXPECTED AND WHAT TO  
12 DO HERE.

13 BUT CURRENTLY THE APPLICATION INSTRUCTIONS  
14 SAY DESCRIBE HOW THE RESEARCH TEAM HAD OR WILL  
15 INCORPORATE DIVERSE AND INCLUSIVE PERSPECTIVES AND  
16 EXPERIENCE IN THE IMPLEMENTATION OF THE RESEARCH  
17 PROJECT, INCLUDING, FOR EXAMPLE, INCLUSION OF TEAM  
18 MEMBERS FROM DIFFERENT SOCIOECONOMIC BACKGROUNDS.

19 AND SO ONE OF THE ELEMENTS THAT MAKES THIS  
20 SECTION ALSO CHALLENGING FOR THE GRANTS WORKING  
21 GROUP TO ASSESS IS THIS WARNING THAT WE PRESENTED TO  
22 THEM THAT BY STATE LAW CIRM IS PROHIBITED FROM  
23 TAKING RACE, ETHNICITY, NATIONAL ORIGIN, OR GENDER  
24 INTO ACCOUNT IN MAKING GRANT DECISIONS, MEANING THAT  
25 AS THEY DISCUSS AND EVALUATE THIS PARTICULAR

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1 SECTION, IT CANNOT BE SOLELY BASED ON OR MAKE SOLE  
2 REFERENCE TO THESE ELEMENTS. AND SO THE EVALUATIONS  
3 NEED TO BE FOCUSED ON OTHER FACTORS SUCH AS  
4 SOCIOECONOMIC STATUS OR THOSE THAT ARE FIRST IN  
5 THEIR FAMILY TO ATTEND COLLEGE.

6 SO THE SCORING, AGAIN, ON THAT DEI SECTION  
7 BY PATIENT ADVOCATE MEMBERS WAS, AT LEAST IN THIS  
8 INITIAL RUN, DONE ON A SCALE OF ZERO TO TEN WITH TEN  
9 BEING THE BEST POSSIBLE SCORE. WE COLLECTED  
10 COMMENTS IN ORDER TO PROVIDE JUSTIFICATION FOR THOSE  
11 SCORES. AND AS MENTIONED BEFORE, THIS PROCESS IS  
12 NEW, SO WE ARE ANTICIPATING THAT IMPROVEMENTS ARE  
13 GOING TO BE MADE AS WE GO ALONG, AND WE ARE USING  
14 THE FEEDBACK FROM OUR PATIENT ADVOCATE MEMBERS AS  
15 WELL AS OUR APPLICANTS WHO ARE PUTTING IN AND  
16 REQUESTING GUIDANCE ON THOSE SECTIONS. SO EXPECT TO  
17 SEE MORE ON THIS AS WE DEVELOP IT.

18 ANOTHER IMPORTANT NOTE REGARDING THIS  
19 PARTICULAR REVIEW IS THAT THE TWO APPLICATIONS THAT  
20 ARE BEING CONSIDERED ARE RESUBMITTED APPLICATIONS.  
21 SO THEY ORIGINALLY APPLIED IN AUGUST OF 2020 UNDER  
22 PROP 71 FUNDING AND RECEIVED A SCORE OF 2. AND SO  
23 WITH A SCORE OF 2, MEANING THAT THEY GET THE  
24 OPPORTUNITY TO REVISE AND RESUBMIT, UNFORTUNATELY WE  
25 WERE AT A POINT WHERE THERE WAS NO CIRM FUNDING

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1 AVAILABLE FOR THEM TO DO THAT, AND THAT WOULDN'T  
2 OCCUR UNTIL WE REESTABLISHED FUNDING UNDER PROP 14.

3 SO WITH THE ISSUING OF THIS NEW CORE SET  
4 OF PROGRAM ANNOUNCEMENTS, THE APPLICANTS  
5 RESUBMITTED, AND SO WE ARE SEEING THEM NOW AS  
6 REVISED APPLICATIONS. BUT ALSO IT'S IMPORTANT TO  
7 NOTE THAT THE NEW ELEMENTS OF DATA SHARING AND DEI  
8 WERE NOT COMPONENTS OF THE ORIGINAL APPLICATION NOR  
9 OF THE ORIGINAL REVIEW, BUT THE APPLICANTS DID  
10 SUBMIT SUPPLEMENTARY INFORMATION THAT ADDRESSED  
11 THOSE AREAS AND WERE THEN LOOKED AT BY THE GRANTS  
12 WORKING GROUP IN THE MOST RECENT REVIEW.

13 OKAY. SO BEFORE I GO INTO THEN EACH OF  
14 THE APPLICATIONS, ARE THERE QUESTIONS ABOUT THE  
15 BACKGROUND AND THE PROCESS? OS, DO YOU WANT TO SAY  
16 ANYTHING AT THIS POINT?

17 DR. STEWARD: I'M SORRY. I HAVE TO GO TO  
18 MY PHONE BECAUSE THE INTERNET IS REALLY UNSTABLE ON  
19 MY OFFICE COMPUTER HERE.

20 SO JUST TO EMPHASIZE WHAT GIL SAID ABOUT  
21 THE DEI, THIS WAS SOMETHING THAT ACTUALLY WE HAD A  
22 LOT OF DISCUSSION ABOUT. AND I THINK THAT WHAT GIL  
23 SAID ABOUT IT BEING A SORT OF TRIAL RUN IS VERY  
24 IMPORTANT HERE. WE REALLY REALIZED THAT THERE'S A  
25 LOT OF SORT OF MOVING PARTS TO THIS AND NEED TO GET

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1 IT REALLY BETTER EXPLAINED TO BOTH THE APPLICANTS  
2 AND THE REVIEW GROUP. SO I'LL JUST EMPHASIZES THAT.

3 AND ALSO JUST TO SAY THAT BOTH OF THESE  
4 APPLICANTS, AND, GIL, MAYBE YOU CAN CORRECT ME, SO  
5 THEY CAME IN UNDER THE EARLIER RFP. IT ACTUALLY  
6 DIDN'T HAVE A SECTION 5 IN THEIR REVISED  
7 APPLICATION, BUT THEY WERE ASKED TO PROVIDE  
8 INFORMATION REGARDING THAT. SO IT'S A LITTLE BIT  
9 DIFFERENT THAN WE'LL SEE GOING FORWARD AND JUST TO  
10 SORT OF EMPHASIZE THAT FOR EVERYBODY BEFORE WE  
11 ACTUALLY START THE CONSIDERATION. THANK YOU. BUT  
12 PLEASE ANYBODY ASK ANY QUESTIONS NOW BEFORE WE  
13 ACTUALLY GET INTO THE APPLICATIONS THEMSELVES.

14 MR. TORRES: YES. DR. STEWARD, IT'S ART.  
15 I JUST WANTED TO REMIND OURSELVES THAT PERHAPS WE  
16 SHOULD REACH OUT TO GENERAL COUNSEL FOR UC BECAUSE  
17 ON THE BOARD OF REGENTS WE'VE BEEN DEALING WITH THIS  
18 ISSUE OBVIOUSLY ONCE PROP 16 DID NOT PASS AND HOW WE  
19 APPLY THIS TO ADMISSION STANDARDS AND A WHOLE LOT OF  
20 OTHER EMPLOYMENT ISSUES BECAUSE IT'S VERY RELEVANT  
21 TO WHAT WE ARE DISCUSSING HERE. SO I WILL TRY AND  
22 GET A LEGAL COUNSEL'S OPINION FROM UC SO THAT WE ARE  
23 IN SYNC WITH OUR INSTITUTIONS.

24 DR. STEWARD: THANK YOU. THAT'S, I THINK,  
25 AN EXCELLENT WAY TO MOVE FORWARD ON THIS. THANK

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1 YOU, ART.

2 MS. BONNEVILLE: OS, ADRIANA HAS HER HAND  
3 RAISED.

4 DR. STEWARD: YES. I SEE THAT. YES,  
5 ADRIANA.

6 DR. PADILLA: YES. THANK YOU. I JUST  
7 WANTED TO KNOW HAVE YOU WORKED OUT, GIL, THE PROCESS  
8 OF HOW THE CRITERIA ARE GOING TO BE DEVELOPED OVER  
9 TIME ON THE DEI STATUS BECAUSE WE TALK ABOUT  
10 DIVERSITY, BUT I WAS ALSO INTERESTED IN HOW THAT  
11 PERTAINS TO INCLUSION AND EQUITY FOR, FOR INSTANCE,  
12 UNDERSERVED COMMUNITIES IN CALIFORNIA AND HOW THESE  
13 RESEARCH STUDIES WOULD ADDRESS THAT PARTICULARLY.

14 DR. SAMBRANO: RIGHT. THAT'S A GREAT  
15 QUESTION, AND I THINK THAT'S PART OF WHAT WE NEED TO  
16 THINK THROUGH MORE CAREFULLY AND BE ABLE TO DEVELOP  
17 THE EXPECTATIONS FOR THESE TYPES OF PROJECTS.

