BEFORE THE
JOINT MEETING OF THE
FINANCE AND SCIENCE SUBCOMMITTEES
OF THE
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE
TO THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT

REGULAR MEETING

LOCATION: VIA ZOOM

DATE: MAY 29, 2026
2:15 P.M.

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

FILE NO.: 2026-12

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MAY 29, 2026; 2:15 P.M.

CHAIRMAN FISCHER-COLBRIE: OKAY, SCOTT. WE'VE GOT QUITE A FULL AGENDA. MAYBE WE CAN START TAKING THE ROLL.

MR. TOCHER: SURE. ABSOLUTELY. SO THIS IS A JOINT MEETING OF THE SCIENCE AND FINANCE SUBCOMMITTEES OF THE ICOC. SO I WILL CALL ROLL FOR BOTH.

GEORGE BLUMENTHAL.

DR. BLUMENTHAL: HERE.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: PRESENT.

MR. TOCHER: JOYCE SACKEY.

DR. SACKEY: PRESENT.

MR. TOCHER: DEBORAH DEAS OR MONICA CARSON. ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

CHAIRMAN FISCHER-COLBRIE: HERE.

MR. TOCHER: ELENA FLOWERS. JUDY GASSON. VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: HERE.

MR. TOCHER: PAT LEVITT. SHLOMO MELMED.

DR. MELMED: HERE.

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MR. TOCHER: CAROLYN MELTZER. CHRIS MIASKOWSKI.

DR. MIASKOWSKI: HERE.

MR. TOCHER: JOE PANETTA.

MR. PANETTA: HERE.

MR. TOCHER: SHAUNA STARK.

DR. STARK: HERE.

MR. TOCHER: KAROL WATSON.

DR. WATSON: HERE.

MR. TOCHER: AND KEITH YAMAMOTO.

DR. YAMAMOTO: HERE.

MR. TOCHER: GREAT. THANKS VERY MUCH. AND WE HAVE A QUORUM OF THE FINANCE AND I BELIEVE SCIENCE. SOMEONE IS JUST COMING IN.

CHAIRMAN FISCHER-COLBRIE: OKAY.

MR. TOCHER: AND WE'RE GOOD TO GO, MARK.

CHAIRMAN FISCHER-COLBRIE: GREAT. THANK YOU, SCOTT.

WITH THAT, I'LL TURN IT OVER TO JONATHAN THOMAS FOR AN INTRODUCTORY COMMENT.

DR. THOMAS: THANK YOU, MARK. AND GOOD AFTERNOON, EVERYBODY. WE HAVE AN AGENDA PACKED WITH A COMBINATION OF SOMEWHAT DISPARATE TOPICS FROM THE WORLDS OF FINANCE AND SCIENCE. THE ORDER, AS YOU SEE IN YOUR MATERIALS, WE'LL BE STARTING WITH

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DISCUSSION OF THE INFR9 CONCEPT PLAN, A DATA AND SOFTWARE ENGINEERING, DATA SHARING AND SOFTWARE ENGINEERING. WE'LL PROCEED TO A BRIEF DISCUSSION OF AMENDMENTS TO THE PDEV AND RAPID CONCEPT PLANS, FOLLOWED BY A DISCUSSION OF -- CONTINUATION OF THE DISCUSSION OF THE MARCH SUBCOMMITTEE -- SORRY -- MARCH ICOC MEETING WHEN WE SWITCHED OVER FROM THE PREFERENCES TO THE CURRENT SYSTEM.

THIS DISCUSSION IN PARTICULAR FOCUSING ON PATIENT PERSPECTIVE SCORES, WHICH IS AN ADDITIONAL TOPIC IN VOLUME CONTROL. THAT WILL BE SUCCEEDED BY A PRESENTATION ON THE RESEARCH BUDGET AND FINALLY ANOTHER ON THE ADMIN BUDGET. SO IT'S QUITE A FULL AGENDA HERE.

SO WITHOUT FURTHER ADO, TO INTRODUCE THE INFR9 CONCEPT ITEM ON THE AGENDA, I WANT TO TURN IT OVER TO ROSA.

DR. CANET-AVILES: THANK YOU, J.T. AND MEMBERS OF THE SCIENCE SUBCOMMITTEE OF THE ICOC AND MEMBERS OF THE FINANCE SUBCOMMITTEE. I'M VERY HAPPY TO INTRODUCE DR. JANIE BYRUM, WHO IS A SENIOR OFFICER AT CIRM AND HAS BEEN SPEARHEADING THE DEVELOPMENT OF THIS INFRASTRUCTURE PROGRAMMING. AND WITHOUT LESS FURTHER ADO, JANIE, PLEASE TAKE IT OVER. THERE'S A LOT TO DISCUSS. SO I'M LOOKING

FORWARD TO THE PRESENTATION. THANK YOU.

DR. BYRUM: THANK YOU, ROSA. AND THANK YOU TO THE BOARD MEMBERS FOR YOUR TIME TODAY. MY NAME IS JANIE BYRUM, AND IT'S MY PLEASURE TO PROPOSE ON BEHALF OF THE CIRM TEAM THE CONCEPT PLAN FOR DATA SCIENCE AND SOFTWARE ENGINEERING AWARDS, OR INFRACTRUCTURE9.

SO OUR MISSION DRIVES US, AND CIRM'S MISSION IS TO ACCELERATE WORLD-CLASS SCIENCE TO DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND THE WORLD.

FOR TODAY'S CONCEPT, WE'LL BEGIN WITH BACKGROUND INFORMATION AND MOVE INTO THE ELEMENTS OF THE CONCEPT SHOWN HERE.

SO I WANT TO BEGIN BY EMPHASIZING THAT LIFE SCIENCES, INCLUDING REGENERATIVE MEDICINE, HAS SEEN MASSIVE DATA GROWTH IN THE LAST 20 YEARS. AND WE NEED TRANSFORMATIVE TOOLS TO HELP RESEARCHERS CAPITALIZE ON THAT DATA. AND THIS IS DUE TO SEVERAL FACTORS: TECHNOLOGICAL ADVANCEMENT, INCLUDING IN LIFE SCIENCES AND ADVANCES IN COMPUTATION; INCREASED INVESTMENT IN RESEARCH AND DEVELOPMENT; AND MORE DATA ACCESSIBILITY DUE TO DATA SHARING.

SO DATA GENERATION IS DOUBLING EVERY TWO

TO THREE YEARS, AND WE NEED SOFTWARE TOOLS TO CAPITALIZE ON THE VALUE AND VARIETY OF DATA. AND THESE DATA ARE RICH, BUT THEY'RE UNDERUTILIZED, AND THEY MUST BE INTEGRATED TO ALLOW FOR COMPARISONS ACROSS DATASETS, ACROSS MODELS, AND ACROSS DISCIPLINES. SO WE NEED TOOLS TO INTEGRATE DATA AT A LARGE SCALE AND BE ABLE TO INTEGRATE DIFFERENT TYPES OF DATA. AND I'LL ELABORATE ON THAT IN A FEW SLIDES.

SO THIS IS A QUOTE BY FRANCIS COLLINS, THE FORMER HEAD OF THE NIH, ADDRESSING AN HHS HOUSE SUBCOMMITTEE ABOUT THE FUTURE OF BIOMEDICAL RESEARCH. AND HE SAYS, "THE CHALLENGE IS HOW TO STORE, RETRIEVE, INTEGRATE, AND ANALYZE THIS MOUNTAIN OF COMPLEX DATA." AND IT UNDERSCORES THAT WE NEED TO BE ABLE TO LEVERAGE ALL THE DATA THAT WE'RE GENERATING SO THAT WE CAN REVEAL MEANINGFUL INSIGHTS.

AND CIRM HAS A GOAL OF MAXIMIZING THE VALUE OF THIS DATA FOR TWO REASONS. IF THESE DATA REMAIN SILOED, WE'RE LEAVING INSIGHTS ON THE TABLE AND SCIENCE WILL BE SLOWER, AND IT'S ALSO INEFFICIENT. BEING ABLE TO SQUEEZE THE JUICE OUT OF INDIVIDUAL DATASETS BY SHARING THEM AND COMBINING THEM WITH OTHER DATASETS REDUCES THE AMOUNT OF DATA

GENERATION THAT HAS TO BE FUNDED IN THE FIRST PLACE.

SO RECENTLY, IN 2023, CIRM BEGAN TRACKING RESEARCH DATASETS GENERATED BY OUR AWARDEES, AND WE SEE THAT CIRM RESEARCHERS GENERATE VAST AMOUNTS OF DIVERSE DATA. ILLUSTRATED HERE IS THE VARIETY OF DATASETS FROM DIFFERENT TECHNIQUES OR APPROACHES. AND THESE DATASETS WERE TRACKED USING CIRM DATA SHARING AND MANAGEMENT PLANS OR DSMP'S. AND YOU CAN LEARN MORE INFORMATION ABOUT THESE DATASETS IN THE CIRM DATA EXPLORER. THIS IS A PLATFORM TO PROMOTE THE FINDABILITY OF CIRM-FUNDED DATASETS TO OTHER RESEARCHERS.

SO SOME OF THESE DATASETS ARE PUBLICLY AVAILABLE, AND SOME OF THESE ARE STILL IN PROGRESS. AND SO THIS IS PRIMARILY DATA FROM OUR DISCOVERY STAGE AWARDS, BUT WE HAVE RECENTLY IMPLEMENTED DATA SHARING AND MANAGEMENT PLANS FOR OUR PRECLINICAL AND CLINICAL AWARDS. AND WE'LL BE TRACKING THOSE AS WELL.

AND SO I WANT TO EMPHASIZE THE VARIETY OF DATA TYPES AND THE VOLUME. SO EACH CIRCLE IS PROPORTIONAL TO THE NUMBER OF DATASETS GENERATED USING THAT TECHNIQUE. AND SO YOU CAN SEE WE HAVE A LOT OF TRANSCRIPTOMICS, FOR EXAMPLE, AND SINGLE-CELL TRANSCRIPTOMICS. AND ADDITIONALLY, WITH ANY

TECHNIQUE CATEGORY, THERE ARE SUBAPPROACHES. EACH OF THE SMALLER CIRCLES WITHIN THE LARGER CATEGORIES IS A DIFFERENT FLAVOR OF THE BROADER CATEGORY. AND THEIR SIZES ARE ALSO PROPORTIONAL TO THE NUMBER OF DATASETS. AND THESE DATA ARE GENERATED USING A LOT OF DIFFERENT APPROACHES, AND IT'S A HUGE CHALLENGE TO COMPARE THE DATA ACROSS TECHNIQUES. AND THAT'S LIMITING WHAT WE CAN LEARN FROM THESE DATASETS.

SO IN ADDITION TO THE DIVERSITY OF DATA ACROSS TECHNIQUES, DATA IS ALSO GENERATED ACROSS SCALES AND MODELS, INCLUDING ANIMAL MODELS, CELLULAR AND MOLECULAR DATA, ELECTRONIC HEALTH RECORDS, AND PATIENT DATA FROM TRIALS. AND BEING ABLE TO BRING THESE DATA TOGETHER WILL ENABLE RESEARCHERS TO DEVELOP MORE COMPLEX, MORE ACCURATE BIOLOGICAL MODELS, AND THEY CAN ASK FOR NUANCED QUESTIONS.

SO MORE CONNECTIONS EQUALS MORE POTENTIAL TO FIND TARGETS OR BIOMARKERS AND BECAUSE THERE'S A FULLER PICTURE THAT IS INTERPRETABLE BY RESEARCHERS.

SO HOW CAN WE INTEGRATE AND ANALYZE THE MOUNTAIN OF COMPLEX DATA? WE CAN BUILD SOFTWARE TOOLS TO INTEGRATE DATA, AND THIS WILL ACCELERATE RESEARCH. SO DURING THE STRATEGIC ALLOCATION FRAMEWORK, CIRM DEFINED AN AMBITIOUS GOAL TO CATYLIZE THE IDENTIFICATION AND VALIDATION OF AT

LEAST FOUR NOVEL TARGETS AND BIOMARKERS, ENSURING INTEGRATION INTO PRECLINICAL OR CLINICAL RESEARCH FOR DISEASES IN CALIFORNIA. AND THERE WAS A RECOMMENDATION AT THE TIME TO ENABLE DATA SCIENCE COLLABORATIVE EFFORTS VIA DEDICATED GRANTS.

AND TO INCREASE THE PROBABILITY THAT CIRM REALIZES THIS GOAL OF IDENTIFYING AND VALIDATING FOUR NOVEL TARGETS OR BIOMARKERS, WE CAN SUPPORT SOFTWARE PROJECTS THAT HELP RESEARCHERS MAKE CONNECTIONS BETWEEN DIFFERENT TYPES OF DATA, ENABLING MORE IMPACTFUL DATA SCIENCE. AND WE CAN DO THIS BY ADDRESSING RESEARCH BOTTLENECKS BY SUPPORTING SOFTWARE PROJECTS. AND I'LL OUTLINE SOME OF THESE RESEARCH BOTTLENECKS IN THE NEXT SLIDE.

SO MULTIMODAL DATA, INCLUDING PATIENT DATA AND DATA ACROSS SCALES, DISEASES, AND BIOLOGICAL SYSTEMS, NEED TO BE INTEGRATED TO BE LEVERAGE FOR BIOLOGICAL INSIGHT. AND THIS REQUIRES SIGNIFICANT INVESTMENT. WE'VE ALREADY DISCUSSED A BIT OF THAT. BUT ADDITIONALLY, SOFTWARE TOOLS ARE NEEDED TO ACCELERATE STEM CELL-BASED AND GENETIC RESEARCH. AND THERE'S A LACK OF DEDICATED FUNDING FOR THE DEVELOPMENT AND MAINTENANCE OF OPEN-SOURCE SOFTWARE THAT'S CRUCIAL FOR THE DISCOVERY OF POTENTIAL THERAPEUTICS.

WE SURVEYED OUR REMIND AWARDEES AT THE REMIND ANNUAL MEETING, AND THE BIGGEST BOTTLENECKS TO EMPLOYING CUTTING-EDGE DATA SCIENCE IN THEIR LABS WERE FUNDING FOR A DATA SCIENTIST AND SOFTWARE TOOLS THAT ARE USER FRIENDLY. AND THESE BOTTLENECKS CAN BE ADDRESSED THROUGH A PROGRAM THAT DEVELOPS AND SUSTAINS OPEN-SOURCE SOFTWARE THAT DRIVES REGENERATIVE MEDICINE RESEARCH AND CAN CATALYZE DATA SCIENCE RESEARCH TO INTEGRATE AND EXPAND THE IMPACT OF CIRM-FUNDED DATASETS AND OTHER DATASETS.

SO WHAT IS OPEN-SOURCE SOFTWARE? OPEN-SOURCE SOFTWARE IS SOFTWARE WHOSE CODE IS PUBLICLY AVAILABLE, ALLOWING ANYONE TO VIEW IT, MODIFY IT, ENHANCE IT, AND REDISTRIBUTE IT. AND I WANTED TO GIVE AN EXAMPLE OF AN OPEN-SOURCE SOFTWARE THAT'S BEEN ESSENTIAL IN LIFE SCIENCES.

SO THIS IS SCIKIT LEARN, WHICH IS A MACHINE LEARNING LIBRARY FOR A PROGRAMMING LANGUAGE CALLED PYTHON. AND THE NAME COMES FROM A SCIENTIFIC TOOLKIT FOR MACHINE LEARNING. AND THIS TOOLKIT IS THE MOST POPULAR MACHINE LEARNING FRAMEWORK. AND IN A SURVEY OF 24,000 PEOPLE, 80 PERCENT OF RESPONDENTS USE IT. AND ON GITHUB, WHICH IS A CODE REPOSITORY, OVER 65,000 PEOPLE HAVE GIVEN IT STARS, WHICH IS EQUIVALENT TO LIKING IT ON SOCIAL MEDIA. THE

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ORIGINAL PAPER INTRODUCING THIS PACKAGE HAS BEEN CITED OVER 130,000 TIMES.

AND SO WHAT DOES IT DO? IT'S A SOFTWARE TOOLKIT FOR SCIENTISTS THAT ARE NOT EXPERTS IN CODING OR MACHINE LEARNING. AND IT CAN BE USED TO LEARN FROM A DATASET, AND IT CAN HELP WITH PREDICTIONS SUCH AS -- BASED ON WHAT'S IN THIS DATASET AND WHAT THE MODEL IS TRAINED ON, WHAT'S GOING TO HAPPEN NEXT. IT HELPS TO ASSIST WITH CLASSIFICATION. SO DOES THIS IMAGE BELONG TO DISEASED OR HEALTHY TISSUE? OR CLUSTERING, CAN WE GROUP THE CELLS WITH SIMILAR PHENOTYPES TOGETHER?

AND IT STARTED AS A SMALL PROJECT BEING BUILT ONE SUMMER BY A PH.D. STUDENT. BUT SINCE IT WAS OPEN SOURCE AND THERE WAS A NEED FOR IT IN THE FIELD, THE USER COMMUNITY BUILT UPON IT AND DEVELOPED IT OVER TIME INTO WHAT IT IS TODAY. AND IT'S MADE DATA SCIENCE ACCESSIBLE TO RESEARCHERS, AND IT'S NOT AN ESSENTIAL OPEN-SOURCE SOFTWARE PACKAGE FOR SCIENTISTS.

SO I JUST TOLD YOU THAT COMPUTATIONAL SOFTWARE AND INFRASTRUCTURE ARE INTEGRAL TO SCIENTIFIC RESEARCH. AND THE RESEARCH ENTERPRISE INCREASINGLY RELIES ON OPEN-SOURCE SOFTWARE. AND TODAY WE ARE PROPOSING A CONCEPT PLAN FOR DATA

SCIENCE AND SOFTWARE ENGINEERING AWARDS TO SUPPORT OPEN-SOURCE SOFTWARE THAT HAS A SPECIFIC SCOPE OF SOLVING DATA INTEGRATION BARRIERS IN REGENERATIVE MEDICINE.

