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

REGULAR MEETING

LOCATION: VIA ZOOM

DATE: OCTOBER 14, 2022
10 A.M.

REPORTER: BETH C. DRAIN, CA CSR
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I N D E X

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FRIDAY, OCTOBER 14, 2022; 10 A.M.

CHAIRMAN GOLDSTEIN: MARIA MILLAN, CONGRATULATIONS.

DR. MILLAN: THANK YOU SO MUCH. IT WAS A GREAT HONOR, AND IT WAS REALLY JUST WONDERFUL TO HAVE CIRM RECOGNIZED. THANK YOU TO THE BOARD MEMBERS, J.T., ART, AND YSABEL WHO WERE ABLE TO MAKE IT LAST NIGHT. THANK YOU. AND TEAM MEMBERS WHO WERE THERE.

MR. TORRES: STEVE JUELSGAARD.

DR. MILLAN: AND STEVE JUELSGAARD. ABSOLUTELY.

CHAIRMAN GOLDSTEIN: GREAT. LET'S GET GOING. SO LET ME CALL US TO ORDER AND ASK MARIANNE TO CALL THE ROLL.

MS. DEQUINA-VILLABLANCA: DOUG, I WANT TO BE SURE THAT THE RECORDING HAS STARTED. GOT IT.

CHAIRMAN GOLDSTEIN: I THOUGHT IT DID.

MS. DEQUINA-VILLABLANCA: HAIFAA ABDULHOC. DEBORAH DEAS.

DR. DEAS: HERE.

MS. DEQUINA-VILLABLANCA: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: HERE.

MS. DEQUINA-VILLABLANCA: ELENA FLOWERS.
DR. FLOWERS: PRESENT.
MS. DEQUINA-VILLABLANCA: JUDY GASSON.
DR. GASSON: HERE.
MS. DEQUINA-VILLABLANCA: LARRY GOLDSTEIN.
CHAIRMAN GOLDSTEIN: I'M HERE.
MS. DEQUINA-VILLABLANCA: DAVID HIGGINS. PAT LEVITT.
DR. LEVITT: HERE.
MS. DEQUINA-VILLABLANCA: SHLOMO MELMED.
DR. MELMED: HERE.
MS. DEQUINA-VILLABLANCA: CHRISTINE MIASKOWSKI. JONATHAN THOMAS.
CHAIRMAN THOMAS: HERE.
MS. DEQUINA-VILLABLANCA: ART TORRES.
CHAIRMAN THOMAS: BACK IN ONE SECOND.
MS. DEQUINA-VILLABLANCA: ART, DID I HEAR YOU? IS HE ON?
MS. BONNEVILLE: HE'S THERE. HE SAID PRESENT.
MS. DEQUINA-VILLABLANCA: GOT IT. SORRY. DIDN'T HEAR YOU.
KAROL WATSON.
DR. WATSON: HERE.
MS. DEQUINA-VILLABLANCA: KEITH YAMAMOTO.

DR. YAMAMOTO: HERE.

MS. DEQUINA-VILLABLANCA: ALL RIGHT. WE HAVE A QUORUM.

CHAIRMAN GOLDSTEIN: FANTASTIC. WE HAVE ONE MAJOR ITEM THIS MORNING, WHICH IS PRESENTATION OF THE CONCEPT PLAN FOR SHARED LABS. WHO'S GOING?

DR. GRIESHAMMER: IT WILL BE ME.

CHAIRMAN GOLDSTEIN: OKAY. GO FOR IT, UTA.

DR. GRIESHAMMER: THANK YOU. I'M GOING TO SHARE MY SCREEN. CAN YOU GUYS SEE MY POWERPOINT RIGHT NOW?

MR. TORRES: YES.

DR. GRIESHAMMER: IN FULL PRESENTATION MODE. ALL RIGHT. VERY GOOD.

SO THANK YOU, DR. GOLDSTEIN, AND GOOD MORNING, EVERYONE. I'LL BE PRESENTING THE PROPOSED CONCEPT FOR SHARED RESOURCE LABORATORIES FOR STEM CELL-BASED MODELING. THIS IS AN INFRASTRUCTURE PROGRAM. IT'S DESIGNED TO ALIGN WITH CIRM'S MISSION TO ACCELERATE WORLD-CLASS SCIENCE AND TO DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND WORLD.

SHARED RESOURCE LABORATORIES, IF APPROVED,

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WILL BE THE FIRST OF THE COMPETENCY HUBS ENVISIONED IN OUR STRATEGIC PLAN UNDER ADVANCING WORLD-CLASS SCIENCE. THIS PROGRAM ALSO TOUCHES ON BUILDING KNOWLEDGE NETWORKS AND BUILDING A DIVERSE AND HIGHLY SKILLED WORKFORCE.

SO BEFORE I INTRODUCE YOU TO THE CONCEPT FOR SHARED RESOURCE LABS FOR STEM CELL-BASED MODELING AND GO OVER THE OPPORTUNITIES AND NEEDS WE INTEND TO ADDRESS, I'D LIKE TO PROVIDE SOME HISTORICAL CONTEXT FOR THE STEM CELL-BASED MODELING FIELD.

SO AS YOU ALL KNOW, IN 1998 THE DERIVATION OF HUMAN EMBRYONIC STEM CELLS WAS FIRST PUBLISHED. A FEW YEARS LATER IN 2001, FEDERAL FUNDING FOR HUMAN EMBRYONIC STEM CELL RESEARCH, WHILE AFFIRMED, WAS RESTRICTED TO THE EXISTING HUMAN EMBRYONIC STEM CELL LINES AT THE TIME. IN 2004 CALIFORNIA VOTERS THEN APPROVED PROPOSITION 71, LEADING TO THE CREATION OF CIRM. AND ONE OF THE INFRASTRUCTURE PROGRAMS CIRM PUT INTO PLACE TO PROVIDE CALIFORNIA RESEARCHERS WITH ACCESS TO CRITICAL FUNDING FOR HUMAN EMBRYONIC STEM CELL RESEARCH WAS THE SHARED LABS AWARDS PROGRAM, PROVIDING ACCESS TO DEDICATED RESEARCH SPACE, TO SPECIALIZED INSTRUMENTATION, HUMAN EMBRYONIC STEM CELLS LINES, AND TRAINING FOR

RESEARCHERS AND STUDENTS, MAKING THE EMERGING FIELD OF HUMAN EMBRYONIC STEM CELL RESEARCH MORE ACCESSIBLE TO CALIFORNIA RESEARCHERS.

DURING THE TIME THE SHARED LABS WERE ACTIVE, TWO IMPORTANT EVENTS OCCURRED. IN 2007 THE DERIVATION OF HUMAN INDUCED PLURIPOTENT STEM CELL LINES WAS FIRST PUBLISHED, AND THEN IN 2009 THE FEDERAL GOVERNMENT LIFTED THE LIMITATIONS THAT HAD BEEN PLACED BY THE PREVIOUS ADMINISTRATION.

SO ONE OF THE MAIN APPLICATIONS OF HUMAN PLURIPOTENT STEM CELLS LIES IN THE USE OF STEM CELLS TO CREATE MODELS OF HUMAN DISEASE BY DIFFERENTIATING THE CELLS INTO CELL TYPES RELEVANT FOR THE DISEASE UNDER INVESTIGATION. OVER THE LAST TWO DECADES, MUCH PROGRESS HAS BEEN MADE IN REFINING THE DIFFERENTIATION PROTOCOLS AND CREATING MORE COMPLEX MODELS IN A DISH, SUCH AS ORGANOIDS AND TISSUES ON CHIPS, BUT CHALLENGES REMAIN, AND I'LL GO OVER THAT IN THE NEXT SLIDE.

ANOTHER GROUNDBREAKING DISCOVERY THAT'S IMPORTANT FOR THESE STEM CELL-BASED MODELS WAS REPORTED IN 2012, DEMONSTRATING THE CRISPR-CAS9 SYSTEM, DEMONSTRATING THAT NATURALLY OCCURRING GENOME EDITING SYSTEM IN BACTERIA CAN BE USED AS A GENOME EDITING TOOL IN OTHER CELLS, INCLUDING HUMAN

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CELLS, MAKING STEM CELL-BASED MODELS AN EVEN MORE POWERFUL TOOL FOR STUDYING DISEASES AND DISCOVERING NEW BIOMARKERS AND THERAPEUTIC TARGETS.