18 WE ARE ALSO TRYING TO IMPLEMENT THIS  
19 ACROSS THE DIFFERENT TYPES OF PROJECTS THAT WE FUND,  
20 SO ALSO IN DISCOVERY AND TRANSLATION. AND SO WHAT  
21 THE EXPECTATIONS FOR DEI WOULD BE ACROSS ALL OF  
22 THOSE DIFFERENT TYPES OF PROJECTS WOULD LIKELY  
23 DIFFER AS WELL. AND SO I THINK THAT DEVELOPMENT OF  
24 IT IS GOING TO REQUIRE US JUST TO HAVE MORE  
25 CONVERSATIONS PARTICULARLY WITH GRANTS WORKING GROUP

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1 PATIENT ADVOCATE MEMBERS IN ORDER TO MORE FULLY  
2 DEVELOP IT.

3 DR. PADILLA: SO IS THAT LIKE A WORK GROUP  
4 THAT'S ALREADY IN PROCESS, OR WHAT IS THE TIMELINE  
5 FOR THAT?

6 DR. SAMBRANO: SO WE DON'T YET HAVE A  
7 TIMELINE FOR IT, BUT WE'VE BEGUN DISCUSSIONS WITH  
8 GRANTS WORKING GROUP PATIENT ADVOCATE MEMBERS. AND  
9 SO THAT IS SOMETHING THAT IS ONGOING AND WE WILL  
10 HAVE TO DEVELOP.

11 DR. PADILLA: OKAY. SO WE'LL GET SOME  
12 INFORMATION ON THAT DOWN THE ROAD?

13 DR. SAMBRANO: YES, ABSOLUTELY.

14 DR. PADILLA: GREAT.

15 DR. STEWARD: IF I COULD JUST EMPHASIZE  
16 SOMETHING THAT GIL SAID BECAUSE IT'S REALLY  
17 IMPORTANT. WHAT YOU'RE ACTUALLY ASKING ABOUT IN  
18 TERMS OF OUTREACH IS COVERED UNDER SECTION 5  
19 CURRENTLY AND IS SOMETHING THAT WE HAVE BEEN DOING  
20 FOR QUITE A WHILE AND, AS GIL SAID, ACTUALLY IS  
21 INCORPORATED INTO BOTH STATE AND FEDERAL LAWS AS  
22 WELL. SO FROM THAT POINT OF VIEW, THAT'S ONE ASPECT  
23 OF THIS THAT IS ALREADY IN PLACE VERY FIRMLY.

24 AND THEN THE SEPARATE DEI CONSIDERATION,  
25 WHICH REALLY RELATES PRIMARILY TO THE TEAM, IS THE



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1 ONE I THINK THAT IS GOING TO BE THE ONE THAT IS  
2 GOING FORWARD GOING TO NEED MORE WORK. AM I STATING  
3 THAT CORRECTLY, GIL?

4 DR. SAMBRANO: YES. THAT'S RIGHT, OS.  
5 THAT'S CORRECT.

6 DR. STEWARD: THANK YOU. HOPE THAT  
7 CLARIFIES. LET'S SEE. WE HAVE A HAND FROM YSABEL.

8 MS. DURON: YES. THANK YOU. FIRST OF  
9 ALL, I'M GLAD THAT ART IS GOING TO CHECK IN WITH THE  
10 LAWYERS BECAUSE THE VERY NATURE OF THE "BY STATE LAW  
11 CIRM IS PROHIBITED" SAYS ONE THING, AND THAT REALLY  
12 TIES HANDS BECAUSE PART -- AND I'M GLAD WE ARE  
13 LOOKING AT COMPOSITION OF THE RESEARCH GROUPS. ONE,  
14 THIS IS A WAY BY BRINGING IN INVESTIGATORS OF COLOR,  
15 RACIAL AND ETHNIC GROUPS WE ARE IMPROVING THE  
16 PIPELINE. WE ARE HELPING AN UNDERSERVED COMMUNITY  
17 HAVE THESE EXPERTS. BUT BEYOND THAT, IT STRIKES ME  
18 THAT THEY BRING WITH THEM NOT ONLY LIVED EXPERIENCE,  
19 BUT CULTURE AND LANGUAGE THAT IS ADDITIONAL VALUE TO  
20 THE RESEARCH TEAM AND WITHOUT IT MIGHT NOT BE ABLE  
21 TO DO THE RECRUITMENT NECESSARY, THE OUTREACH  
22 NECESSARY THAT IS ALREADY CREATING THE  
23 TRUSTWORTHINESS WITH THOSE COMMUNITIES WITH WHOM  
24 THEY WISH TO ENGAGE.

25 SO I HAVE A LITTLE PROBLEM WHEN YOU'RE

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1 DISCOUNTING SOMEONE'S RACE OR ETHNICITY, AND I'M  
2 HOPING THAT WE GET THE NUANCE CLARITY ON THAT  
3 BECAUSE THAT SOUNDS JUST STRICTLY PROHIBITED. YOU  
4 CAN'T EVEN THINK ABOUT THAT, AND I THINK THERE MUST  
5 BE A NUANCE TO THAT INTERPRETATION BECAUSE, IN FACT,  
6 IF WE DON'T HAVE PEOPLE WHO BRING THEIR RACE AND  
7 ETHNICITY TO THE TABLE, THEN IT'S THE SAME OLE, SAME  
8 OLE. THANK YOU.

9 DR. STEWARD: I THINK I HAVE A HAND FROM  
10 AL ROWLETT.

11 MR. ROWLETT: THANK YOU. I DON'T WANT TO  
12 REPEAT EVERYTHING THAT OS SAID. MY PERSPECTIVE  
13 AROUND THIS AND CERTAINLY FOR MY COLLEAGUES ON THE  
14 BOARD, THE COMMITMENT THAT WE'VE MADE AS EVALUATORS  
15 IS TO PROVIDE STAFF WITH INFORMATION THAT WILL  
16 RESULT IN THE KIND OF PROCESS IMPROVEMENTS THAT WE  
17 ALL WANT AND THAT ARE CONSISTENT WITH THE  
18 LEGISLATION, SPECIFICALLY AS IT RELATES TO THE  
19 INCLUSION OF PEOPLE WITH LIVED EXPERIENCE, I.E.,  
20 EITHER AS PART OF A GROUP THAT IS LEADING  
21 APPLICATIONS OR CERTAINLY MAKING SURE THAT IT IS  
22 REFLECTED IN THE APPLICATION, AND THAT THE  
23 PERSPECTIVE OF PEOPLE WITH LIVED EXPERIENCE IS NOT  
24 ONLY IMPORTANT, BUT FROM MY PERSPECTIVE ESSENTIAL,  
25 AGAIN, TAKING INTO CONSIDERATION THE SOCIAL

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1 DETERMINANTS OF THE HEALTH. AND, AGAIN, THAT  
2 PERSPECTIVE AND MAKING SURE THAT IT'S REFLECTED IN  
3 THE RESPONSES THAT WE GET.

4 AND THEN I THINK I WANT TO ASSERT THAT GIL  
5 IS RIGHT ON WHEN HE SAID THAT THE INCLUSION OF THE  
6 REVIEWERS IS RESULTING IN US ASKING APPLICANTS  
7 BETTER QUESTIONS AND THAT AS WE ASK BETTER  
8 QUESTIONS, WE'RE GOING TO GET BETTER, MORE  
9 COMPREHENSIVE RESPONSES THAT ARE NOT REFLECTIVE OF  
10 THE KIND OF WORK THAT TYPICALLY EXCLUDES PEOPLE OF  
11 COLOR, BUT IS MORE INCLUSIVE OF PEOPLE OF COLOR,  
12 UNDERSERVED AND UNSERVED COMMUNITIES.

13 DR. STEWARD: GOOD. THANK YOU. I DON'T  
14 SEE ANY MORE HANDS. WAIT. STEVE JUELSGAARD.

15 MR. JUELSGAARD: YES. SO I'M NOT SURE HOW  
16 MANY PEOPLE ARE AS VERSED IN THE NEW PROPOSITION 14  
17 THESE DAYS, PARTICULARLY WITH REGARD TO SOMETHING  
18 CALLED THE TREATMENTS AND CURES ACCESSIBILITY AND  
19 AFFORDABILITY WORKING GROUP. BUT THERE ARE TWO  
20 PARTICULAR SECTIONS IN WHAT THAT GROUP IS SUPPOSED  
21 TO BE AIMED AT THAT I'M JUST GOING TO READ TO YOU  
22 BECAUSE THEY ADDRESS SOMETHING ADRIANA MENTIONED  
23 EARLIER.

24 THE FIRST IS THAT THIS GROUP IS TO  
25 RECOMMEND TO THE GOVERNING BOARD, THAT'S US,

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1 POLICIES AND PROGRAMS TO HELP CALIFORNIANS OBTAIN  
2 ACCESS TO HUMAN CLINICAL TRIALS AND TO MAKE  
3 TREATMENTS AND CURES ARISING FROM INSTITUTE-FUNDED  
4 RESEARCH AVAILABLE TO CALIFORNIA PATIENTS THROUGHOUT  
5 CALIFORNIA.