SO CIRM CAN SUPPORT REUSABLE, SCALABLE SOFTWARE TOOLS TO LINK DIVERSE DATASETS. AND THIS WILL ACCELERATE RESEARCH IN REGENERATIVE MEDICINE AND ULTIMATELY MAXIMIZE THE POTENTIAL OF CIRM-FUNDED DATA.

WE RECEIVED FEEDBACK THAT WE ALREADY SUPPORT DATA SCIENCE PROJECTS IN OUR DISCOVERY AWARDS. AND HERE I WANT TO HIGHLIGHT THAT SOFTWARE TOOLS COMING OUT OF INFRACTRUCTURE9 WOULD BE TO DISTINGUISH FROM THOSE RESULTING FROM OUR EXISTING DISCOVERY PROGRAMS. SO TOOLS SUPPORTED BY OUR DISCOVERY PROGRAMS ARE GENERALLY ANCILLARY TO RESEARCH PROJECTS WITH NO REQUIREMENTS FOR SOFTWARE ENGINEERING STANDARDS OR BEST PRACTICES. AND THEY'RE ALSO HIGHLY SPECIALIZED FOR A SPECIFIC RESEARCH QUESTION, AND OFTEN THEY DON'T HAVE A PLAN FOR DEPLOYMENT OF THE TOOL FOR COMMUNITY USE. AND MAINTENANCE OFTEN ENDS WHEN THE PAPER IS PUBLISHED OR THE TRAINEE LEAVES THE LAB.

AND SO INFRACTRUCTURE9 PROJECTS WOULD FOLLOW OPEN-SOURCE BEST PRACTICES RESULTING IN TOOLS

WITH ENHANCED SCALABILITY, REUSABILITY, AND REPRODUCIBILITY. AND THROUGH A DEDICATED GRANT MECHANISM WITH REQUIREMENTS THAT ARE TAILORED FOR SOFTWARE TOOLS, WE CAN HAVE A COLLECTION OF TOOLS THAT ARE BUILT FOR EXTENSION AND COMMUNITY USE IN MIND AND THAT HAVE A PLAN FOR MAINTENANCE.

SO NOW WE'LL MOVE INTO THE SCOPE AND STRUCTURE OF THE CONCEPT FOR THE DATA SCIENCE AND SOFTWARE ENGINEERING AWARDS. AND I'LL START BY PREVIEWING THE PROPOSED GUIDING PRINCIPLES.

SO AS A REMINDER, GUIDING PRINCIPLES HELP CIRM SHAPE ITS PORTFOLIO. AND THE INFRACTRUCTURE9 PORTFOLIO WILL ADDRESS BARRIERS TO INTEGRATING MULTIMODAL DATA IN REGENERATIVE MEDICINE. IT WILL INNOVATE THROUGH OPEN AND COLLABORATIVE SOFTWARE DEVELOPMENT TO ACCELERATE RESEARCH. IT WILL CREATE BROADLY APPLICABLE AND VALIDATED TOOLS THAT MAXIMIZE THE VALUE OF CIRM-FUNDED DATA. AND THESE GUIDING PRINCIPLES WILL INFORM THE SELECTION AND REVIEW CRITERIA AS WELL AS CIRM TEAM RECOMMENDATION POST GRANTS WORKING GROUP REVIEW.

SO THE OVERARCHING OBJECTIVE OF THIS PROGRAM IS TO SUPPORT THE DEVELOPMENT, MAINTENANCE, AND/OR EXTENSION OF INNOVATIVE, OPEN-SOURCE SOFTWARE FOR INTEGRATION OF DISPARATE DATA TYPES TO

ACCELERATE RESEARCH IN REGENERATIVE MEDICINE. THE EXPECTED OUTCOME IS THE DEVELOPMENT AND DEPLOYMENT OF AN OPEN-SOURCE SOFTWARE TOOL TO SOLVE A MULTIMODAL DATA INTEGRATION BOTTLENECK IN STEM CELL-BASED AND GENETIC THERAPY RESEARCH THAT HAS WIDE APPLICABILITY AND SCALABLE IMPACT. AND THE APPROACH IS INVESTIGATOR PAIRS LEADING INTERDISCIPLINARY SOFTWARE ENGINEERING PROJECTS.

WE PROPOSE THAT THE SCOPE SHOULD FOCUS ON SOFTWARE TOOLS; THAT IS COMPUTATIONAL TOOLS, PIPELINES, OR RESOURCES, TO ADDRESS DATA INTEGRATION BOTTLENECKS TO CATALYZE DATA SCIENCE IN REGENERATIVE MEDICINE RESEARCH. SO THIS SCOPE WOULD BRING ABOUT TOOLS THAT ACCELERATE THE IDENTIFICATION OR VALIDATION OF TARGETS AND BIOMARKERS. AND WE FOCUSED THE SCOPE TO A SPECIFIC BOTTLENECK, AND WE'RE SUPPORTING THE STAGE OF RESEARCH WHERE WE KNOW THERE'S A NEED FOR THIS PROGRAM, WHICH IS AT THE DISCOVERY STAGE.

SO EXAMPLES OF TYPES OF APPROACHES ARE AI OR ML APPROACHES FOR IN SILICO SCREENING, PROTEIN DESIGN, MOLECULE GENERATION, CELL AND GENE ENGINEERING, ET CETERA. OR KNOWLEDGE GRAPHS FOR BRIDGING STRUCTURES, BEHAVIOR ASSAYS, FUNCTIONAL GENOMICS DATA, SPATIAL DATA, AND PATHWAY OR NETWORK

DATA. AND A KNOWLEDGE GRAPH IS A FRAMEWORK FOR CONNECTING DIVERSE DATA SOURCES. THEY'RE USED FOR MODELING COMPLEX NETWORKS TO MAP RELATIONSHIPS BETWEEN GENES, PATHWAYS, DISEASES, DRUG TARGETS AND TREATMENTS, ET CETERA.

SO HOW COULD THESE APPROACHES BE APPLIED? SPECIFIC EXAMPLES OF APPLICATIONS INCLUDE CELL ANALYTIC SOFTWARE TO READ OUT PRESENT AND FUTURE CELL STATES AND BEHAVIOR WITHOUT DECONSTRUCTING THE CELLS OR A NEW OMICS ANALYSIS TOOL TO INTEGRATE SPATIAL TRANSCRIPTOMICS DATA WITH MULTI-ELECTRODE DATA TO LINK SPATIAL GENE EXPRESSION AND ELECTRICAL SIGNALING TO UNDERSTAND DISEASE MECHANISMS AND IDENTIFY NEW TARGETS.

MOVING INTO THE AWARD STRUCTURE AND BUDGET. THIS PROGRAM IS PROPOSED TO HAVE AN ANNUAL CALL WITH AN AWARD DURATION OF UP TO TWO YEARS. THE AWARD AMOUNT IS UP TO $500,000 TOTAL COSTS, FUNDING 15 TO 20 AWARDS PER CALL WITH AN ANNUAL BUDGET OF $10 MILLION.

IN TERMS OF ELIGIBILITY, THE APPLICANT MUST MEET CIRM'S DEFINITION OF A CALIFORNIA ORGANIZATION. WE'LL HAVE TWO CALIFORNIA-BASED INVESTIGATORS, AND THE CO-INVESTIGATOR MUST NOT BE FROM THE SAME LAB AS THE PRINCIPAL INVESTIGATOR.

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THERE WILL BE REQUIREMENTS FOR BOTH REGENERATIVE MEDICINE EXPERTISE AS WELL AS COMPUTATIONAL EXPERTISE ON THE APPLICANT TEAM. AND THE EFFORT FOR BOTH INVESTIGATORS IS A 5-PERCENT MINIMUM.

THE PROJECT ELIGIBILITY, THE PROJECT MUST BE IN SCOPE AND DEVELOP OPEN-SOURCE SOFTWARE THAT COULD LEAD TO THE EXPECTED OUTCOME THAT'S DEFINED IN THE INFRACTRUCTURE9 OBJECTIVE.

FOR APPLICATION AND REVIEW PROCESSES, INFRACTRUCTURE9 WILL ADOPT A GRANTS WORKING GROUP SELECTION PROCESS TO ALLOW THE GRANTS WORKING GROUP TO SELECT APPLICATIONS THAT ARE MOST RESPONSIVE TO THE FUNDING OPPORTUNITY AND HOLD THE GREATEST POTENTIAL FOR IMPACT AND ALLOW CIRM PREPLANNING FOR IMPROVED SCIENTIFIC AND TECHNICAL REVIEW. AND THE INFRACTRUCTURE9 PROGRAM WILL ALSO ADOPT A 1 TO 100 NUMERICAL GWG SCORING SYSTEM TO ALIGN ACROSS CIRM PROGRAMS AND IMPROVE GRANULARITY AND VISIBILITY FOR SCORE DRIVING DECISIONS. AND THE SELECTION AND REVIEW CRITERIA AND CIRM TEAM RECOMMENDATIONS POST GWG WOULD BE DEVELOPED IN ALIGNMENT WITH THE GUIDING PRINCIPLES.

THE PROPOSED TIMELINE BEGINS WITH THE CONCEPT GOING TO THE JUNE ICOC FOR APPROVAL. AND IN SEPTEMBER THE PA CAN BE POSTED. AND THERE'S A

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LONGER WINDOW WHEN THE APPLICATIONS ARE DUE IN JANUARY TO MAY FOR REVIEW TO ALLOW FOR THE GWG SELECTION PROCESS. AND THE GRANTS WORKING GROUP RECOMMENDATIONS WOULD GO TO THE BOARD AT THE ARS MEETING IN JUNE OF 2027 WITH THE AWARD CONTRACTING WINDOW IMMEDIATELY FOLLOWING.

I'LL WRAP UP BY SHARING THAT WE HAVE AN OUTREACH PLAN IN DEVELOPMENT TO ENSURE THAT POTENTIAL APPLICANTS ARE MADE AWARE OF THE FUNDING OPPORTUNITY. SO IN ADDITION TO TARGETING OUR EXISTING AWARDEE PORTFOLIO, WE INTEND TARGETING OUTREACH TO NON-UC'S, COMMUNITY COLLEGES, AND CAL STATE UNIVERSITIES. WE THINK THIS PROGRAM HAS THE POTENTIAL TO BE MORE ACCESSIBLE TO THESE INSTITUTIONS RELATIVE TO R & D AWARDS BECAUSE THE PROGRAM REQUIRES LESS CAPITAL EQUIPMENT AND PHYSICAL LAB SPACE, AND THE AWARD CAN BE ACCOMPLISHED WITH COMPUTATIONAL RESOURCES AND PERSONNEL.

WE ALSO PLAN TO REACH OUT TO PROFESSIONAL ORGANIZATIONS AND DATA SCIENCE AND INFORMATICS NETWORKS AND ACADEMIC DEPARTMENTS TO SPREAD THE WORD. AND THESE ARE SOME OF THE TOOLS THAT WE CAN USE IN COLLABORATION WITH OUR COMMUNICATIONS DEPARTMENT TO ENSURE THAT WE'RE REACHING OUR TARGET AUDIENCES.

SO WE'RE VERY KEEN TO HEAR YOUR FEEDBACK, AND THANK YOU VERY MUCH FOR YOUR ATTENTION AND CONSIDERATION OF THIS CONCEPT. I'LL STOP HERE FOR DISCUSSION. AND ULTIMATELY THE CIRM TEAM WOULD LIKE TO REQUEST YOUR ENDORSEMENT TO MOVE THE DATA SCIENCE AND SOFTWARE ENGINEERING CONCEPT PLAN TO THE FULL BOARD IN JUNE.

CHAIRMAN FISCHER-COLBRIE: GREAT. BEFORE MOVING THE DISCUSSION FORWARD, LET'S GO AHEAD WITH A MOTION AND A SECOND FOR APPROVAL.

MR. PANETTA: SO MOVED.

DR. LEVITT: SECOND.

MR. TOCHER: SORRY. JOE IS NOT A MEMBER OF THE SCIENCE SUBCOMMITTEE. WE NEED THE MAKER OF THE MOTION AND THE SECOND TO COME FROM THE SCIENCE SUBCOMMITTEE.

MR. PANETTA: SORRY. I WAS TOO EXCITED ABOUT IT.

MR. TOCHER: THAT'S FINE, JOE. WE'LL NEED YOU IN A FEW MINUTES FOR FINANCE.

DR. DULIEGE: I SECOND.

MR. TOCHER: I APOLOGIZE. WHO WAS THE MAKER OF THE MOTION?

DR. YAMAMOTO: I'LL MAKE THE MOTION. I WAS GOING TO SECOND, BUT I'M HAPPY TO MAKE THE

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MOTION.

MR. TOCHER: GREAT. THANK YOU, KEITH. AND ANNE-MARIE, I'M AFRAID YOU'RE NOT A MEMBER OF THE SCIENCE SUBCOMMITTEE.

DR. DULIEGE: I'M A MEMBER OF THE FINANCE SUBCOMMITTEE.

DR. LEVITT: I'D SECOND, SCOTT.

MR. TOCHER: THANK YOU VERY MUCH. THANK YOU. PAT LEVITT IS THE SECOND.

CHAIRMAN FISCHER-COLBRIE: GREAT. WITH THAT, LET'S OPEN UP FOR DISCUSSION BY THE COLLECTIVE COMMITTEE MEMBERS. AND, CLAUDETTE, IF I CAN -- I DON'T NECESSARILY SEE ALL THE HANDS RAISED THAT MIGHT BE THERE. SO IF YOU CAN INFORM ME.

MS. MANDAC: WE HAVE MARIA FIRST.

VICE CHAIR BONNEVILLE: THANKS. THANKS, JANIE, FOR THIS PRESENTATION.

I WANTED TO -- I WANTED TO ASK AGAIN. SO I BELIEVE WHEN WE SPOKE YESTERDAY BECAUSE I HAD SOME QUESTIONS AROUND THE BUDGET, SO THIS IS A BUDGET -- SO I REALIZE THAT EVERY YEAR THE BOARD WOULD APPROVE IT IN ITS BUDGET FOR THAT YEAR, BUT THIS IS SLATED FOR UP TO $80 MILLION; IS THAT CORRECT?

DR. BYRUM: SO THE TOTAL BUDGET IS $10

MILLION FOR THIS YEAR. AND IN TERMS OF HOW MANY YEARS, THIS IS SOMETHING THE BOARD WILL HAVE TO DECIDE BASED ON PROJECTIONS THAT ARE GOING TO BE PRESENTED AT THE JUNE MEETING. AND I'D LIKE TO DEFER TO ROSA IF SHE HAS ANY FURTHER REMARKS ON THE BUDGET. BUT THERE IS SUBSTANTIAL BUDGET ALLOCATED TOWARD THIS PROGRAM.

VICE CHAIR BONNEVILLE: OKAY. SO THAT WOULD BE -- SO WE WOULD ANTICIPATE -- SO IT'S 10 MILLION A YEAR, AND I THINK WE HAD TALKED ABOUT EIGHT. SO WE'RE THINKING OF SUPPORTING THIS, THEN, FOR THE NEXT EIGHT YEARS POTENTIALLY. SO I JUST WANTED TO JUST BE CLEAR ON THAT. AND, AGAIN, I REALIZE THAT IT COMES TO THE BOARD EVERY YEAR.

DR. BYRUM: YES.

VICE CHAIR BONNEVILLE: BUT IT'S A SUBSTANTIAL INVESTMENT IN THIS PROGRAM POTENTIALLY. SO I JUST WANTED TO CALL THAT OUT. I THINK IT'S IMPORTANT TO UNDERSTAND THAT.

IF WE DID NOT CONTINUE TO FUND IT EVERY YEAR, WOULD THAT PUT THE PROGRAM AT RISK? OR WOULD WE HAVE DETERMINED THAT WE JUST DIDN'T NEED IT ANYMORE AND SO, THEREFORE, WE'RE NOT ASKING FOR IT? AND THEN HOW DO WE MAKE THOSE DETERMINATIONS BECAUSE I THINK THAT'S IMPORTANT TO UNDERSTAND FROM AN

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OVERALL PROGRAM SCOPE?

DR. CANET-AVILES: JANIE, I'LL TAKE THIS ONE IF YOU DON'T MIND. THANK YOU, MARIA.

SO RIGHT NOW WE HAVE SEEN IN THE PROJECTIONS THERE IS $10 MILLION SLOTTED FROM NOW TILL END OF CIRM FUNDING. HOWEVER, THIS COULD COME -- WE COULD BE COMING WITH OUTCOMES EVERY YEAR. AND ALSO WITH NEEDS, THERE MIGHT BE -- WE WILL BE LEARNING ABOUT THE APPLICATION. AND THESE TOOLS ARE GOING TO ADVANCE, AND THERE MIGHT BE NEEDS IN DIFFERENT AREAS OF OUR PORTFOLIO AS WELL. SO THAT COULD BE UP TO THE BOARD. INITIALLY THEY ARE UP TO $80 MILLION THAT COULD BE INVESTED IN THIS, BUT THAT DOESN'T NECESSARILY MEAN THAT THE BOARD WILL WANT TO INVEST IN IT. AND IT WILL NOT -- THIS IS INDEPENDENT EVERY YEAR.

VICE CHAIR BONNEVILLE: OKAY. I JUST WANTED TO MAKE SURE THAT THAT WAS -- THAT IT DIDN'T -- LIKE IF WE DECIDED IN TWO YEARS WE DIDN'T WANT THIS --

DR. CANET-AVILES: YOU HAVE NO OBLIGATION. WHAT YOU ARE APPROVING IS THIS IS A PILOT TO SEE IF IT WILL BENEFIT -- AS WE MOVE, IT WILL BENEFIT.

VICE CHAIR BONNEVILLE: OKAY. AND THEN WHEN WE -- WHEN WE STARTED PUTTING THIS -- NOT ME.

I HAD NOTHING TO DO WITH THIS. BUT WHEN YOU ALL WERE PUTTING THE CONCEPT TOGETHER, DID YOU TALK TO SOME OF THE EXTERNAL BODIES THAT WOULD BE AFFECTED BY THIS AND JUST GET AN UNDERSTANDING OF THE WILLINGNESS OF FOLKS TO PARTICIPATE IN THIS SORT OF PROGRAM? AND JUST A LITTLE COLOR AROUND THAT WOULD BE GREAT.

