

BETH C. DRAIN, CA CSR NO. 7152

BEFORE 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: VIA ZOOM

DATE: DECEMBER 11, 2020
12 P.M.

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

FILE NO.: 2020-21

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I N D E X

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION:	
1. CALL TO ORDER.	3
2. ROLL CALL.	3
ACTION ITEMS:	
3. CONSIDERATION OF CIRM RESEARCH BUDGET FOR 1/1/21-6/30/21.	4
4. CONSIDERATION OF CONCEPT CHANGES TO EXISTING CLINICAL, DISCOVERY AND TRANSLATION STAGE PROGRAMS.	10
5. PUBLIC COMMENT.	NONE
6. ADJOURNMENT.	36

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FRIDAY, DECEMBER 11, 2020.

12 NOON.

CHAIRMAN STEWARD: ALL RIGHT. LET'S GO
AHEAD AND CONVENE THE MEETING. MARIA, COULD YOU
CALL THE ROLL.

MS. BONNEVILLE: SURE. OS STEWARD.

CHAIRMAN STEWARD: HERE.

MS. BONNEVILLE: DEBORAH DEAS.

DR. DEAS: HERE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE. JUDY
GASSON.

DR. GASSON: HERE.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: STEVE JUELSGAARD.

MR. JUELSGAARD: HERE.

MS. BONNEVILLE: SHLOMO MELMED. ART
TORRES.

MR. TORRES: HERE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

MS. BONNEVILLE: KRISTINA VUORI.

SO WE HAVE A QUORUM. OS, IF YOU WANT TO
START.

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1 CHAIRMAN STEWARD: OKAY. EXCELLENT. SO
2 TODAY WE'LL BE CONSIDERING PROPOSALS FOR BRINGING
3 OUT, RAMPING UP, WHATEVER YOU WANT TO CALL IT, AS WE
4 MOVE INTO THE PROP 14 ERA. I SUSPECT WE HAVE A
5 PRESENTATION. AND, MARIA, WHO IS GOING TO BE DOING
6 THAT?

7 MS. BONNEVILLE: JENNIFER LEWIS WILL BE
8 PRESENTING THE BUDGET, AND THEN GIL SAMBRANO WILL BE
9 PRESENTING THE CONCEPT PLANS.

10 CHAIRMAN STEWARD: EXCELLENT. OKAY.
11 THANK YOU. JENNIFER, IF YOU COULD GO AHEAD AND LEAD
12 OUT, THAT WOULD BE TERRIFIC.

13 MS. LEWIS: THANKS, OS. THANKS, DOUG. SO
14 TODAY I'LL BE PRESENTING TO YOU OUR CURRENT BUDGET
15 ALLOCATION AND OUR PROPOSAL FOR A BUDGET, ADDITIONAL
16 FUNDS FOR THE NEXT SIX MONTHS.

17 SO AS A REMINDER, FIRST, I WANTED TO
18 REVIEW OUR CURRENT BUDGET ALLOCATION. AS YOU
19 RECALL, THE BOARD HAS ALLOCATED FUNDS TO THE
20 CLINICAL PROGRAM FOR THE CURE SICKLE CELL
21 PARTNERSHIP WITH NHLBI OF \$30 MILLION AND 1.84
22 MILLION FOR PROGRESSION AWARDS FOR THE DISC2
23 PROGRAM, WHICH TOTALS A CURRENT ALLOCATION OF 31.84
24 MILLION.

25 AS OF TODAY, THERE IS 17.4 MILLION

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1 REMAINING IN THE CURE SICKLE CELL ALLOCATION AND
2 ABOUT \$350,000 REMAINING IN THE PROGRESSION AWARDS
3 ALLOCATION FOR A TOTAL OF 17.8 MILLION IN REMAINING
4 RESEARCH DOLLARS.

5 I ALSO WANTED TO POINT OUT AND NOTE THAT,
6 AS OF THE END OF NOVEMBER, THERE'S AN ADDITIONAL 8.8
7 MILLION IN UNCOMMITTED FUNDS DUE TO RETURNED FUNDS
8 FROM RETURNED FUNDS FROM OUR CURRENT ACTIVE
9 PORTFOLIO.

10 SO THIS NEXT SLIDE DISPLAYS OUR PROPOSED
11 REQUEST FOR ADDITIONAL RESEARCH FUNDS FOR THE PERIOD
12 OF JANUARY THROUGH JUNE OF 2021. AND THIS IS TO
13 RESTART OUR CORE FUNDING PILLARS FOR CLINICAL,
14 TRANSLATION, AND QUEST.

15 TODAY DR. GIL SAMBRANO WILL BE PRESENTING
16 THE CONCEPT PLANS TO RESTART THESE CORE PROGRAMS.
17 AS YOU CAN SEE FROM THIS SLIDE, WE ARE REQUESTING
18 \$100 MILLION TO RELAUNCH OUR MONTHLY REOCCURRING
19 CYCLE OF THE CLINICAL PROGRAM OFFERING, 60 MILLION
20 TO OPEN THE TRANSLATION PROGRAM FOR ONE REVIEW
21 CYCLE, AND 22 MILLION TO RELAUNCH THE QUEST PROGRAM
22 FOR ONE REVIEW CYCLE. THE TOTAL PROPOSED ALLOCATION
23 TO FUND THESE NEW AWARDS OVER THE NEXT SIX MONTHS IN
24 THESE AREAS IS \$182 MILLION, WHICH WE ESTIMATE COULD
25 ADD ABOUT 36 NEW AWARDS TO THE CIRM PORTFOLIO.

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1 IN JUNE OF 2021, WE PLAN TO BRING AN
2 ANNUAL RESEARCH BUDGET FOR THIS COMMITTEE TO
3 CONSIDER IN CONCERT WITH ANY NEW CONCEPT PLANS ALONG
4 WITH THE STRATEGIC PLAN.

5 SO TODAY AT THIS TIME WE ARE REQUESTING
6 THE SCIENCE SUBCOMMITTEE APPROVE THIS RECOMMENDATION
7 TO THE ICOC FOR THIS ADDITIONAL \$182 MILLION TO
8 SUPPORT RESEARCH PROGRAMS AS PROPOSED FOR JANUARY
9 THROUGH JUNE OF 2021. AND THAT CONCLUDES MY
10 PRESENTATION, AND I'M HAPPY TO TAKE QUESTIONS ABOUT
11 THIS BUDGET.

12 CHAIRMAN STEWARD: THANK YOU. AND HAS THE
13 FINANCE COMMITTEE ACTED ON THIS YET?

14 MS. LEWIS: THE FINANCE COMMITTEE MET ON
15 TUESDAY TO REVIEW THE ADMINISTRATIVE AND OPERATIONS
16 BUDGET, BUT WE DID NOT DISCUSS THE RESEARCH BUDGET.

17 CHAIRMAN STEWARD: OKAY. THANK YOU. ANY
18 COMMENTS, QUESTIONS?

19 MS. BONNEVILLE: STEVE HAD A COMMENT, BUT
20 HE IS ON MUTE. SO I JUST WANTED TO LET HIM KNOW.

21 MR. JUELSGAARD: I WAS JUST GOING TO SAY
22 TO OS, NOW THAT I'M NOT ON MUTE, THIS ISN'T REALLY
23 THE PROVINCE OF THE FINANCE COMMITTEE. IT'S MORE
24 THE ADMINISTRATIVE SIDE THAT WE DEAL WITH. THIS IS
25 JUST ALWAYS HANDLED BY THE SCIENCE SUBCOMMITTEE AND

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1 THEN THE BOARD.