6 SECOND PROVISION READS AS FOLLOWS.  
7 THEY'RE ALSO TO RECOMMEND TO US, THE GOVERNING  
8 BOARD, POLICIES AND PROGRAMS TO HELP CALIFORNIANS  
9 AFFORD TO PARTICIPATE IN HUMAN CLINICAL TRIALS AND  
10 TO MAKE TREATMENTS AND CURES ARISING FROM  
11 INSTITUTE-FUNDED RESEARCH AFFORDABLE TO CALIFORNIA  
12 PATIENTS REGARDLESS OF FINANCIAL MEANS.

13 SO WE HAVE A GROUP, I TAKE IT, THAT'S  
14 STILL BEING FORMED, BUT THEIR GOAL IS TO ADVISE US  
15 OF POLICIES THAT WE MIGHT ADOPT THAT WOULD REACH OUT  
16 TO UNDERSERVED COMMUNITIES AND ALSO POTENTIALLY HELP  
17 PAY PEOPLE IN THOSE UNDERSERVED COMMUNITIES IN  
18 ASSOCIATION WITH BEING IN CLINICAL TRIALS. SO WE  
19 HAVE HELP COMING, I HOPE.

20 MR. TORRES: YES. YES, YOU DO, STEVE. AS  
21 CHAIR OF THAT NEW WORKING GROUP, AND YOU'RE RIGHT,  
22 WE HAVEN'T FINISHED NAMING ALL OF PARTICIPANTS THAT  
23 ARE ARTICULATED IN THE LANGUAGE THAT BOB AND I WROTE  
24 FOR PROP 14 ON THAT VERY ISSUE, AND WE ARE STARTING  
25 TO DO THAT. BUT I'VE ALSO BEEN WORKING ON IT AS

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1 WELL IN PREPARATION FOR OUR FIRST MEETING WHEN WE  
2 CAN AT LEAST BEGIN TO OUTLINE THE GENERAL OUTLINES  
3 OF WHAT'S GOING ON. I TOOK PARTICULAR STEPS IN  
4 BRINGING COVERED CALIFORNIA NEGOTIATORS TO CIRM  
5 EARLY ON, ABOUT A YEAR AGO, TO BEGIN DISCUSSIONS ON  
6 AFFORDABILITY ISSUES AND HOW TO REACH OUT TO  
7 THIRD-PARTY PAYERS.

8 WE ALSO HAVE A GOOD FORMULA THAT WE'VE  
9 BEEN WORKING WITH SINCE 1996 AT THE ORGAN TRANSPLANT  
10 FOUNDATION, ONE LEGACY, OF WHICH I'M THE VICE CHAIR,  
11 WHICH SPEAKS DIRECTLY TO WHAT YOU JUST SAID. AND  
12 THAT IS HOW DO WE ESTABLISH CRITERIA SO THAT WE CAN  
13 HELP CAREGIVERS AND THEIR PATIENTS COME TO A  
14 LOCATION WHICH IS FAR FROM THEIR HOME AND STILL BE  
15 ABLE TO PAY FOR THEIR MINIMUM OF EXPENSES. SO I'LL  
16 GET MUCH MORE INTO DETAIL AS WE EVOLVE AND THE FIRST  
17 MEETING IS HELD, HOPEFULLY SOON. THANK YOU, STEVE.

18 MR. JUELSGAARD: YOU'RE WELCOME, ART.  
19 JUST ONE FOLLOW-UP TO THAT. SO IT SEEMS TO ME THAT  
20 THE LANGUAGE THAT'S WRITTEN HERE IN WHAT'S DESIRED  
21 IS BROAD ENOUGH TO ALLOW CIRM ITSELF TO ESTABLISH  
22 FUNDING MECHANISMS FROM CIRM FUNDS TO ASSIST IN  
23 PROVIDING ACCESS TO UNDERSERVED COMMUNITIES.

24 MR. TORRES: YES. YOU'RE ABSOLUTELY  
25 RIGHT, STEVE. THE WAY WE HANDLE IT WITH ONE LEGACY

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1 IS THAT WE CREATE SPECIFIC FOUNDATIONS THAT WE FUND.  
2 FOR EXAMPLE, WE HAVE THE AVA FOUNDATION, WHICH IS  
3 DIRECTLY LINKED TO HEART TRANSPLANT PATIENTS, AND WE  
4 FUND THEM BY ABOUT A HUNDRED THOUSAND A YEAR, AND  
5 THEY RAISE A LOT OF THEIR OWN MONEY. AND THAT  
6 DIRECTLY ASSISTS HEART TRANSPLANT PATIENTS AND THEIR  
7 CAREGIVERS. WE ARE MORE FORTUNATE IN THAT WE HAVE  
8 THE FUNDING AND WILL HAVE THE FUNDING AVAILABLE TO  
9 HELP AT LEAST BEGIN THE FIRST STEPS OF THAT  
10 FINANCING FOR STEM CELL PATIENTS AND THEIR  
11 CAREGIVERS AND THEIR COSTS.

12 MR. JUELSGAARD: GREAT. THANKS.

13 DR. STEWARD: GOOD. ANY OTHER QUESTIONS  
14 OR COMMENTS? I WANT TO MAKE SURE THAT WE HAVE A  
15 ROBUST DISCUSSION ABOUT THIS. THANKS FOR EVERYBODY  
16 PROVIDING THEIR INPUT HERE. ANYTHING ELSE? I DON'T  
17 SEE ANY HANDS. MARIA, DO YOU SEE ANY HANDS THAT I'M  
18 MISSING?

19 MS. BONNEVILLE: NO, I DO NOT.

20 DR. STEWARD: OKAY. GREAT. SO WE CAN, I  
21 THINK, GO AHEAD AND MOVE TO CONSIDERATION OF THE  
22 FIRST APPLICATION. GIL, IF I CAN TURN IT BACK OVER  
23 TO YOU.

24 DR. SAMBRANO: OKAY. THANK YOU, OS. SO  
25 THE FIRST APPLICATION TO BE CONSIDERED IS 12153. SO

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1 THIS IS A CAR T-CELL THERAPY FOR PEDIATRIC BRAIN  
2 TUMORS. THIS IS AN AUTOLOGOUS THERAPY OF A CHIMERIC  
3 ANTIGEN RECEPTOR T-CELL CELL THERAPY. AND IT IS  
4 ENGINEERED TO TARGET AN ANTIGEN ON PEDIATRIC  
5 MALIGNANT BRAIN TUMORS. THE INDICATION IS FOR  
6 RECURRENT OR REFRACTORY MALIGNANT PEDIATRIC BRAIN  
7 TUMORS THAT EXPRESS THAT TUMOR-ASSOCIATED ANTIGEN.

8 THE GOAL OF THIS PARTICULAR STUDY IS TO  
9 COMPLETE A PHASE 1 TRIAL. THE FUNDS REQUESTED IS  
10 8.4 MILLION FOR THIS STUDY.

11 JUST TO PROVIDE SOME BACKGROUND  
12 INFORMATION, BRAIN TUMORS ARE THE LEADING CAUSE OF  
13 SOLID TUMOR CANCER DEATH IN CHILDREN BETWEEN THE  
14 AGES OF ZERO AND 14, AND IT IS THE SECOND MOST  
15 COMMON CANCER IN CHILDREN AFTER LEUKEMIA. AND THE  
16 PROGNOSIS FOR PEDIATRIC PATIENTS THAT HAVE  
17 AGGRESSIVE BRAIN TUMORS IS VERY POOR AND OFTEN IS  
18 JUST A FEW MONTHS. THE PROPOSED THERAPY WOULD OFFER  
19 THE POSSIBILITY OF IMPROVED PATIENT OUTCOMES THAT  
20 COULD INCLUDE TUMOR SHRINKAGE AND REGRESSION. AND  
21 THE APPROACH WOULD PROVIDE A THERAPEUTIC OPTION WITH  
22 IMPROVED TOLERABILITY AND FEWER SIDE EFFECTS THAN  
23 THE CURRENT STANDARD OF CARE, WHICH IS MOSTLY  
24 RADIATION THERAPY AND IN SOME CASES NEUROSURGICAL  
25 RESECTION.

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1                    WHY IS THIS A STEM CELL PROJECT?

2                    THERAPEUTIC CANDIDATE CONTAINS MEMORY T-CELLS.

3                    IN LOOKING AT OUR PORTFOLIO PROJECTS OF  
4                    PROJECTS WE HAVE FUNDED THAT MIGHT BE RELATED OR  
5                    SIMILAR TO THIS, ON THIS TABLE IS LISTED THE CURRENT  
6                    APPLICATION AND THEN TWO OTHER PROJECTS. SO THERE  
7                    IS ANOTHER PHASE 1 CLINICAL TRIAL FOCUSED ON  
8                    MALIGNANT GLIOMA, IN THIS CASE IN ADULTS. IT IS BY  
9                    THE SAME TEAM, AND IT'S USING THE SAME CANDIDATE IN  
10                   ADULT PATIENTS. SO LARGELY A SIMILAR STUDY, BUT A  
11                   DIFFERENT PATIENT POPULATION.