DR. CANET-AVILES: JANIE, PLEASE, YOU CAN TAKE THIS.

DR. BYRUM: YES. WE TALKED TO OUR EXISTING GRANTEE COMMUNITY AND WE ALSO TALKED TO FUNDERS THAT FUND OR HAVE IN THE PAST FUNDED SIMILAR ACTIVITIES UNDER DIFFERENT AWARD MECHANISMS. AND THERE IS APPETITE FOR THESE ACTIVITIES TO BE SUPPORTED BY A GRANT MECHANISM.

VICE CHAIR BONNEVILLE: THANKS, JANIE.

MS. MANDAC: JUDY NEXT.

DR. GASSON: LOOKING FOR MY MUTE BUTTON. SORRY. THANK YOU VERY MUCH FOR THE PRESENTATION. THAT WAS REALLY VERY CLEAR. AND I HAVE NO DOUBT IN MY MIND THAT THIS IS AN ENORMOUS PROBLEM, AND IT'S BEEN A PROBLEM FOR A REALLY LONG TIME AND IT'S GETTING WORSE.

WHEN I READ THIS YESTERDAY, I HAD TWO QUESTIONS. ONE IS DO WE KNOW THAT THIS IS THE RIGHT

AMOUNT OF FUNDING TO HAVE AN IMPACT? OR HOW DID WE COME TO THE CONCLUSION? AND I GUESS I VIEWED THIS YESTERDAY AS A LITTLE BIT ADJACENT TO KIND OF OUR CORE MISSION, WHICH IS WE DO SUPPORT INFRASTRUCTURE, WE DO SUPPORT EDUCATION, AND ALL SORTS OF RESEARCH FROM BASIC, TRANSLATIONAL, CLINICAL. IT'S BEEN MY EXPERIENCE, AND, AGAIN, I AM ABSOLUTELY NOT A DATA SCIENTIST, BUT IT'S BEEN MY EXPERIENCE THAT THIS HAS BEEN A REALLY EXTREMELY CHALLENGING AREA TO TRY TO COME UP WITH SOME TOOLS THAT AN AVERAGE LABORATORY WITH GOOD PEOPLE CAN REALLY USE.

AND SO WHAT ARE WE GOING TO DO DIFFERENTLY, AND IS THIS PART -- HAVE WE DECIDED THAT THIS IS PART OF OUR CORE MISSION, OR IS THIS SOMETHING THAT SHOULD BE DONE BY OTHER ORGANIZATIONS IN THIS SPACE? I GUESS I'M JUST TRYING TO UNDERSTAND WHAT IS THE LOGIC. I UNDERSTAND THAT OUR GRANTEES HAVE REQUESTED THIS, BUT ARE WE REALLY THE RIGHT PEOPLE AND IS THIS REALLY THE RIGHT AMOUNT OF FUNDING? THANK YOU.

DR. BYRUM: THANK YOU VERY MUCH. THOSE ARE IMPORTANT POINTS. SO TO FIRST ADDRESS ITS RELEVANCE TO OUR CORE MISSION, I DO BELIEVE THAT CIRM, PART OF ITS MISSION IS SUPPORTING TECHNOLOGY DEVELOPMENT AND TOOL DEVELOPMENT THAT WILL

ACCELERATE RESEARCH. AND ALSO THIS PROGRAM WAS DESIGNED TO MAXIMIZE THE VALUE OF CIRM'S INITIAL INVESTMENT IN ITS RESEARCH AWARDS TO ACCELERATE RESEARCH BY LEVERAGING THE DATA THAT'S ALREADY BEEN GENERATED BY THOSE AWARDEES AND BY THE BROADER FIELD.

AND THE GOAL IS TO HAVE ROBUST TOOLS THAT LIVE BEYOND AN INITIAL RESEARCH PROJECT AND THAT WILL CONNECT DATASETS AND RESEARCHERS THROUGH COLLABORATIONS THAT CANNOT HAVE BEEN ACHIEVED AS, FOR EXAMPLE, LIKE A SUPPLEMENT TO CIRM'S EXISTING OFFERINGS. AND I THINK IT WILL ENABLE US TO ACHIEVE GOAL 1 FASTER, WHICH IS IDENTIFYING POTENTIAL TARGETS AND BIOMARKERS, AND IT WILL ALSO BRING NEEDED COMPUTATIONAL EXPERTISE TO REGENERATIVE MEDICINE LABS.

IN TERMS OF THE FUNDING AMOUNT, I CAN SHARE HOW WE ARRIVED AT THAT. SO I'LL SHARE A LANDSCAPE OF SIMILAR FUNDING OPPORTUNITIES AND THEIR AWARD AMOUNTS AND DURATION. I'M STILL SHARING, CORRECT? AND SO THESE ARE DIFFERENT FUNDING OPPORTUNITIES, SOME OF WHICH STILL EXIST, SOME OF WHICH HAVE BEEN DEPRECATED, AND THEIR DURATION AND THEIR FUNDING AMOUNTS. AND WE ARE SUPPORTING SOMETHING THAT IS SLIGHTLY MORE GENEROUS THAN THESE

TO ACCOUNT, NOT ONLY FOR INFLATION AND THE INCREASED COSTS OF COMPUTATIONAL RESOURCES, BUT TO INVEST IN MAKING TOOLS THAT ARE ROBUST AND WILL BE USED BY THE COMMUNITY. WE'RE ALSO ADDING IN REQUIREMENTS FOR ENSURING THAT THERE IS ADOPTION BY THE COMMUNITY AND THAT THERE WILL BE COMMUNITY USERS THAT WILL CONTINUE TO MAINTAIN THESE TOOLS OVER TIME.

DR. GASSON: ARE YOU SHARING YOUR SCREEN?

DR. BYRUM: I THOUGHT I WAS STILL.

DR. YAMAMOTO: NO, YOU WEREN'T.

DR. BYRUM: LET'S SEE. THANK YOU.

DR. GASSON: WE SEE YOU. WE JUST DON'T SEE YOUR SCREEN.

DR. BYRUM: OKAY. YOU SEE THIS?

DR. GASSON: YES. NOW WE DO.

DR. BYRUM: OKAY. SORRY. YES. SO HERE IS A SHORT LIST OF FUNDING OPPORTUNITIES THAT ARE SUPPORTING SIMILAR ACTIVITIES. THEY'RE NOT COMPLETELY OBVIOUSLY THE SAME, BUT SOME ARE DEVELOPING SOFTWARE TOOLS FOR OPEN SCIENCE FOR DIFFERENT DOMAINS AND THEIR AWARD AMOUNTS. AND SO OUR AWARD AMOUNT IS 500,000, AND IT WILL BE UP TO TWO YEARS DURATION.

DR. GASSON: OKAY. THANK YOU.

MS. MANDAC: AND THEN SHAUNA.

DR. STARK: THANK YOU. THANK YOU FOR PROPOSING THAT PROPOSAL. I GUESS I THINK MAYBE A LITTLE BIT ALONG THE LINES OF WHAT'S BEEN BROUGHT UP SO FAR WHERE I LOVE THIS IDEA AND I THINK IT'S ACTUALLY REALLY IMPORTANT AND IT DOES SERVE A BIG PROBLEM, I THINK THE 80 MILLION, THE POTENTIAL $80 MILLION PRICE TAG FEELS LIKE A LOT FOR IT. BUT I ALSO UNDERSTAND THAT WE'RE NOT BEING ASKED TO APPROVE THAT ALL IN ONE FELL SWOOP. SO IT SORT OF LET'S THIS RUN OUT AS A PILOT, SEE WHAT COMES BACK FROM IT, AND THEN WE CAN MAKE THAT DETERMINATION AS WE GO. BUT I DO DEFINITELY SEE THE VALUE FOR THE PROGRAM.

DR. BYRUM: THANK YOU. THANK YOU. AND I DO WANT TO COMMENT A BIT ABOUT HOW WE CAN POTENTIALLY CAPITALIZE ON THE MOST SUCCESSFUL PROJECTS OVER TIME. SO THE INITIAL FUNDING ROUNDS WILL GENERATE A COLLECTION OF SOFTWARE TOOLS. AND THESE AWARDS ARE SHORT. THEY'RE TWO-YEAR AWARDS. AND AFTER THE FIRST SEVERAL YEARS, TOOLS THAT HAVE GAINED TRACTION IN THE REGENERATIVE MEDICINE COMMUNITY, THEY CAN REAPPLY TO EXPAND THE SCOPE OF THEIR PROJECTS. OR CIRM MIGHT EVALUATE WHETHER THERE ARE PROJECTS THAT WE WANT TO INVEST IN ON A LARGER SCALE. FOR EXAMPLE, TURNING AN INDIVIDUAL

SOFTWARE PACKAGE INTO A LARGER SOFTWARE LIBRARY IN EXTENDED USE CASES IN REACH, PARTICULARLY IF IT'S POISED TO HELP US REACH ONE OF OUR IMPACT GOALS.

SO THOSE ARE DIFFERENT APPROACHES THAT WE CAN TAKE IF THE BOARD DETERMINES THAT WOULD BE APPROPRIATE TO DO SO. BUT RIGHT NOW THE 10 MILLION ANNUAL BUDGET FOR ONE YEAR IS WHAT IS BEING UP FOR APPROVAL.

MS. MANDAC: AND KEITH NEXT.

DR. YAMAMOTO: I THINK PAT'S NEXT.

MS. MANDAC: SORRY. PAT AND THEN KEITH.

DR. LEVITT: AGE BEFORE BEAUTY, RIGHT, KEITH? IS THAT HOW IT GOES?

SO I LIKE THIS A LOT. AND I DO THINK THAT -- ONE THING THAT WAS CLARIFIED FOR ME WAS THAT WHO IS GOING TO REVIEW THIS? THE GWG IS GOING TO HAVE WHAT I WOULD CALL A SPECIAL EMPHASIS PANEL THE WAY IT'S DONE AT SOME CERTAIN FEDERAL AGENCIES. WHEN THERE'S A NEW PROGRAM, THEY HAVE EXPERTS IN THIS AREA. SO THAT'S ONE THING THAT'S REALLY IMPORTANT BECAUSE THEY'RE THE ONES WHO ARE GOING TO JUDGE, NOT JUST QUALITY, BUT I THINK IMPACT WILL BE REALLY IMPORTANT.

THE RFA THAT COMES OUT HAS TO -- IT NEEDS TO BE IMPACTFUL IN THE SENSE THAT THESE TOOLS ARE

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GOING TO BE BROADLY ABLE TO BE UTILIZED, NOT JUST SHARED, BUT SOMETIMES THESE SORTS OF THINGS ARE, THESE PLATFORMS ARE SHARED, BUT NOT EASY TO USE. AND THEN PEOPLE DON'T USE IT. RIGHT? SO THAT'S ONE THING. SO I COMMEND YOU FOR THAT.

THE OTHER THING THAT I THINK IT DOES REALLY WELL IS OFTENTIMES IN DATA SCIENCE, THE DATA SCIENTISTS ARE LEFT TO THEIR OWN DEVICES TO TRY TO UNDERSTAND THE DATA. RIGHT? IN CERTAIN AREAS IT'S PRETTY STRAIGHTFORWARD. I WOULD SAY IN GENOMICS IT'S MUCH MORE STRAIGHTFORWARD THAN IT IS IN THESE OTHER AREAS IN WHICH CIRM HAS INVESTED A LOT OF MONEY, PARTICULARLY ON THE CLINICAL SIDE. SO IT'S FORCING THAT PARTNERSHIP, WHICH I THINK WILL SAVE US A LOT OF TIME. AND WE CAN GENERATE ALL THE DATA IN THE WORLD, AND WE ARE GENERATING A LOT OF DATA IN THE WORLD, BUT UNLESS WE HAVE WAYS OF ANALYZING IT BETTER THAN WHAT WE'RE DOING NOW, IT'S GOING TO SIT ON THE SHELF TO SOME EXTENT. SO I LIKE THE PROGRAM A LOT.

DR. BYRUM: THANKS SO MUCH FOR YOUR COMMENTS.

DR. YAMAMOTO: JANIE, THANKS FOR THE PRESENTATION. YOU CLEARLY HAVE PUT A LOT OF WORK AND THOUGHT INTO THIS, AND WE APPRECIATE THAT.

MY QUESTION WAS -- IS REALLY RELEVANT TO THE SLIDE YOU HAD UP A MOMENT AGO ABOUT SHOWING OTHER PROGRAMS THAT ARE SUPPORTING PROGRAMS OF THIS SORT. AND, OF COURSE, THE POWER OF OPEN SOURCE IS THAT SOFTWARE CAN BE WRITTEN FOR A PARTICULAR APPLICATION, BUT THEN CAN BE ADAPTABLE TO OTHERS. NIH IS THE ONLY AGENCY I WAS AWARE OF. YOU PUT UP A LOT MORE. BUT NIH IS AN AGENCY THAT I'M AWARE HAS ACTUALLY SEVERAL PROGRAMS FOR SOFTWARE DEVELOPMENT.

AND SO MY QUESTION IS WHAT'S THE SPECIAL NEED FOR CIRM TO BE SUPPORTING SOFTWARE DEVELOPMENT IN THIS DOMAIN WHEN THERE ARE OTHER AGENCIES THAT ARE SUPPORTING SOFTWARE DEVELOPMENT THAT ALSO IS OPEN SOURCE AND COULD BE ADAPTED? IS THERE SOMETHING SPECIAL ABOUT THE WAY THAT YOU'RE GOING TO BE FRAMING THESE CHALLENGES FOR INVESTIGATORS THAT WILL GENERATE PROGRAMS OF IMMEDIATE USE FOR STEM CELL RESEARCH, OR I GUESS ANOTHER WAY TO PUT IT IS APPARENT IN LOOKING AT WHAT PRODUCTS ARE BEING GENERATED IN SOME OF THESE OTHER PROGRAMS, THAT THERE'S A NEED FOR SOFTWARE DEVELOPMENT THAT IS SPECIALIZED FOR STEM CELL RESEARCH?

DR. BYRUM: THANK YOU. YES. I THINK THIS SPECIFIC GAP IN OUR PORTFOLIO IS CONNECTING THESE DIFFERENT REGENERATIVE MEDICINE DATASETS SO THAT

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THEY'RE MORE INTEROPERABLE WITH CUTTING-EDGE COMPUTATIONAL INFRASTRUCTURE, WHETHER THAT IS AI OR NOVEL STATISTICAL FRAMEWORKS, OR KNOWLEDGE GRAPHS SO THAT THESE DATASETS THAT ARE DOMAIN SPECIFIC CAN BE INTEGRATED TO GLEAN INSIGHTS. AND WE DO HAVE IN OUR DISCOVERY PROGRAMS SOME NETWORK OR CONSORTIA TYPE OF AWARDS LIKE DISC4 THAT ARE GENERATING A LOT OF DATA. AND THEY HAVE A LOT OF POTENTIAL COLLABORATING, INTERACTING OPPORTUNITIES. AND SOME OF THIS IS HAPPENING ORGANICALLY.

BUT IF WE CAN SUPPORT THAT SYSTEMATICALLY THROUGH PROGRAMS THAT HAVE REQUIREMENTS TAILORED FOR SOFTWARE ENGINEERING TOOLS SO THAT THOSE TOOLS ARE USEFUL FOR OUR AWARDEES, BUT ALSO FOR THE COMMUNITY IN THAT THEY HAVE A LEG TO STAND ON IN TERMS OF BEING BROADLY USEFUL AND MAINTAINABLE, THEN THAT IS SOMETHING THAT WE'RE TRYING TO SUPPORT IN THIS PROGRAM, SOMETHING THAT WILL HAVE DIRECT IMPACT FOR OUR AWARDEES AND THE DATA TYPES THAT THEY'RE USING IN THEIR LABS AND HELP THEM INTERFACE WITH LARGER MODELS THAT THEY CAN USE FOR THEIR APPLICATION.

DR. YAMAMOTO: SO ARE YOU SAYING THAT -- JUST TO FOLLOW UP. ARE YOU SAYING THAT IN LOOKING AT THE PRODUCTS THAT ARE EMERGING FROM SOME OF THE NIH PROGRAMS, THAT IT'S APPARENT THAT CIRM REALLY

NEEDS TO MAKE THIS KIND OF INVESTMENT, WHICH SEVERAL PEOPLE HAVE ALREADY SAID IT'S A FAIR AMOUNT OF MONEY, IN ORDER TO REALLY COME UP WITH PRODUCTS THAT WILL BE SPECIFICALLY USEFUL FOR STEM CELL RESEARCH WHERE YOU THINK THAT THE STUFF COMING OUT OF NIH AND OTHER AGENCIES IS NOT ACTUALLY GENERATING THAT?

DR. BYRUM: I WOULD NOT SAY THAT THE STUFF COMING OUT OF NIH IS NOT RELEVANT TO OUR AWARDEES AND IT'S NOT USEFUL FOR THEM. I DO THINK THAT THE AREA IS STILL UNDERFUNDED AND THAT HAVING MORE FUNDING IN THIS AREA IN A TARGETING AREA WHERE WE KNOW IT WILL HAVE IMPACT FOR REGENERATIVE MEDICINE RESEARCHERS WILL BE MORE IMPACTFUL THAN JUST HOPING THAT THE NIH IS GOING TO FUND INVESTIGATORS THAT ARE BUILDING TOOLS THAT WILL ALSO BE USEFUL FOR OUR AWARDEES.

DR. YAMAMOTO: I GUESS -- SO PERFECTLY GOOD ANSWER. AND I GUESS THAT IN A WAY WILL SET UP THE KIND OF TESTS THAT WE'LL EXERT AS WE BEGIN TO SEE SOME OF THESE PRODUCTS EMERGE, WHETHER THERE'S A REAL INCREMENT IN THE RATE OF USEFULNESS AND APPLICABILITY OF THESE PRODUCTS THAT ARE COMING OUT OF CIRM RESEARCH AS OPPOSED TO OTHER AGENCIES. SO THAT'S GREAT. THANK YOU.