2 CHAIRMAN THOMAS: MARIA, CAN I ADD A
3 COMMENT HERE?

4 MS. BONNEVILLE: YES. GO AHEAD. AND OS
5 IS ON MUTE. I SAW HIM ALSO TALKING. I'M READING
6 LIPS TODAY. IT'S PERFECT.

7 CHAIRMAN THOMAS: SO JUST TO REVIEW THE
8 PROCESS FOR EVERYBODY, THE FUNDING WILL, OF COURSE,
9 COME FROM NEW BONDS ISSUED BY THE STATE. JENN AND I
10 TALKED TO THE STATE TREASURER'S OFFICE TO DISCUSS
11 THIS PROCESS A COUPLE OF WEEKS AGO. AND IT
12 BASICALLY WILL BE TO RESURRECT WHAT WE'VE DONE
13 HISTORICALLY, WHICH IS EVERY SIX MONTHS WE TALK TO
14 FIRST THE DEPARTMENT OF FINANCE AND THE GOVERNOR'S
15 OFFICE TO LAY OUT WHAT WE BELIEVE WILL BE THE
16 FUNDING NEEDS FOR THE NEXT SIX MONTHS. AND ONCE
17 THEY SIGN OFF ON THAT, THEY THEN DIRECT THE STATE
18 TREASURER'S OFFICE TO ISSUE BONDS ON BEHALF OF CIRM,
19 WHICH IS DONE AS PART OF A SEMIANNUAL FUNDING
20 ISSUANCE THEY DO ON BEHALF OF ALL STATE AGENCIES
21 ONCE IN THE SPRING AND ONCE IN THE FALL. THOSE
22 FUNDS ARE THEN HELD FOR OUR PURPOSES AT THE STATE
23 LEVEL UNTIL SUCH TIME AS WE NEED TO DISBURSE THEM.

24 THE TIMING OF THIS WORKS OUT ACTUALLY VERY
25 WELL BECAUSE THE FIRST REVIEWS THAT WE BELIEVE WE

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1 WILL HAVE IN THE CLIN AWARDS WILL BE IN MARCH, WHICH
2 WILL GO TO AN APPLICATION REVIEW SUBCOMMITTEE IN
3 APRIL. AND AS THOSE AWARDS ARE MADE, THAT WILL
4 DOVETAIL VIRTUALLY PRECISELY WITH THE STATE
5 TREASURER'S ISSUANCE OF THE FIRST NEW TRANCHE OF
6 BONDS UNDER PROP 14 FOR THE AWARDS. AND SO THE
7 HUNDRED EIGHTY-TWO MILLION THAT JENN IS REQUESTING
8 WILL BE FUNDED OUT OF THAT.

9 AND SO ALL WE NEED TO DO HERE TO TRIGGER
10 THAT DISCUSSION IS TO APPROVE THIS MEASURE, WHICH
11 THEN, OF COURSE, WILL BE BROUGHT TO THE FULL BOARD
12 ON DECEMBER 21 FOR CONSIDERATION. BUT THIS IS SORT
13 OF GOING TO BE A VERY SEAMLESS PROCESS GIVEN THE
14 TIMING OF THE STATE'S BOND ISSUANCE, AND WE SHOULD
15 BE IN VERY GOOD SHAPE TO FUND EVERYTHING GOING
16 FORWARD.

17 CHAIRMAN STEWARD: GREAT. THANKS, J.T.
18 JENNIFER OR SOMEONE, COULD YOU SAY A WORD ABOUT HOW
19 THE SPECIFIC AMOUNT, THE TOTAL AMOUNT, AND THE
20 DIFFERENT BUCKETS WITHIN THAT AMOUNT WERE DERIVED?

21 MS. LEWIS: SURE. SO WE LOOKED BACK
22 HISTORICALLY AT OUR FUNDING CYCLES OVER THE PAST
23 SEVERAL YEARS AND CLIN AS WELL AS TRANSLATION AND
24 QUEST TO LOOK AT AVERAGE AWARD SIZE WITHIN THE AWARD
25 CAPS THAT DR. SAMBRANO WILL BE PRESENTING LATER AS

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1 WELL AS HOW MANY APPLICATIONS WERE AWARDED OR DEEMED
2 MERITORIOUS AS WELL AS TAKING INTO CONSIDERATION WE
3 HAVEN'T HAD, SPECIFICALLY FOR TRANSLATION, A ROUND.
4 IT'S BEEN AWHILE. SO MAKING SURE THAT WE WERE
5 ESTIMATING THE DEMAND THAT COULD HAPPEN AS WELL.

6 CHAIRMAN STEWARD: OKAY. GOOD. THANK YOU
7 VERY MUCH.

8 QUESTIONS FROM OTHER MEMBERS OF THE
9 COMMITTEE? IF NOT, I THINK THIS IS AN ACTION ITEM.
10 SO IF WE COULD HAVE A MOTION TO APPROVE THIS
11 PROPOSAL TO GO FORWARD TO THE FULL BOARD FOR
12 CONSIDERATION.

13 MR. JUELSGAARD: OS, I MAKE THAT MOTION.
14 I MOVE THAT WE ACCEPT THIS PROPOSAL.

15 CHAIRMAN STEWARD: IS THERE A SECOND?

16 DR. DEAS: SECOND.

17 CHAIRMAN STEWARD: GOOD. SO ANY FURTHER
18 DISCUSSION? IF NOT, WE CAN ASK FOR PUBLIC COMMENT
19 IF THERE ARE ANY.

20 MS. BONNEVILLE: I DO NOT SEE ANY HANDS
21 RAISED. IF YOU HAVE PUBLIC COMMENT, IF YOU COULD
22 PLEASE RAISE YOUR HAND. I DON'T SEE ANY, OS.

23 CHAIRMAN STEWARD: OKAY. EXCELLENT.
24 MARIA, COULD YOU CALL THE ROLL.

25 MS. BONNEVILLE: OS STEWARD.

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1 CHAIRMAN STEWARD: YES.
2 MS. BONNEVILLE: DEBORAH DEAS.
3 DR. DEAS: YES.
4 MS. BONNEVILLE: ANNE-MARIE DULIEGE.
5 DR. DULIEGE: YES.
6 MS. BONNEVILLE: JUDY GASSON.
7 DR. GASSON: YES.
8 MS. BONNEVILLE: DAVID HIGGINS.
9 DR. HIGGINS: YES.
10 MS. BONNEVILLE: STEVE JUELSGAARD.
11 MR. JUELSGAARD: YES.
12 MS. BONNEVILLE: DR. MELMED. ART TORRES.
13 MR. TORRES: AYE.
14 MS. BONNEVILLE: JONATHAN THOMAS.
15 CHAIRMAN THOMAS: YES.
16 MS. BONNEVILLE: KRISTINA VUORI. THE
17 MOTION CARRIES.
18 CHAIRMAN STEWARD: EXCELLENT. SO WE'LL
19 MOVE TO THE SECOND CONSIDERATION THAT WE NEED TO
20 HAVE TODAY, WHICH IS A PRESENTATION, I THINK, BY
21 GIL; IS THAT CORRECT?
22 MS. BONNEVILLE: IT IS.
23 CHAIRMAN STEWARD: EXCELLENT. I'LL TURN
24 THE MICROPHONE OVER TO YOU.
25 DR. SAMBRANO: THANK YOU, OS. SO GOOD

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1 AFTERNOON, EVERYBODY. AS YOU KNOW, WE HAVE HAD A
2 SET OF RECURRING DISCOVERY, TRANSLATIONAL, AND
3 CLINICAL FUNDING OPPORTUNITIES SINCE 2015 IN ORDER
4 TO SUPPORT STEM CELL-BASED RESEARCH. HOWEVER, IN
5 THE LAST COUPLE OF YEARS -- AND, DOUG, COULD YOU GO
6 TO THE NEXT SLIDE PLEASE? IN THE LAST COUPLE OF
7 YEARS, THERE HAVE BEEN LIMITED FUNDS IN THE
8 AVAILABLE BUDGET, AND SO CERTAINLY THAT HAS
9 PREVENTED US FROM OPENING SOME OF THOSE CORE
10 PROGRAMS. AND THEN WE'VE ALSO HAD SOME
11 MODIFICATIONS THAT WERE MADE IN RESPONSE TO THINGS
12 SUCH AS THE COVID-19 PROGRAM. BUT NOW WITH PROP 14
13 PASSING, WE HAVE THE OPPORTUNITY TO RESTART MANY OF
14 THESE PROGRAMS. AND SO WE WOULD LIKE TO BEGIN WITH
15 OUR CORE DISC, TRAN, AND CLIN PROGRAMS MUCH AS WE
16 HAD BEFORE ALL OF THAT HAPPENED WITH THE BUDGET
17 LIMITATIONS.