12                   THERE IS ANOTHER SOMEWHAT RELATED STUDY  
13                   THAT WE ARE FUNDING. IT'S ALSO A PHASE 1 CLINICAL  
14                   TRIAL. THAT ONE IS FOCUSED ON USING A SIMILAR  
15                   T-CELL THERAPY APPROACH, BUT IT IS FOR BRAIN  
16                   METASTASES FROM HER2 POSITIVE BREAST CANCER CELLS.

17                   THE APPLICANT, AS MENTIONED, HAS RECEIVED  
18                   PREVIOUS CIRM FUNDING. AND SO LISTED HERE ARE TWO  
19                   PREVIOUS PROJECTS. THE OTHER ONE IS THE PHASE 1  
20                   CLINICAL TRIAL THAT WE JUST MENTIONED THAT HAS  
21                   PROGRESSED QUITE WELL AND ACHIEVED ALL MILESTONES ON  
22                   TIME, AND THEY ARE ON TRACK FOR COMPLETING THEIR  
23                   LAST MILESTONE BY NOVEMBER 2021 WHEN THEY WOULD WRAP  
24                   UP THAT PROJECT. THEY ALSO RECEIVED A TRANSLATIONAL  
25                   AWARD IN THE PAST THAT HELPED DEVELOP THIS OVERALL



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1 THERAPEUTIC CANDIDATE.

2 SO THE RECOMMENDATION FROM THE GRANTS  
3 WORKING GROUP WAS A SCORE OF 1 WITH 11 MEMBERS OF  
4 THE WORKING GROUP GIVING IT A SCORE OF 1. THERE  
5 WERE FOUR MEMBERS THAT GAVE IT A SCORE OF 2 AND NO  
6 MEMBERS THAT GAVE IT A SCORE OF 3. THIS HAD A DEI  
7 SCORE OF 9. CIRM'S TEAM RECOMMENDATION IS TO FUND  
8 THIS APPLICATION, CONCURRING WITH THE GRANTS WORKING  
9 GROUP RECOMMENDATION, FOR AN AWARD AMOUNT OF 8.4  
10 MILLION. AND SO I WILL PAUSE THERE.

11 DR. HIGGINS: GIL, MAY I ASK A QUESTION  
12 PLEASE? THIS IS DAVID IN SAN DIEGO.

13 DR. SAMBRANO: ABSOLUTELY.

14 DR. HIGGINS: WHAT DEI SCORE WOULD  
15 INDEPENDENTLY KILL THIS APPLICATION IF IT  
16 WERE -- WHAT IF THE DEI SCORE WAS 1 AND ALL THE  
17 OTHER SCORES WERE AS PRESENTED? WHAT WOULD THAT DO  
18 TO THE PROCESS?

19 DR. SAMBRANO: WELL, I THINK THAT IS UP TO  
20 THE APPLICATION REVIEW SUBCOMMITTEE. SO WHAT WE DO  
21 IS PRESENT THE RECOMMENDATIONS AND THE SCORES AS  
22 WERE DESIGNATED BY THE GROUP, BUT ULTIMATELY I THINK  
23 THAT BECOMES PART OF PROGRAMMATIC REVIEW THAT  
24 HAPPENS HERE IN TERMS OF WHAT WEIGHT YOU WISH TO  
25 GIVE IT RELATIVE TO THE OVERALL SCIENTIFIC MERIT OF

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1 THE APPLICATION.

2 DR. HIGGINS: SO IT'S NOT GOING TO BE  
3 FORMULAIC. IT'S GOING TO BE ON AN INDIVIDUAL BASIS.

4 DR. SAMBRANO: THAT'S RIGHT.

5 DR. HIGGINS: OKAY.

6 MR. HARRISON: GIL, COULD I JUST JUMP IN  
7 THERE QUICKLY. DAVID, I THINK THAT'S -- YOUR  
8 QUESTION IS ONE OF THE VERY REASONS THAT WE VIEW THE  
9 CURRENT DEI SCORES AS A TEST RUN BECAUSE WE NEED TO  
10 DEVELOP MORE AND MORE CLEARLY CRITERIA BOTH FOR THE  
11 EVALUATION AND FOR THE PRESENTATION OF INFORMATION  
12 BY THE APPLICANTS THEMSELVES. AND BECAUSE THE  
13 PROCESS IS EVOLVING AND WE HAVE NOT YET ACHIEVED  
14 THAT LEVEL OF CLARITY, WE ARE AT THIS STAGE NOT  
15 CONSIDERING THE DEI SCORES AS PART OF YOUR  
16 DECISION-MAKING. THEY'RE THERE FOR INFORMATION  
17 PURPOSES ONLY WHILE WE CONTINUE TO REFINE THE  
18 PROCESS.

19 DR. HIGGINS: THANK YOU, JAMES.  
20 THAT'S -- AS USUAL YOU'RE VERY CLEAR. BUT MY  
21 QUESTION SORT OF HAS TO DO NOT WITH HOW WE'RE GOING  
22 TO ARRIVE AT A SCORE THAT WE ARE HAPPY WITH, BUT  
23 WHAT ARE WE GOING TO DO WITH THAT SCORE. SO  
24 ESSENTIALLY THE SLIDE IN FRONT OF US WE'VE GOT TWO  
25 SCORES. WE'VE GOT A 1 AND A 9, SAY. ARE THEY EQUAL

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1 WEIGHT, OR DOES THE 9 DEI EMPHASIS, IS IT ONE-FIFTH  
2 OF THE TOTAL SCORE? IS THERE SOME WAY IT  
3 AUTOMATICALLY GETS AVERAGED IN, OR IS THIS SOMETHING  
4 THAT WILL BE DONE ON A CASE-BY-CASE BASIS?

5 SO THIS TIME I THINK THE DEI SCORE IS  
6 REALLY IMPORTANT AND THE NEXT APPLICANT I DON'T  
7 THINK IT'S AS IMPORTANT. DOES THAT MAKE SENSE? THE  
8 QUESTION MAKE SENSE?

9 DR. STEWARD: I THINK IT MAKES GREAT  
10 SENSE. THANK YOU. YES.

11 MR. HARRISON: AND I THINK THOSE ARE THE  
12 TYPES OF QUESTIONS THAT WE WILL BE EVALUATING AS WE  
13 CONSIDER HOW TO MOVE FORWARD IN UTILIZING, BOTH  
14 APPLYING THE DEI CRITERIA, THE SCORING METHODOLOGY,  
15 WHAT'S THE DIFFERENCE BETWEEN A SIX AND A NINE, FOR  
16 EXAMPLE, AND THEN WHAT THE GROUP'S THOUGHTS ARE WITH  
17 RESPECT TO HOW THOSE SCORES ARE THEN UTILIZED IN THE  
18 ULTIMATE FUNDING DECISIONS.

19 DR. HIGGINS: OKAY. JAMES, I'M ABSOLUTELY  
20 SATISFIED. THAT'S A PERFECT ANSWER. THANK YOU.

21 MS. DURON: YSABEL HERE.

22 DR. STEWARD: YES, YSABEL. GO AHEAD.  
23 THANK YOU.

24 MS. DURON: THANK YOU, OS. I'M GLAD THAT  
25 DAVID RAISED THE QUESTION BECAUSE I HAVE THAT SAME

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1 KIND OF A CURIOSITY BOTH WHEN IT COMES TO THE DEI,  
2 BUT ALSO WHEN IT COMES TO THE INCLUSION PLAN. SO  
3 LET'S SAY THE INCLUSION PLAN SHOWS THAT THEY'RE  
4 REALLY SCORING -- I HOPE THAT'S NOT ME MAKING ALL  
5 THE SQUEAKS -- THE INCLUSION PLAN SHOWS THAT THEY'VE  
6 GOT A VERY ROBUST ENGAGEMENT PLAN AND THAT THEY'VE  
7 LOOKED AT -- I'M SORRY ABOUT THAT -- YOU LOOK AT THE  
8 INCLUSION PLAN. IT'S VERY ROBUST. IT TAKES INTO  
9 ACCOUNT THE IMPACT OF THESE BRAIN CANCERS ON  
10 CHILDREN OF COLOR WHO OFTENTIMES DON'T END UP IN THE  
11 BEST OF TREATMENT AND CARE CIRCUMSTANCE AND DON'T  
12 HAVE ACCESS TO THE HIGHEST QUALITY KIND OF  
13 SCIENTIFIC DIAGNOSIS AND ASSESSMENT.