DR. BYRUM: ABSOLUTELY. AND ONE OTHER

NOTE THAT I'LL ADD IS THAT ONE OF THE REQUIREMENTS OF THIS PROGRAM WILL BE TO HAVE COMMUNITY AND CONTRIBUTOR ENGAGEMENT ACTIVITIES DURING THE DEVELOPMENT OF THE TOOL SO THAT THE POTENTIAL USERS WILL BE ABLE TO PROVIDE FEEDBACK EITHER THROUGH USER FEEDBACK CHANNELS OR HACKATHONS OR DIFFERENT TYPES OF ACTIVITIES SO THAT THEY CAN HAVE AN IMPACT ON THE EVENTUAL UTILITY OF THE TOOL AND HAS MORE LIKELIHOOD OF BEING ADOPTED BY MORE USERS.

DR. YAMAMOTO: EXCELLENT. THANK YOU.

MS. MANDAC: MARK, THERE ARE NO ADDITIONAL HANDS RAISED.

CHAIRMAN FISCHER-COLBRIE: OKAY. GREAT. IF WE CAN HAVE A CALL FOR A VOTE, SCOTT.

MR. TOCHER: SURE. YOU BET.

MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

CHAIRMAN FISCHER-COLBRIE: YES.

MR. TOCHER: JUDY GASSON.

DR. GASSON: YES.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN FISCHER-COLBRIE: YES.

MR. TOCHER: PAT LEVITT.

DR. LEVITT: YES.

MR. TOCHER: SHLOMO MELMED.
DR. MELMED: YES.
MR. TOCHER: CHRIS MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: SHAUNA STARK.
DR. STARK: YES.
MR. TOCHER: KAROL WATSON.
DR. WATSON: YES.
MR. TOCHER: AND KEITH YAMAMOTO.
DR. YAMAMOTO: YES.
MR. TOCHER: GREAT. THANKS VERY MUCH. MOTION CARRIES. MARK.
CHAIRMAN FISCHER-COLBRIE: GREAT. WITH THAT, WE'LL TURN OVER THE NEXT AGENDA ITEM OVER TO ROSA.
DR. CANET-AVILES: THANK YOU, MARK. LET ME JUST GET TO MY -- IT HAPPENS FOR BEING -- TRYING TO MULTITASK. RIGHT?
SO THE NEXT ITEM IS ACTUALLY BROUGHT TO THE SCIENCE SUBCOMMITTEE AND FINANCE SUBCOMMITTEE THROUGH MEMORANDUM. AND THIS MEMORANDUM IS BASICALLY REGARDING THE AMENDMENTS FOR THE CLINICAL DEVELOPMENT AND THE RAPID CONCEPT PLANS. AND WHAT WE ARE ASKING IS -- THERE'S NO SLIDES FOR THIS. IT'S GOING TO BE SHORT. AND WHAT THE TEAM PROPOSES

IS AMENDMENTS TO THESE TWO PROGRAMS, THE CONCEPT PLANS, TO INCORPORATE TWO ELIGIBILITY CRITERIA.

THE BOARD HAD INITIALLY APPROVED THESE PROGRAMS, THE CONCEPT PLANS, FOR PDEV AND FOR -- IN MARCH OF 2025 WITH AN AMENDMENT IN 2026, IN MARCH '26, AND THEN THE RARE DISEASE ACCELERATION PLATFORM AND INNOVATION AND DELIVERY, THE RAPID PROGRAM, CONCEPT PLAN IN JANUARY OF THIS YEAR.

WHILE WE WERE IMPLEMENTING THE PROGRAMS, THE TEAM, WHICH IS NOW, WE ARE IMPLEMENTING THEM NOW, THE TEAM REALIZED THAT BOTH CONCEPT PLANS COULD BENEFIT FROM THE ADDITION OF TWO ELIGIBILITY CRITERIA THAT ARE ALREADY IN THE CLIN2 PROGRAM. AND THE PROPOSAL IS TO ADDITION THE FOLLOWING ELIGIBILITY CRITERIA.

ONE HAS TO DO WITH THE CIRM APPLICANT BEING REQUIRED TO SERVE AS THE IND SPONSOR FOR THE PROPOSED THERAPEUTICS. SO THE MPT THAT'S NAMED AS THE SPONSOR OF THE IND SHOULD BE THE CIRM APPLICANT.

AND THE SECOND ONE COULD BE THAT THE APPLICANTS MUST INCORPORATE THAT AT LEAST ONE CALIFORNIA CLINICAL TRIAL SITE AS APPROPRIATE TO THE STAGE AND THE SCOPE OF THE PROPOSED ACTIVITIES. THIS INCLUDES CONSIDERATION OF CALIFORNIA SITES AND CLINICAL DEVELOPMENT PLANNING ACTIVITIES, INCLUSION

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OF A CALIFORNIA SITE IN CLINICAL TRIAL SITE OPPORTUNITIES IS PROPOSED, AND INCLUSION OF AT LEAST CALIFORNIA SITE IN CLINICAL TRIAL CONDUCT AS APPLICABLE. AND THAT WOULD BE IN THE RAPID VALIDATION AWARDS.

APPLICANTS WOULD HAVE TO JUSTIFY THE INCLUSION OF ANY SITES THAT WERE LOCATED OUTSIDE OF CALIFORNIA AND WILL BE ENCOURAGED TO USE OUR ALPHA CLINIC INFRASTRUCTURE SITES WHEN FEASIBLE.

AND THE PROPOSED CHANGES ARE SUPPORTED BY THREE CONSIDERATIONS. THE FIRST ONE IS THE PATIENT ACCESS AND STATE BENEFIT. THE SECOND IS OPERATIONAL OVERSIGHT AND ACCOUNTABILITY, REQUIRING THAT THE CIRM APPLICANT TO SERVE AS THE IND SPONSOR WILL ENSURE APPROPRIATE OVERSIGHT, ACCOUNTABILITY, AND ALIGNMENT BETWEEN THE FUNDED ENTITY AND THE REGULATORY RESPONSIBILITY FOR THE CLINICAL PROGRAM. AND THE THIRD ONE, THE PROGRAMMATIC CONSISTENCY BECAUSE WE ARE ALIGNING THE REQUIREMENTS FROM THE PRECLINICAL, PDEV AND RAPID, AND WITH THE CLIN2 WHICH PROMOTES CONSISTENCY AND PROGRAM IMPLEMENTATION AND CLARITY FOR APPLICANTS AS WELL AS CONSISTENCY IN REVIEW.

AND IN SUMMARY, THE CIRM TEAM REQUESTS THAT THE SCIENCE SUBCOMMITTEE RECOMMEND APPROVAL OF

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THE TWO ADDITIONAL ELIGIBILITY CRITERIA FOR THESE CONCEPT PLANS TO THE FULL BOARD, AND IT COULD GO IN THIS MEMO.

ANY QUESTIONS?

CHAIRMAN FISCHER-COLBRIE: GREAT. BEFORE WE GET INTO DISCUSSION OR QUESTIONS, IF WE COULD GET A MOTION AND A SECOND FOR AUTHORIZATION OF THE AMENDMENTS.

DR. GASSON: SO MOVED.

CHAIRMAN IMBASCIANI: SECOND.

CHAIRMAN FISCHER-COLBRIE: GREAT.

MR. TOCHER: SORRY. WHO WAS THE SECOND?

CHAIRMAN IMBASCIANI: VITO.

MR. TOCHER: GREAT. THANK YOU.

CHAIRMAN FISCHER-COLBRIE: GREAT. WITH THAT, LET'S OPEN UP FOR QUESTIONS. AND, CLAUDETTE, IF YOU CAN GUIDE THAT.

MS. MANDAC: DR. MELMED.

DR. MELMED: THANK YOU. THANK YOU, ROSA. THESE ARE VERY IMPORTANT PROGRAMS. CLINICAL TRIALS AND CLINICAL RESEARCH ARE EXTREMELY COMPLICATED. AND I DON'T KNOW WHY WE'RE RESTRICTING THE PI TO BE THE IND HOLDER. MANY IND HOLDERS DON'T HAVE TO BE THE PI, AND SOMETIMES IT'S THE SENIOR PERSON IN THE LAB OR IN THE PROGRAM. THE PI MAY BE SOMEBODY

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LATERAL OR MORE ON JUNIOR.

SO CAN YOU EXPLAIN MORE CLEARLY WHY CIRM WOULD PREFER THAT THEY BE THE SAME PERSON? I MEAN THERE ARE SO MANY BURDENS FOR CLINICAL RESEARCH. JUST ADDING ANOTHER BURDEN WITHOUT MORE CLEAR JUSTIFICATION SEEMS TO ME TO BE A LITTLE BIT INCONGRUOUS. MAYBE YOU CAN JUST TELL US WHAT YOUR THINKING IS.

DR. CANET-AVILES: THANK YOU, DR. MELMED. I THINK THE IND SPONSOR, WHICH COULD BE THE MPT NAMED AS THE SPONSOR ON THE IND FOR THE PROPOSED THERAPEUTICS OR IN THE CASE OF THE PI, IF IT'S AN INVESTIGATOR SPONSOR IND. AND AS I MENTIONED, WHAT WE ARE THINKING HERE IS OPERATIONAL OVERSIGHT AND ACCOUNTABILITY. WE ARE REQUIRING THAT THE PI WHICH IS RESPONSIBLE FOR THAT AWARD WILL BE THE IND SPONSOR AS WELL, ENSURING APPROPRIATE OVERSIGHT AND ACCOUNTABILITY AND ALIGNMENT BETWEEN WHAT THE FUNDED ENTITY AND THE REGULATORY RESPONSIBILITY FOR THE CLINICAL PROGRAM ARE.

AND I DO NOT UNDERSTAND WHY THE PI WHO WOULD BE THE PERSON THAT COULD HAVE APPLIED FOR THE AWARD THAT'S LEAVING THAT AWARD COULD NOT BE ABLE TO ALSO BE THE SPONSOR OF THE IND.

DR. MELMED: I KNOW YOU'RE REQUIRING IT,

BUT YOU'RE NOT EXPLAINING TO US WHY YOU'RE REQUIRING IT BECAUSE THE IND IS USUALLY HELD BY A SENIOR PERSON AND/OR BE ACTIVE IN THE CLINICAL TRIAL. AND I HAVEN'T HEARD FROM YOU A RATIONALE FOR WHY IT SHOULD BE THE SAME PERSON. WE'RE JUST PUTTING AN EXTRA BURDEN ON THE CLINICAL TEAM. AND I KNOW YOU'RE REQUIRING IT, BUT CAN YOU EXPLAIN TO US -- GIVE US MORE OF A RATIONALE WHY BECAUSE THE IND HOLDER, MAYBE SOMEBODY WHO'S SENIOR WHO IS NOT ACTIVE CLINICALLY WHO'S REGISTERED THE IND, MAYBE EVEN TEN YEARS AGO, FIVE YEARS AGO, AND MAY NOT BE THE PI. AND IF THE PI IS FELT BY THE PEER REVIEWERS TO BE COMPETENT AND UP TO OUR STANDARDS, THEN THAT SHOULD BE THE CRITERION. BUT THIS IS AN ADMINISTRATIVE BURDEN WHICH WE'RE ADDING WHICH I DON'T SEE THE BENEFIT FOR.

DR. CANET-AVILES: I DON'T KNOW. WE WOULD HAVE TO DISCUSS IT OFFLINE. I DON'T KNOW IF JENN LEWIS WHO HAS BEEN DEVELOPING THEM, AND THESE ARE SOME OF THE ELIGIBILITY REQUIREMENTS. OR GIL WOULD LIKE TO WEIGH INTO THIS OR J.T.

DR. SAMBRANO: I CAN --

DR. CANET-AVILES: IT WAS OPERATIONAL OVERSIGHT AND ACCOUNTABILITY. PLEASE GO AHEAD, GIL.

DR. SAMBRANO: YEAH. I CAN ADD. SO IT'S

A GOOD QUESTION. IT'S ALSO SOMETHING THAT WE ESTABLISHED MORE THAN TEN YEARS AGO AS A REQUIREMENT FOR OUR CLINICAL TRIALS. AND THE THINKING, I THINK, AS ROSA WAS SAYING, WAS THAT WE WANT TO MAKE SURE THAT WE HAVE THE ACCOUNTABILITY FROM THE APPLICANT ORGANIZATION, WHICH OFTEN IS THE IND HOLDER AS WELL, IT'S NOT OFTEN NECESSARILY AN INDIVIDUAL, BUT IN THE CASES WHERE IT WOULD BE AN INDIVIDUAL, SUCH AS AN INVESTIGATOR LED IND, WE WOULD WANT THEM TO BE THE SAME.

AGAIN, IT'S BECAUSE THERE ARE REGULATORY CHANGES THAT CAN HAPPEN TO THE CLINICAL TRIAL THAT WE WANT TO HAVE ACCESS TO AND BE AWARE OF WHILE MANAGING THE AWARD SO THAT THEY ARE CONCORDANT AND THAT THERE ISN'T ANYTHING THAT HAPPENS INDEPENDENTLY OF THAT AWARD OR IN A WAY THAT IT AFFECTS THE AWARD SUCH THAT IT THEN CAN'T BE SUCCEED.

SO BY MAKING THIS REQUIREMENT, THEN WE ENSURE THAT THERE'S UNITY BETWEEN THE AWARD ACTIVITIES AS WELL AS THE ACTIVITIES THAT ARE HAPPENING UNDER THAT IND. AND SO THAT WAS JUST SOMETHING THAT FROM THE ONSET WE ESTABLISHED, AND I THINK THIS ADDITION INTO THE ELIGIBILITY CRITERIA IS SIMPLY ALIGNING IT WITH WHAT WE'VE DONE IN THE PAST.

DR. CANET-AVILES: THANK YOU, GIL. AND

JUST TO CLARIFY --

CHAIRMAN FISCHER-COLBRIE: I CAN ANSWER --

DR. CANET-AVILES: -- A CLIN2 ALREADY --

CHAIRMAN FISCHER-COLBRIE: IF I COULD ASK FOR A CLARIFICATION. GIL, YOU INDICATED THIS IS INHERENTLY SOMETHING THAT WE ESTABLISHED TEN YEARS AGO. IS THIS THEN A PHENOMENON OF JUST ENSURING A SPECIFIC CALL-OUT FOR THOSE PROGRAMS WITHIN THE PDEV STRUCTURE? IS THAT INHERENTLY HOW WE'RE THINKING ABOUT THIS?

DR. SAMBRANO: YES. I BELIEVE SO, BUT I THINK ROSA CAN CLARIFY THAT.

DR. CANET-AVILES: YEAH. NO. BASICALLY WE FORGOT TO ADD IT IN THE PDEV AND THE RAPID. IT WASN'T IN THE CONCEPT. IT SHOULD HAVE BEEN ADDED IN THE CONCEPT. AND IT WAS JUST A MISTAKE THAT WE MADE IN THE CONCEPT DEVELOPMENT. SO WE ARE JUST BRINGING IT BACK BECAUSE WE DO NEED TO AMEND THE CONCEPTS. AND THIS IS JUST AS SIMPLE AS THAT.

CHAIRMAN FISCHER-COLBRIE: OKAY. BUT THIS REPRESENTS OUR POLICY FOR TEN YEARS?

DR. CANET-AVILES: YES.

CHAIRMAN FISCHER-COLBRIE: IS THAT ACCURATE?

DR. CANET-AVILES: YES, THAT IS CORRECT.

CHAIRMAN FISCHER-COLBRIE: OKAY. THANK YOU. OTHER DISCUSSION OR QUESTIONS? OKAY. SCOTT, IF YOU COULD CALL FOR A VOTE UNLESS THERE'S ANOTHER QUESTION.

MR. TOCHER: IT DOESN'T APPEAR THAT THERE'S ANOTHER QUESTION. MARIA BONNEVILLE.

DR. THOMAS: ACTUALLY, SCOTT, CAN I JUST STEP IN HERE? SO JUST I WANT TO REEMPHASIZE WHAT GIL AND ROSA HAVE SAID, THAT THIS IS MERELY A -- THIS IS ALMOST AN ADMINISTRATIVE TASK HERE TO HARMONIZE WHAT WE HAVE DONE FOR TEN YEARS AND EMBODY IT IN WHAT WE HAVE GOING FORWARD. SO TO ME THIS MAKES TOTAL SENSE.

I DO UNDERSTAND SHLOMO'S POINT, BUT THIS WAS AN ISSUE THAT WAS DISCUSSED AND FORMALIZED MANY YEARS AGO. DOESN'T MEAN IT'S NECESSARILY THE RIGHT MOVE IN TODAY'S TIMES, BUT I BELIEVE IT IS, AND IT DOES JUST BRING THINGS FULL CIRCLE. SO I JUST WANTED TO ADD THAT.

CHAIRMAN FISCHER-COLBRIE: THANK YOU, J.T. UNLESS THERE'S -- CONTINUE.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

CHAIRMAN FISCHER-COLBRIE: YES.
MR. TOCHER: JUDY GASSON.
DR. GASSON: YES.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN FISCHER-COLBRIE: YES.
MR. TOCHER: PAT LEVITT.
DR. LEVITT: YES.
MR. TOCHER: SHLOMO MELMED.
DR. MELMED: YES.
MR. TOCHER: CHRIS MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: SHAUNA STARK.
DR. STARK: YES.
MR. TOCHER: KAROL WATSON.
DR. WATSON: YES.
MR. TOCHER: AND KEITH YAMAMOTO.
DR. YAMAMOTO: YES.
MR. TOCHER: GREAT. THANK YOU. MARK, THAT MOTION CARRIED.
CHAIRMAN FISCHER-COLBRIE: GREAT. THANKS, SCOTT.
AND WITH THAT, LET'S GO TO THE NEXT AGENDA ITEM ON PATIENT PERSPECTIVE. AND I THINK THAT'S GOING TO BE LED BY GIL.
DR. SAMBRANO: YES, THANK YOU VERY MUCH.

SO LET ME SHARE MY SCREEN AND THE GET THE PRESENTATION GOING. OKAY. SO HOPEFULLY YOU CAN SEE THE FULL SCREEN. OKAY. PERFECT.

ALL RIGHT. SO THANK YOU VERY MUCH. I WANT TO PRESENT TO YOU OUR PROPOSAL FOR A PATIENT PERSPECTIVE SCORE AND GIVE YOU A LITTLE BACKGROUND ON HOW WE GOT HERE.