18 SO OUR GOAL IS TO RELAUNCH WITH ONLY THE
19 NECESSARY CHANGES SO THAT WE CAN START THEM UP AS
20 QUICKLY AS WE CAN. HOWEVER, JUST IN ANTICIPATION OF
21 WHAT WE PLAN FOR THE FUTURE, WE DO PLAN TO BRING
22 MORE COMPREHENSIVE CHANGES LATER ON THAT WOULD ALIGN
23 WITH THE STRATEGIC PLAN THAT WE WILL BRING TO YOU IN
24 JUNE OF NEXT YEAR.

25 SO NEXT SLIDE PLEASE. SO JUST AS PART OF

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1 THE OVERVIEW, THE PROPOSED RELAUNCH WOULD ACCOMPLISH
2 A FEW THINGS. ONE, IT WOULD RESTORE SOME OF THE
3 FEATURES SUCH AS THE AWARD LIMITS. IN MANY CASES WE
4 DECREASED AMOUNTS. SO IT WOULD BRING THOSE BACK UP.
5 THE AWARD DURATION, IT WOULD EXTEND IT TO THE FULL
6 CAPACITY THAT WE HAD BEFORE. AND OTHER ELEMENTS
7 THAT WERE AVAILABLE PRIOR TO THE COVID-19 PROGRAM.

8 THE PROPOSED CONCEPTS WOULD AT THE SAME
9 TIME RETAIN MANY OF THE RECENT ELEMENTS THAT WERE
10 ADDED WHICH WE THOUGHT OFFERED GREAT VALUE, SUCH AS
11 ADDRESSING THE NEEDS OF THE UNDERSERVED COMMUNITIES,
12 SO THAT WOULD BE RETAINED, AS WELL AS ADDING SOME
13 NEW REQUIREMENTS, SUCH AS THE DATA SHARING PLAN,
14 WHICH I WILL BRIEFLY DISCUSS. THE CHANGES ALSO IN
15 SOME CASES ALIGN THE CONCEPTS WITH PROP 14
16 REQUIREMENTS AND DEFINITIONS.

17 NEXT SLIDE PLEASE. SO LET ME JUST BEGIN
18 BY GIVING YOU THE OVERVIEW OF THE GLOBAL CHANGES
19 THAT ARE HAPPENING ACROSS ALL THE CONCEPTS. SO ONE
20 OF THOSE IS THE ADDITION OF A REQUIREMENT FOR ALL
21 APPLICANTS TO PROVIDE A DATA SHARING PLAN AND AN
22 ALLOWANCE FOR THEM TO INCLUDE RELATED COSTS IN THE
23 BUDGET.

24 AND SO HOW THIS WORKS IS THAT THE
25 APPLICANTS MUST IN THEIR PROPOSAL INCLUDE A PLAN

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1 THAT DESCRIBES THE TYPE OF DATA SHARED, HOW IT WILL
2 BE COLLECTED, WHERE IT WILL BE DEPOSITED, THE
3 TIMELINE FOR THE COLLECTION AND DEPOSITING OF THAT
4 DATA, AND THE ASSOCIATED COSTS THAT WOULD GO WITH
5 THAT. AND SO THIS WILL BE SUBJECT TO GWG REVIEW
6 AND, THUS, WILL BE EVALUATED AS PART OF THE
7 APPLICATION.

8 AND SO THIS IS A BEGINNING TO WHAT WE HOPE
9 WILL BE MORE DEFINED REQUIREMENTS AROUND THE DATA
10 SHARING, BUT WE THOUGHT IT WAS AT LEAST IMPORTANT TO
11 BEGIN WITH A REQUIREMENT FOR APPLICANTS TO TELL US
12 WHAT THEIR DATA SHARING PLAN WOULD BE AND OBVIOUSLY
13 TO ENCOURAGE THE APPROPRIATE SHARING AND USE OF
14 DATA.

15 NEXT, WE ARE ALSO REMOVING A REQUIREMENT
16 TO DEEM GENE THERAPY PROJECTS A VITAL RESEARCH
17 OPPORTUNITY BY THE GWG. SO THE REASON FOR THIS IS
18 THAT UNDER PROP 14, THE SCOPE OVER WHICH CIRM HAS
19 AUTHORITY HAS EXPANDED. SO IT NOW INCLUDES GENE
20 THERAPY. AND SO, THEREFORE, WE DON'T NEED THE VITAL
21 RESEARCH OPPORTUNITY COMPONENT TO BE WEIGHED IN BY
22 THE GWG FOR THAT. SO WE ARE STRIKING THAT OUT. AND
23 THEN ALSO JUST BROADLY INCLUDING GENE THERAPY
24 PROJECTS AS IN SCOPE FOR CIRM FUNDING MUCH IN THE
25 SAME WAY AS GENERAL STEM CELL PROJECTS ARE ALLOWED.

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1 WE ARE ALSO ADDING WHERE IT WAS NOT
2 PREVIOUSLY INCLUDED THE REQUIREMENT TO ADDRESS THE
3 NEEDS OF THE UNDERSERVED RACIAL/ETHNIC COMMUNITIES
4 THROUGHOUT THESE CONCEPTS.

5 NEXT SLIDE PLEASE, DOUG. SO THESE CHANGES
6 ARE SPECIFIC TO THE DISC2 PROGRAM. SO THE DISC2
7 PROGRAM, AS YOU MAY REMEMBER, THE DISCOVERY AWARDS
8 ARE INTENDED TO IDENTIFY A CANDIDATE THERAPEUTIC, A
9 MEDICAL DEVICE, DIAGNOSTIC, OR TOOL. SO HERE SOME
10 OF THE CHANGES ARE RELATED TO THE COST. SO WE ARE
11 RESTORING THE DIRECT PROJECT COSTS TO ALLOW UP TO
12 900,000 FOR THERAPEUTIC CANDIDATES AND UP TO 500,000
13 FOR A DIAGNOSTIC, DEVICE, OR A TOOL. WE ARE
14 RESTORING THE DURATION TO 24 MONTHS. WE PREVIOUSLY
15 HAD THAT AT 12 MONTHS. WE ARE RESTORING THE PI
16 PERCENT EFFORT REQUIREMENT TO 20 PERCENT. AND ALSO
17 UPDATING THE PROJECT INITIATION TO BE WITHIN 60 DAYS
18 OF APPROVAL. OUR LESSONS IN BEING ABLE TO BE A
19 LITTLE BIT FASTER DURING OUR PROCESS HAS ALLOWED US
20 TO ACTUALLY IMPROVE UPON THAT. SO WE ARE MAKING THE
21 PROJECT INITIATION TIME SHORTER THAN IT WAS IN THE
22 PAST.

23 NEXT SLIDE PLEASE. FOR THE TRAN PROGRAM
24 THERE'S NOT MUCH THAT IS CHANGING IN THE CONCEPT
25 DOCUMENTS SIMPLY BECAUSE WE REALLY DIDN'T MAKE THAT

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1 MANY CHANGES AS IT WAS NOT OFFERED. WE ARE MAKING
2 THE SAME UPDATE TO THE PROJECT INITIATION TIMELINE,
3 SHORTENING THAT UP A BIT, AND THEN ALSO JUST MAKING
4 SURE THAT WE ARE OFFERING ALL FOUR FLAVORS OF THE
5 TRAN PROGRAM. THAT MEANS THAT WE WILL ALLOW FUNDING
6 FOR THERAPEUTICS, DEVICES, DIAGNOSTICS, AND TOOLS,
7 WHICH EACH OF THOSE, 1, 2, 3, 4, REPRESENT.

8 NEXT SLIDE PLEASE. FINALLY, THE PROPOSED
9 CHANGES TO THE CLINICAL PROGRAM. WE WOULD BE
10 LAUNCHING CLIN1, WHICH IS FOR IND-ENABLING WORK;
11 CLIN2, WHICH SUPPORTS CLINICAL TRIALS; AND CLIN3,
12 WHICH SPORTS ACTIVITIES FOR REGISTRATION AND
13 APPROVAL OF A THERAPY FOR THOSE THAT HAVE AN
14 EXISTING CLIN2. AND MOST OF THESE CHANGES FALL ON
15 CLIN2.