14 SO IF THAT IS HIGH IN TERMS OF ITS SCORE,  
15 THEN I MIGHT HAVE LESS CONCERN THAT THE DEI SCORE IS  
16 NOT AS MUCH INCLUSIVE OF A LARGE GROUP OF  
17 INVESTIGATORS FROM THESE COMMUNITIES SO THAT THERE  
18 PROVIDES SOME BALANCE. BUT IF BOTH ARE LOW, THEN I  
19 WOULD HAVE A GREAT DEAL OF CONCERN THAT ONE OF THE  
20 MAJOR REASONS FOR CONSIDERING INCLUSION IS NOT BEING  
21 PROMOTED SIMPLY BECAUSE HISTORY SHOWS US THAT UNLESS  
22 WE ARE IN FRONT OF YOU, YOU'RE NOT NECESSARILY  
23 THINKING ABOUT US. AND, THEREFORE, THIS IS WHY WE  
24 KEEP ASKING FOR INCLUSION AND PLANS THAT ARE VERY  
25 SPECIFIC AND HAVE OUTCOMES AS A RESULT OF THOSE

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1 PLANS THAT MAKES FOLKS HAVE TO DO SOMETHING AS  
2 OPPOSED TO WE'LL CONSIDER IT. AND THAT INCLUDES FOR  
3 ME THE REVIEW TEAM WHO WILL SAY, "WELL, THAT'S GOOD.  
4 WE'LL THINK ABOUT IT," INSTEAD OF IT BEING REQUIRED  
5 AS ONE OF THE SCIENTIFIC SCORES. VERY HIGH, NOT  
6 JUST --

7 JUST AT THIS POINT IN TIME I'VE SEEN  
8 ENOUGH RESEARCH APPLICATIONS WHERE THEY CHECK A BOX  
9 AND THEN THEY DON'T LIVE UP TO THE EXPECTATION THAT  
10 THEY DO MUCH BEYOND THE CHECKING THE BOX. AND SO  
11 I'M WANTING US TO HOLD PEOPLE'S FEET TO THE FIRE AT  
12 EVERY LEVEL, BE IT THE DEI SCORE OR BE IT AT THE  
13 INCLUSION PLAN, THAT THERE ARE, IN FACT -- YOU LOSE  
14 POINTS IF YOU DON'T HAVE A STRONG PLAN, PERIOD.  
15 WHAT DO THEY SAY? NO STOP HERE. SORRY, OS. MAYBE  
16 YOU CAN HELP WITH THAT ONE. BUT THIS IS WHERE I  
17 THINK WE NEED TO BE NOW. AND GIVEN THE NUANCES WE  
18 TALKED ABOUT THAT ART IS GOING TO LOOK INTO ABOUT IT  
19 CAN'T BE JUST ON RACE, ET CETERA, ET CETERA, IN  
20 TERMS OF THIS, I STILL THINK WE NEED TO GET AS CLOSE  
21 TO THAT EDUCATION AS WE CAN WITH HOW MUCH WE CAN  
22 MAKE PEOPLE RESPOND. THANKS.

23 DR. STEWARD: THANK YOU, YSABEL. I JUST  
24 WANT TO REMIND EVERYBODY OF WHAT GIL SAID IN THE  
25 BEGINNING. AND THAT IS THAT THE ISSUE OF INCLUSION

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1 IN THE CLINICAL ACTIVITIES IN ALL ASPECTS OF THE  
2 PROPOSAL ITSELF IS ACTUALLY CRITERION 5. THAT IS  
3 PART OF THE SCORED CRITERIA. IT'S NOT SCORED  
4 SEPARATELY. THAT'S ACTUALLY IMPORTANT. SO THE DEI  
5 SCORE IS SEPARATE FROM THAT ALTHOUGH YOU MIGHT  
6 CONSIDER THIS -- IT IS OBVIOUSLY A CRITERION  
7 RELATING TO INCLUSION, BUT IT IS PART OF THE  
8 APPLICATION, IT'S SCORED, IT IS FACTORED INTO THE  
9 OVERALL SCORE OF THE APPLICATION BY THE GRANTS  
10 WORKING GROUP, WHICH, OF COURSE, INCLUDES PATIENT  
11 ADVOCATES ON IT. SO, AGAIN, THE DEI THAT WE ARE  
12 SORT OF TALKING ABOUT HERE, THAT SEPARATE SCORE,  
13 RELATES TO THE OTHER ISSUE. THANK YOU. JUST TO SAY  
14 AGAIN WHAT GIL SAID, BUT I JUST WANT TO MAKE IT  
15 REALLY CRYSTAL CLEAR TO EVERYBODY AS WE ARE LOOKING  
16 AT EVERYTHING GOING FORWARD. THANK YOU.

17 ANY OTHER QUESTIONS, COMMENTS?

18 DR. MARTIN: THIS IS DAVE MARTIN. I AM  
19 HAVING DIFFICULTY, IT MAY BE MY COMPUTER, BUT  
20 CERTAINLY THINGS ARE GETTING FROZEN, INCLUDING THE  
21 AUDIO. BUT MY QUESTION OR TECHNICAL QUESTIONS THAT  
22 ARE RELATED, THE FIRST IS CAN YOU SHARE WHAT THE  
23 TARGET IS HERE FOR THIS CAR T? AND THEN THE SECOND  
24 IS WHAT ELSE IS GOING ON AGAINST THAT TARGET WITH  
25 OUR AUTOLOGOUS CAR T'S FOR PEDIATRIC BRAIN TUMORS?

1 DR. SAMBRANO: CERTAINLY. SO THE TARGET  
2 IS IL-13 RECEPTOR ALPHA 2. AND THIS IS THE SAME  
3 TARGET THAT THE PREVIOUS TRIAL IN ADULT PATIENTS  
4 THAT IS ONGOING IS ALSO DESIGNED TO TARGET. THE  
5 OTHER ELEMENTS THIS TRIAL IS TRYING TO ASSESS IS THE  
6 EFFECT OF LYMPHODEPLETION IN THE PATIENTS AS A  
7 MECHANISM OF INCREASING THE EFFECTIVENESS OF THE CAR  
8 T THERAPY AS WELL AS DOING AN INTRACRANIAL  
9 VENTRICULAR ADMINISTRATION OF THE CAR T-CELL THERAPY  
10 AND TESTING THAT IN THE PATIENTS.

11 SO THOSE TWO ADDITIONAL ELEMENTS ARE A  
12 COMPONENT OF THIS TRIAL THAT I THINK MAKES IT UNIQUE  
13 AMONG OTHER TRIALS THAT ARE ALSO TARGETING MALIGNANT  
14 BRAIN TUMORS.

15 DR. MARTIN: AND IS THE TARGET THE SAME,  
16 THE MOLECULAR TARGET THE SAME AS WHAT'S IN THE  
17 FIELD?

18 DR. SAMBRANO: THE MOLECULAR TARGET IS NOT  
19 NECESSARILY THE SAME. IT HAS BEEN STUDIED IN OTHER  
20 TRIALS, BUT THERE ARE TRIALS THAT ARE TESTING OTHER  
21 MOLECULAR TARGETS AS WELL.

22 DR. MARTIN: THANK YOU. I'LL MAKE ONE  
23 OTHER COMMENT. BEING IN THIS BUSINESS, I'M VERY  
24 COGNIZANT OF THE COST OF PHASE 1S. THIS IS  
25 VERY -- QUITE HIGH COMPARED TO WHAT I'M AWARE OF FOR

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1 AUTOLOGOUS PHASE 1 STUDIES.

2 DR. DULIEGE: ALONG THOSE LINES, HOW MANY  
3 HEALTHY PATIENTS, ACTUALLY IN THAT CASE, WOULD THAT  
4 INCLUDE?

5 DR. SAMBRANO: YOU KNOW, THAT'S A GOOD  
6 QUESTION. I DON'T HAVE THE ANSWER RIGHT IN FRONT OF  
7 ME, BUT I CAN FIND IT VERY QUICKLY FOR YOU.

8 DR. DULIEGE: BECAUSE THE COST IS NOT  
9 SOLELY RELATED TO THE NUMBER OF SUBJECTS, BUT IT IS  
10 LARGELY INFLUENCED BY THAT NUMBER.

11 DR. SAMBRANO: SURE.

12 DR. DULIEGE: AND ALSO CAN WE KNOW OR  
13 MAYBE DOES IT MATTER OR NOT WHETHER THIS APPLICATION  
14 COMES FROM AN ACADEMIC CENTER VERSUS A BIOPHARMA  
15 COMPANY? AND I ASSUME THAT WE CANNOT KNOW THAT AND  
16 THAT IT SHOULD NOT INFLUENCE OUR ASSESSMENT OF THE  
17 SCIENTIFIC MERIT OF THE PROPOSAL; IS THAT RIGHT?

18 DR. SAMBRANO: SO, YES, IT SHOULDN'T  
19 INFLUENCE YOUR ASSESSMENT OF THE PROPOSAL, BUT I  
20 THINK IT IS IMPORTANT TO KNOW THAT THERE IS A  
21 DISTINCTION IN TERMS OF AN ACADEMIC ENTITY APPLYING  
22 BECAUSE THERE ARE THE INDIRECT AND FACILITIES COSTS  
23 THAT ARE GREATER SO THAT THAT INFLUENCES THE TOTAL  
24 AMOUNT THAT IS OFTEN REQUESTED.