AND, AS ALWAYS, WE BEGIN WITH A STATEMENT OF OUR MISSION, BUT I THINK, PARTICULARLY IN THIS CASE, THE PROPOSAL TO ADD A PATIENT PERSPECTIVE SCORE REALLY DOES ALIGN WITH OUR MISSION. AND IT ALLOWS PARTICULARLY OUR PATIENT ADVOCATE MEMBERS OF THE BOARD THAT SERVE ON THE GRANTS WORKING GROUP TO MORE FULLY PARTICIPATE IN ACHIEVING THIS MISSION, AT LEAST WHEN IT COMES TO THE GRANT WORKING GROUP REVIEWS.

SO THE PURPOSE OF THIS PATIENT PERSPECTIVE SCORE IS ULTIMATELY TO PROVIDE OUR PATIENT ADVOCATE AND NURSE MEMBERS OF THE GRANTS WORKING GROUP A FORMAL MECHANISM TO SHOW THEIR VIEWPOINT OF APPLICATIONS THAT ARE UNDER REVIEW. THEY PARTICIPATE ALREADY IN EVALUATING OUR CLINICAL PDEV APPLICATIONS; BUT OTHER THAN PROVIDING A SUGGESTED SCIENTIFIC SCORE, THEY DON'T HAVE A FORMAL WAY OF OTHERWISE PRESENTING WHAT THEIR VIEWPOINT ON THE

APPLICATION IS. AND SO THIS HELPS FORMALIZE THAT.

IT ALSO HELPS US FOCUS THEIR REVIEW ON APPLICATION ELEMENTS THAT ARE GOING TO BE MOST RELEVANT TO PATIENT ADVOCATE AND NURSE MEMBERS. AND BY DOING SO, I THINK WE ALSO ENHANCE THE DISCUSSION THAT HAPPENS AT THE GRANTS WORKING GROUP AND BRINGS THOSE PATIENT ADVOCATE AND NURSE MEMBERS A MUCH MORE ENHANCED ROLE, WHICH ULTIMATELY WAS OUR GOAL.

AND SO IN TERMS OF HOW THIS WORKS, ONLY THE PATIENT ADVOCATE AND NURSE MEMBERS OF THE GRANTS WORKING GROUP WOULD PROVIDE THIS PARTICULAR PATIENT PERSPECTIVE SCORE. AND IT WOULD BE USED IN THOSE FUNDING OPPORTUNITIES WHERE WE FORMALLY ASSIGN PATIENT ADVOCATES TO AN APPLICATION, SUCH AS THE CLIN AND PDEV PROGRAMS, BUT NOT DISCOVERY PROGRAMS. THE DISCOVERY PROGRAMS TYPICALLY HAVE TOO MANY APPLICATIONS FOR THAT TO BE PRACTICAL. AND THE CRITERIA THAT I'LL DESCRIBE TO YOU WOULD NOT NECESSARILY BE RELEVANT TO THOSE AS WELL.

AND SO AS SUCH, WE'RE GOING TO HAVE A SET OF REVIEW CRITERIA THAT ARE FOCUSED ON PATIENT-CENTERED ELEMENTS IN ORDER TO INFORM WHAT THAT SCORE WOULD BE. SO LET ME TELL YOU MORE ABOUT THAT.

SO THE REVIEW CRITERIA FOR THE PATIENT

PERSPECTIVE ARE AS SHOWN HERE. IN THINKING ABOUT HOW WE WOULD COME UP WITH A SET OF CRITERIA, WE LOOKED AT OTHER ORGANIZATIONS, OTHER FUNDING AGENCIES, SUCH AS PCORI AND OTHERS, THAT INCLUDE PATIENT ADVOCATES OR PATIENT MEMBERS AS PART OF THEIR REVIEW COMMITTEES AND HAVE AN EYE TOWARDS THINKING ABOUT PATIENT-CENTERED ELEMENTS IN ASSESSING APPLICATIONS.

SO FROM LOOKING ACROSS THESE, THERE WERE A FEW THEMES THAT WERE COMMON AMONG THEM, AND SO THOSE INFORMED WHAT YOU SEE HERE. AND SO STARTING OUT WITH RELEVANCE, I TRIED TO SUMMARIZE THESE WITH A ONE- OR TWO-WORD PHRASE AND A QUESTION TO MAKE IT SIMPLER.

SO FOR RELEVANCE, DOES THE PROJECT ADDRESS A REAL AND SIGNIFICANT PROBLEM FOR PATIENTS?

PATIENT BENEFIT, IF THIS THERAPY WERE TO BE SUCCESSFUL, WOULD IT MAKE A MEANINGFUL DIFFERENCE TO PATIENTS?

IS THIS PROJECT PATIENT CENTERED, MEANING IS THE PROPOSAL DESIGNED WITH THE AFFECTED PATIENT POPULATION IN MIND?

PATIENT ENGAGEMENT, IS THE PATIENT PERSPECTIVE INCLUDED AND USED TO INFORM THERAPEUTIC OBJECTIVES BY THE APPLICANT TEAM?

AND, LASTLY, CALIFORNIA BENEFIT, ULTIMATELY HOW BENEFICIAL WOULD THIS THERAPY BE FOR PEOPLE IN CALIFORNIA? THINKING OF IT IN A BROAD SENSE, NOT NECESSARILY TRYING TO DISTINGUISH OR COUNT HOW MANY SPECIFIC CALIFORNIANS ARE AFFECTED BY A DISEASE, BUT JUST GENERALLY THAT IT HAS AN IMPACT AND VALUE TO CALIFORNIA.

MANY OF THESE CRITERIA, PARTICULARLY THE RELEVANCE AND PATIENT BENEFIT, ARE ALIGNED WITH THE VALUE PROPOSITION THAT WE ASK SCIENTIFIC MEMBERS TO ADDRESS AS WELL. AND SO I THINK THIS ALIGNS WITH IT SO THAT IT ALSO ENHANCES THE CONVERSATION AND BRINGS THE PATIENT ADVOCATES AND SCIENTISTS TOGETHER IN DISCUSSING AND THINKING ABOUT THE VALUE PROPOSITION OF APPLICATIONS.

THE PATIENT-CENTERED ELEMENTS AS WELL AS PATIENT ENGAGEMENT ARE RELATED TO THE POPULATION IMPACT, ELEMENTS THAT ARE, AGAIN, ALREADY IN THE CRITERIA THAT WE UTILIZE FOR THE SCIENTIFIC MEMBERS. SO I THINK, IN GENERAL, THERE IS ALIGNMENT THAT WILL ALLOW THESE CRITERIA TO COMPLEMENT WHAT THE SCIENTIFIC MEMBERS ARE ALREADY DOING AND PROVIDING INDEPENDENTLY IN THEIR OWN SCORE.

THE SCORING METHODOLOGY THAT WE PROPOSE IS A SIMPLE ONE TO FIVE SCALE THAT HELPS US ASSIGN A

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-920-3543 CACSR7152@OUTLOOK.COM

VALUE TO EACH SCORE AND ALSO JUST MAKES IT PRETTY STRAIGHTFORWARD TO INTERPRET. WITH FIVE BEING THE HIGHEST POSSIBLE SCORE WOULD MEAN THAT, IF WE THINK OF PATIENT VALUE AS THE COMPOSITE OF THE CRITERIA THAT I JUST DESCRIBED TO YOU, AN APPLICATION THAT SCORES A FIVE WOULD HAVE EXCEPTIONAL OVERALL PATIENT VALUE. SOMETHING THAT SCORES A THREE WOULD HAVE A MODERATE PATIENT VALUE. SOMETHING THAT GETS A ONE WOULD BE INADEQUATE PATIENT VALUE AND OTHERS IN BETWEEN.

SO THIS IS THE PROPOSED SCORING SCALE. AND, OF COURSE, ONE OF THE THINGS THAT WE DISCUSSED WITH OUR PATIENT ADVOCATE MEMBERS THAT SERVE ON THE GRANTS WORKING GROUP IS THAT HAVING A ROBUST DISCUSSION IS GOING TO BE REALLY KEY AND IMPORTANT IN NOT ONLY INFORMING THIS SCORE, BUT ALSO ENSURING THAT THE SCORES BETWEEN SCIENTIFIC MEMBERS IN THEIR OWN SCORING ARE ALIGNED WITH THE THINKING AND INCORPORATE THE PERSPECTIVE OF PATIENTS AND VICE VERSA.

AND SO WE IMAGINE THERE MIGHT BE SITUATIONS WHERE THERE MIGHT BE DIFFERENCES IN SCORES, AND THAT SUCH DIFFERENCES IN SCORES IF YOU, FOR EXAMPLE, HAVE A HIGH SCIENTIFIC SCORE BUT A LOW PATIENT PERSPECTIVE SCORE, THAT THAT WOULD TRIGGER

DISCUSSIONS WITHIN THE GRANTS WORKING GROUP TO RESOLVE AND ADDRESS SO THAT WE CAN BRING THAT RATIONALE TO THE BOARD SHOULD IT REMAIN -- SHOULD THAT DIFFERENCE REMAIN.

SO WHEN BRINGING THE PATIENT PERSPECTIVE SCORE AND THE APPLICATIONS TO THE APPLICATION REVIEW SUBCOMMITTEE, WHAT WE WANT TO DO IS MAKE SURE THAT, BECAUSE WE HAVE TWO DIFFERENT SCORES, IT IS CLEAR WHAT TO DO WITH THEM. SO, OF COURSE, THE SCIENTIFIC SCORE IS GENERALLY WHAT DETERMINES THE FUNDING RECOMMENDATION. ANYTHING THAT'S 85 OR ABOVE IS RECOMMENDED FOR FUNDING BY THE SCIENTIFIC PANEL, AND BELOW THAT IT IS NOT. AND SO BY FIRST DEFINING THAT FUNDABLE POOL OF APPLICATIONS BASED ON THE SCIENTIFIC SCORE, THEN WE WOULD WANT TO PRIORITIZE APPLICATIONS THAT RECEIVE ALSO A HIGH PATIENT PERSPECTIVE SCORE BECAUSE ULTIMATELY THEY REPRESENT WHAT WE WANT, GOOD SCIENCE AND A GOOD SCORE FROM THE PERSPECTIVE OF PATIENTS.

FOR ANYTHING THAT DOESN'T MEET THAT REQUIREMENT, MEANING IT HAS A HIGH SCIENTIFIC SCORE, BUT A LOW PATIENT PERSPECTIVE SCORE, AND HERE WE MEAN A SCORE OF TWO OR LESS IN THAT SCALE OF ONE TO FIVE, WE WOULD TRIGGER OR REQUIRE A DISCUSSION OF THAT APPLICATION IN ORDER TO JUSTIFY FUNDING IT

GIVEN THAT THERE IS SUCH A DIFFERENCE IN THE SCORING.

THE KEY POINTS FROM THE GRANTS WORKING GROUP DISCUSSIONS ON ANY DIFFERENCES AND/OR RATIONALE WOULD BE REFLECTED IN THE REVIEW SUMMARY. SO THAT WOULD BE SOMETHING THAT WOULD BE AVAILABLE AND PRESENTED TO THE BOARD FOR DISCUSSION SHOULD THAT BE THE CASE.

I WANT TO JUST SHOW YOU A REALLY QUICK EXAMPLE, AND THIS IS ALL A MADE-UP TABLE OF PDEV APPLICATIONS THAT ALL SCORED VERY HIGHLY SCIENTIFICALLY FROM 88 TO 92, ACCOMPANIED NOW BY WHAT WOULD BE A PATIENT PERSPECTIVE SCORE WHERE WE SHOW QUITE A VARIETY IN TERMS OF THE SCORING.

SO IN THE CASE OF THE THIRD APPLICATION IN THIS LIST THAT HAD A LOW PATIENT PERSPECTIVE SCORE, WE WOULD WANT TO TRIGGER A DISCUSSION OF THAT TO UNDERSTAND WHY IT HAD A LOWER SCORE THAN THE OTHERS.

I THINK, ALSO, IN THE CONTEXT OF HAVING OFTEN MORE APPLICATIONS RECOMMENDED FOR FUNDING THAN WE CAN ACTUALLY AFFORD TO FUND, THIS PROVIDES ANOTHER LAYER OF CONSIDERATION IN TERMS OF LOOKING AT THESE APPLICATIONS AND DETERMINING WHAT ULTIMATELY WE FUND. AND SO, FOR EXAMPLE, IF OUT OF THESE FIVE WE CAN ONLY FUND THREE, THE SCIENTIFIC

SCORE AND THAT RANK ORDER IS INFORMATIVE, BUT THEN LAYERING ON THE PATIENT PERSPECTIVE SCORE GIVES YOU MORE INFORMATION THAT MIGHT HELP DETERMINE WHAT ULTIMATELY GETS FUNDED. IN THIS CASE, FOR EXAMPLE, THE BOARD MIGHT CHOOSE TO FUND THE FIRST -- THE TOP TWO, SKIP OVER THE THIRD ONE AND, INSTEAD, FUND THE FOURTH. BUT, OF COURSE, THAT WOULD FOLLOW A DISCUSSION BY THE ARS.

ALL RIGHT. SO THAT'S THE PROPOSAL. I WANT TO JUST TELL YOU A LITTLE BIT ABOUT THE NEXT STEPS IN ROLLING THIS OUT. IF EVERYONE AGREES THAT THIS IS AN APPROACH THAT WE WANT TO TAKE AND THAT WE WANT TO ADOPT, WE WOULD BRING THIS TO THE FULL BOARD IN JUNE. WE WOULD IN JULY POST THE REVISED PROGRAM ANNOUNCEMENT FOR CLIN AND PDEV, WHICH ARE THE MOST IMPACTED AT THE MOMENT. AND THE FIRST INSTANCE WHERE THIS WOULD BE UTILIZED WOULD BE IN THE OCTOBER GRANTS WORKING GROUP REVIEW AND THEN BROUGHT TO THE BOARD IN DECEMBER. FOR PDEV THIS WOULD HAPPEN AT THE FEBRUARY GRANTS WORKING GROUP REVIEW OF NEXT YEAR FOLLOWED BY THE THEN MARCH ICOC.

PART OF WHAT WE WANT TO MAKE SURE WE DO AS WELL IS INFORM APPLICANTS IN THE PROGRAM ANNOUNCEMENT OF EXACTLY WHAT THE CRITERIA ARE, THE FACT THAT THERE IS A PATIENT PERSPECTIVE SCORE, AND

WHAT THAT MEANS. WE WANT TO BE AVAILABLE TO INFORM APPLICANTS ABOUT THIS SHOULD THEY HAVE QUESTIONS. WE ARE ALSO READY TO PROVIDE ADDITIONAL TRAINING TO REVIEWERS ON WHAT THIS SCORE IS ABOUT, HOW TO ENSURE THAT THIS IS INCORPORATED IN THE DISCUSSION, PARTICULARLY THOSE THAT CHAIR OUR REVIEW MEETINGS, SO THAT WE CAN MAKE SURE THAT THIS IS APPROPRIATELY INCORPORATED.

SO THOSE ARE THE NEXT STEPS. AND THAT'S AT THE END OF THE PRESENTATION. SO THANK YOU VERY MUCH, AND I'M HAPPY TO TAKE QUESTIONS.

MS. MANDAC: MARK AND THEN JOYCE FOLLOWED BY MARIA.

CHAIRMAN FISCHER-COLBRIE: GIL, JUST FOR CLARIFICATION. SUBSTANTIVELY, WE'RE NOT ASKING FOR A VOTE AT THIS TIME. THIS IS AN INFORMATIONAL PIECE. IT'S PART OF AN ONGOING DISCUSSION THAT'S GOING ON REAL-TIME. AND OBVIOUSLY WHAT WOULD OCCUR CERTAINLY FOR THE BOARD ARS MEETING COMING UP LATER; IS THAT CORRECT?

DR. SAMBRANO: YES. SO THIS IS -- SO THIS IS AN ITEM WHERE WE ARE PRESENTING WHAT WE PROPOSE TO DO IN TERMS OF THE SCORING MECHANISM AND BRING IT ABOUT. I THINK IT DOES NOT FORMALLY REQUIRE A VOTE, BUT I THINK HAVING YOUR BLESSING AS TO THIS IS A

PROCESS THAT WE WOULD LIKE TO ADOPT, AND HAVING YOUR FEEDBACK ON IT WOULD CERTAINLY BE IMPORTANT.

CHAIRMAN FISCHER-COLBRIE: OKAY. WITH THAT, LET'S CONTINUE THE DISCUSSION AND THEN MAKE THAT DETERMINATION ON THE FORMAL VOTE AS PART OF THAT.

MS. MANDAC: JOYCE.

CHAIRMAN FISCHER-COLBRIE: CLAUDETTE, IF YOU COULD GUIDE TRAFFIC. THANK YOU.

DR. SACKEY: THANK YOU. SO, GIL, THANK YOU FOR YOUR PRESENTATION, AND I AM ALL SUPPORTIVE OF HAVING A SORT OF STRUCTURED PROCESS IN PLACE FOR WHEN A DISCUSSION OUGHT TO TAKE PLACE AND OBVIOUSLY WHEN THERE'S A VARIANCE, THAT'S AN OBVIOUS TIME.

I GUESS WHAT I'M WONDERING ABOUT IS IT SOUNDS LIKE THE WAY YOU'RE PROPOSING THIS, AND MAYBE I MISUNDERSTOOD YOU, IS THAT WHEN THE SCIENTIFIC SCORE IS HIGH AND THE PATIENT SCORE, PERSPECTIVE SCORE, IS LOW, THERE WILL BE A DISCUSSION. AND I JUST WANT TO MAKE SURE THAT THAT PROCESS DOESN'T POTENTIALLY UNINTENTIONALLY PUT PRESSURE ON THE PATIENTS TO SORT OF FEEL LIKE THEY HAVE TO JUSTIFY THEIR LOW SCORE BECAUSE IT WAS HIGH SCIENTIFIC SCORE.