WITH THE PASSAGE NOW OF PROPOSITION 14 IN 2020, WE HAVE AN OPPORTUNITY TO LEVERAGE EXISTING CAPABILITIES AND ADDRESS NEEDS IN THE FIELD AND TO HELP ADVANCE WORLD-CLASS SCIENCE BY ESTABLISHING CORE RESOURCES ACROSS THE STATE. AND IF APPROVED, THE CIRM SHARED RESOURCE LABS WOULD START OPERATIONS IN '23-'24. SO ACTUALLY WOULD BE FUNDED IN THAT TIME FRAME AND START OPERATIONS SOMETIME LATER. I'LL SHOW THAT LATER.

SO WHAT ARE THE OPPORTUNITIES, AND WHAT ARE THE NEEDS THAT WE INTEND TO ADDRESS WITH THE SHARED RESOURCE LABS CONCEPT? THERE'S ABUNDANT SCIENTIFIC STRENGTH, INNOVATION, AND EXPERTISE IN THE CALIFORNIA RESEARCH COMMUNITY TO CAPITALIZE ON THE PROMISE OF STEM CELL-BASED MODELING, AND WE CAN ALSO LEVERAGE SOME OF THE INFRASTRUCTURE, SOME SUPPORTED WITH PROPOSITION 71 SHARED LABS AS CORE LABS AND PROVIDERS OF TRAINING AND COURSES.

BASED ON STAKEHOLDER INPUT THAT WE HAVE GATHERED THROUGH TOWN HALLS, SURVEYS, AND WORKSHOPS, THERE ARE IMPORTANT NEEDS THAT CAN BE ADDRESSED WITH A SHARED RESOURCE LABS PROGRAM. THERE ARE MANY

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LABORATORIES THAT DO NOT YET USE STEM CELL-BASED MODELING, BUT ARE INTERESTED IN ACQUIRING THAT EXPERTISE. AND ON THE OTHER HAND, THERE ARE MANY LABORATORIES IN CALIFORNIA THAT ARE WELL VERSED IN STEM CELL-BASED MODELING AND ARE ALREADY SHARING THEIR EXPERTISE, BUT CAN'T REALLY MEET THE DEMAND AS IT IS TIME CONSUMING AND COSTLY TO DIVERT RESOURCES TO TRAINING OF OTHERS IN THE TECHNOLOGY.

SO IN ADDITION TO THESE INFRASTRUCTURE NEEDS, THERE ARE ALSO SCIENTIFIC CHALLENGES IN THE FIELD, THAT THE FIELD IS FACING RELATED TO THE LIMITED REPRODUCIBILITY OF FINDINGS ACROSS LABS AND MODELS USED. AND THERE'S ALSO A NEED TO BETTER UNDERSTAND THE PREDICTIVE VALUE OF STEM CELL-BASED MODELS FOR HUMAN BIOLOGY AND DISEASE.

BASED ON THESE OPPORTUNITIES AND NEEDS, WE ARE PROPOSING TO FUND A SHARED RESOURCE LABS PROGRAM THAT WOULD HAVE THE FOLLOWING FUNCTIONS. IT WOULD PROVIDE RESEARCHERS LOCALLY AT GRANTEE INSTITUTIONS AND REGIONALLY AT NEIGHBORING INSTITUTIONS WITH ACCESS TO CELL CULTURE FACILITIES FOR CONDUCTING STEM CELL-BASED MODELING EXPERIMENTS AND ACCESS TO HIGHLY SPECIALIZED TECHNOLOGIES THAT ARE NEEDED FOR THE IMPLEMENTATION AND ANALYSIS OF THESE STEM CELL-BASED MODELS.

THE PROGRAM WOULD ALSO PROVIDE RESEARCHERS LOCALLY AND ACROSS CALIFORNIA ACCESS TO WELL-CHARACTERIZED, UNMODIFIED, OR MODIFIED HUMAN PLURIPOTENT STEM CELL COLLECTIONS. IT WOULD PROVIDE ACCESS TO PARTIALLY OR FULLY DIFFERENTIATED STEM CELL MODELS AND WOULD PROVIDE ACCESS TO TRAINING OF RESEARCHERS AND CONDUCTING STEM CELL-BASED MODELING EXPERIMENTS.

THE SHARED RESOURCE LABS PROGRAM WOULD ALSO PROVIDE EDUCATORS, INCLUDING THOSE IN CIRM'S EDUCATION PROGRAMS, WITH ACCESS TO FORMAL TECHNIQUES COURSES FOR STUDENT EDUCATION. AND WE'D ASK APPLICANTS TO BE CREATIVE AND OFFER OTHER STUDENT EXPERIENCES WITH STEM CELL-BASED MODELING TO ATTRACT STUDENTS INTO THE STEM CELL FIELD.

AND, FINALLY, WE EXPECT FUNDED SHARED RESOURCE LABS TO BECOME SELF-SUSTAINING BY THE END OF THE AWARD PERIOD.

SO NOT ALL LABORATORIES WITH RESEARCH AGENDAS AND HYPOTHESES THAT COULD BE ADDRESSED ARE USING STEM CELL-BASED MODELS HAVE ACCESS TO RELEVANT LOCAL INFRASTRUCTURE AND EXPERTISE. AND SO TO ENSURE BROAD ACCESS TO STEM CELL-BASED MODELS ACROSS CALIFORNIA, WE ENVISION TWO TYPES OF SHARED RESOURCE LABORATORIES.

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ONE THAT WE CALL ESTABLISHING SHARED RESOURCE LABS, AND I WILL OCCASIONALLY REFER TO SHARED RESOURCE LABS AS SRL'S. SO ESTABLISHING SRL'S WILL PROVIDE ACCESS TO STEM CELL-BASED MODELING EXPERTISE IN GEOGRAPHIC AREAS WHERE ACCESS TO MODELS IS CURRENTLY LIMITED WHILE THE ENHANCING AND EXPANSION SRL'S TARGET INSTITUTIONS THAT HAVE CUTTING-EDGE STEM CELL-BASED MODELING EXPERTISE.

ESTABLISHING SRL'S WOULD BE FUNDED TO RENOVATE SPACE FOR A CORE FACILITY AND THEN EQUIP IT WHILE ENHANCING EXPANSION SRL'S WOULD BE FUNDED TO EQUIP EXISTING CORE SPACE. BOTH TYPES OF SRL WOULD THEN BE EXPECTED TO ESTABLISH THE EXPERTISE IN THE STEM CELL-BASED MODELS IN THEIR CORE FACILITIES, AND THEY WOULD THEN OPERATE THE CORES BY PROVIDING ACCESS TO THE CORE FACILITY AND SPECIALIZED SERVICES AND EQUIPMENT. THEY WOULD SHARE THEIR MODELS AND EXPERTISE AND RESOURCES BROADLY. THEY WILL TRAIN RESEARCHERS AND WOULD PROVIDE EDUCATIONAL RESOURCES AND ACTIVITIES.

WE WOULD ASK FOR APPLICATIONS TO PROPOSE ALSO FORMAL TECHNIQUES COURSES, AND THIS WOULD BE OPTIONAL, AND WE WOULD PROVIDE EXTRA FUNDS FOR THOSE APPLICANTS WHO WILL OFFER SUCH COURSES.

SINCE THE TWO SHARED RESOURCE LAB TYPES

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DIFFER IN FOCUS AND SCOPE, APPLICATIONS WILL BE SOLICITED THROUGH TWO SEPARATE RFA'S, AND THEIR NAMES ARE INDICATED RIGHT HERE.

SO ONCE FUNDED, ALL SHARED RESOURCE LABS ARE EXPECTED TO FUNCTION AS PART OF A NETWORK, AND CIRM WILL COORDINATE A STEERING COMMITTEE THAT WILL DRIVE NETWORK FUNCTIONS. AND I WILL DESCRIBE THIS STEERING COMMITTEE AND ITS FUNCTIONS IN A FEW SLIDES DOWN. THE INDIVIDUAL SHARED LABS AND THE NETWORK AS A WHOLE WILL THEN WORK TO ACHIEVE THE OVERALL OBJECTIVE OF THIS FUNDING OPPORTUNITY TO PROVIDE BROAD ACCESS TO MODELS, STEM CELL-BASED MODELS, ACROSS CALIFORNIA, TO ADVANCE STANDARDS AND REPRODUCIBILITY IN THE STEM CELL-BASED MODELING FIELD, TO PROVIDE ACCESS TO EDUCATIONAL OPPORTUNITIES, AND TO DEVELOP A SUSTAINABLE STEM CELL CORE INFRASTRUCTURE IN CALIFORNIA.