25 SO IN THIS CASE, BEING AN ACADEMIC



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1 INSTITUTION, SOME OF THE COSTS OR A SIGNIFICANT  
2 AMOUNT OF COSTS ARE RELATED TO THAT AS WELL AND NOT  
3 ALL DIRECT COSTS THAT ARE GOING TO THE TRIAL PER SE.

4 DR. DULIEGE: THANK YOU. VERY CLEAR.

5 DR. MARTIN: AND SOME EXAMPLES, AS I  
6 UNDERSTAND IT OR RECALL, THE ACADEMIC INSTITUTIONS  
7 HAVE WAIVED OR SIGNIFICANTLY REDUCED THE INDIRECT  
8 COSTS THAT ARE IMPOSED.

9 DR. SAMBRANO: SO IT'S RARE FOR AN  
10 ACADEMIC INSTITUTION TO WAIVE THE INDIRECT COSTS.  
11 BUT CERTAINLY FOR A COMPANY, MANY DO AND CHOOSE TO  
12 DO THAT, BUT ALSO THEY ARE LIMITED TO ONLY 35  
13 PERCENT TOTAL FACILITIES COSTS. SO THEY GENERALLY  
14 CANNOT CLAIM AS MUCH AS AN ACADEMIC INSTITUTION  
15 WOULD.

16 DR. DULIEGE: BUT, GIL, THE REASON WHY WE  
17 ARE SCHOOLING IS NOT SO MUCH ABOUT INDIRECT COSTS,  
18 BUT JUST BETTER UNDERSTANDING OF THE ENTITY  
19 PROPOSING THIS EFFORT THAT HOPEFULLY WE ARE ABOUT TO  
20 FUND AS OTHER FINANCIAL LEVERAGES. YES, YOU'RE  
21 RIGHT, THERE IS INDIRECT COSTS WITH AN ACADEMIC  
22 INSTITUTION, BUT A BIOPHARMA COMPANY WOULD HAVE TO  
23 PAY A HEFTY PRICE TO A CRO TO DO THE JOB, AND THAT  
24 COMES, AGAIN, A CRO OR OTHER ACTUALLY ACADEMIC  
25 INSTITUTION TO ENROLL VOLUNTEERS COMES WITH AN

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1 INDIRECT COST. SO MY THOUGHTS WERE MORE I THINK  
2 BIOPHARMA, IF IT WERE TO DO IT, AND I UNDERSTAND  
3 IT'S NOT THE CASE, WOULD HAVE MORE LEVERAGE TO GET  
4 SOURCES FROM OTHER FUNDING, PARTICULARLY ANGEL  
5 INVESTORS. BUT I THINK HERE I'M GETTING BEYOND THE  
6 POINT OF SCIENTIFIC MERIT, AND THAT'S WHERE THE  
7 NUMBER OF SUBJECTS WOULD INFLUENCE POTENTIALLY OUR  
8 ASSESSMENT OF THE VALUE OF THE COST VERSUS THE  
9 OUTCOME.

10 DR. STEWARD: THANK YOU. I ACTUALLY -- I  
11 DO AGREE PERHAPS THAT WE ARE GETTING INTO TERRITORY  
12 THAT'S BEYOND OUR CONSIDERATION OF SCIENTIFIC MERIT,  
13 NOT THAT IT SHOULDN'T BE CONSIDERED, BUT I'M NOT  
14 SURE QUITE WHAT LEVEL OF DISCUSSION WE SHOULD HAVE  
15 ABOUT IT. I SEE A HAND FROM STEVE JUELSGAARD HERE.  
16 THANK YOU.

17 MR. JUELSGAARD: SO QUITE SOME TIME AGO,  
18 YEARS AGO, THIS WHOLE ISSUE OF THE AMOUNT OF MONEY  
19 THAT'S BEING ASKED FOR, DOES IT LINE UP WITH WHAT  
20 THE WORK TO BE DONE IS? AND SO WE INSTITUTED A  
21 BUDGET REVIEW PROCESS, OR AT LEAST AT THAT TIME WE  
22 DID, WHERE THE PROGRAM WAS AN ISSUE TO BE SHIPPED  
23 OFF TO SOMEBODY WHO WAS FAMILIAR WITH COSTS  
24 ASSOCIATED WITH DOING TRIALS, AND THEY WERE TO GIVE  
25 US A THUMBS UP OR THUMBS DOWN AS TO WHETHER OR NOT

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1     THEY THOUGHT THAT THE COSTS THAT WOULD BE -- THE  
2     AMOUNT OF MONEY THAT WAS BEING ASKED FOR WAS  
3     APPROPRIATE FOR THE SCOPE OF WORK.

4             SO I DON'T KNOW WHETHER WE STILL DO THAT  
5     OR NOT, AND I GUESS THAT'S REALLY MY QUESTION.

6             DR. SAMBRANO:   SO WE --

7             DR. STEWARD:   YES, GIL, PLEASE.

8             DR. SAMBRANO:   SO WE DON'T DO THAT.  WE  
9     ARE DOING IT IN-HOUSE.  SO WHAT WE ASSESS IS  
10    GENERALLY WHETHER THE COSTS ARE ALLOWABLE, WHETHER  
11    THEY ARE COMPARABLE TO WHAT WE OBSERVE IN REAL COSTS  
12    FROM OTHER AWARDS THAT WE'VE ISSUED.  SO BASED ON  
13    DATA THAT WE HAVE, WE MAKE THOSE COMPARISONS, BUT WE  
14    HAVE NOT ACTUALLY FOR QUITE A WHILE PRESENTED IT TO  
15    ANOTHER ENTITY TO DO A BUDGET REVIEW AS I THINK WE  
16    HAD ORIGINALLY INTENDED SEVERAL YEARS AGO.

17            DR. STEWARD:   THANK YOU, GIL.  AND IF I  
18    COULD JUST MAKE AN AMENDMENT TO MY STATEMENT.  WHEN  
19    I WAS TALKING ABOUT GETTING INTO TERRITORY THAT  
20    PERHAPS IS BEYOND SCIENTIFIC MERIT, THAT REFERRED TO  
21    CONSIDERATIONS OF INDIRECT COSTS.  AND THAT'S WHERE  
22    WE ACTUALLY HAVE DEFINED VALUES.  IF YOU WANT, IT'S  
23    ALL SORT OF FORMULAIC.  THE ISSUE OF COST OF THE  
24    RESEARCH PROGRAM ITSELF IS A SEPARATE ISSUE THAT, AT  
25    LEAST IN MY OPINION, IS A TOPIC FOR DISCUSSION HERE.

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1 BUT I JUST WANTED TO SEPARATE THOSE TWO. ONE IS  
2 REALLY MORE TOTALLY CONTRACTUAL DEFINED BY LAW  
3 ACTUALLY, AND THE OTHER IS SOMETHING THAT HOW MUCH  
4 DOES RESEARCH ACTUALLY COST AND HOW MUCH ARE THEY  
5 ASKING FOR IT. THANK YOU.

6 OTHER QUESTIONS OR COMMENTS?

7 DR. DULIEGE: INDEED, OS, I REALLY  
8 APPRECIATE THAT YOU'RE MAKING THIS DISTINCTION WHICH  
9 WE SHOULD ALL MAKE, BUT MY QUESTION TO GIL AND TO  
10 THE CIRM IS THAT WE ARE VOTING FOR SCIENTIFIC MERIT.  
11 WE GET IT. BUT IN ADDITION TO THAT, WAS THIS OR  
12 WILL THERE BE THE REVIEW THAT STEVEN ALLUDED TO,  
13 WHICH IS THE FINANCIAL CONSIDERATION? ARE THEY  
14 ASKING TOO MUCH FOR WHAT THEY INTEND TO DO? AND HOW  
15 WOULD THAT INFLUENCE ULTIMATELY THEM RECEIVING THE  
16 GRANT?

17 DR. SAMBRANO: SO WE DO A BUDGET  
18 ASSESSMENT, AGAIN, THAT IS PERIPHERAL AT THE  
19 BEGINNING THAT IS DONE IN-HOUSE TO JUST ASSESS  
20 WHETHER THEY HAVE THE APPROPRIATE GENERALIZED  
21 BUDGET, BUT WE DO A MORE DETAILED BUDGET REVIEW  
22 AFTER AN AWARD IS APPROVED. AND SO OFTENTIMES THERE  
23 WILL BE COSTS THAT ARE REMOVED EITHER BECAUSE  
24 THEY'RE NOT ALLOWABLE OR FOUND TO BE EXCESSIVE. AND  
25 SO IN TERMS OF DETERMINING WHETHER A COST IS

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1 EXCESSIVE, THAT CAN COME FROM THE GRANTS WORKING  
2 GROUP. SO EITHER WE GET COMMENTARY FROM GRANTS  
3 WORKING GROUP REVIEWERS THAT SUGGEST THAT WE LOOK AT  
4 SPECIFIC ITEMS OR COSTS OR IN OUR COMPARISON TO  
5 OTHER AWARDS THAT WE'VE ISSUED.