AND SO I'M WONDERING IF YOU WILL SET

THINGS UP SO THERE WILL BE DISCUSSION ON BOTH ENDS. SO IF THERE'S A HIGH PATIENT SCORE, BUT THE SCIENTIFIC SCORE IS LOW, ARE WE GOING TO ASK THE SCIENTIFIC REVIEW TEAM TO EXPLAIN THAT SO THAT IT DOESN'T SEEM LIKE WE ARE ONLY SELECTIVELY PICKING WHEN THE PATIENT SCORE IS LOW TO HAVE A CONVERSATION SO SOMEHOW WE'RE NOT INADVERTENTLY SORT OF FORCING THEM TO SORT OF BEAR THE BURDEN OF REDUCING THE VARIANCE BETWEEN THE TWO SCORES. DO YOU SEE WHAT I'M GETTING AT?

DR. SAMBRANO: YES. AND SO I THINK IF THERE IS ANY DIFFERENCE AT THE GRANTS WORKING GROUP MEETING ITSELF, WE WOULD ENSURE THAT THERE IS A DISCUSSION. AND EITHER THERE IS A RESOLUTION, MEANING THAT THE SCIENTIFIC MEMBERS MAY INFLUENCE THE PATIENT PERSPECTIVE SCORE OR VICE VERSA, AND THEY MAY ALIGN. IF AFTER THAT, WE STILL HAVE A DIFFERENCE, THE DRIVER FOR ULTIMATELY WHAT WE FUND IS THE SCIENTIFIC SCORE. AND SO IF WE HAVE A LOW SCIENTIFIC SCORE, THEN IT KIND OF DOESN'T MATTER THAT THE PATIENT PERSPECTIVE SCORE IS HIGH. AND SO THAT'S WHY WE'RE FOCUSING ON THOSE THAT ARE RECOMMENDED FOR FUNDING OR THOSE THAT HAVE THE POTENTIAL TO BE FUNDED IS WHERE WE WOULD LOOK AT POTENTIAL DIFFERENCES IN, THEN, THE PATIENT

PERSPECTIVE SCORE. AND ONLY IN THE CASES, THEN, WHERE WE HAVE A REAL DIFFERENCE WOULD WE WANT TO HAVE AND TRIGGER A DISCUSSION.

DR. SACKEY: SO, GIL, THANK YOU. I THINK YOU CONFIRMED WHAT I WAS SUSPECTING, WHICH IS THE SCIENTIFIC SCORE IS WEIGHTED MORE HEAVILY THAN THE PATIENT PERSPECTIVE SCORE. AND I GET WHERE YOU'RE COMING FROM. I GUESS I JUST WANT TO GIVE US A LITTLE CAUTION THERE, THAT WHEN WE'RE INVITING THE PATIENT PERSPECTIVE TO SORT OF JUSTIFY WHY THEY'RE GIVING A LOW SCORE, WE CREATE AN ENVIRONMENT THAT IS SEEN LIKE WE'RE PUTTING UNDUE PRESSURE AND SAYING, HEY, YOU NEED TO -- THERE'S A DISCREPANCY HERE, AND YOU NEED TO SORT OF GET WITH THE PROGRAM BECAUSE THE SCIENTIFIC SCORE REALLY LITERALLY TRUMPS EVERYTHING.

DR. SAMBRANO: YEAH. OR MAY NOT FROM A PROGRAMMATIC PERSPECTIVE. AND I THINK THAT IS -- I MEAN IT'S A VERY GOOD QUESTION. BUT I GUESS I'M TRYING TO IMAGINE A SITUATION IN WHICH YOU WOULD HAVE A DIFFERENCE. I MEAN I WOULD BE CONCERNED ABOUT AN APPLICATION THAT FROM A SCIENTIFIC PERSPECTIVE SCORES WELL BECAUSE MAYBE IT'S AN EXCITING PROJECT; BUT FROM THE PATIENT PERSPECTIVE, IT'S SOMETHING WHERE THEY HAVE VIEWED IT AS THIS ISN'T OF ACTUAL VALUE TO PATIENTS. EITHER THE

THERAPY IS NOT IMPACTFUL TO PATIENTS, PATIENTS WOULD NOT ADOPT IT, BUT THIS IS ALSO SOMETHING THAT SCIENTIFIC MEMBERS OFTEN CONSIDER. SO I THINK THE LIKELIHOOD THAT YOU ARE GOING TO HAVE THAT DISCREPANCY IS GOING TO BE RARE.

BUT IF WE DO, THEN THE JUSTIFICATION IS SIMPLY ABOUT WHY WOULD WE FUND THIS, ACKNOWLEDGING THAT IT GOT A GOOD SCIENTIFIC SCORE, BUT ALSO POTENTIALLY KNOWING THAT THERE IS A CONCERN AS IT RELATES TO THE PATIENT VALUE. AND IF THERE IS A REASON WHY WE SHOULD FUND IT DESPITE THIS, MAYBE DUE TO MISUNDERSTANDING OR ANYTHING ELSE, THEN I THINK AT LEAST HAVING THAT DISCUSSION ALLOWS US TO MORE COMFORTABLY MOVE FORWARD WITH FUNDING IT. BUT IT SHOULD NOT NECESSARILY PRECLUDE IT FROM BEING FUNDED.

DR. SACKEY: THANK YOU.

DR. SAMBRANO: THANK YOU FOR THE QUESTION. MARIA.

VICE CHAIR BONNEVILLE: I WANTED TO SAY I LOVE THAT WE HAVE SORT OF AN EXTRA NEW DATA POINT TO CONSIDER AT THE APPLICATION REVIEW SUBCOMMITTEE BECAUSE I THINK IT'S GOING TO HELP US AS WE -- WE'VE TALKED ABOUT THIS A LOT -- AS WE START TO GET MORE AND MORE APPLICATIONS, WE HAVE LESS FUNDING, IT IS

REALLY JUST ANOTHER -- IT'S A GREAT ADDED WAY OF DETERMINING WHICH DIRECTION WE SHOULD GO. SO I LOVE THIS. SO THANK YOU.

AND THE SECOND THING IS, AND I WANT TO SAY THANKS TO YOU AND TO THE OTHER TEAMS, I KNOW WE FIRST STARTED TALKING ABOUT THIS, THE IMPLEMENTATION SEEMED LIKE IT COULD BE LONGER. AND THEN YOU GUYS CAME BACK AND SAID, NO, WE CAN MAKE IT HAPPEN SOONER. SO I WANT TO SAY THANK YOU FOR THAT. I REALLY APPRECIATE THAT YOU CONSIDERED THAT AND THAT MADE IT HAPPEN. SO THANK YOU.

DR. SAMBRANO: WELCOME.

DR. MIASKOWSKI: THANK YOU. THANKS, GIL AND THE TEAM, FOR DOING THIS. IT'S BEEN BACK AND FORTH, AND IT'S, I THINK, A REALLY, REALLY IMPORTANT THING.

JOYCE, I WANTED TO TALK A LITTLE BIT IN RELATIONSHIP TO YOUR COMMENT HAVING SERVED ON THE GWG. FROM MY PERSPECTIVE, THESE CRITERIA FORMALIZE WHAT THE PATIENT ADVOCATES AND NURSE MEMBERS ARE SAYING. AND I'VE BEEN ON THE GWG, I GUESS, NOW MAYBE FOUR OR FIVE YEARS. THE CHARACTER HAS CHANGED A LOT OF THOSE MEETINGS. AND I THINK WHAT YOU'RE A LITTLE BIT WORRIED ABOUT, GIVEN THE MEMBERS NOW, THE DYNAMIC IS WORKED OUT IN THE MEETING FROM MY

PERSPECTIVE.

AND THERE HAVE BEEN RECENTLY APPLICATIONS THAT HAD A BORDERLINE SCIENTIFIC SCORE WHERE PATIENT ADVOCATES AND NURSE MEMBERS HAVE SPOKEN AND SAID -- I REMEMBER I WAS ON ONE FOR A PEDIATRIC CONDITION WHERE THERE WASN'T EVEN A PEDIATRICIAN CONSULTED OR A MEMBER OF THE TEAM AND THAT WASN'T NOTICED. BUT AS WE TALKED ABOUT IT, WE BEGAN TO APPRECIATE THAT THAT WAS IMPORTANT. AND THESE DISCUSSIONS HAPPEN BEFORE THE FINAL SCORES ARE PUT IN.

SO I GUESS I'D JUST LIKE TO REASSURE YOU THIS IS GOING TO GIVE US A FORMALIZATION OF WHAT WE'RE ALREADY COMMENTING ON WITH A NUMBER. AND I THINK IT WILL HELP WITH THE DYNAMIC IN TERMS OF CONSIDERING THIS VERY, VERY IMPORTANT PART OF THE APPLICATIONS. SO...

DR. SACKEY: THANK YOU SO MUCH. THAT'S REALLY HELPFUL. APPRECIATE THAT.

DR. MIASKOWSKI: ONE CAVEAT I COULD SEE, GIL, THAT I WANT TO RAISE IS IF WE HAD AN APPLICATION THAT HAD AN 84 SCORE AND IT GOT A FIVE AND IT WAS RIGHT ON THINK BORDERLINE, THAT MIGHT BE ONE WHERE WE DO BRING IT FORWARD TO SAY WHAT'S THE VALUE PROPOSITION HERE. SO I OFFER THAT.

DR. SAMBRANO: ABSOLUTELY.

DR. MIASKOWSKI: BUT REALLY I DON'T KNOW IF THE OTHERS AGREE. IT'S BECOME A REALLY WONDERFUL EXPERIENCE TO SERVE ON THIS COMMITTEE. SO I JUST WANTED IT GIVE YOU THAT PERSPECTIVE.

MS. MANDAC: VITO.

CHAIRMAN IMBASCIANI: HI. YES. THANK YOU. CHRISTINE, THAT WAS REALLY A WONDERFUL SUMMARY OF THE PATIENT ADVOCATE PARTICIPATION AND ALL THE GRANTS WORKING GROUPS THAT I PARTICIPATE IN, AND I'M GLAD YOU RESPONDED TO JOYCE'S CONCERN AND YOU DID IT SO WELL AND IT WAS VERY ARTICULATE AND POWERFUL.

I WANT TO MAKE A COMMENT, NOT A QUESTION, GIL, ON THE ONE PAGE OF YOUR PRESENTATION THAT ACTUALLY HAS THE ONE THROUGH FIVE SCORING SYSTEM.

DR. SAMBRANO: YES. DO YOU WANT ME TO --

CHAIRMAN IMBASCIANI: IF YOU WOULD, JUST TO BRING IT UP. SO AND THIS IS IN THE SPIRIT OF JUST GOING AROUND AND KICKING THE TIRES BECAUSE I REALLY DO LIKE THE WORK THAT YOUR TEAM DID ON THIS AND SUPPORT THE WHOLE EFFORT. I THINK YOU'VE COME UP WITH SOMETHING THAT'S GOING TO BE VERY POWERFUL AND IMPACTFUL.

THAT ONE. THAT ONE.

THIS LOOKS LIKE SO EASY THAT ANYBODY COULD

PUT SOMETHING LIKE THIS TOGETHER, BUT THERE'S ACTUALLY AN AWFUL LOT OF RESEARCH. I WENT ONTO THE WEBSITES OF A NUMBER OF PATIENT-CENTERED OUTCOME SCORING SYSTEMS. YOU REFERENCE ONE, PCORI, WHICH HAPPENS TO BE A RESEARCH INSTITUTE. AND THERE'S A LOT OF RESEARCH THAT GOES BEHIND A SCORING SYSTEM CREATION SUCH AS THIS ONE. AND IT'S RESEARCHED, IT'S STRUCTURED, AND IT ACTUALLY IS WIDELY USED.

AND MY COMMENT IS ONLY THAT I THINK THAT WHAT YOU'VE COME UP WITH IS THE PERFECT SORT OF DISTILLATION OF MANY OF THOSE SYSTEMS AND WORDED IT APPROPRIATELY FOR CIRM'S MISSION WITH RESPECT TO OUR OWN GWG. SO I LIKE THIS VERY MUCH. THANK YOU.

DR. SAMBRANO: THANK YOU.

MS. MANDAC: J.T., YOU HAVE YOUR HAND RAISED?

DR. THOMAS: YES. SO A COUPLE THINGS. ONE IS I WANT TO GIVE A PARTICULAR SHOUT-OUT TO CHRIS WHO RAISED THE NOTION OF HAVING A SCORING SYSTEM LIKE THIS FOR PATIENT ADVOCATES AND, FURTHERMORE, DUBBED IT THE PATIENT PERSPECTIVE SCORE. SO THANK YOU VERY MUCH, CHRIS, FOR RAISING THAT IN A PREVIOUS DISCUSSION.

AND THE THING THAT I THINK IS SO PROFOUND ABOUT THIS IS THAT, GIVEN THE ADDED RESPONSIBILITY

OF THE ARS NOW IN THE NEW REGIME POST PREFERENCES, THIS GIVES PATIENT ADVOCATES AN ENHANCED ROLE, A DOUBLY IMPORTANT ROLE BOTH IN BEING ABLE TO PRESENT THEIR PERSPECTIVE IN THE GWG, BUT ALSO TO HAVE IT AS A FRONT AND CENTER POINT OF DISCUSSION AT THE ARS ITSELF.

SO I THINK THIS IS A MATERIAL ADVANCE IN THE EFFORT TO REALLY EMPHASIZE THE ROLE AND CONTRIBUTIONS OF THE PATIENT ADVOCATES. SO, CHRIS, THANKS VERY MUCH FOR THE IDEA.

CHAIRMAN FISCHER-COLBRIE: ANY OTHER COMMENTS OR QUESTIONS? I GUESS, THEN, IN ORDER TO HELP FACILITATE THE NEXT STEPS, WE CAN GO AHEAD AND DO A VOTE. SO IF WE COULD DO A MOTION AND A SECOND.

DR. DULIEGE: I'M NOT SURE IF I CAN MOVE.

CHAIRMAN IMBASCIANI: WHAT'S THE MOTION?

CHAIRMAN FISCHER-COLBRIE: SCIENCE COMMITTEE, ANYBODY DO A MOTION AND A SECOND?

DR. LEVITT: I'LL DO A MOTION.

VICE CHAIR BONNEVILLE: SO MOVED. I'LL DO SECOND.

CHAIRMAN FISCHER-COLBRIE: THANK YOU, PAT. OKAY. WITH THAT, SCOTT, IF YOU'VE GOT RECORDED THE NAMES FOR THAT, WE CAN GO AHEAD WITH A VOTE.

MR. TOCHER: SURE. I WOULD JUST QUICKLY

ASK. THIS WOULD BE A MOTION TO RECOMMEND SUPPORT OF THIS PROGRAM AS OUTLINED TO THE FULL BOARD IN JUNE.

DR. LEVITT: CORRECT.

CHAIRMAN FISCHER-COLBRIE: THAT'S CORRECT. THANK YOU --

MR. TOCHER: OKAY. AND IS THERE ANY PUBLIC COMMENT?

CHAIRMAN IMBASCIANI: -- FOR THE CLARIFICATION.

MR. TOCHER: SURE. IS THERE ANY PUBLIC COMMENT AS WELL BEYOND THE BOARD? I DON'T SEE ANY.

MS. MORALEZ: THERE DOESN'T SEEM TO BE.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

CHAIRMAN FISCHER-COLBRIE: YES.

MR. TOCHER: JUDY GASSON.

DR. GASSON: YES.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: YES.

MR. TOCHER: PAT LEVITT.

DR. LEVITT: YES.

MR. TOCHER: SHLOMO MELMED.

DR. MELMED: YES.

MR. TOCHER: CHRIS MIASKOWSKI.

DR. MIASKOWSKI: YES.
MR. TOCHER: SHAUNA STARK.
DR. STARK: THAT WAS A YES.
MR. TOCHER: THANK YOU. KAROL WATSON.
DR. WATSON: YES.
MR. TOCHER: AND KEITH YAMAMOTO.
DR. YAMAMOTO: YES.
MR. TOCHER: THANKS VERY MUCH. MARK, THE MOTION CARRIED.
CHAIRMAN FISCHER-COLBRIE: GREAT. EXCELLENT.
AND WITH THAT, LET'S MOVE FORWARD WITH THE CONSIDERATION OF RESEARCH BUDGET FOR NEXT YEAR. AND I BELIEVE THAT'S GOING TO BE HEADED UP JENNIFER.
MS. LEWIS: THANK YOU, MARK, AND THANK YOU, MEMBERS OF THE BOARD. GOOD NEWS. WE ARE MORE THAN HALFWAY THROUGH THE AGENDA. SO I APPRECIATE YOU STICKING WITH US THROUGH THIS AND YOUR TIME TODAY.
MY NAME IS JENNIFER LEWIS, AND I'M THE VICE PRESIDENT OF OPERATIONS AT CIRM. AND I'LL BE PRESENTING TO YOU THE RESEARCH BUDGET PROPOSAL FOR FISCAL YEAR 26/27.
AND AS WITH EVERYTHING AT CIRM, WE START WITH OUR MISSION, AND THAT'S NO DIFFERENT AS WE

THINK ABOUT HOW WE DEPLOY OUR FUNDS. AND YOU WILL SEE THAT AS WE GO THROUGH THIS PRESENTATION.

SO TODAY I'LL COVER AN OVERVIEW OF OUR GRANT FUNDS, A LOOK BACK AT FISCAL YEAR 25/26 AND THE APPROVED RESEARCH BUDGET AND ACTUALS, AND THEN A REVIEW OF THE PROPOSED RESEARCH BUDGET.

SO THIS SLIDE SHOWS THE TOTAL FUNDS AVAILABLE THAT CIRM HAS FOR RESEARCH. AND THE 7.72 BILLION INCLUDES PROP 14, PROP 71 FUNDS, AND THEN ANY FUNDS THAT HAVE BEEN RECEIVED FROM LOAN REVENUES FROM OUR LOAN PROGRAM. SO THOSE ARE GRANTS THAT ARE TURNED INTO LOANS.

AS YOU CAN SEE, THIS NUMBER HAS CHANGED SINCE LAST YEAR. IT INCREASED TO 57 PERCENT. SO AS TO DATE WE HAVE ENCUMBERED 4.43 BILLION, AND THERE IS A REMAINING BALANCE OF 3.29 BILLION.