AS FOR THE FUNDING, WE WOULD OFFER PER AWARD AS LISTED IN THE TOP ROW HERE. THE TWO AWARD AMOUNTS WITHIN EACH SRL TYPE REFLECT FUNDS NEEDED FOR OFFERING A FORMAL STEM CELL TECHNIQUES COURSE, WHICH IS OPTIONAL. AND THE TWO AWARD AMOUNTS, THE DIFFERENCE BETWEEN THE TWO AWARD AMOUNTS BETWEEN THE TWO SRL TYPES REFLECT THE RENOVATION FUNDS THAT WOULD BE PROVIDED FOR THE ESTABLISHING SRL'S.

THE AWARD DURATION FOR THESE AWARDS WILL BE FIVE YEARS. THE MAIN GOAL OF THE ESTABLISHING SHARED RESOURCE LABS IS TO ESTABLISH NEW RESOURCES AND EXPERTISE AND TO HAVE A NOVEL IMPACT IN THE LOCAL SCIENTIFIC COMMUNITY WHILE THE MAIN GOAL OF THE ENHANCING EXPANSION SRL'S WOULD BE TO SHARE THE EXISTING EXPERTISE, BOTH LOCALLY, BUT ALSO ACROSS CALIFORNIA.

COFUNDING WILL BE REQUIRED FROM ENHANCING EXPANSION SRL'S WITH AT LEAST 20 PERCENT OF OPERATIONAL COSTS COVERED BY THOSE AWARDS, BUT SUCH COFUNDING WILL NOT BE REQUIRED FROM THE ESTABLISHING SRL'S.

THE TOTAL BUDGET REQUESTED FOR THIS PROGRAM WOULD BE $50 MILLION WITH 26 MILLION FOR BUILD AND EQUIP FUNDS, AND THE BUILD AND EQUIP, AS SHOWN HERE, WITH 24 MILLION FOR OPERATIONAL FUNDS.

SO I HAVE NOW A FEW SLIDES TO GO OVER SOME OF THE DETAILS OF THIS CONCEPT PROPOSAL, HOW IT WOULD BE RUN, HOW THE AWARDS BE RUN AND ADMINISTERED. WE ARE PROPOSING TO DIVIDE THESE FIVE-YEAR AWARDS INTO THREE PHASES, PHASES A, B, AND C. SHOWN HERE ARE THE OUTCOME METRICS FOR EACH OF THE PHASES FOR THE ESTABLISHING SHARED RESOURCE LABS.

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BY THE END OF PHASE A, WHICH LASTS 18 MONTHS, THE SHARED RESOURCE LABS CORE FACILITY SHOULD BECOME OPERATIONAL AND SHOULD BE RENOVATED AND EQUIPPED STEM CELL-BASED MODELS AND THE RESEARCH TRAINING AND STUDENT EDUCATIONAL PROGRAMS SHOULD BE ESTABLISHED.

IN PHASE B, WHICH LASTS TWO YEARS AND ENCOMPASSES CIRM-SUPPORTED OPERATIONS, FULLY CIRM-SUPPORTED OPERATIONS THAT ARE MEASURED BY THE UTILIZATION RATE OF THE CORE FACILITY WITH A FOCUS ON LABS THAT HAVE LIMITED ACCESS TO STEM CELL-BASED MODELING EXPERTISE CURRENTLY. WE WOULD LOOK AT THE SUSTAINED ENROLLMENT AND RESEARCHER TRAINING AND STUDENT EDUCATIONAL PROGRAMS. WE WOULD LOOK AT THE SUCCESS RATE OF PROJECTS UTILIZING THE CORE, SUCH AS THE DATA THAT IS BEING GENERATED IN EARLY PUBLICATIONS, LEVERAGED FUNDING. AND WE'D EXPECT THE DELIVERY OF A PLAN FOR OPERATIONS AT 50 PERCENT OF CIRM FUNDING DURING THE DELIVERY OF THIS PLAN DURING PHASE B IN PREPARATION FOR PHASE C, THE FINAL 18 MONTHS, WHICH WILL CONTINUE OPERATIONS AT 50 PERCENT CIRM OPERATIONAL FUNDING.

THE SAME SUCCESS METRICS FROM PHASE B WOULD APPLY PLUS WE'D EXPECT DELIVERY OF A PLAN FOR INDEPENDENT OPERATIONS HALFWAY THROUGH THIS PHASE,

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AND WE WOULD CERTAINLY EXPECT ALSO ALREADY DURING PHASE B AND IN PHASE C OVERALL CONTRIBUTIONS TO THE SHARED RESOURCE LAB NETWORK FUNCTIONS.

NOW, THIS SLIDE IS VERY SIMILAR TO THE PREVIOUS ONE, ELABORATING ON THE ENHANCING EXPANSION SHARED RESOURCE LABS. THE PHASING IS DIFFERENT AND THE OUTCOME METRICS ARE VERY SIMILAR. PHASE A FOR THE ENHANCING EXPANSION SRL'S WOULD BE JUST SIX MONTHS SINCE THERE IS NO BUILD PHASE FOR THOSE SHARED LABS. AND DURING THIS PHASE THE OUTCOMES WOULD BE VERY SIMILAR, ALMOST IDENTICAL, TO THE ONES FOR THE ESTABLISHING SRL'S.

IN PHASE B, WHICH WOULD LAST 30 MONTHS OR TWO AND A HALF YEARS, FOR CIRM SUPPORTED OPERATIONS, AGAIN, IT WOULD BE MEASURED BY THE UTILIZATION RATE OF THE CORE FACILITY, SUSTAINED ENROLLMENT, AND RESEARCHER TRAINING AND EDUCATIONAL PROGRAMS, THE LEVEL OF BROAD -- HERE WE WOULD ALSO LOOK AT THE LEVEL OF BROAD SHARING OF MODELS ACROSS CALIFORNIA, THE SUCCESS RATE OF THE PROJECTS THAT ARE UTILIZING THE CORE AND THAT ARE UTILIZING IN THIS CASE ALSO THE BROADLY SHARED MODELS. AND, AGAIN, WE WOULD LOOK FOR DELIVERY OF A PLAN FOR OPERATIONS AT 50 PERCENT.

AND THEN THE FINAL PHASE C, TWO YEARS

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WOULD HAVE, AGAIN, THE SAME METRICS AS PHASE B, DELIVERY OF A PLAN FOR INDEPENDENT OPERATIONS AND CONTRIBUTIONS TO SHARED RESOURCE LAB NETWORK FUNCTIONS.

SO I'D LIKE TO GO OVER SOME OF THE ELIGIBILITY REQUIREMENTS FOR THE SHARED RESOURCE LABS PROGRAM AND SOME OF THE PROP 14 STIPULATIONS THAT ARE ADDRESSED BY THIS PROGRAM. WE WOULD REQUIRE THAT THE MODELING EXPERTISE THAT IS OFFERED WITHIN THE SHARED RESOURCE LABS BE LIMITED TO IN VITRO MODELS USING HUMAN STEM OR PROGENITOR CELLS. CALIFORNIA NONPROFIT RESEARCH INSTITUTIONS WOULD BE ELIGIBLE, AND WE WOULD EXPECT -- AND WE WOULD ONLY ACCEPT ONE APPLICATION PER INSTITUTION. THE PROGRAM DIRECTORS THAT RUN THESE SHARED RESOURCE LABS MUST COMMIT AT LEAST 20 PERCENT EFFORT.

PURSUANT TO PROPOSITION 14, SHARED RESOURCE LABS ARE INTENDED TO BE OPERATIONAL IN THE FIRST FIVE YEARS FOLLOWING THE EFFECTIVE DATE OF THE INITIATIVE. IN THIS CASE INITIATIVE MEANS THE PROPOSITION 14 WHICH WAS EFFECTIVE DECEMBER 2020. SO, THEREFORE, THE APPLICATIONS MUST PROPOSE PLANS THAT ARE ACHIEVABLE WITHIN THE PHASES THAT ARE OUTLINED IN THE PREVIOUS SLIDE, ESPECIALLY PHASE A THAT LEADS TO OPERATIONS BEING READY OF THESE SHARED

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LABS.