16 HERE WE WOULD BE RESTORING THE AWARD
17 LIMITS. AND SO THERE IS A TABLE THAT LISTS THOSE IN
18 THE CONCEPT DOCUMENT THAT WAS DISTRIBUTED, BUT THOSE
19 ARE RESTORED TO WHAT WE HAD BEFORE. WE MORE
20 RECENTLY DECREASED THE AWARD AMOUNTS TO ABOUT 75
21 PERCENT OF WHAT WE HAD. SO WE ARE GOING BACK TO A
22 HUNDRED PERCENT. THE AWARD DURATION IS RESTORED TO
23 A MAXIMUM OF FOUR YEARS. WE HAD DECREASED THAT TO
24 THREE YEARS SINCE WE DID NOT KNOW WHETHER WE WOULD
25 HAVE A WINDOW TO MANAGE AWARDS BEYOND 2023. PROJECT

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1 INITIATION HAS BEEN RESTORED TO 45 DAYS FROM
2 APPROVAL BY THE BOARD. AND WE ARE PROPOSING THE
3 CHANGE OF PERCENT EFFORT FOR PROJECT MANAGER TO 50
4 PERCENT FOR THESE CLIN2 AWARDS. WE PREVIOUSLY HAD
5 THIS AT 75 PERCENT, BUT OUR EXPERIENCE OVER THE LAST
6 SEVERAL YEARS OF MANAGING THESE AWARDS SUGGESTS THAT
7 50 PERCENT IS MORE THAN ADEQUATE FOR THIS. SO WE
8 WENT AHEAD AND PROPOSED THAT CHANGE.

9 AND THEN WE ALSO HAVE A CLARIFICATION.
10 THE LANGUAGE IN SOME PLACES IS UNCLEAR. AND
11 SPECIFICALLY IN ONE AREA WITH REGARDS TO THERAPEUTIC
12 ELIGIBILITY, WE JUST WANT TO MAKE CLEAR THAT
13 MINIMALLY MANIPULATED BONE MARROW, CORD BLOOD, OR
14 UNMODIFIED HSC'S ARE ELIGIBLE FOR PHASE 2 OR PHASE 3
15 CLINICAL TRIALS.

16 NEXT SLIDE. SO THAT'S THE SUMMARY OF THE
17 OVERALL CHANGES. AS MENTIONED, THE CONCEPT
18 DOCUMENTS WITH THOSE TRACK CHANGES WERE DISTRIBUTED.
19 SO I'M HAPPY TO ADDRESS ANY OF THOSE QUESTIONS THAT
20 YOU MAY HAVE, BUT OUR REQUEST TO YOU IS SIMPLY TO
21 APPROVE THE PROPOSED AMENDMENTS FOR DISC, TRAN, AND
22 CLIN SO THAT WE CAN MOVE THEM ON TO THE FULL BOARD.

23 DR. DEAS: YES. I HAVE NOT NECESSARILY A
24 QUESTION. CAN YOU HEAR ME?

25 DR. SAMBRANO: YES.

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1 DR. DEAS: THIS IS DEBORAH DEAS. IN
2 LOOKING AT SOME OF THE CHANGES AND THE ADDITIONS,
3 ESPECIALLY THE ONE RELATED TO ADDRESSING NEEDS OF
4 UNDERSERVED RACIAL AND ETHNIC COMMUNITIES IMPACT, I
5 REALLY THINK THAT WE SHOULD, THROUGH A LENS OF
6 DIVERSITY, EQUITY, AND INCLUSION, GO A STEP FURTHER;
7 WHEREAS, THE INVESTIGATORS SHOULD LIST IN THE
8 APPLICATION HOW THEY'RE GOING TO ADDRESS THE NEEDS
9 OF UNDERREPRESENTED COMMUNITIES OF WHAT WOULD BE THE
10 IMPACT. HOWEVER, I WOULD LIKE TO SEE THE EXTENT
11 THAT THEY ARE ENGAGING PEOPLE FROM UNDERREPRESENTED
12 BACKGROUNDS IN THE WORK THAT THEY DO EITHER AS PI,
13 CO-I, STAFF, AND OTHERS.

14 AND THEN I'D LIKE TO SEE EVEN IN THE
15 APPLICATION THAT WE BEGIN TO LOOK AT SOME OF THE
16 DEMOGRAPHIC DATA OF THOSE INDIVIDUALS INVOLVED SO
17 THAT WE ENSURE THAT WE ARE PROMOTING DIVERSITY,
18 EQUITY, AND INCLUSION.

19 MR. TORRES: WHAT LANGUAGE WOULD YOU
20 SUGGEST, DEAN?

21 DR. DEAS: WELL, NIH HAS SOME LANGUAGE,
22 AND NIH ACTUALLY YOU HAVE TO -- YOU LIST SOME OF THE
23 DEMOGRAPHICS AS WELL. SO WE MAY BE ABLE TO LOOK TO
24 THE INSTITUTES TO GET SOME OF THE LANGUAGE AND SORT
25 OF FOLLOW THAT.

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1 ADDITIONALLY, WHAT I HAD IN MIND, NIH ALSO
2 HAS PROGRAMS WHERE WE CAN IMPLEMENT SUPPLEMENT
3 GRANTS TO AWARDEES THAT COME FROM UNDERREPRESENTED
4 BACKGROUNDS IF THEY CAN ALIGN WITH A MAJOR GRANT
5 THAT WE HAVE.

6 I THINK CIRM MAY WANT TO TAKE NOTICE OF
7 THAT AS WELL IN ORDER TO IMPROVE OUR DIVERSITY,
8 EQUITY, AND INCLUSION.

9 MR. TORRES: MR. CHAIRMAN?

10 CHAIRMAN STEWARD: THANK YOU. YES.
11 QUESTION, COMMENT? ART.

12 MR. TORRES: I WOULD LIKE TO SEE US
13 INCORPORATE THOSE SUGGESTIONS AND INCORPORATE THE
14 ENDEAVORS TO SEARCH OUT FOR THE APPROPRIATE LANGUAGE
15 IN THIS AREA NOT ONLY BECAUSE I BELIEVE THAT WE HAVE
16 BEEN LACKING IN DIVERSITY, ESPECIALLY WITH PI'S
17 ACROSS THE STATE, BUT ALSO SOMETHING THAT I PICKED
18 UP DURING THE CAMPAIGN AS I VISITED WITH VARIOUS
19 GROUPS, ESPECIALLY LATINO AND AFRICAN-AMERICAN AND
20 NATIVE AMERICANS, FOR THAT MATTER, TO GET THEIR
21 SUPPORT FOR PROP 14, OF COURSE ON MY OWN TIME AND ON
22 WEEKENDS. BUT THE REAL ISSUE WAS MISTRUST, AND
23 ESPECIALLY FROM THE AFRICAN-AMERICAN, LATINO
24 COMMUNITIES, MISTRUST OF THE SCIENCE, MISTRUST OF
25 WHO'S DOING THE SCIENCE, AND MISTRUST IN THE END

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1 PRODUCT. AND WE'RE SEEING THAT NOW WITH COVID, THE
2 VACCINE UTILIZATION AND HOW WE HAVE TO REACH OUT --
3 I'M GLAD THAT PRESIDENT OBAMA AND BUSH AND CLINTON
4 ARE GOING TO DO THEIR VACCINATIONS AS SOON AS
5 POSSIBLE. BUT AT THE END OF THE DAY, WE HAVE TO
6 SHOW SOME COMMITMENT BECAUSE A LOT OF THESE
7 COMMUNITIES SUPPORTED US BY REISSUING PROP 14. WE
8 HAVE TO SHOW THAT WE UNDERSTOOD AND HEARD THEIR
9 CONCERNS AND THEIR MESSAGES BY IMPLEMENTING LANGUAGE
10 THAT EVEN IF THE NIH ALREADY HAS, WE SHOULD BE
11 HAVING AS WELL. THAT'S MY SUGGESTION.

12 CHAIRMAN STEWARD: THANK YOU. OTHER
13 COMMENTS?

14 DR. GASSON: I ACTUALLY HAVE A QUESTION
15 FOR GIL. I UNDERSTAND HOW GENE THERAPY IS NOW IN
16 SCOPE OF PROP 14 AND IT NO LONGER NEEDS THE VITAL
17 RESEARCH OPPORTUNITY EXCEPTION. MY QUESTION IS
18 GOING FORWARD WILL WE STILL ENTERTAIN PROPOSALS TO
19 FUND VITAL RESEARCH OPPORTUNITIES? AND IF SO, CAN
20 YOU GIVE ME AN EXAMPLE OF WHAT ONE WOULD BE?