6 NOW, THE OTHER IMPORTANT THING TO NOTE IS  
7 THAT THE AMOUNT THAT IS APPROVED IS BASICALLY THE  
8 MAXIMUM AMOUNT THAT CAN BE ISSUED TO THAT AWARDEE OR  
9 GRANTEE. AND SO THE REAL COSTS ARE MONITORED OVER  
10 TIME BECAUSE WE HAVE AN ONGOING ASSESSMENT IN  
11 PROGRESS OF THE PROJECT. SO IN MANY CASES THE TOTAL  
12 AWARD AMOUNT THAT'S APPROVED IS NOT NECESSARILY  
13 SPENT GIVEN THE OVERSIGHT OVER THE PERIOD OF THE  
14 AWARD.

15 AND THEN JUST I WANT TO ADD THAT YOU WERE  
16 ASKING FOR THE NUMBER OF PATIENTS IN THIS STUDY  
17 WHICH IS 22 FOR THIS PARTICULAR ONE.

18 DR. DULIEGE: THANK YOU. VERY CLEAR.  
19 VERY HELPFUL.

20 MS. LEWIS: GIL, CAN I JUMP IN REALLY  
21 QUICK. JUST WANT TO ADD SO WE DO DO, AS GIL  
22 MENTIONED, A BENCHMARKING OF THE INTERNAL PORTFOLIO.  
23 AND SO WE DID AN ANALYSIS OF SIMILAR PROJECTS IN CAR  
24 T THAT ARE AUTOLOGOUS. AND THIS CAME IN THAT THE  
25 COST PER PATIENT RANKED AMONGST THOSE PROGRAMS AT

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1 THE 41 PERCENTILE. SO IT'S ON THE LOWER END IN  
2 COMPARISON TO THE REST OF THE PORTFOLIO. NOW,  
3 AGAIN, THAT'S NOT ASSESSING EACH INDIVIDUAL COST IN  
4 A GRANULAR WAY, BUT THAT JUST GIVES YOU A BROADER  
5 PORTFOLIO PERSPECTIVE OF THE BENCHMARKING IF THAT  
6 HELPS IN CONSIDERING THIS REQUEST.

7 DR. STEWARD: THANK YOU. THAT'S VERY  
8 HELPFUL. MUCH APPRECIATED.

9 OKAY. I THINK WE ARE TO THE POINT WHERE  
10 WE NEED A MOTION. DO I HEAR A MOTION?

11 DR. DULIEGE: I'M HAPPY TO DO A MOTION.

12 MR. ROWLETT: THIS IS AL. I'LL SECOND.

13 DR. STEWARD: ALL RIGHT. I TAKE IT THAT  
14 WAS A MOTION TO APPROVE, BUT JUST TO SAY THAT OUT  
15 LOUD. ANY FURTHER DISCUSSION BY THE BOARD? DO WE  
16 HAVE PUBLIC COMMENT?

17 MS. BONNEVILLE: I DON'T SEE ANY HANDS  
18 RAISED.

19 DR. STEWARD: OKAY. EXCELLENT. SO,  
20 MARIA, COULD YOU CALL THE ROLL.

21 MS. BONNEVILLE: SURE. DAN BERNAL.

22 MR. BERNAL: AYE.

23 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

24 DR. DULIEGE: YES.

25 MS. BONNEVILLE: YSABEL DURON.

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1 MS. DURON: YES.  
2 MS. BONNEVILLE: MARK FISCHER-COLBRIE.  
3 DR. FISCHER-COLBRIE: YES.  
4 MS. BONNEVILLE: ELENA FLOWERS.  
5 DR. FLOWERS: YES.  
6 MS. BONNEVILLE: DAVID HIGGINS.  
7 DR. HIGGINS: YES.  
8 MS. BONNEVILLE: STEVE JUELSGAARD.  
9 MR. JUELSGAARD: YES.  
10 MS. BONNEVILLE: DAVE MARTIN. DAVE. CAN  
11 I SEE YOU? CHRISTINE MIASKOWSKI. LAUREN MILLER  
12 ROGEN.  
13 MS. MILLER-ROGEN: YES.  
14 MS. BONNEVILLE: ADRIANA PADILLA.  
15 DR. PADILLA: YES.  
16 MS. BONNEVILLE: JOE PANETTA.  
17 MR. PANETTA: YES.  
18 MS. BONNEVILLE: AL ROWLETT.  
19 MR. ROWLETT: YES.  
20 MS. BONNEVILLE: OS STEWARD.  
21 DR. STEWARD: YES.  
22 MS. BONNEVILLE: JONATHAN THOMAS.  
23 CHAIRMAN THOMAS: YES.  
24 MS. BONNEVILLE: ART TORRES.  
25 MR. TORRES: AYE.

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1 MS. BONNEVILLE: KAROL WATSON.

2 DR. WATSON: YES.

3 MS. BONNEVILLE: DIANE WINOKUR. THANK  
4 YOU. AND THE MOTION CARRIES.

5 DR. STEWARD: EXCELLENT. SO THANKS,  
6 EVERYBODY. THAT WAS A GREAT WAY TO START TO HAVE A  
7 THOROUGH DISCUSSION ABOUT ALL THE DIFFERENT ASPECTS  
8 THAT WE'RE GOING TO BE CONSIDERING HERE. SO I'M IN  
9 CONFLICT ON THE NEXT APPLICATION, SO WILL PASS THE  
10 GAVEL, SO TO SPEAK, OVER TO J.T., AND I WILL SIGN  
11 OFF. THANK YOU.

12 CHAIRMAN THOMAS: THANK YOU VERY MUCH, OS.  
13 THAT WAS A GREAT DISCUSSION BOTH ON THE INCLUSION  
14 DEI ELEMENTS AS WELL AS THE QUESTIONS ON THE BUDGET  
15 FOR THAT AWARD. AND I THINK BOTH ARE HIGHLY TOPICAL  
16 AND VERY HELPFUL. SO THANK YOU, EVERYBODY, FOR YOUR  
17 INPUT ACROSS THE BOARD.

18 SO WE ARE ON TO OUR SECOND AND FINAL  
19 APPLICATION. WE WILL START WITH A PRESENTATION BY  
20 GIL.

21 DR. SAMBRANO: THANK YOU. SO THE NEXT  
22 APPLICATION IS 12149. THIS IS AN MONOCLONAL  
23 ANTIBODY TARGETING LEUKOCYTE IMMUNOGLOBULIN-LIKE  
24 RECEPTOR B4, AND THE INDICATION IS ACUTE MYELOID  
25 LEUKEMIA WITH MONOCYTIC DIFFERENTIATION AND CHRONIC



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1 MYELOMONOCYTIC LEUKEMIA OR CMML. AND THE GOAL OF  
2 THIS APPLICATION IS TO COMPLETE A PHASE 1 TRIAL.  
3 THE FUNDS REQUESTED IS 6 MILLION. THE APPLICANT IS  
4 PROVIDING APPROXIMATELY 3 MILLION IN CO-FUNDING FOR  
5 THIS APPLICATION.

6 A LITTLE BIT ABOUT AML. THERE'S ABOUT  
7 20,000 NEW CASE OF AML THAT ARE DIAGNOSED EACH YEAR  
8 IN THE U.S. WITH A FIVE-YEAR SURVIVAL RATE OF ABOUT  
9 29 PERCENT. CHRONIC MYELOMONOCYTIC LEUKEMIA HAS AN  
10 INCIDENCE OF ABOUT 4 PER MILLION PEOPLE, BUT ABOUT  
11 15 TO 30 PERCENT OF THOSE CASES WILL ADVANCE TO AML.

12 THE PROPOSED THERAPY TARGETS THIS SUBSET  
13 OF AML WHICH REPRESENTS ABOUT 30 PERCENT OF AML, AND  
14 SOME THERAPEUTIC OPTIONS ARE NOT EFFECTIVE IN THE  
15 SUBPOPULATION OF PATIENTS, AND THE PROPOSED THERAPY  
16 OFFERS A NEW AND POTENTIALLY EFFECTIVE OPTION IN  
17 THESE PATIENTS.

18 WHY IS THIS A STEM CELL PROJECT? THE  
19 PROPOSED THERAPEUTIC CANDIDATE TARGETS CANCER STEM  
20 CELLS AS THE PRIMARY MECHANISM OF ACTION.