AND JUST A CLARIFICATION. THIS INCLUDES ALL APPROVALS THAT HAVE OCCURRED DURING THE MARCH ICOC -- MARCH ARS MEETING.

THIS NEXT SLIDE SHOWS SPECIFICALLY PROP 14. SO PROPOSITION 14 HAS SPECIFIC ALLOCATIONS FOR CERTAIN TYPES OF PROGRAMS IN THE RESEARCH BUDGET. OF THE 3.4 BILLION THAT IS ALLOCATED FOR RESEARCH, THERAPY DEVELOPMENT, AND THERAPY DELIVERY, TO DATE WE'VE COMMITTED ROUGHLY JUST OVER ONE BILLION. FOR

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DISEASES OF THE BRAIN AND CENTRAL NERVOUS SYSTEM, TO DATE WE'VE COMMITTED 655 MILLION. AND FOR ACCESS AND AFFORDABILITY, AND APOLOGIES FOR THIS GRAPHIC, BUT WE HAVE 96 MILLION. AND TO DATE WE'VE COMMITTED 2 MILLION WITH 94 MILLION REMAINING.

ADDITIONALLY, PROP 14 HAS TWO ADDITIONAL EARMARKS FOR PARTICULAR PROGRAMS UNDERNEATH THE RESEARCH BUCKET. AND THIS INCLUDES SHARED RESOURCE LABS, WHICH IS 26 MILLION. AND TO DATE WE'VE COMMITTED 21 MILLION WITH 5 MILLION REMAINING. AND ADDITIONALLY, 78 MILLION FOR COMMUNITY CARE CENTERS OF EXCELLENCE. AND AS THIS COMMITTEE RECALLS, THE BOARD APPROVED THIS YEAR 27 MILLION FOR THREE COMMUNITY CARE CENTERS OF EXCELLENCE.

AND THEN, LASTLY, THIS SHOWS OUR HISTORICAL RESEARCH BUDGET PERFORMANCE SINCE 2021 AT THE START OF PROP 14. AND THE COMMITTED IS IN ORANGE AND UNCOMMITTED IN GREEN, BUT THAT'S ALSO THIS PENDING IN BLUE. AND WHAT I WANTED TO POINT OUT HERE IS THAT HISTORICALLY, SINCE 2021, THROUGH JUNE OF 2025, OUR PERFORMANCE HAS RESULTED WITH AN UNSPENT BALANCE OF ROUGHLY 27 PERCENT ON AVERAGE. AND THIS YEAR WE'RE LOOKING TO HAVE AN UNSPENT BALANCE OF ROUGHLY 14 PERCENT. AND I'LL EXPLAIN THAT MORE AS I LOOK AT THE ACTUALS, BUT I JUST

WANTED TO SHOW THAT. AS WE'VE STARTED TO HAVE THE STRATEGIC ALLOCATION FRAMEWORK AND EXECUTING ON THAT AND LOOKING AT OUR PLANNING, WE'VE REALLY STARTED TO DELIVER AND BE ABLE TO PLAN THAT OUT.

SO NOW I'LL DIVE INTO THE FISCAL YEAR 25/26 APPROVED RESEARCH BUDGET. AS YOU WILL RECALL, THE APPROVED BUDGET WAS 505 MILLION. TO DATE THE BOARD HAS COMMITTED 373 MILLION TOWARDS THAT BUDGET. AT THE JUNE ICOC, WE'LL HAVE TWO PROGRAM APPROVALS FOR OUR CLINICAL PROGRAM AND PRECLINICAL DEVELOPMENT PROGRAM. AND WE EXPECT TO END THE YEAR AT 435 MILLION, WHICH LEAVES A VARIANCE OF ROUGHLY 70 MILLION.

AND WHAT I'D LIKE TO FOCUS ON FOR YOU IS I'LL GO LINE BY LINE TO SHARE WITH YOU WHAT DRIVES THAT VARIANCE IN PARTICULAR.

FOR OUR CLINICAL DEVELOPMENT PROGRAM, YOU WILL SEE A $39-MILLION VARIANCE. THIS VARIANCE IS DUE TO ESSENTIALLY TIMING. ORIGINALLY AT THE BEGINNING OF THE YEAR, WE HAD ESTIMATED WE'D HAVE FOUR FUNDING CYCLES. BUT DUE TO THE IMPLEMENTATION OF NEW REVIEW PROCESSES AND SUCH, ONE REVIEW DID NOT OCCUR WITHIN THIS FISCAL YEAR. AND THE ACTUAL APPROVAL WILL OCCUR SHORTLY AFTER THE BEGINNING OF THE NEXT FISCAL YEAR. SO DUE TO THAT, THERE IS A

BALANCE THAT WE WOULD EXPECT AS WE ARE SHORT ONE REVIEW CYCLE FOR THAT PROGRAM.

FOR PRECLINICAL DEVELOPMENT, THERE IS A BALANCE OF 1.9 MILLION, WHICH IS DUE TO VARIANCES IN AWARD AMOUNTS AND PLANNING. SIMILARLY, WITH THE DISCOVERY PORTFOLIO, THERE IS 4.3 REMAINING THAT IS DRIVEN PRIMARILY BY THE DISC4 MULTIDISCIPLINARY PROGRAM.

THEN THERE'S THE EDUCATION VARIANCE WHICH SHOWS 56 PERCENT. AND THE REASON FOR THIS VARIANCE IS WE DID DELIVER ON SEVERAL CONFERENCES FOR GRANTEES, PARTICULARLY FOR OUR DISC4 COLLABORATIVE RESEARCH PROGRAM, FOR EDUCATION PROGRAMS FOR SPARK AND TRAINING CONFERENCES. HOWEVER, DUE TO THE ACTIVITY INTERNALLY IN LAUNCHING NEW CONCEPTS AND NEW PROCESSES AND REVIEWS, WE DIDN'T HAVE THE CAPACITY TO REALLY SCOPE OUT NEW CONFERENCES. HOWEVER, YOU WILL SEE IN THE NEXT FISCAL YEAR WE DO HAVE PLANNED AND WILL BE ABLE TO DELIVER ON NEW CONFERENCES FOR NEW CONCEPTS.

AND THEN, LASTLY, THE MAIN DRIVER OF THIS VARIANCE IS 24 MILLION FOR OUR INFRASTRUCTURE PILLAR. AND WHAT DRIVES THIS IS TWO THINGS. ONE IS THE COMMUNITY CARE CENTERS OF EXCELLENCE, AND THE BOARD APPROVED THREE AWARDS EARLIER THIS YEAR.

HOWEVER, THERE IS $9 MILLION REMAINING, WHICH THE BOARD HAS APPROVED A CONCEPT WHICH IS CURRENTLY OPEN FOR COMMUNITY CARE CENTERS OF EXCELLENCE NORTHERN CALIFORNIA AWARD. SO YOU WILL SEE THAT REQUEST IN THE NEXT YEAR'S FISCAL YEAR PLANNING.

ADDITIONALLY, WE HAD PLANNED IN THIS FISCAL YEAR TO BRING FORTH A COMPLEMENTARY PROGRAM TO THE COMMUNITY CARE CENTERS OF EXCELLENCE FOR COMMUNITY-BASED ORGANIZATIONS AND OUTREACH. DURING THE YEAR THE TEAM BROUGHT FORTH A STRATEGY FOR ACCESS AND AFFORDABILITY AS WELL AS WE RECENTLY HAD THE FULFILLMENT OF A VACANCY IN THAT AREA FOR A LEADER OF THE PATIENT ACCESS TEAM. AND SO THOSE PLANS ARE STILL ONGOING AND WILL BE COMING TO THE BOARD, BUT THEY JUST DIDN'T RESULT IN THIS FISCAL YEAR.

SO NOW I'LL GET INTO FISCAL YEAR 26/27 PROPOSED RESEARCH BUDGET. THE MAJOR DRIVERS OF THIS RESEARCH BUDGET, SO HERE ARE THE ACTIVITIES THAT WILL BE OCCURRING AND APPLICATIONS THAT WILL COME FORTH TO THE ARS THIS YEAR. RESEARCH AND DEVELOPMENT, YOU WILL SEE THE REGULAR CYCLES OF PDEV, RAPID, THE NEW RAPID PROGRAM THAT WAS APPROVED THIS YEAR, DISC4 AND DISC5, THERE WILL BE APPROVALS THROUGH THE FISCAL YEAR. THIS BUDGET INCLUDES NEW

CONCEPTS SUCH AS THE DATA SOFTWARE ENGINEERING CONCEPT THAT MY COLLEAGUE JANIE PRESENTED EARLIER TODAY AS WELL AS AN UPDATED CONCEPT TO THE CLIN2. THE TEAM WILL BE COMING WITH AN AMENDMENT FOR LATE-STAGE BLA-RELATED ACTIVITIES.

IN EDUCATION YOU WILL SEE ACTIVITIES RELATED TO CONFERENCE GRANTS, AS MENTIONED; BUT, IN ADDITION, WE'LL BE REQUESTING AN ALLOCATION OF FUNDS FOR A RENEWAL FOR THE BRIDGES/COMPASS PROGRAM -- APOLOGIES -- A RENEWAL FOR THE CIRM SCHOLARS PROGRAM. AND IN ADDITION, YOU WILL SEE FUNDS ALLOCATED FOR THE SPARK AND THE BRIDGES/COMPASS PROGRAM.

AND, LASTLY, THERE ARE FUNDS ALLOCATED, AS MENTIONED, FOR THE COMMUNITY CARE CENTERS OF EXCELLENCE NORTHERN CALIFORNIA.

SO HERE'S A BREAKDOWN OF WHAT THAT LOOKS LIKE. FOR THE DISCOVERY BUDGET, WE'RE REQUESTING 136.5 MILLION. THIS IS 84 MILLION FOR THE DISC4 MULTIDISCIPLINARY COLLABORATION AWARDS, WHICH SHOULD YIELD ROUGHLY SIX AWARDS. IN ADDITION, THIS IS FOR THE DISC5 FOUNDATION AWARDS, WHICH IS 52.5 MILLION AND ROUGHLY 21 AWARDS.

FOR THE PRECLINICAL BUDGET, WE'RE REQUESTING 146 MILLION. THAT IS 91 MILLION FOR

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PRECLINICAL DEVELOPMENT AWARDS, AND THAT CAN RANGE BETWEEN 7 AND 12 AWARDS. AS YOU RECALL, THAT PROGRAM HAS TWO ENTRY POINTS. THERE CAN BE A REQUEST FOR THE FULL SCOPE OF PRECLINICAL DEVELOPMENT OR A REQUEST TO COME IN AT WHAT WE CALL LATE STAGE FOR LESS DOLLARS.

IN ADDITION, THE RAPID PROGRAM WILL BE -- THE FIRST RAPID AWARDS WILL BE APPROVED THIS YEAR, AND THAT ALLOCATION IS 55 MILLION, WHICH COULD YIELD ROUGHLY TWO TO THREE AWARDS.

AND THEN, LASTLY, WE'RE REQUESTING 160 MILLION FOR THE CLINICAL BUDGET, WHICH WOULD YIELD ANYWHERE BETWEEN 11 AND 20 AWARDS DEPENDING ON THE PHASE THAT THE AWARDS COME IN AT.

AND THEN, LASTLY, AS MENTIONED, EDUCATION BUDGET, WE'RE REQUESTING A TOTAL OF 200.5 MILLION. THAT'S FOR THE EDUC8 PROGRAM, 99 MILLION FOR 18 AWARDS. WE WILL BE BRINGING FORTH IN SEPTEMBER OF THIS YEAR A REQUEST FOR AN AWARD EXTENSION FOR THE EDUC4 CIRM SCHOLARS PROGRAM AND CURRENTLY SETTING ASIDE 90 MILLION AS WE DEVELOP THAT PROPOSAL. WE ARE REQUESTING 9 MILLION FOR EDUC3 WHICH WOULD YIELD 12 AWARDS, AND THEN 2.5 MILLION FOR EDUC1 FOR SEVEN TO TEN CONFERENCES.

AND THEN, LASTLY, THE TOTAL INFRASTRUCTURE

BUDGET REQUEST IS 19 MILLION. THIS IS FOR ONE AWARD FOR THE COMMUNITY CARE CENTERS OF EXCELLENCE DELIVERY AT 9 MILLION. AND THEN $10 MILLION FOR THE DATA SCIENCE AND SOFTWARE ENGINEERING AWARDS.

AND SO HERE IS A SUMMARY. THAT BRINGS THE TOTAL TO 662 MILLION FOR THE BUDGET REQUEST FOR THIS YEAR. AND I'D LIKE TO OPEN IT UP FOR ANY QUESTIONS OR DISCUSSION.

CHAIRMAN FISCHER-COLBRIE: YEAH. AND BEFORE WE GET INTO THE DISCUSSION, IF WE CAN GET A MOTION AND A SECOND FOR APPROVAL OF THE RECOMMENDED BUDGET.

CHAIRMAN IMBASCIANI: I MOVE THAT THE BUDGET BE ACCEPTED.

DR. DULIEGE: AND I SECOND. HAPPY TO SECOND.

CHAIRMAN FISCHER-COLBRIE: GREAT. AND WITH THAT, LET'S OPEN IT UP FOR DISCUSSION.

MR. TOCHER: SORRY, MARK. THIS IS SCOTT. THIS IS WILL BE VOTED ON BY THE SCIENCE SUBCOMMITTEE. FINANCE, YOU'RE UP NEXT, I PROMISE. BUT FOR THIS, IT WILL BE SCIENCE SUBCOMMITTEE AGAIN. SO IF WE COULD HAVE ANOTHER MEMBER MAKE THE SECOND.

DR. LEVITT: I'LL SECOND.

CHAIRMAN FISCHER-COLBRIE: THANKS, PAT.

MR. TOCHER: GREAT. THANK YOU.

CHAIRMAN FISCHER-COLBRIE: OKAY. QUESTIONS FROM THE BUDGET? CLAUDETTE, I DON'T KNOW IF YOU SEE ANYBODY WITH A HAND RAISED.

MS. MANDAC: NO HANDS RAISED SO FAR, MARK.

CHAIRMAN FISCHER-COLBRIE: OKAY. ANY PUBLIC COMMENT OR QUESTIONS?

MS. MANDAC: THERE ARE NO HANDS RAISED FROM THE PUBLIC EITHER.

CHAIRMAN IMBASCIANI: WELL --

CHAIRMAN FISCHER-COLBRIE: IS THAT -- VITO, DID YOU HAVE --

CHAIRMAN IMBASCIANI: YEAH. ACTUALLY SORT OF LIKE A DEVIL'S ADVOCATE QUESTION. SOMEBODY FROM THE PUBLIC MAY ASK OR SOMEBODY FROM THE BOARD MIGHT ASK HOW IS IT OUR BUDGET ASK SEEMS TO EXCEED THE AMOUNT OF DOLLARS THAT WE CAN OBTAIN BY THE SALE OF BONDS EACH YEAR.

MS. LEWIS: SURE. YEAH. SO FOR EVERYONE'S KNOWLEDGE, THE PROP 14 DELINEATES HOW MUCH WE CAN REQUEST EACH YEAR FOR OUR BUDGET AS WELL AS SALE OF BONDS. THERE'S AN EARMARK THERE.

IN TERMS OF THE -- FIRST OFF, ANNUAL REQUESTS, ANY TIME WE HAVE AN UNCOMMITTED BALANCE IN A GIVEN YEAR, WE CAN CARRY FORWARD THOSE FUNDS TO

ALLOCATE TO FUTURE YEARS. AND AS SHOWN IN THE HISTORICAL PERFORMANCE SLIDE, WE HAVE HAD SEVERAL YEARS WHERE WE HAVE NOT REACHED THAT THRESHOLD. AND SO WE CARRY FORWARD THAT BALANCE.

IN ADDITION, THAT INCLUDES ALSO WITH OUR SALE OF BONDS. SO THERE IS A THRESHOLD CAP FOR THAT, BUT THIS 662 MILLION WON'T BE ALL BE ALLOCATED IN THIS YEAR CASH SPENT. THAT BOND SALE IS FOR CASH SPENT. THAT CASH SPENT IS FOR ACTIVE AWARDS AND PROBABLY INITIAL PAYMENTS FOR SEVERAL OF THESE PROGRAMS THAT WILL BE APPROVED THIS YEAR.

CHAIRMAN IMBASCIANI: THANKS, JENN.

MR. TOCHER: ALL RIGHT. I'LL PROCEED WITH THE ROLL. SORRY, MARK.

CHAIRMAN FISCHER-COLBRIE: THANK YOU. NO, THAT WAS THE CORRECT. SO THANK YOU.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

CHAIRMAN FISCHER-COLBRIE: YES.

MR. TOCHER: JUDY GASSON.

DR. GASSON: YES.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: YES.

MR. TOCHER: PAT LEVITT.

DR. LEVITT: YES.
MR. TOCHER: SHLOMO MELMED.
DR. MELMED: YES.
MR. TOCHER: CHRIS MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: SHAUNA STARK.
DR. STARK: YES.
MR. TOCHER: KAROL WATSON.
DR. WATSON: YES.
MR. TOCHER: AND KEITH YAMAMOTO.
DR. YAMAMOTO: YES.
MR. TOCHER: GREAT. THANK YOU VERY MUCH, MARK. THAT MOTION CARRIES.
CHAIRMAN FISCHER-COLBRIE: GREAT. WITH THAT, LET'S CONTINUE ON WITH THE NEXT AGENDA ITEM, AND THAT'S GOING TO BE HANDLED BY THE FINANCE SUBCOMMITTEE.
DR. BLUMENTHAL: SO I GUESS I WILL TAKE OVER NOW AND INVITE MICHELLE LEWIS, WHO'S OUR DIRECTOR OF FINANCE, TO GIVE HER PRESENTATION.
MS. LEWIS: THANK YOU. ALL RIGHT. GOOD AFTERNOON, EVERYONE. MY NAME IS MICHELLE LEWIS. I AM THE DIRECTOR OF FINANCE HERE AT CIRM, AND I'M HERE TODAY WITH OUR PROPOSED FISCAL YEAR 26/27 ADMINISTRATIVE BUDGET.