CIRM SHALL ALSO, ACCORDING TO PROPOSITION 14, ENHANCE THE GEOGRAPHIC DISTRIBUTION OF RESOURCES ACROSS THE STATE AND WOULD PRIORITIZE APPLICATIONS THAT OFFER MATCHING FUNDS. AND SO THOSE STIPULATIONS ARE BUILT INTO THIS CONCEPT.

I'D LIKE TO GO BRIEFLY OVER THE PLANS THAT WE EXPECT APPLICANTS TO PROVIDE PLANS TO ADDRESS DIVERSITY, EQUITY, AND INCLUSION IN THEIR PROJECTS. THESE PLANS SHOULD PROPOSE ACTIVITIES -- THESE PLANS SHOULD DESCRIBE HOW THE PROPOSED ACTIVITIES WILL ENSURE THAT USERS OF THE SHARED CORES AND RECIPIENTS OF THE STEM CELL-BASED MODELS REPRESENT DIVERSE GOALS, APPROACHES, PERSPECTIVES, AND BACKGROUNDS. THEY SHOULD DESCRIBE HOW ANY PROPOSED EDUCATIONAL ACTIVITIES WILL ENSURE PARTICIPATION BY UNDERSERVED POPULATIONS. SHOULD ALSO DESCRIBE HOW THE SHARED RESOURCES LABS TEAMS AND OTHER CONTRIBUTORS WILL BRING DIVERSE AND INCLUSIVE PERSPECTIVES AND EXPERIENCES TO THE IMPLEMENTATION OF THE PROPOSED ACTIVITIES. AND THEY SHOULD DESCRIBE HOW THE SHARED RESOURCE LABS WILL OFFER STEM CELL LINES ANCESTRAL AND SEX DIVERSITY THAT MAY INCREASE THE APPLICABILITY OF THE RESEARCH OUTCOMES TO DIVERSE POPULATIONS.

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THE SHARED RESOURCE LAB APPLICATIONS MUST ALSO INCLUDE A KNOWLEDGE SHARING PLAN TO DESCRIBE PROCESSES AND SYSTEMS THE APPLICANT PROPOSES FOR ADVERTISING ACCESS TO THEIR MODELS FOR SHARING AND BEST PRACTICES, FOR CREATING AND USING MODELS, AND FOR SHARING THEIR KNOWLEDGE AND OTHER RESOURCES. THEY SHOULD ALSO DESCRIBE APPROACHES TOWARDS STANDARDIZING THE CELL LINES AND REAGENTS AND APPROACHES FOR THE QUALITY CONTROL AND VALIDATION THAT WILL BE USED FOR THE MODELS.

SHARED RESOURCE LAB APPLICATIONS MUST ALSO INCLUDE A DATA SHARING AND MANAGEMENT PLAN. SINCE DATA GENERATED DURING SHARED RESOURCE LAB OPERATIONS, SUCH AS OMICS AND FAQ'S DATA FOR CELL MODEL QUALITY CONTROL AND VALIDATION, MAY BE USEFUL FOR DEVELOPING APPROACHES TOWARD IMPROVING REPRODUCIBILITY OF STEM CELL-BASED MODELS. THAT'S WHY THE DATA GENERATED IN THE RESEARCH THAT'S SUPPORTED BY THESE SHARED RESOURCE LABS WILL FOLLOW THEIR OWN DATA SHARING PLANS THAT ARE INHERENT TO THE RESEARCH PROJECT. WE ARE INTERESTED IN CAPTURING THE DATA THAT IS GENERATED AS PART OF OPERATIONS.

SO THIS IS -- I THINK I'M ALMOST DONE, SECOND TO LAST SLIDE. BUT I WANT TO GO OVER THE

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STEERING COMMITTEE, THE NETWORK FUNCTIONS OF THE SHARED LABS. THE KNOWLEDGE AND DATA SHARING PLANS I DESCRIBED ON THE PREVIOUS SLIDE WILL BE A STARTING POINT FOR THESE NETWORK FUNCTIONS.

SO CIRM, AS I SAID, WILL COORDINATE A STEERING COMMITTEE OF THE AWARDEES AND EXTERNAL STAKEHOLDERS TO FACILITATE THE DEVELOPMENT OF PROCESSES AND SYSTEMS FOR SHARING NETWORKWIDE OFFERINGS, BEST PRACTICES, KNOWLEDGE, AND RESOURCES. THIS WOULD ALSO FACILITATE THE IMPLEMENTATION OF QUALITY STANDARDS, MATERIALS, AND CELL LINES ACROSS THE NETWORK, AND WOULD FACILITATE THE DEVELOPMENT OF COLLABORATIVE APPROACHES WITHIN THIS NETWORK TO HELP OR THINK ABOUT IMPROVING REPRODUCIBILITY OF STEM CELL-BASED MODELS.

SO IN MY LAST SLIDE HERE I PROVIDE A SUMMARY OF THE CONCEPT FOR SHARED RESOURCE LABS FOR STEM CELL-BASED MODELING. THE PROGRAM BUDGET WE ARE PROPOSING AS $50 MILLION TOTAL WITH BUILD AND EQUIP FUNDS UP TO $26 MILLION AND OPERATION FUNDS OF UP TO $24 MILLION. THE AWARD CAPS FOR ESTABLISHING SRL'S IS 5.4 AND $4.4 MILLION DEPENDING ON WHETHER THEY OFFER A TECHNIQUES COURSE. AND THE AWARD CAPS FOR ENHANCING AND EXPANSION SRL'S WOULD BE $4.3 MILLION OR $3 MILLION, AGAIN, DEPENDING ON WHETHER THEY'RE

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OFFERING A TECHNIQUES COURSE.

THE ALLOWABLE COSTS ARE FACILITIES BUILD OR I SHOULD SAY BUILD COSTS, RENOVATION COSTS FOR THE EXPANSION SRL'S ONLY, AND THEN DIRECT PROJECT COSTS, FACILITIES COSTS, AND INDIRECT COSTS. AND THEN, AS I MENTIONED, COFUNDING IS REQUIRED AT 20 PERCENT OF OPERATIONAL COSTS FOR THE ENHANCING EXPANSION SHARED RESOURCE LABS. CALIFORNIA NONPROFIT RESEARCH INSTITUTIONS ARE ELIGIBLE TO APPLY.

SO I'D LIKE TO ASK AT THE VERY END OF THIS PRESENTATION NOW FOR YOUR APPROVAL TO TAKE THIS CONCEPT TO THE ICOC IN A FEW WEEKS. THANK YOU. HAPPY TO ANSWER ANY QUESTIONS.

CHAIRMAN GOLDSTEIN: SO WHY DON'T WE HAVE A MOTION TO PASS, AND THEN WE CAN OPEN IT FOR DISCUSSION.

MR. TORRES: MOVE TO APPROVE.

DR. MELMED: SECOND.

CHAIRMAN GOLDSTEIN: WE HAD A SECOND THERE SOMEWHERE.

MS. BONNEVILLE: DR. MELMED.

CHAIRMAN GOLDSTEIN: OKAY. THANK YOU VERY MUCH. OKAY. WE ARE NOW OPEN FOR DISCUSSION. ART.

MR. TORRES: YES. THANK YOU. UTA, MAYBE

I MISSED IT, BUT YOU ARE GOING TO HAVE AN ADVISORY COUNCIL, BUT WHO WILL DETERMINE AND REVIEW THESE APPLICATIONS BEFORE THEY COME BACK TO THE ICOC FOR APPROVAL?

DR. GRIESHAMMER: THIS WILL BE -- ACTUALLY IT'S A GOOD QUESTION. IT WILL BE PARTLY OUR NORMAL PROCESS OF THE GRANTS WORKING GROUP REVIEW --

MR. TORRES: OKAY.

DR. GRIESHAMMER: -- FOR THE OPERATIONS AND THE MAJOR EQUIPMENT ACTUALLY; BUT SINCE THERE IS A FACILITIES RENOVATION COMPONENT TO ONE OF THESE RFA'S, THERE WILL ACTUALLY ALSO BE A FACILITIES WORKING GROUP REVIEWING THAT AND COMING UP WITH RECOMMENDATIONS FOR THE BOARD.