21 SO IN TERMS OF RELATED CIRM PORTFOLIO  
22 PROJECTS, WE SUPPORT SEVERAL PROJECTS THAT BROADLY  
23 IMPACT LEUKEMIAS AND LYMPHOMAS; HOWEVER, AT LEAST  
24 CURRENTLY ACTIVE WE DON'T HAVE ANY IN THE PORTFOLIO.  
25 WE HAVE HAD TWO PREVIOUS TRIALS THAT WERE RELATED TO

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1 AML THAT WE SUPPORTED, BUT NONE THAT SPECIFICALLY  
2 TARGET MYELOMONOCYTIC OR MONOCYTIC AML. AND THIS  
3 PARTICULAR APPLICANT DOES NOT HAVE PREVIOUS CIRM  
4 FUNDING.

5 THE GRANTS WORKING GROUP RECOMMENDATION  
6 FOR THIS APPLICATION IS A SCORE OF 1, MEANING IT HAS  
7 EXCEPTIONAL MERIT. THERE WERE 11 MEMBERS THAT  
8 SCORED THIS A 1. THERE WAS ONE MEMBER THAT SCORED  
9 THIS A 2 AND NO MEMBERS THAT SCORED THIS A 3. THE  
10 DEI SCORE IN THIS CASE IS A 10. THE CIRM TEAM  
11 RECOMMENDATION IS TO FUND THIS APPLICATION IN  
12 CONCURRENCE WITH THE GWG RECOMMENDATION FOR AN AWARD  
13 AMOUNT OF 6 MILLION. J.T.

14 CHAIRMAN THOMAS: THANK YOU, GIL. DO WE  
15 HAVE A MOTION TO APPROVE?

16 DR. HIGGINS: SO MOVED. THIS IS DAVID IN  
17 SAN DIEGO.

18 CHAIRMAN THOMAS: THANK YOU, DAVID. IS  
19 THERE A SECOND?

20 MS. DURON: SECOND. YSABEL.

21 CHAIRMAN THOMAS: THANK YOU, YSABEL.  
22 QUESTIONS OR COMMENTS BY MEMBERS OF THE BOARD?

23 DR. HIGGINS: THIS IS DAVID IN SAN DIEGO.  
24 I JUST WANTED TO, AS A REVIEWER FOR THE DEI ASPECT  
25 OF THIS GRANT, I WAS -- I DON'T HAVE A LOT OF

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1 EXPERIENCE REVIEWING THIS KIND OF THING, BUT WITH  
2 THAT CAVEAT I WAS INCREDIBLY IMPRESSED WITH HOW  
3 CREATIVE AND HOW MANY DIFFERENT WAYS THEY CAME TO  
4 THE SAME GOAL OF PROMOTING DIVERSITY. VERY  
5 IMPRESSED.

6 CHAIRMAN THOMAS: THANK YOU, DAVID. OTHER  
7 QUESTIONS OR COMMENTS BY MEMBERS OF THE BOARD?

8 MS. DURON: YSABEL HERE. SIMPLY BACK TO  
9 DAVID. I'D CERTAINLY LOVE TO HEAR MORE. PERHAPS WE  
10 CAN TAKE AN OCCASION TO TALK ABOUT WHAT LOOKS  
11 CREATIVE VERSUS WHAT IS NOT AND THINGS WE CAN  
12 RECOMMEND AS BEST PRACTICE KIND OF PROGRAMS AND  
13 PROJECTS.

14 DR. HIGGINS: I WOULD LOVE TO DO THAT. I  
15 NEED THAT KIND OF EDUCATION TRAINING. I WOULD LOVE  
16 TO DO THAT.

17 MS. DURON: THANK YOU.

18 CHAIRMAN THOMAS: OTHER COMMENTS?

19 MR. ROWLETT: THIS IS AL. TO YSABEL'S  
20 POINT, WE MADE SOME RECOMMENDATIONS OR I MADE SOME  
21 RECOMMENDATIONS TO STAFF REGARDING WHAT CRITERIA  
22 THEY MIGHT WANT TO CONSIDER AND HOW THEY MIGHT WANT  
23 TO ADVISE FUTURE APPLICATIONS AND IN WHAT CONTEXT  
24 THEY MIGHT WANT TO CONVENE REVIEWERS TO HAVE  
25 DISCUSSIONS IN ORDER TO ADVANCE PROCESS IMPROVEMENT.

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1 SO WE ARE CERTAINLY THINKING THE SAME WAY, YSABEL.

2 MS. DURON: THAT'S GREAT, AL. THANKS.

3 CHAIRMAN THOMAS: THANK YOU ALL. OTHER

4 COMMENTS BY MEMBERS OF THE BOARD? ARE THERE

5 COMMENTS FROM MEMBERS OF THE PUBLIC?

6 MS. BONNEVILLE: THERE ARE NONE.

7 CHAIRMAN THOMAS: HEARING NONE, MARIA,

8 WILL YOU PLEASE CALL THE ROLL.

9 MS. BONNEVILLE: YES. DAN BERNAL.

10 MR. BERNAL: AYE.

11 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

12 DR. DULIEGE: YES.

13 MS. BONNEVILLE: YSABEL DURON.

14 MS. DURON: YES.

15 MS. BONNEVILLE: MARK FISCHER-COLBRIE.

16 DR. FISCHER-COLBRIE: YES.

17 MS. BONNEVILLE: DAVID HIGGINS.

18 DR. HIGGINS: YES.

19 MS. BONNEVILLE: STEVE JUELSGAARD.

20 MR. JUELSGAARD: YES.

21 MS. BONNEVILLE: DAVE MARTIN.

22 DR. MARTIN: YES. AND I ALSO TRIED TO

23 VOTE YES ON THE PREVIOUS ONE JUST FOR COMPLETION.

24 MS. BONNEVILLE: THANK YOU.

25 DR. MARTIN: BUT JUST UNSTABLE I.T.

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1 MS. BONNEVILLE: NO PROBLEM. THANK YOU SO  
2 MUCH FOR CLARIFYING THAT.

3 LAUREN MILLER ROGEN.

4 MS. MILLER-ROGEN: YES.

5 MS. BONNEVILLE: ADRIANA PADILLA.

6 DR. PADILLA: YES.

7 MS. BONNEVILLE: JOE PANETTA.

8 MR. PANETTA: YES.

9 MS. BONNEVILLE: AL ROWLETT.

10 MR. ROWLETT: YES.

11 MS. BONNEVILLE: JONATHAN THOMAS.

12 CHAIRMAN THOMAS: YES.

13 MS. BONNEVILLE: KAROL WATSON.

14 DR. WATSON: YES.

15 MS. BONNEVILLE: THANK YOU. AND DIANE  
16 WINOKUR. THANK YOU SO MUCH. THAT MOTION CARRIES.

17 CHAIRMAN THOMAS: THANK YOU, MARIA. THAT  
18 CONCLUDES THE ACTION ITEMS. WE ARE NOW DOWN TO  
19 PUBLIC COMMENT ON ANY TOPIC ANYBODY WOULD LIKE TO  
20 DISCUSS. DO WE HAVE ANY SUCH PUBLIC COMMENT?

21 MS. BONNEVILLE: NO.

22 CHAIRMAN THOMAS: OKAY. IN THAT CASE,  
23 MARIA, COULD YOU JUST REMIND EVERYBODY WHEN THE NEXT  
24 MEETING OF THE ICOC WILL BE?

25 MS. BONNEVILLE: SURE. WE HAVE A MAY

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1 MEETING, SO THANKS TO EVERYONE WHO RESPONDED AND IS  
2 ALLOWING US TO HAVE A MEETING BY ATTENDING. WE HAVE  
3 QUORUM FOR MAY 17TH FROM TWELVE TO THREE. THERE  
4 WILL BE ACTION ITEMS FOR THE FULL BOARD TO CONSIDER.  
5 THAT SHOULD PROBABLY TAKE ABOUT AN HOUR OR AN HOUR  
6 AND A HALF AT MOST. AND THEN THE REST OF THE TIME  
7 WILL BE FOR THE APPLICATION REVIEW SUBCOMMITTEE TO  
8 CONSIDER TRANSLATION PROJECT APPLICATIONS. SO THANK  
9 YOU.

10 MR. TORRES: MARIA, DID I MISS A VOTE  
11 BECAUSE I WAS MUTED?

12 MS. BONNEVILLE: NO.

13 MR. TORRES: OKAY.

14 MS. BONNEVILLE: THANK YOU. YOU'RE ALL  
15 GOOD. THANKS, ART.

16 CHAIRMAN THOMAS: OKAY. WELL, I THINK  
17 THAT CONCLUDES THINGS UNTIL MAY 17TH. EVERYBODY  
18 HAVE A WONDERFUL SPRING, AND WE WILL SEE YOU ALL  
19 THEN. THANKS VERY MUCH.

20 MS. BONNEVILLE: THANKS, EVERYONE.

21 (THE MEETING WAS THEN CONCLUDED AT 11 A.M.)  
22  
23  
24  
25

**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 ZOOM PROCEEDINGS BEFORE THE APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON APRIL 20, 2021, 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, CA CSR 7152  
133 HENNA COURT  
SANDPOINT, IDAHO  
(208) 920-3543