AND AS STATED BEFORE, OUR BUDGET IS CREATED WITH OUR MISSION IN MIND. TODAY WE'RE GOING TO DO A BRIEF OVERVIEW OF PROPOSITION 14. WE'RE GOING TO GO OVER THE FINANCIAL RESULTS FOR THE 25/26 FISCAL YEAR, AND THEN GO INTO OUR PROPOSED BUDGET FOR THE 26/27 FISCAL YEAR.

SO JUST AN OVERVIEW OF PROP 14. THIS GRAPH SHOWS THE MAJOR CATEGORIES WHERE THE FUNDS ARE ALLOTTED FOR THE $5.5 BILLION PROPOSITION. WE'RE ALLOWED TO SPEND 4.9 BILLION ON GRANT FUNDING, WHICH WAS THE PREVIOUS PRESENTATION. AND ON THE NEXT SLIDE, WE'RE GOING TO GO INTO MORE DETAIL ON THE ADMINISTRATIVE SIDE.

SO THIS SLIDE SHOWS OUR FUNDING CATEGORIES. THERE ARE THREE MAJOR CATEGORIES. AND OUR FIRST CATEGORY IS CAPITALIZED INTEREST AND COSTS OF ISSUANCE, WHICH ARE COSTS ASSOCIATED WITH THE ISSUANCE OF BONDS TO FUND OUR ACTIVITIES. FIRST, THE PROPOSITION STATES THAT ALL INTEREST ON ANY BOND ISSUED THROUGH THE FIFTH FULL CALENDAR YEAR FROM THE START OF THE BOND WILL BE PAID FROM THE BOND PROCEEDS. THIS IS CALLED CAPITALIZED INTEREST.

SECOND, THERE ARE ALSO FEES THAT ARE PAID TO PROFESSIONALS ASSOCIATED WITH BOND SALES, AND THOSE ARE CALLED COSTS OF ISSUANCE. BOTH OF THESE

REDUCE THE AMOUNT BOND PROCEEDS THAT WE WILL BE ALLOWED TO SPEND. THE PROPOSITION DOESN'T STIPULATE A SET AMOUNT THAT THE BOND AUTHORITY CAN BE REDUCED. CIRM ESTIMATED THAT THE CAPITALIZED INTEREST AND COSTS OF ISSUANCE WOULD TOTAL ABOUT 100 MILLION, AND THAT'S WHAT WAS BUDGETED.

WE ARE NOW PAST THAT FIVE-YEAR MARK. SO CIRM'S AUTHORITY HAS BEEN REDUCED BY 85 MILLION FOR THOSE TWO PURPOSES.

OUR NEXT CATEGORY IS DIRECT GRANT ADMINISTRATION, AND THAT HAS THREE SUBCATEGORIES. THE FIRST ONE IS GRANT COMPLIANCE FOR 100 MILLION. TO DATE, AS OF APRIL 30, 2026, WE'VE SPENT $18.5 MILLION WITH 81.5 REMAINING.

FOR OUR ACCESS AND AFFORDABILITY, WHICH IS 55 MILLION, WE HAVE SPENT 5.5 MILLION WITH 49.5 REMAINING.

FOR GRANT ADMINISTRATION, WHICH IS 165 MILLION, WE HAVE SPENT 35.7 WITH 129.3 REMAINING.

OUR FINAL CATEGORY IS CIRM ADMINISTRATION, WHICH IS 192.5 MILLION. WE'VE SPENT 45.4 MILLION WITH 147.1 MILLION REMAINING.

NEXT WE'LL DISCUSS THE RESULTS FOR THE 25/26 FISCAL YEAR. JUST SOME CONTEXT FOR THE BUDGET. RECRUITMENT CONTINUED DUE TO NEW AND

INCREASED BUSINESS ACTIVITIES. WE RECRUITED SEVEN VACANT POSITIONS. OUR CURRENT STAFF HEAD COUNT IS 68, AND WE HAVE FOUR POSITIONS THAT ARE CURRENTLY IN RECRUITMENT. WE ALSO COMPLETED THE FIRST YEAR OF AWARDING GRANTS UNDER THE NEW STRATEGIC ALLOCATION FRAMEWORK WITH THE TEAM FOCUSED ON STRENGTHENING INTERNAL BUSINESS OPERATIONS AND CROSS-FUNCTIONAL ALIGNMENT.

THIS SHOWS THE PROJECTED FINANCIAL RESULTS FOR THE 25/26 FISCAL YEAR. IN THIS GRAPH, THE FIRST COLUMN SHOWS OUR CATEGORY OF EXPENDITURES. WE HAVE EMPLOYEE EXPENSES, WHICH IS OUR LABOR COST; EXTERNAL SERVICES, WHICH ARE CONTRACTS WITH OUTSIDE VENDORS; WE HAVE REVIEWS, MEETINGS AND WORKSHOPS; MEMBERSHIPS AND TRAINING; TRAVEL; EQUIPMENT AND SUPPLIES, WHICH IS ALSO SOFTWARE AND TELECOM, AND THEN FACILITIES.

OUR APPROVED BUDGET FOR THE 25/26 FISCAL YEAR WAS 34.8 MILLION. OUR ESTIMATE TO FINISH IS 28.7 MILLION. THAT VARIANCE OF BUDGET TO ACTUALS IS 6 MILLION -- JUST A LITTLE OVER 6 MILLION, WHICH IS A 17-PERCENT VARIANCE. AND I JUST WANTED TO POINT OUT THAT LAST YEAR'S VARIANCE WAS 21 PERCENT. SO WE HAVE BETTERED OUR VARIANCE IN BUDGET TO ACTUALS BY 4 PERCENT.

THE MAJOR DRIVER OF THOSE BUDGET VARIANCES

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WERE THE TRAVEL AND TRAINING CATEGORIES. SO OUR BUSINESS OPERATIONS INCREASED, WHICH DID NOT ALLOW FOR TIME FOR PLANNED TRAVEL AND TRAINING. ALSO, IN THE REVIEWS, MEETINGS, AND WORKSHOPS CATEGORY, OUR PROGRAM EXPERT REVIEWERS FOR AWARDS MANAGEMENT WERE BUDGETED AS A CONTINGENCY. THE ROLLOUT OF THE REVIEWERS LAUNCHED LATER THAN ANTICIPATED; HOWEVER, THE PDEV TEAM RECENTLY LAUNCHED THEIRS AND ARE EXPECTING TO SPEND APPROXIMATELY $6,000 BY THE END OF THIS FISCAL YEAR, AND WE'LL SEE AN INCREASE NEXT FISCAL YEAR.

NEXT, WE'LL GO OVER THE PROPOSED ADMINISTRATIVE BUDGET FOR THE 26/27 FISCAL YEAR. THIS IS OUR PROPOSED ADMINISTRATIVE BUDGET, AND THIS SLIDE SHOWS OUR BUDGET-TO-BUDGET VARIANCE. OUR PROPOSED BUDGET FOR THE 26/27 FISCAL YEAR IS $36,238,240. AND COMPARED TO OUR 25/26 BUDGET, IT IS A VARIANCE OF $1,424,147, WHICH IS A 4-PERCENT INCREASE.

THIS SLIDE SHOWS OUR PROPOSED BUDGET VERSUS OUR ESTIMATED TO FINISH FOR 25/26. SO WE HAVE OUR PROPOSED BUDGET OF 36.2 MILLION. OUR ESTIMATE TO FINISH IS 28.7 MILLION, WHICH LEAVES US WITH A VARIANCE OF 7.4 MILLION AND A 21-PERCENT VARIANCE.

SO MAJOR DRIVERS OF OUR BUDGET ARE THE MEMBERSHIPS AND TRAINING CATEGORIES. SO WE ANTICIPATE THAT TRAINING EXPENDITURES WILL CONTINUE AT A LOWER RATE. THEREFORE, WE'VE ADJUSTED THE BUDGET TO MORE CLOSELY REFLECT THE HISTORICAL ACTUALS. WE ALSO MAINTAINED OUR TRAVEL BUDGET AND DIDN'T INCREASE IT, AND WE REDUCED THE FACILITIES BUDGET SLIGHTLY DUE TO THE COMPLETION OF SOME SPECIAL PROJECTS.

FOR OUR EQUIPMENT AND SUPPLIES CATEGORY, WE INCREASED THE I.T. SOFTWARE BUDGET TO SUPPORT GROWTH IN STAFFING AND NEW PROJECTS.

AND FOR OUR EMPLOYEE EXPENSES CATEGORY, WE HAVE A SALARY INCREASE WITH A FEW COMPONENTS. THERE IS A PERFORMANCE-BASED MERIT INCREASE OF 2 PERCENT FOR ELIGIBLE STAFF. THERE'S A 3-PERCENT COST OF LIVING INCREASE. WE HAVE UPDATED THE LEAVE BUYOUT FOR EMPLOYEE DEPARTURES OR RETIREMENT. THAT LEAVE BUYOUT IS COMPOSED OF THE STAFF VACATION HOURS THAT ARE ALL THEIR PROPERTY. THIS IS A LIABILITY FOR US AS WE ARE REQUIRED TO CASH OUT THOSE HOURS SHOULD THEY DECIDE TO LEAVE THE AGENCY. THIS RESERVES AN AMOUNT EQUAL TO ONE STAFF MEMBER FROM EACH COST CENTER AS WE CANNOT PREDICT WHO WILL LEAVE. THIS ALLOWS THE COST CENTERS TO BACKFILL THEIR POSITIONS

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WITHOUT IMPACTING THEIR BUDGETS. AND WE ARE ALSO REQUESTING ONE FULL-TIME EMPLOYEE.

JUST AS A NOTE, THE COST OF LIVING AND MERIT APPLIES TO THE CHAIR, VICE CHAIR, AND PRESIDENT. THIS MAKES THE INCREASES AVAILABLE IN THE BUDGET SHOULD THE BOARD CHOOSE TO AWARD THIS AS PART OF THE LEADERSHIP EVALUATION PROCESS.

FOR OUR BUDGET RISK FACTORS, WE'VE GOING TO CONTINUALLY ACTIVELY MANAGE COSTS; HOWEVER, THERE ARE TWO FACTORS THAT ARE DIFFICULT TO CONTROL. THE FIRST BEING RECRUITMENT AND PERSONNEL GROWTH, AND THE SECOND BEING INCREASED COSTS FOR GOODS AND SERVICES DUE TO INFLATION.

AND, FINALLY, WE WOULD REQUEST THAT THE FINANCE AND SCIENCE SUBCOMMITTEES RECOMMEND APPROVAL OF THIS ADMINISTRATIVE BUDGET TO THE FULL BOARD IN THE AMOUNT OF $36,238,240.

ARE THERE ANY QUESTIONS?

DR. BLUMENTHAL: BEFORE WE TAKE QUESTIONS, COULD I ASK FOR A MOTION TO RECOMMEND THIS BUDGET TO THE FULL BOARD?

DR. SACKEY: SO MOVE.

DR. DULIEGE: I SECOND.

DR. BLUMENTHAL: THANK YOU. OKAY. NOW WE CAN OPEN IT UP FOR QUESTIONS. JOYCE.

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DR. SACKEY: THANK YOU. GEORGE, I WANTED TO ASK -- THERE WAS A SLIDE, MICHELLE, THAT YOU SHARED OF THE HISTORIC BUDGET VERSUS THE ACTUALS OVER THE LAST SEVERAL YEARS. AND IT SEEMS LIKE WE REALLY UNDERSPEND CONSISTENTLY. AND SO I APPRECIATED THE FACT THAT YOU MADE A POINT THAT THE BUDGET IS BEING ADJUSTED TO MATCH HISTORICAL ACTUALS WHEN IT CAME TO MEMBERSHIP AND TRAINING. BUT I'M WONDERING WHETHER A SIMILAR ADJUSTMENT MIGHT NEED TO BE MADE IN THE OTHER CATEGORIES, PARTICULARLY THOSE CATEGORIES WHERE WE ARE CONSISTENTLY UNDERSPENDING.

MS. LEWIS: YES. SO WHILE I HIGHLIGHTED THE TRAINING, THE TRAVEL BUDGET STAYED THE SAME. WE DO ANTICIPATE, NOW THAT WE'VE DONE SOME INTERNAL BUSINESS PRACTICES, THAT THE TRAVEL WILL INCREASE. WE ALSO DID A VERY MINIMAL INCREASE TO EXTERNAL SERVICES. ONLY A 1 PERCENT. AND THE SAME WITH THE REVIEWS, MEETINGS, AND WORKSHOPS. SO WE ARE LOOKING AT THIS AS WE SPEND IN ACTUALS TO ENSURE THAT OUR BUDGET IS ADJUSTED ACCORDINGLY TO THOSE HISTORICALS ONCE WE HAVE ACTUAL FIGURES.

DR. SACKEY: SO I MIGHT HAVE MISREAD THE SLIDE, THAT IT SHOWED HISTORICALLY HOW WE FUND EXPENSE THEN.

MS. LEWIS: I THINK THAT WAS IN THE

PREVIOUS PRESENTATION.

DR. SACKEY: OKAY. FOR SOME REASON I THOUGHT I SAW IT IN YOURS. BUT I CAN GO BACK TO MY MATERIALS.

MS. LEWIS: IF THAT HELPS.

DR. SACKEY: YEAH. THANK YOU.

DR. BLUMENTHAL: THANKS, JOYCE. ANNE-MARIE.

DR. DULIEGE: YEAH. MICHELLE, WHAT'S THIS BUDGET REPRESENT AS A PROPORTION OF THE TOTAL FOR THIS YEAR?

MS. LEWIS: I'M SORRY.

DR. DULIEGE: WHAT PORTION OF THE TOTAL BUDGET DOES IT REPRESENT? THE ADMINISTRATIVE BUDGET IS WHICH PROPORTION OF THE TOTAL BUDGET APPROXIMATELY?

MS. LEWIS: I'M SORRY. I DON'T HAVE THAT. THE TOTAL OF OUR 5.5 BILLION?

DR. DULIEGE: THE PLAN, THE PROPOSED BUDGET FOR NEXT YEAR.

MS. LEWIS: THE PROPOSED BUDGET FOR NEXT YEAR FOR THE 36.2 MILLION?

DR. DULIEGE: NO. THE PROPOSED BUDGET FOR THE ENTIRE SPENDING FOR NEXT YEAR, I WANT TO KNOW HOW MUCH --

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DR. LEVITT: I THINK IT'S SEVEN --

DR. DULIEGE: HOW MUCH WE'RE SPENDING ON ADMINISTRATIVE COST VERSUS PROGRAMMATIC COSTS.

MS. LEWIS: OH, I WOULD HAVE TO CALCULATE -- VERSUS THE PROPOSED 662 MILLION?

DR. LEVITT: IT'S ABOUT 7 PERCENT.

DR. DULIEGE: GOOD. THANK YOU. VERY REASONABLE. THANK YOU.

DR. BLUMENTHAL: GREAT. THANK YOU. JOE.

MR. PANETTA: THANKS, GEORGE. MICHELLE, THAT WAS A GREAT PRESENTATION. AND THANKS FOR BEING SO FISCALLY RESPONSIBLE.

I'M LOOKING AT THE EMPLOYEE EXPENSE, AND I'M NOT QUITE SURE IF I QUITE CAUGHT IT. BUT YOU MENTIONED OPEN POSITIONS THAT WERE FILLED, AND I'M NOT CLEAR ON WHETHER THOSE WERE POSITIONS THAT WERE FILLED. ARE THOSE POSITIONS FOR THIS YEAR, AND WHAT'S THE PROPOSAL FOR NEXT YEAR?

MS. LEWIS: SO WE HAD VACANCIES THAT WE FILLED THIS YEAR. WE DID FILL SEVEN VACANCIES. THE PROPOSAL FOR NEXT YEAR IS TO ONLY ADD ONE MORE POSITION TO OUR CURRENT LIST.

MR. PANETTA: AND THAT'S TO BE A LITTLE BIT MORE CONSERVATIVE, OR IS THAT JUST BECAUSE THERE ISN'T ANY MORE NEED THAN ONE POSITION?

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MS. LEWIS: CORRECT. WE WANT TO MAKE SURE THAT WE'RE ONLY ADDING POSITIONS IF THEY'RE NEEDED. AND THERE WAS A NEED FOR ONE BECAUSE WE HAD CURRENT VACANCIES THAT WE'RE STILL FILLING.

MR. PANETTA: OKAY. THANK YOU.

DR. BLUMENTHAL: EXCELLENT. ARE THERE ANY OTHER QUESTIONS FROM THE BOARD? ARE THERE ANY OTHER QUESTIONS FROM THE --

DR. THOMAS: LOOKS LIKE JOE HAS GOT HIS HAND RAISED, GEORGE.

MR. PANETTA: JOE DIDN'T TAKE HIS HAND DOWN. SORRY.

DR. BLUMENTHAL: IS THERE ANY PUBLIC COMMENT?

MS. MANDAC: THERE ARE NO HANDS RAISED, GEORGE.

DR. BLUMENTHAL: OKAY. GREAT. SO I THINK WE CAN PROCEED TO VOTE.

MR. TOCHER: GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: YES.

MR. TOCHER: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: YES.

MR. TOCHER: SHLOMO MELMED.

DR. MELMED: YES.

MR. TOCHER: JOE PANETTA.

MR. PANETTA: YES.

MR. TOCHER: JOYCE SACKEY.

DR. SACKEY: YES.

MR. TOCHER: GREAT. THANK YOU VERY MUCH, GEORGE. THE MOTION CARRIED.

DR. BLUMENTHAL: GREAT. THANK YOU. I THINK THAT TAKES US THROUGH MOST OF OUR AGENDA. IS THERE ANY MORE PUBLIC COMMENT?

MS. MANDAC: NO HANDS.

DR. BLUMENTHAL: NOT HEARING ANY, IS THERE ANY OTHER BUSINESS THAT NEEDS TO BE RAISED? HEARING NONE, I THINK WE CAN DECLARE THIS MEETING ADJOURNED.

(THE MEETING WAS THEN CONCLUDED AT 4:04 P.M.)

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-920-3543 CACSR7152@OUTLOOK.COM

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 VIRTUAL PROCEEDINGS BEFORE THE JOINT SCIENCE AND FINANCE SUBCOMMITTEES OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON MAY 29, 2026, 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