21 DR. SAMBRANO: YES. SO OUR AUTHORITY
22 STILL ALLOWS FOR VITAL RESEARCH OPPORTUNITY
23 CONSIDERATION OF OTHER AREAS, BUT USUALLY HOW WE
24 HAVE WORKED THAT IS THAT WE BRING CONCEPTS ABOUT AN
25 AREA OF RESEARCH THAT COULD BE A VITAL RESEARCH

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1 OPPORTUNITY TO YOU, TO THE BOARD; AND IF WE GET
2 APPROVAL, THEN WE WOULD INCLUDE IT AS PART OF OUR
3 SCOPE WITHIN SOME OR ALL OF OUR FUNDING OPPORTUNITY
4 PROGRAMS.

5 DR. GASSON: THANK YOU, GIL.

6 CHAIRMAN STEWARD: OKAY. YEAH. SO, MARIA
7 MILLAN, I THINK THAT YOU MIGHT HAVE A COMMENT
8 RELATED TO THIS ISSUE. IF WE COULD ASK YOU TO --

9 DR. MILLAN: THANK YOU, DR. STEWARD. IT'S
10 MARIA MILLAN. I WANTED TO, FIRST OF ALL, THANK THE
11 BOARD FOR SO MUCH INPUT INTO THIS VERY IMPORTANT
12 TOPIC OF DIVERSITY, EQUITY, AND INCLUSION. AND TO
13 ALSO LET YOU KNOW THAT IN THE MIDST OF OUR STRATEGIC
14 PLANNING, WE'RE TRYING TO WORK OUT A WAY THAT THIS
15 IS -- AS MUCH AS THIS PROBLEM IS SYSTEMIC, THAT WE
16 ACTUALLY EMBED IT IN ALL ASPECTS OF HOW WE DO
17 BUSINESS. SO YOU'LL START TO SEE SOME OF THAT
18 COMING FORWARD IN A LOT OF WAYS.

19 BUT TO ADDRESS THE IMMEDIATE COMMENTS OF
20 DR. DEAS, ABSOLUTELY. AND THE STANDARDS, BOTH FROM
21 NIH AND THE FDA REGARDING THESE TOPICS THAT HAVE
22 BEEN BROUGHT FORWARD BY LEADERSHIP, INCLUDING DR.
23 ABLA CREASEY, WHO'S OUR HEAD OF THERAPEUTICS, AND
24 WE'RE UNDER WAY WITH OUR OPERATIONAL TEAM. WE ARE
25 ABLE TO, EVEN UNDER THE CURRENT REQUIREMENTS FOR

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1 REPORTING, ABLE TO MAKE SURE THAT WE IMPROVE OUR WAY
2 OF CAPTURING THE INFORMATION, THE DEMOGRAPHICS, AND
3 ALL THAT YOU HAVE STATED AS VERY IMPORTANT. WE HAVE
4 SOME OF IT, IT'S NOT AS COMPLETE AS IT COULD BE AND
5 IT'S NOT AS DEEP AS IT COULD BE, SO WE'RE WORKING
6 OPERATIONALLY ALREADY TO IMPROVE UPON THAT WITH
7 JENNIFER LEWIS AND GRANTS MANAGEMENT.

8 AND THEN REGARDING WORKFORCE DEVELOPMENT,
9 AND EQUITY AND DIVERSITY IN THE WORKPLACE,
10 ABSOLUTELY NO. 1 TOP PRIORITY FOR US. JUST SOME
11 IMPORTANT EXAMPLES OF HOW WE CONTINUE TO INSTITUTE
12 THIS, BUT RECENTLY I'VE HAD FEEDBACK FROM OUR
13 GRANTEES THAT THEY ARE REALLY VERY IMPRESSED BY HOW
14 OUR CIRM TEAM WAS VERY, VERY STRICT. EVEN IN OUR
15 PAST GRANTEE MEETING, THEY REEVALUATED THEIR
16 SPEAKERS BECAUSE THERE WERE SOME FOLKS THAT YOU KIND
17 OF IMMEDIATELY GO TO TO INVITE AS SPEAKERS. AND
18 THEY SAID, BECAUSE OF CIRM, AND THESE WERE WOMEN
19 MINORITIES, THEY SAID, I FORGOT THAT WE SHOULD LOOK
20 AT THIS. SO ALL OF US NEED TO BE REMINDED IN
21 EVERYTHING WE DO TO MAKE SURE THAT WE HAVE
22 APPROPRIATE REPRESENTATION EVEN WITHIN OUR PI'S, OUR
23 STUDENTS, AND EVERYTHING ELSE.

24 SO SENATOR TORRES HAS BEEN PUSHING US ON
25 THIS FOR A VERY LONG TIME, ALWAYS REMINDS US, AND

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1 WE'RE TAKING IT VERY SERIOUSLY. BUT YOU WILL SEE
2 SOME MORE ROLLOUT AS YOU START SEEING KIND OF THE
3 STRATEGIC CONCEPTS THE IDEA THIS SHOULD BE WOVEN
4 INTO THE FABRIC OF EVERYTHING WE DO AT CIRM FROM
5 OPERATIONS, POTENTIAL AWARDS, THE WAY WE CONDUCT
6 RESEARCH, AND TO THE TYPE OF WORKFORCE AND
7 LEADERSHIP WE ARE BUILDING BECAUSE OF OUR PROGRAMS.

8 THANK YOU SO MUCH FOR THE OPPORTUNITY TO
9 SHARE THAT.

10 CHAIRMAN STEWARD: THANK YOU, MARIA.
11 THAT'S GREAT.

12 DR. DEAS: THANK YOU.

13 CHAIRMAN STEWARD: SO ARE THERE ANY OTHER
14 COMMENTS ALONG THESE LINES?

15 MR. JUELSGAARD: OS, I HAVE A COMMENT
16 ABOUT THE DATA SHARING WHENEVER WE GET TO THAT.

17 CHAIRMAN STEWARD: SURE. NOW IS AS GOOD A
18 TIME.

19 MR. JUELSGAARD: SO I'D LIKE TO KNOW,
20 FIRST OF ALL, WHAT GAVE GENESIS TO WRITING THIS
21 PARAGRAPH ON DATA SHARING. WHO DECIDED THAT WE
22 NEEDED TO DO THAT AND WHY?

23 DR. MILLAN: DO YOU WANT ME TO ANSWER
24 THAT, OS?

25 CHAIRMAN STEWARD: YES, PLEASE.

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1 DR. MILLAN: SO IN THIS PROCESS THAT WE'RE
2 GOING THROUGH, THIS PROCESS OF STRATEGIC THINKING
3 AND CONCEPTS THAT WE'RE DEVELOPING WITH OUR BOARD,
4 EXTERNAL STAKEHOLDERS, AND THROUGH OUR OWN DILIGENCE
5 IN TERMS OF WHAT'S OUT THERE IN THE WORLD, ONE OF
6 THE THINGS THAT'S FRONT AND CENTER IS THAT, IN ORDER
7 TO REALLY GAIN TRUE ACCELERATION AND VALUE IN THE
8 RESEARCH WE FUND, WE JUST NEED TO DO BETTER IN TERMS
9 OF FORMING THESE KNOWLEDGE NETWORKS AND CAPTURING
10 THE DATA AND MAKING IT IN A WAY THAT'S ACCEPTABLE TO
11 ALL PARTIES AND, OF COURSE, PROTECTS PRIVACY AND ALL
12 OF THOSE TYPES OF THINGS, BUT THAT WE ARE JUST NOT
13 AS GOOD AS A COMMUNITY, AS A SCIENTIFIC COMMUNITY,
14 IN BEING ABLE AND HAVING THE DISCIPLINE. EVEN NIH
15 HAS A STRATEGIC PLAN RELATED TO DATA SHARING JUST
16 BECAUSE THEY KNOW THAT THIS IS ABSOLUTELY CRUCIAL.