MR. TORRES: THOSE GROUPS HAVE ALREADY BEEN APPOINTED?

DR. GRIESHAMMER: NO. WE'RE WORKING WITH REVIEW TO PUT THOSE TOGETHER.

MS. BONNEVILLE: THE FACILITIES WORKING GROUP IS IN THE PROCESS OF BEING PUT TOGETHER, ART. SO RECOMMENDATIONS ARE WELCOME.

MR. TORRES: THANK YOU SO MUCH.

CHAIRMAN GOLDSTEIN: OKAY. SHLOMO.

DR. MELMED: THIS IS TERRIFIC, WELL THOUGHT THROUGH. THANK YOU. IT WAS A VERY

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COMPELLING PRESENTATION.

DR. GRIESHAMMER: THANK YOU.

DR. MELMED: CAN YOU JUST TELL US HOW YOU DETERMINED THE NUMBERS OF ESTABLISHED STEM CELL LABS VERSUS INSTITUTIONS THAT DON'T HAVE STEM CELL LABS? SO ARE WE DOING TOO MUCH OF ONE AND NOT THE OTHER? IS THERE A BALANCE? ARE THERE ENOUGH INSTITUTIONS WHICH DON'T HAVE STEM CELL LABS WHICH COULD HAVE LABS? MAYBE WE ARE OVERFUNDING OR UNDERFUNDING THAT NEED. AND PERHAPS WE SHOULD HAVE TWO SEPARATE STRATEGIC NEEDS FILLED. MAYBE YOU CAN HELP US UNDERSTAND HOW YOU CAME TO THAT BALANCE.

DR. GRIESHAMMER: YEAH. SO WE HAVE A VERY ROUGH SORT OF PREDICTION OF HOW MANY AWARDS WE MIGHT BE MAKING IN THIS PROGRAM, BUT IT'S ALWAYS HARD TO PREDICT EXACTLY HOW MANY APPLICATIONS, OF COURSE, WE'RE GOING TO GET AND HOW MERITORIOUS THEY WILL BE. BUT WE DO -- WELL, WE DO KNOW THAT CALIFORNIA, FROM OUR SHARED LABS EXPERIENCE FROM PROPOSITION 71, WE KNOW WE HAVE A LOT OF UNIVERSITIES THAT HAVE CUTTING-EDGE EXPERTISE IN STEM CELL-BASED MODELING, AND WE ACTUALLY EXPECT TO GET A VERY GOOD NUMBER OF APPLICATIONS FROM THEM.

IN TERMS OF THE ESTABLISHING SHARED RESOURCE LABS, THAT'S REALLY TARGETED TO BRINGING

RESEARCH OPPORTUNITIES TO, FOR INSTANCE, UNIVERSITIES AND RESEARCH INSTITUTIONS IN THE INLAND EMPIRE AND OTHER AREAS THAT ARE UNDERREPRESENTED AND THAT CAN PROVE IN THEIR APPLICATION THAT BY WHAT THEY'RE OFFERING, THAT LABS THAT CURRENTLY ARE REALLY LIMITED BY NOT HAVING INFRASTRUCTURE NEAR THEM CAN EXCEL IN USING THESE TECHNOLOGIES.

DR. MELMED: MY QUESTION WAS MORE QUANTITATIVE. FOR EXAMPLE, DO WE HAVE ENOUGH OF THOSE AND IS THAT A GROUP? OR DO WE HAVE TOO FEW? HOW DID YOU DETERMINE THE RATIO? MAYBE WE'RE UNDERFUNDING.

DR. CANET-AVILES: LARRY, AM I ALLOWED TO PROVIDE AN ANSWER HERE?

CHAIRMAN GOLDSTEIN: YES. THAT WOULD BE HELPFUL, ROSA.

DR. CANET-AVILES: SO, DR. MELMED, WE ARE ACTUALLY -- SO AS YOU RECALL, WE ALSO HAD A WORKSHOP IN PREPARATION FOR THE PLANNING OF THIS. WE LOOKED AT THE LANDSCAPE, THE LANDSCAPE STUDY IN THE STATE OF CALIFORNIA, FOR THOSE TYPE OF INSTITUTIONS BASED ON POTENTIAL APPLICANTS IN THE INLAND EMPIRE AND OTHER AREAS THAT MIGHT NOT HAVE HAD ACCESS. WE CONTACTED MANY OF THEM. WE ASKED THEM IF THEY COULD TELL US OF OTHERS THAT MIGHT BE IN SIMILAR

SITUATIONS.

SO WE DID AN ESTIMATE THAT WE THINK IS PRETTY -- IS PROBABLY PLUS/MINUS 10 PERCENT THAT WE MIGHT BE MISSING. SO WITH THAT, WE MADE THE ESTIMATES FOR THE NUMBERS THAT WE ARE PUTTING HERE. AND GIVEN THE CONSTRAINTS THAT WE HAVE IN TERMS OF BUILDING, WHICH WAS UP TO THE $26 MILLION GIVEN PROP 14, WE WANTED TO MAXIMIZE THE EFFECT OF THESE TWO RFA'S. SO THERE WILL BE TWO RFA'S THAT WILL BE SEPARATE, BUT THEY WILL BE WITHIN THIS CONCEPT. I HOPE THAT ANSWERS YOUR QUESTION.

DR. MELMED: SO YOU CAN'T TELL US HOW MANY WE EXPECT FOR THE FIRST ONE. ARE WE GOING TO BE FUNDING FIVE NEW LABS, TEN NEW LABS, 20?

DR. CANET-AVILES: WE CAN GIVE YOU THE ESTIMATES. IT'S, OF COURSE, ESTIMATE. UTA, YOU CAN GIVE ABOUT THE ESTIMATE OF WHAT WE ARE THINKING. AND THAT'S HOW WE CALCULATED THE BUDGET AS WELL.

DR. GRIESHAMMER: OUR CURRENT -- THE ESTIMATES WE HAVE USED ARE AROUND TEN OF THE ENHANCING EXPANSION ONES AND FOUR OF THE ESTABLISHING ONES. SORRY THAT I ACTUALLY DIDN'T MENTION THAT.

DR. MELMED: THANK YOU.

CHAIRMAN GOLDSTEIN: PAT, THANK YOU FOR

YOUR PATIENCE. YOU'RE UP.

DR. LEVITT: THANK YOU. SO GREAT PRESENTATION, AND I THINK THE CONCEPT IS GREAT. ONCE IT'S IN OPERATION, I THINK IT WILL MAKE A HUGE DIFFERENCE IN TERMS OF THE BROAD UTILIZATION OF THIS TECHNOLOGY.

SO SEVERAL COMMENTS AND QUESTIONS. PHASE 1, WHICH IS A CONSTRUCTION PHASE, IS 18 MONTHS. AND IN MY OWN PANDEMIC TIME EXPERIENCE, 18 MONTHS FOR EVEN MINOR RENOVATIONS IS EXTREMELY DIFFICULT. SO I THINK YOU NEED TO LOOK PRETTY HARD AT PHASE 1. THERE ARE SUPPLY CHAIN ISSUES. FOR EXAMPLE, IF YOU JUST WANT TO GET IN WORKSTATIONS THAT WOULD FURNISH LABS WHERE THEY'RE DOING THE ANALYTICAL WORK, IT CAN TAKE 9 TO 12 MONTHS TO GET THOSE WORKSTATIONS IN FROM THE FURNITURE SUPPLIERS. SO I THINK 18 MONTHS IS UNLIKELY FOR THOSE WHO ARE STARTING FROM SCRATCH, IN PARTICULAR, FOR THOSE INSTITUTIONS WHERE THEY NEED TO HAVE AN ARCHITECT COME IN AND DETERMINE WHAT WOULD NEED TO BE MODIFIED IN TERMS OF CURRENT SPACE. SO THAT'S ONE COMPONENT.