17 SO IT'S SOMETHING THAT HAS COME UP IN A
18 SPECIFIC PANEL THAT DR. KEITH YAMAMOTO FROM OUR
19 BOARD ACTUALLY LED AT THE RECENT GRANTEE MEETING,
20 WHICH WAS EXCELLENT. WE HAD LEADERS FROM AROUND THE
21 COUNTRY, FROM EX-FDA-ERS, TO PRIVATE INDUSTRY,
22 VERILY FROM THE PRIVATE SECTOR, ACADEMIA, PATIENT
23 ADVOCATES, THOSE WHO ARE SPECIFICALLY FOCUSED ON
24 DIVERSITY AND RESEARCH. ALL OF THEM WERE ON THE
25 PANEL FROM THE DUKE RESEARCH POLICY MARGOLIS CENTER

1 AT DUKE.

2 SO THE WHOLE PANEL HAD JUST GIVEN A VERY
3 STRONG CASE FOR HOW, NOT ONLY IS THIS SOMETHING WE
4 SHOULD DO, IT'S SOMETHING THAT IS ABSOLUTELY
5 CRITICAL IN RESEARCH TODAY, ESPECIALLY WITH THE TYPE
6 OF INFORMATION THAT CIRM GRANTEES ARE GENERATING.
7 WE EACH CARRY, I DON'T KNOW, I THINK HE SAID THREE
8 OR FOUR TERABYTES OF DATA, EACH OF US HAVE THREE OR
9 FOUR TERABYTES OF DATA THAT ARE OUT THERE IN THE
10 ETHER SPACE. AND IF THERE IS A BETTER WAY THAT WE
11 CAN GET THIS TOGETHER, THAT IT WILL BRING THINGS
12 FORWARD IN TERMS OF OUR ABILITY TO SOLVE THE
13 PROBLEMS BECAUSE WHAT HAPPENS IS THERE'S ALL OF
14 THESE INFORMATIONS IN DIFFERENT SILOS.

15 SO, OF COURSE, WE'RE NOT GOING TO SOLVE
16 THE WHOLE THING, BUT WHAT WE CAN DO IS APPLY
17 DISCIPLINE TO THE RESEARCH WE DO FUND. THERE ARE
18 ALREADY EXISTING REPOSITORIES THAT EXIST AND ARE
19 LARGE REPOSITORIES WHERE PEOPLE SHOULD BE PUTTING
20 THEIR INFORMATION, BUT MAYBE THERE'S NO STRUCTURE OR
21 ACCOUNTABILITY FOR DOING THAT. SO THIS IS THE FIRST
22 STEP. IT'S NOT PRESCRIPTIVE. IT SIMPLY SAYS TO
23 START OFF WITH, GIVE US THE BEST PLAN FOR HOW YOUR
24 DATA IS GOING TO BE SHARED AND WHERE IT'S GOING TO
25 GO. IT SHOULD BE INFORMATIVE. AND THEN FROM THERE,

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1 WE CAN COME UP WITH A RATIONAL PLAN WITH MORE INPUT
2 FROM ALL OF THE DIFFERENT AREAS OF EXPERTISE THAT'S
3 NEEDED TO BE BROUGHT FORWARD TO THE BOARD IN THE
4 EVOLUTION OF THIS WHOLE KIND OF IDEALISTIC, BUT
5 NECESSARY AND ACHIEVABLE IF WE DO IT, GOAL OF DATA
6 SHARING AND BEING BETTER ABOUT USING ALL OF THE DATA
7 GENERATED TO BRING RESEARCH FORWARD FOR THE ENTIRE
8 COMMUNITY.

9 CHAIRMAN STEWARD: I CAN JUST ADD TO THAT
10 ACTUALLY, MARIA. ONE OF THE THINGS THAT I THINK WAS
11 MAYBE A TRIGGER FOR CONTINUING DISCUSSION ON THIS
12 WAS OUR MEETING LAST YEAR, THE TOWN HALL MEETING,
13 WHERE THIS WHOLE ISSUE OF DATA SHARING CAME UP. AND
14 THERE WAS A VERY STRONG FEELING AT THAT MEETING
15 ABOUT THE IMPORTANCE OF DATA SHARING AND WHAT WAS
16 BEING LOST BECAUSE OF THE LACK OF IT.

17 I THINK THAT I MIGHT HAVE SAID AT ONE
18 POINT WHEN SOMEBODY KIND OF RAISED AN ISSUE, I
19 BELIEVE I SAID, "WELL, IF INVESTIGATORS WANT TO TAKE
20 CIRM MONEY, THEN THIS IS ONE OF THE CONDITIONS THAT
21 IS A REASONABLE CONDITION." SO IT HAS A MUCH DEEPER
22 HISTORY, I THINK, EVEN THAN FROM THE TIME OF --

23 DR. MILLAN: ABSOLUTELY. THAT'S
24 ABSOLUTELY TRUE. THAT WAS A GWG FEEDBACK MEETING.
25 AND, YES, OS, YOU DID SAY THAT, AND WE TAKE IT VERY

1 SERIOUSLY AND WE CONTINUED ON THROUGH THE STRATEGIC
2 CONCEPTS SPACE.

3 MR. JUELSGAARD: SO MY BIGGEST CONCERN IS
4 IN THE AREA OF INTELLECTUAL PROPERTY AND
5 CONFIDENTIAL INFORMATION. THAT DOESN'T SEEM TO BE
6 DISTINGUISHED HERE IN THE DATA SHARING PLAN, THAT
7 THERE'S AN EXPECTATION THAT ANYTHING THAT A PARTY
8 CONSIDERS TO BE THEIR CONFIDENTIAL INFORMATION OR
9 THEIR INTELLECTUAL PROPERTY, THERE'S NO EVEN THOUGHT
10 OF SHARING THAT DATA. SO TO CARVE THAT OUT RIGHT UP
11 FRONT BECAUSE OTHERWISE I SEE THIS AS A DISINCENTIVE
12 TO A NUMBER OF PARTIES WHO, IN ORDER TO BE ABLE TO
13 DEVELOP COMPOUNDS, AND THIS IS PARTICULARLY TRUE IN
14 THOSE CLIN AWARDS AND ALSO TO SOME EXTENT IN THE
15 TRANSLATIONAL AWARDS, IF YOU'RE IN THE POSITION OF
16 HAVING TO RELEASE WHAT YOU CONSIDER TO BE VERY
17 CONFIDENTIAL DATA THAT BECOMES PUBLIC INFORMATION,
18 YOU DON'T WANT TO GO THERE. YOU DON'T WANT TO TAKE
19 ANY MONEY THAT PROVIDES FOR THAT.

20 SO THAT'S MY BIGGEST CONCERN SEEING THIS
21 DATA SHARING PLAN LANGUAGE IS THERE'S NOT A
22 CARVE-OUT FOR CONFIDENTIAL INFORMATION OR OTHER
23 RELATED INTELLECTUAL PROPERTY STYLE INFORMATION.

24 DR. MILLAN: IF I MAY JUST COMMENT ON
25 THAT, DR. STEWARD, IS THAT OKAY?

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1 CHAIRMAN STEWARD: YES, PLEASE. I WAS
2 GOING TO CALL ON YOU ANYWAY.

3 DR. MILLAN: SOME OF THE BOARD MEMBERS
4 WANTED TO SPEAK. IS THAT OKAY?

5 SO THERE ARE -- AND IT'S IN THE LANGUAGE
6 IN THE RFA THAT IT ABIDES BY THE F-A-I-R PRINCIPLES
7 THAT NIH ALSO USES. AND THERE ARE ACTUAL STANDARD
8 PRACTICES AND POLICIES THAT HAVE BEEN DEVELOPED IN
9 DATA SHARING. AND THE MOST RECENT EXAMPLES OF THAT
10 ARE IN THE COVID CRISIS WITH ALL THE PHARMA, THERE'S
11 THE GATES FOUNDATION PARTNERSHIP ALONG WITH ALL THE
12 MAJOR PHARMA PLAYERS IN THE COVID RESEARCH. SO
13 THOSE ACCOUNT FOR THE INTELLECTUAL PROPERTY ISSUES
14 THAT ALLOW THE INVESTIGATORS TO PROTECT THEIR
15 INTELLECTUAL PROPERTY WHILE STILL SHARING
16 INFORMATION.