THE OTHER, IN PHASE C FOR BOTH THE ENHANCED GROUP, WHICH I THINK WILL WORK FINE IN TERMS OF THE EXPECTATION OF BEING ABLE TO SUPPORT -- THE INSTITUTION BEING ABLE TO GET INTO THE MODE OF

BEING ABLE TO SUPPORT THE CORE. I REALLY WORRY ABOUT THE NEW SITES HAVING ENOUGH INVESTIGATORS WHO ARE FUNDED TO BE ABLE TO PAY THE FEES BECAUSE THERE IS MENTION IN THE WRITTEN DOCUMENT OF A BUSINESS PLAN FOR CHARGEBACKS THAT WOULD HAVE TO BE DEVELOPED. CHARGEBACKS WORK WHEN YOU HAVE FUNDED INVESTIGATORS. IF YOU DON'T HAVE FUNDED INVESTIGATORS, YOU DON'T HAVE CHARGEBACKS BECAUSE THERE'S NO SOURCE FOR THE DOLLARS.

SO I THINK THAT'S SOMETHING YOU NEED TO LOOK FOR THE NEWLY ESTABLISHED SITES BECAUSE THEY'RE GOING TO HAVE FEWER INVESTIGATORS, AND IT'S GOING TO TAKE THEM TIME TO GET EXTRAMURAL FUNDING. CERTAINLY THE CORE IS GONG TO ENHANCE THEIR OPPORTUNITIES TO GET EXTRAMURAL FUNDING, BUT I'M JUST WORRIED THAT THEY'RE NOT GOING TO BE ABLE TO MEET THE DEMANDS OF THE BUSINESS PLAN.

AND THEN THE THIRD THING IS THERE'S A LOT OF SHARING GOING ON, SHARING OF TECHNOLOGIES, SHARING OF DATA, EVEN SHARING OF EDUCATIONAL MATERIALS. SO IF ONE INSTITUTION IS DEVELOPING A COURSE, WE WOULD WANT THEM TO SHARE THE SYLLABUS, FOR EXAMPLE, SO THAT OTHER INSTITUTIONS DON'T HAVE TO REINVENT THE WHEEL. THEY COULD USE THAT. HAS THERE BEEN A DISCUSSION, OR MAYBE THERE ALREADY

EXISTS, A UNIVERSAL PLATFORM WHERE THESE ENHANCED CORES COULD ACTUALLY USE ONE PLATFORM THAT WOULD HAVE A DIVERSITY OF FIELDS IN WHICH THEY COULD INPUT THEIR INFORMATION, THEIR DATA, THEIR TECHNOLOGIES, THEIR EDUCATIONAL INITIATIVES, ET CETERA? AND THAT MAY COST SOME DOLLARS IN ORDER FOR CIRM TO DEVELOP THAT, BUT I THINK THAT WOULD BE -- IN MY EXPERIENCE AND OTHERS ON THE ZOOM CERTAINLY HAVE THAT. IF YOU'RE IN A NETWORK WHERE YOU'RE REQUIRED TO SHARE, HAVING A UNIVERSAL PLATFORM IS A GAME CHANGER COMPARED TO THE SORT OF AD HOC WAYS IN WHICH NIH, FOR EXAMPLE, OFTEN DOES SHARING.

SO THOSE ARE MY COMMENTS. I THINK THE PLAN LOOKS GREAT, AND I THINK SOME TWEAKING MIGHT BE HELPFUL.

DR. CANET-AVILES: THANK YOU, PAT. LARRY, AM I ALLOWED TO ANSWER THE LAST QUESTION?

CHAIRMAN GOLDSTEIN: YOU BET.

DR. CANET-AVILES: THANK YOU. SO WITH REGARDS TO THE KNOWLEDGE NETWORKS, AS YOU KNOW, WE ARE WORKING TOWARDS THE BUILDING OF THE IMPLEMENTATION OF THE ADVANCE WORLD CLASS SCIENCE TEAM, AND ONE OF THE GOALS IS BUILDING KNOWLEDGE NETWORKS. WE ARE DEVELOPING A CONCEPT FOR A DATA AND SHARING ECOSYSTEM. AND THE FIRST IMPLEMENTATION

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IS GOING TO BE FOCUSED ON DATA COLLABORATIVE AND MANAGEMENT CENTER FOCUSED ON RESEARCH DATA, BUT WE WILL ALSO, GIVEN THAT THESE WILL IMPLEMENT THOSE KNOWLEDGE PLATFORM, THAT COULD HAVE SOME SPACES THAT COULD BE DEDICATED FOR EDUCATION AND TRAINING PROTOCOLS AND SHARING PROTOCOLS, ET CETERA. SO THAT'S GOING TO BE PART OF IT. IT MIGHT GO IN STAGES, BUT IT'S A CONCEPT THAT WILL BE COMING TO THE BOARD. BUT THAT'S A VERY APPROPRIATE QUESTION, AND WE APPRECIATE YOU BRINGING IT UP. THANK YOU.

DR. LEVITT: IN THE PLAN, IF YOU ADDED THAT, I THINK THAT'S A GREAT IDEA. I THINK THAT'S EXACTLY WHAT NEEDS TO BE DEVELOPED, AND YOU'RE ALREADY IN THE PROCESS OF DOING IT, YOU'RE GOING TO BE IN THE PROCESS OF DOING THAT, ADDING THAT LANGUAGE TO THE PLAN, THAT THERE'S GOING TO BE A UNIVERSAL KNOWLEDGE PLATFORM REQUIRED TO BE USED, WOULD BE HELPFUL FOR THE FULL BOARD WHEN THEY GO THROUGH THIS MATERIAL.

DR. GRIESHAMMER: IF I CAN JUST ADD TO THAT. AS PART OF THIS PARTICULAR AWARD PROGRAM, THE SHARED LABS THEMSELVES, THAT WILL BE WHAT WILL BE DISCUSSED AS A NETWORK, COMING TOGETHER AND COMING UP WITH WAYS OF COORDINATING WHAT'S BEING OFFERED AND COMING UP WITH THE BEST WAYS OF SHARING ALL

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THAT.

DR. LEVITT: THAT'S GREAT.

DR. GRIESHAMMER: THEN WE'LL WORK TOGETHER.

CHAIRMAN GOLDSTEIN: SO I HAVE A COUPLE OF QUESTIONS. ONE IS JUST FOLLOWING UP ON THAT. DO YOU THINK THAT THERE WILL BE A PLATFORM DEVELOPED IN TIME FOR THE DEPOSITION OF EARLY STAGE DATA AND PROTOCOLS FOR HOW TO DEAL WITH THESE SOMETIMES CRANKY CELLS?

DR. CANET-AVILES: THAT'S A VERY GOOD QUESTION. WITH THE 18 MONTHS, WELL, WHICH MIGHT BE EVEN LONGER IF WE ARE IMPLEMENTING, THE ONLY THING IS THAT THE OTHER, THE EE ONE, THE ENHANCING ONES, ARE GOING TO BE SHORTER. SO WE DON'T KNOW. WE DON'T KNOW IF IT WILL BE READY, BUT WE DEFINITELY ARE PUTTING THE PRESSURE BECAUSE, AS YOU KNOW, WE ALSO HAVE DATA COMING FROM OUR RESEARCH PROGRAMS THAT SHOULD ALREADY BE IN A PLATFORM FOR COLLABORATION. SO THE PRESSURE IS NOT ONLY IN THE CRANKY CELLS AND THE MODELS, IT'S ALREADY IN OUR RESEARCH DATA. AND ESPECIALLY AS WE THINK MORE FOCUSED TOWARDS A NEUROSCIENCE STRATEGY THAT WE WILL BE DEVELOPING, THIS VERY FOCUSED TYPE OF, HOPEFULLY, CONCEPT MODELING, LIKE COMMON MECHANISMS ACROSS

DISEASES AND TRYING TO FIND TARGETS AND BIOMARKERS, THAT IS A NEED THAT WE HAVE, AND THIS IS THE FOCUS. I THINK WE SHOULD REALLY PUSH ON THIS, THE SCMC CONCEPT FIRST AND GET IT IMPLEMENTED AS SOON AS POSSIBLE.

CHAIRMAN GOLDSTEIN: GOOD. THANK YOU. YES. THERE'S GOING TO HAVE TO BE SOMETHING SOON. THERE ARE GOING TO BE A LOT OF NEURAL ORGANOID PROPOSALS WOULD BE MY PREDICTION.

SO MY SECOND QUESTION IS FOLLOWING UP PAT'S QUESTION ABOUT THE CONCERN ABOUT WHETHER 18 MONTHS IS REALLY ENOUGH FOR SOME ORGANIZATIONS TO GET RENOVATION WORK TOGETHER. IS THAT NUMBER OF 18 MONTHS BASED ON A SURVEY OF POTENTIAL INSTITUTIONS? WHERE DOES IT COME FROM? DOES IT INCLUDE A SURVEY OF THAT TYPE BECAUSE I THINK YOU DO NEED TO BE A LITTLE CAREFUL ABOUT THAT UNFORTUNATELY?

DR. GRIESHAMMER: I WOULD SAY THAT, LIKE YOU SAY, IT LOOKS LIKE WE DO NEED TO BE FLEXIBLE. GENERALLY CIRM FUNDING DOES ALLOW, AS YOU KNOW, FOR NO-COST EXTENSIONS. AND SO WHAT I'M HEARING AT BOTH ENDS, ESPECIALLY FOR THE ESTABLISHING SRL'S, WE NEED TO BE READY TO MAYBE ALLOW NO-COST EXTENSIONS THAT MIGHT BE LONGER THAN WE TYPICALLY WOULD ENTERTAIN BECAUSE ULTIMATELY WE REALLY WANT TO MAKE SURE THAT

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THIS WORKS AND NOT CUT SOMEBODY OFF BECAUSE THEY ARE SIX MONTHS OR A YEAR LATE PERHAPS. AND WORK WITH THE AWARDEES TO MAKE THEIR RESOURCE LABS FUNCTIONAL.

CHAIRMAN GOLDSTEIN: ON THE OTHER HAND, YOU PROBABLY DON'T WANT TO FUND AN INSTITUTION WHERE IT TAKES FIVE YEARS TO GET ANYTHING DONE. THAT PERHAPS OUGHT TO BE PART OF THE EVALUATION OF THE PROPOSALS IN SOME WAY. I'M A LITTLE CURIOUS ABOUT WHERE 18 MONTHS CAME FROM. IS THAT BASED ON EXPERIENCE FROM THE DEVELOPMENT OF THE SHARED LABS WHENEVER IT WAS, TEN YEARS AGO?

DR. CANET-AVILES: THAT WAS A LITTLE BIT HOW WE LOOKED AT IT. WE LOOKED AT HOW LONG HAD IT TAKEN THEM TO BE FUNCTIONAL, AND WE EXTRAPOLATED FROM THAT, AS I RECALL.

CHAIRMAN GOLDSTEIN: I GUESS MY FINAL QUESTION IS ARE YOU GOING TO ASK FOR SOME SORT OF DETAILED ACCESS PLAN? SOME INSTITUTIONS HAVE THESE FACILITIES BEHIND SECURITY BECAUSE OF THE OBVIOUS PROBLEMS POTENTIALLY WITH INTERLOPERS. IS THAT SOMETHING YOU ARE GOING TO ASK PEOPLE TO LAY OUT?

DR. GRIESHAMMER: ABSOLUTELY. THAT WILL BE PART -- ONE OF THE PIECES IN THE APPLICATION, THAT WE ASK THEM TO TELL US HOW ARE THEY GOING TO ENSURE THAT PEOPLE KNOW ABOUT THESE OFFERINGS AND

WHAT WILL BE THEIR PLANS TO PROVIDING THIS ACCESS. SO, YES, THE RFA'S WILL LAY OUT HOW IN THE APPLICATION THE APPLICANTS WILL DESCRIBE THE ACCESS PLANS. ABSOLUTELY.

CHAIRMAN GOLDSTEIN: GREAT. ANY OTHER QUESTIONS? OKAY. NOW, REMIND ME. DOES PUBLIC COMMENT COME BEFORE OR AFTER WE VOTE?

MS. BONNEVILLE: BEFORE THE VOTE.

CHAIRMAN GOLDSTEIN: BEFORE THE VOTE. OKAY.

MS. BONNEVILLE: AFTER BOARD MEMBER COMMENT AND BEFORE THE VOTE.

CHAIRMAN GOLDSTEIN: OKAY. SO IF THERE'S NO FURTHER BOARD QUESTIONS OR COMMENTS, I DON'T SEE ANY HANDS.

DR. YAMAMOTO: ACTUALLY, LARRY, COULD I ASK A QUESTION?

CHAIRMAN GOLDSTEIN: YEAH. GO AHEAD, KEITH.

DR. YAMAMOTO: COULD YOU JUST COMMENT A BIT ON -- SO YOU HAVE THIS OVERSIGHT COMMITTEE OR SOMETHING LIKE THAT THAT WILL ESTABLISH QUALITY CONTROL AND VALIDATION METRICS AND STANDARDS. HOW WILL THAT GROUP ACTUALLY OPERATE AND INTERACT WITH THESE CORE LABORATORIES? THE IDEA IS THAT CIRM WILL

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THEN BE CHARGED WITH STANDING UP THESE QC AND VALIDATION METRICS, AND THEN THEY WILL THEN IMPOSE THOSE ON THE SHARED LABS AS THEY ESTABLISH THESE LINES AND SO FORTH. IS THAT THE IDEA? AND HOW WILL THAT ACTUALLY BE DONE? HOW WILL YOU POPULATE THAT OVERSIGHT COMMITTEE, AND HOW WILL THEY THEN GO ABOUT DEFINING WHAT THE QC AND VALIDATION METRICS LOOK LIKE?

DR. GRIESHAMMER: DR. LEVITT, DO YOU WANT ME TO ANSWER THAT FIRST, OR DID YOU WANT TO COMMENT RIGHT AWAY?

DR. LEVITT: NO. YOU SHOULD ANSWER THAT FIRST.

DR. GRIESHAMMER: OKAY. SO THE IDEA IS THAT CIRM WILL CALL A STEERING COMMITTEE WHICH WILL ACTUALLY INCLUDE THE PROGRAM DIRECTORS AND OTHERS THEY MIGHT APPOINT FROM ALL THE FUNDED SHARED RESOURCE LABS AND, IN ADDITION, WILL BRING IN EXTERNAL STAKEHOLDERS FROM ACROSS THE COUNTRY REALLY WHO ARE ALREADY INVOLVED IN ALSO THINKING ABOUT STANDARDIZATION, REPRODUCIBILITY, SUCH AS THE ISSCR AND THE NIH AND OTHER FUNDERS AND INSTITUTIONS THAT ARE DRIVING TOWARD STANDARDIZED MODELING. AND THEN THE IDEA IS TO WORK TOGETHER AS A GROUP TO COME UP WITH WHAT'S FEASIBLE.

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I ANTICIPATE, FOR INSTANCE, THAT THERE SHOULD BE POSSIBILITY -- WHAT WE'VE HEARD FROM OUR WORKSHOPS IS THAT THERE SHOULD BE WAYS THAT PERHAPS THE GROUP CAN AGREE ON CERTAIN STANDARDS OF QUALITY CONTROL FOR THE INPUT STEM CELL LINES AND FOR THE QUALITY CONTROL OF THE ACTUAL MODELS WHILE WE'VE HEARD THAT THE DIFFERENTIATION PROTOCOLS ARE STILL SO MUCH IN DEVELOPMENT, THAT THAT MIGHT NOT BE STANDARDIZABLE. I'M ONLY SAYING THIS TO SAY WE REALLY WANT TO WORK WITH THE GROUPS TO COME UP WITH SOME STANDARDS THAT ARE CONSIDERED FEASIBLE. BUT THAT WILL BE -- DOES THAT ANSWER YOUR QUESTION?

DR. YAMAMOTO: SO IN WORKING WITH THESE OTHER GROUPS, DO YOU ANTICIPATE THAT YOU'LL BEGIN TO GRAVITATE TOWARD KIND OF A COMMON SET OF STANDARDS THAT WOULD BE NATIONALLY AGREED UPON?

DR. GRIESHAMMER: THAT WOULD BE WONDERFUL, AS A MATTER OF FACT.