17 SO THE WAY THIS IS CRAFTED, AS GIL HAS
18 SAID, IT'S NOT PRESCRIPTIVE IN ORDER THAT THE
19 INDIVIDUAL APPLICANT AT THIS STAGE, WE CALL IT THE
20 PHASE 1 ROLLOUT OR THE PRE-ROLLOUT, OF ANY TYPE OF
21 DATA SHARING WILL BE ABLE TO, AS LONG AS THEY GIVE A
22 REASONABLE PLAN, CHOOSE THEIR WAY OF HOW THEY DO
23 DEPOSIT THEIR DATA, BUT WE'LL KNOW WHERE IT IS. SO
24 WE'LL HAVE A TABLE OF CONTENTS, INDEX, WHAT HAVE
25 YOU, AT LEAST TO START OFF WITH THAT SHOULD INFORM A

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1 BETTER WAY OF BEING ABLE TO CREATE THIS KNOWLEDGE
2 NETWORK.

3 CHAIRMAN STEWARD: THANK YOU, DR. MILLAN.
4 ANY OTHER QUESTIONS OR COMMENTS ALONG
5 THOSE LINES?

6 MR. JUELSGAARD: JUST SO I UNDERSTAND
7 THEN, JUST TO TAKE IT DOWN TO A VERY PRACTICAL
8 LEVEL, IF SOMEBODY WRITES IN THEIR DATA SHARING PLAN
9 THAT THEY HAVE NO INTENTION OF SHARING ANYTHING THEY
10 DEEM TO BE CONFIDENTIAL INFORMATION OR OTHERWISE
11 PROTECTABLE INTELLECTUAL PROPERTY, THAT WILL BE
12 FINE, RIGHT?

13 DR. MILLAN: YES. THEY NEED TO PROTECT
14 THEMSELVES.

15 MR. JUELSGAARD: OKAY. GOOD.

16 DR. MILLAN: THERE ARE ALREADY DATA
17 SHARING REQUIREMENTS, PERIOD, FROM DOING ANYTHING.
18 IF THEY HAVE AN IND, THEY HAVE TO DEPOSIT THEIR
19 DATA. THE NIH, IF THEY HAVE ANY NIH FUNDING, THEY
20 NEED TO SHARE THEIR DATA. SO WE ARE JUST TRYING TO
21 MAKE STRIDES FORWARD IN TERMS OF CREATING WAYS THAT
22 IT'S ACTUALLY DONE AND IT'S DONE IN A MORE ORGANIZED
23 FASHION THAT'S USEFUL TO EVERYBODY. THAT'S THE
24 INTENT.

25 CHAIRMAN STEWARD: RIGHT. I THINK THAT

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1 ONE OF THE THINGS THAT THIS WHOLE INITIATIVE IS
2 MEANT TO ACHIEVE IS AN AMPLIFICATION OF THE IMPACT
3 OF THE DATA THAT PEOPLE ARE GENERATING. IN TERMS OF
4 OUTCOMES OF CLINICAL TRIALS, WE STILL HAVE A
5 SITUATION WHERE A LOT OF DATA FROM FAILED CLINICAL
6 TRIALS ARE NOT SHARED. THAT DAMAGES THE FIELD. WE
7 ARE LOSING A TON OF UNDERSTANDING BY NOT HAVING SOME
8 BETTER WAY OF SEEING THOSE THINGS. BUT I THINK,
9 AGAIN, THAT THOSE ARE SORT OF THE NUTS AND BOLTS OF
10 ISSUES THAT WILL HAVE TO BE WORKED OUT GOING FORWARD
11 AS PEOPLE KIND OF BEGIN TO ADAPT TO THIS NEW
12 PARADIGM.

13 MR. JUELSGAARD: THERE COULD BE A LOT OF
14 VALUE IN A FAILED CLINICAL TRIAL THAT YOU DON'T WANT
15 TO DISCLOSE BECAUSE IT POINTS YOU IN A DIFFERENT
16 DIRECTION FOR THE NEXT CLINICAL TRIAL, ET CETERA.
17 SO IT'S A LINE THAT HAS TO BE WALKED. I WOULDN'T
18 NECESSARILY SAY IF YOU HAVE CLINICAL TRIALS, THE
19 DATA HAS TO BE DISCLOSED BECAUSE THERE CAN BE A LOT
20 OF VALUABLE PROPRIETARY INFORMATION CONTAINED WITHIN
21 THAT FAILED CLINICAL TRIAL.

22 DR. MILLAN: DEFINITELY ISSUES THAT NEED
23 TO ALL BE WORKED OUT, BUT I THINK IT CAN BE DONE.

24 CHAIRMAN STEWARD: YEAH. OKAY. ANY
25 FURTHER DISCUSSION, QUESTIONS, COMMENTS?

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1 OUR ACTION ITEM, I THINK, WAS ON THE LAST
2 SLIDE THAT GIL SHOWED, WHICH IS TO HAVE A VOTE TO
3 PASS THIS CONCEPT PLAN ON TO THE BOARD FOR
4 CONSIDERATION AT THE DECEMBER MEETING.

5 MR. TORRES: POINT OF ORDER. DO I NEED TO
6 INCORPORATE A MOTION TO THIS REPORT THAT DEAN DEAS
7 AND I TALKED ABOUT, OR IS IT JUST UNDERSTOOD THAT
8 STAFF UNDERSTANDS THAT THAT'S WHAT AT LEAST SOME OF
9 OUR BOARD MEMBERS PREFER?

10 DR. DEAS: I WOULD PREFER WE HAVE A MOTION
11 AND WE GET THAT IN THERE IN ADDITION TO WHAT I
12 STATED AND ART. I WOULD LIKE TO MAKE SURE THAT, AS
13 WE ARE SCORING THESE AWARDS, THAT THIS IS INCLUDED
14 IN THE SCORING PROCESS AS WELL. IT CERTAINLY
15 INCENTIVIZES THE PI'S TO DO MORE.

16 CHAIRMAN STEWARD: OKAY. I THINK THAT'S
17 GREAT, AND THANK YOU FOR BRINGING IT UP, DR. DEAS.
18 I GUESS I'M A LITTLE CONFUSED ABOUT HOW WE PROCEED
19 PROCEDURALLY HERE, SO TO SPEAK. ART OR MAYBE JAMES,
20 CAN YOU HELP US UNDERSTAND? SHOULD THERE BE A
21 MOTION TO MODIFY BEFORE WE CONSIDER THE WHOLE THING?
22 WHAT IS OUR APPROPRIATE STEP HERE?

23 MR. HARRISON: OS, SINCE THERE'S NO MOTION
24 ON THE TABLE AT THE MOMENT, DR. DEAS OR SENATOR
25 TORRES ARE FREE TO MAKE A MOTION TO RECOMMEND

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1 APPROVAL OF THE CHANGES TO THE CONCEPT PLANS WITH
2 THE INCORPORATION OF LANGUAGE SPECIFYING THAT
3 APPLICANTS NEED TO INCLUDE INFORMATION AND
4 DEMOGRAPHIC DATA REGARDING BOTH UNDERSERVED
5 COMMUNITIES THAT THEY INTEND TO SERVE AS WELL AS
6 REPRESENTATION FROM UNDERSERVED COMMUNITIES AS PART
7 OF THE RESEARCH TEAM.

8 DR. DEAS: RIGHT. GREAT. NICELY
9 RESTATED. AND ALSO ADD THAT THIS WILL BE A PART OF
10 THE SCORING TOO.

11 CHAIRMAN STEWARD: OKAY. THANK YOU.

12 DR. DEAS: SO MOVED.

13 MR. TORRES: I SECOND THAT MOTION BY DEAN
14 DEAS.

15 MR. JUELSGAARD: WHEN YOU SAY IT'S GOING
16 TO BE PART OF THE SCORING, HOW DO YOU INTEND THAT TO
17 WORK?

18 DR. DEAS: WELL, WITH THE SCORING, THERE
19 IS DIFFERENT SECTIONS, I'M SUPPOSING. SO I THINK
20 THERE SHOULD BE A SECTION ON DIVERSITY, EQUITY, AND
21 INCLUSION ON ALL OF THESE GRANTS.