DR. CANET-AVILES: THAT WOULD BE THE GOAL. AND WE WILL WORK TOWARDS THAT BECAUSE IT'S ALSO KIND OF THE PLAN THAT WE HAVE IN TERMS OF CONSORTIA. SO WE ARE ALIGNING WITH THE NIH AND OTHER ORGANIZATIONS, AND ISSCR, FOR EXAMPLE, IT COULD BE ONE OF THE GOALS. AND WE COULD FORM SUBGROUPS OF THE STEERING COMMITTEE, SO WORKING GROUPS THAT COULD

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BE FOCUSED ON THAT, BUT THAT'S -- THE SPECIFICS OF THAT WE NEED TO THINK ABOUT HOW WE WILL DO IT SO THAT IT'S EFFECTIVE BECAUSE TOO MANY PEOPLE IS ALSO NOT GOING TO BE PRODUCTIVE OR EFFECTIVE. SO WE'LL HAVE TO THINK HOW WE WILL DO THAT SPECIFICALLY.

CHAIRMAN GOLDSTEIN: PAT.

DR. LEVITT: ONE OTHER THING I FORGOT TO MENTION. IN YOUR CALCULATION FOR DIFFERENCES BETWEEN THE NEWLY ESTABLISHED AND THE ENHANCED SITES, IN THE CASE WHERE THERE'S GOING TO BE EDUCATIONAL COMPONENTS, 5.4 MILLION VERSUS 4.3 MILLION, THAT'S A $1.1 MILLION DIFFERENCE WHERE THE NEW SITES ARE GOING TO BE DOING CONSTRUCTION IN ORDER TO ESTABLISH A COMPLETELY NEW SITE. SO I DON'T KNOW WHERE THAT NUMBER CAME FROM, WHETHER THERE'S FLEXIBILITY THERE, BECAUSE I THINK COSTS FOR A CONSTRUCTION AND RENOVATIONS ALSO IS VERY DIFFERENT THAN WHAT IT WAS EVEN TWO YEARS AGO. IT'S INCREDIBLY -- IT'S MUCH, MUCH HIGHER NOW, IN SOME CASES 20, 30 PERCENT HIGHER THAN IT WAS EVEN JUST WHEN THE PANDEMIC STARTED. SO I WORRY ABOUT THAT $1.1 MILLION DIFFERENTIAL BECAUSE I CAN SEE HOW THE DOLLARS FOR THE ENHANCED CORES ARE GOING TO WORK OUT FINE. I WORRY THAT FOR THE NEW SITES IT'S GOING TO BE UNDERFUNDED.

SO MAYBE CONSIDER THAT OR MAYBE GET SOME ADVISOR WHO'S DOING LAB CONSTRUCTION TO GIVE YOU A BETTER SENSE OF WHAT COSTS MIGHT BE ON AVERAGE. OF COURSE, IT'S GOING TO VARY FROM INSTITUTION TO INSTITUTION, BUT I JUST WANT TO RAISE THAT AS AN ISSUE TO THINK ABOUT OR AT LEAST BUILD IN SOME FLEXIBILITY.

DR. GRIESHAMMER: YES. I CAN SAY THAT THE PER AWARD BUDGETS THAT WE ARE CONSIDERING, THE SPACE RENOVATION AND THE EQUIPMENT LINE ITEMS ARE BASED ON ACTUALLY WHAT WE DID FUND IN PROPOSITION 71 SHARED LABS. AND IT'S 30 TO 45 PERCENT MORE THAN BACK THEN. SO WE HAVE, BASED ON THAT EXPERIENCE, WE HAVE INCREASED THE ALLOWED COSTS FOR THAT. AND THEN THE DIFFERENCE FOR THE TECHNIQUES COURSE, IT VARIES BETWEEN THE TWO SRL TYPES BECAUSE THE ESTABLISHING ONES WILL HAVE A SHORTER PERIOD OF ACTUALLY OFFERING COURSES IF THEY CHOOSE TO THAN THE MORE ADVANCED ONES.

DR. LEVITT: THE FUNDING OF THE CORES IN PROP 71 WERE AT INSTITUTIONS THAT ALREADY HAD REALLY A VERY RICH ENVIRONMENT FOR RESEARCH INFRASTRUCTURE. AND FOR THIS INITIATIVE, NEW SITES, WHAT YOU ARE ESTIMATING AS FOUR NEW SITES, THEY MAY NOT HAVE THE SAME STARTING POINT. AND SO THAT'S WHAT I'M TALKING

ABOUT. THERE MAY BE SOME NEED TO BUILD IN SOME FLEXIBILITY BECAUSE I THINK THAT DIFFERENTIAL MAY NOT BE ENOUGH TO SUPPORT THE RENOVATIONS THAT WOULD BE NEEDED FOR AN INSTITUTION THAT REALLY OTHERWISE IS RIGHT ON TARGET IN TERMS OF WHAT THEY WANT TO ACCOMPLISH.

DR. GRIESHAMMER: OKAY. THANK YOU.

CHAIRMAN GOLDSTEIN: I'LL JUST COMMENT A LITTLE BIT IN RESPONSE TO PAT'S QUESTION. IT MAY BE THAT THIS WILL BE AN EVALUATION CRITERION ULTIMATELY, WHICH IS THE SPEED AND COST CONTROL IN DEVELOPING THESE FACILITIES AT SOME INSTITUTIONS RELATIVE TO OTHERS.

DR. LEVITT: THAT'S RIGHT. I THINK THAT'S PROBABLY GOING TO BE PART OF THE EVALUATION. BUT SOME OF THIS IS OUT OF THE CONTROL OF THE INSTITUTIONS. TIMELINES MAY NOT, ARE NOT REALLY -- FOR CONSTRUCTION COSTS ARE NOT REALLY CONTROLLED BY THE INSTITUTION. AND DEPENDING UPON WHERE THEY'RE LOCATED IN CALIFORNIA, THE COSTS VARY QUITE A BIT AS WELL.

CHAIRMAN GOLDSTEIN: LET'S SEE. OTHER QUESTIONS FROM THE BOARD? GOING ONCE, TWICE, THRICE. OKAY. PUBLIC COMMENT. WHO'S MANNING THE PHONES?

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MS. BONNEVILLE: I HAVE NO HANDS RAISED.
CHAIRMAN GOLDSTEIN: NO HANDS RAISED. OKAY. THAT'S FINE THEN. I THINK WE'RE UP TO A VOTE. MARIANNE, WILL YOU PLEASE CALL THE ROLL.
MS. DEQUINA-VILLABLANCA: DEBORAH DEAS.
DR. DEAS: YES.
MS. DEQUINA-VILLABLANCA: MARK FISCHER-COLBRIE.
DR. FISCHER-COLBRIE: YES.
MS. DEQUINA-VILLABLANCA: ELENA FLOWERS.
DR. FLOWERS: YES.
MS. DEQUINA-VILLABLANCA: JUDY GASSON.
DR. GASSON: YES.
MS. DEQUINA-VILLABLANCA: LARRY GOLDSTEIN.
CHAIRMAN GOLDSTEIN: YES.
MS. DEQUINA-VILLABLANCA: PAT LEVITT.
DR. LEVITT: YES.
MS. DEQUINA-VILLABLANCA: SHLOMO MELMED.
DR. MELMED: YES.
MS. DEQUINA-VILLABLANCA: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. DEQUINA-VILLABLANCA: ART TORRES.
MR. TORRES: AYE.
MS. DEQUINA-VILLABLANCA: KAROL WATSON.
DR. WATSON: YES.

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MS. DEQUINA-VILLABLANCA: MOTION CARRIES.

CHAIRMAN GOLDSTEIN: OKAY. GOOD. THANK YOU VERY MUCH.

MS. DEQUINA-VILLABLANCA: SORRY. DID I SAY KEITH YAMAMOTO?

DR. YAMAMOTO: YOU CAN PUT A YES.

MS. DEQUINA-VILLABLANCA: OKAY. THANK YOU. THE MOTION CARRIES.

CHAIRMAN THOMAS: ANY NEW ITEMS FROM THIS GROUP? LET'S SEE. DO WE NEED TO DO ANY OTHER PUBLIC COMMENT? NO. GOT NOTHING.

I THINK WITH THAT WE ARE GOOD UNTIL OUR NEXT MEETING. THANK YOU ALL FOR YOUR TIME AND GOOD THOUGHTS.

MR. TORRES: THANK YOU, UTA AND ROSA.

(THE MEETING WAS THEN CONCLUDED AT 10:43 A.M.)

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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE VIRTUAL 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 OCTOBER 14, 2022, 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
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