22 MR. JUELSGAARD: DO YOU THINK A GRANTS
23 WORKING GROUP IS THE RIGHT LEVEL AT WHICH THESE
24 DECISIONS SHOULD BE MADE? ARE THEY REALLY COMPETENT
25 TO WEIGH IN ON THAT SORT OF THING? THIS, FOR ME, IS

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1 ALMOST AN ICOC ISSUE, NOT SO MUCH -- THE GRANTS
2 WORKING GROUP IS ONLY A SCIENTIFIC GROUP, AND NOW
3 WE'RE TRANSMUTING THEM INTO SOMETHING BEYOND THAT.

4 DR. DEAS: OKAY. WELL, WHILE THEY'RE A
5 SCIENTIFIC GROUP, THEY SEND UP TO US THE SCORE OF
6 THOSE GRANTS JUST BASED ON THE SCIENCE. AND WE WANT
7 THOSE GRANTS TO BE BASED ADDITIONALLY ON THESE OTHER
8 FACTORS.

9 CHAIRMAN STEWARD: IF I COULD. I'M ALWAYS
10 A LITTLE NERVOUS. YOU GUYS KNOW ME. I'M VERY MUCH
11 KIND OF, WHATEVER, PROCEDURALLY FOCUSED HERE. I'M
12 ALWAYS A LITTLE NERVOUS IN TRYING TO DO REALLY
13 IMPORTANT THINGS ON THE FLY. AND I'M JUST A LITTLE
14 WORRIED ABOUT TRYING TO DO TOO MUCH HERE TO WORK ALL
15 THIS OUT.

16 I WONDER IF WE COULD HAVE A MOTION THAT
17 DOESN'T REALLY SPECIFY KIND OF THE DETAILS, BUT
18 BRINGS IT FORWARD TO THE BOARD AS AN IMPORTANT
19 ELEMENT FOR DISCUSSION AS PART OF THIS CONCEPT PLAN,
20 BUT ASK THE CIRM TEAM TO MAYBE PUT SOME LANGUAGE TO
21 IT THAT SPELLS OUT WHATEVER A PROPOSAL MIGHT BE IN
22 TERMS OF WHERE THIS REVIEW SHOULD TAKE PLACE,
23 CONSIDERING APPROPRIATELY THE ROLES OF BOARD VERSUS
24 THE GRANTS WORKING GROUP AS DEFINED BY PROP 14.

25 MR. TORRES: AT THE BOARD MEETING.

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1 CHAIRMAN STEWARD: YES, AT THE BOARD
2 MEETING.

3 DR. DEAS: I WAS JUST GOING TO SAY THAT
4 SEEMS REASONABLE, THAT THE CIRM GROUP, THE STAFF,
5 COULD WORK ON THAT AND THEN BE PREPARED TO PRESENT
6 IT AT THE BOARD MEETING.

7 MR. TORRES: BY THAT TIME WE SHOULD HAVE
8 AN ANALYSIS OF WHAT THE NIH DOES SO THAT WE KNOW
9 THAT WE'RE COMPLEMENTING IT IF NOT ENHANCING IT.

10 CHAIRMAN STEWARD: YEAH. THAT WOULD BE
11 GREAT. SO LET ME TRY TO FORMULATE THIS MOTION, AND
12 YOU GUYS CAN CORRECT ME. BUT IT'S SORT OF WHAT
13 JAMES SAID IN THE BEGINNING. BUT THE MOTION WOULD
14 BE TO APPROVE THE CONCEPT PLAN GOING FORWARD WITH A
15 REQUEST TO THE CIRM TEAM TO PUT TOGETHER A PLAN FOR
16 CONSIDERATION OF THE ISSUES OF INCLUSION AND
17 OUTREACH AT ALL LEVELS AND A PROPOSAL FOR WHERE THAT
18 CONSIDERATION SHOULD ACTUALLY -- WHERE THE RANKING
19 OF THAT CONSIDERATION SHOULD ACTUALLY OCCUR, WHETHER
20 IT BE GWG OR AT THE BOARD LEVEL.

21 DR. DEAS: SO THAT SOUNDS GREAT. THE ONLY
22 ADDITION, AMENDMENT THAT I WOULD PUT, INSTEAD OF THE
23 WORD "CONSIDERATION," I WOULD SAY IMPLEMENTATION
24 BECAUSE I THINK WE NEED TO GO BEYOND CONSIDERING IT,
25 BUT TELL US HOW YOU'RE GOING TO IMPLEMENT THIS.

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1 CHAIRMAN STEWARD: OKAY. GOOD. DO WE
2 HAVE THAT MOTION IN SUFFICIENT DETAIL THAT SOMEBODY
3 ACTUALLY CAN SAY IT IN A BETTER WAY THAN I DID?
4 JAMES, I ALWAYS LOOK TO YOU FOR THIS.

5 MR. HARRISON: I'LL GIVE IT A TRY. SO
6 RECOMMEND -- SO THE MOTION WOULD BE TO RECOMMEND
7 APPROVAL OF THE CONCEPT PLAN AMENDMENTS WITH
8 DIRECTION TO THE CIRM TEAM TO PROPOSE LANGUAGE
9 REGARDING IMPLEMENTATION OF A PLAN TO CONSIDER
10 SERVING UNDERSERVED COMMUNITIES AS PART OF AN
11 APPLICATION, CONSIDERATION OF REPRESENTATION FROM
12 UNDERSERVED COMMUNITIES ON RESEARCH TEAMS, AND
13 CONSIDERATION OF THIS INFORMATION IN THE SCORING OF
14 APPLICATIONS.

15 CHAIRMAN STEWARD: GOOD. THAT CAPTURES IT
16 FOR ME. DO WE HAVE A MOTION ON THAT LANGUAGE?

17 DR. DEAS: SO MOVED.

18 MR. TORRES: SECOND.

19 CHAIRMAN STEWARD: AND THE SECOND WAS?

20 MR. TORRES: ART.

21 DR. DEAS: ART.

22 CHAIRMAN STEWARD: OKAY. FURTHER
23 COMMITTEE DISCUSSION? DO WE HAVE PUBLIC COMMENT ON
24 THIS?

25 MS. BONNEVILLE: WE DO NOT HAVE ANY HANDS

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1 RAISED, OS.

2 CHAIRMAN STEWARD: OKAY. EXCELLENT.

3 MARIA, THEN COULD YOU CALL THE ROLL.

4 MS. BONNEVILLE: ABSOLUTELY. OS STEWARD.

5 CHAIRMAN STEWARD: YES.

6 MS. BONNEVILLE: DEBORAH DEAS.

7 DR. DEAS: YES.

8 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

9 DR. DULIEGE: YES.

10 MS. BONNEVILLE: JUDY GASSON. JUDY,
11 YOU'RE ON MUTE, I THINK, BUT I THINK YOU SAID YES.

12 I READ LIPS. OKAY.

13 DAVID HIGGINS.

14 DR. HIGGINS: YES.

15 MS. BONNEVILLE: STEVE JUELSGAARD.

16 MR. JUELSGAARD: YES.

17 MS. BONNEVILLE: ART TORRES.

18 MR. TORRES: AYE.

19 MS. BONNEVILLE: JONATHAN THOMAS.

20 CHAIRMAN THOMAS: YES.

21 MS. BONNEVILLE: THE MOTION CARRIES.

22 CHAIRMAN STEWARD: THANK YOU. I THINK
23 THAT CONCLUDES OUR BUSINESS TODAY.

24 MS. BONNEVILLE: IT DOES.

25 CHAIRMAN STEWARD: GREAT. OKAY. WELL, IF

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1 THERE ARE NO OTHER COMMENTS, ENTERTAIN A MOTION TO
2 ADJOURN. SOMEBODY, COME ON.

3 CHAIRMAN THOMAS: EXCELLENT JOB,
4 MR. CHAIRMAN. MOVE WE ADJOURN.

5 CHAIRMAN STEWARD: WE'RE GOING TO TAKE
6 SOMEBODY'S NOD AS A SECOND. THANK YOU ALL FOR
7 ATTENDING. I THOUGHT THAT WAS A REALLY GOOD
8 DISCUSSION, AND WE'LL LOOK FORWARD TO SEEING YOU AT
9 THE NEXT BOARD MEETING IN DECEMBER.

10 (THE MEETING WAS THEN CONCLUDED AT 12:50 P.M.)
11
12
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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 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 DECEMBER 11, 2020, 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.

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