

Stem Cell Agency Banks on \$32 million New Approach to Advance Research

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San Francisco, CA – When you need money you go to the bank. But when researchers need high quality stem cells where do they go to get those? Soon they'll be able to go to a stem cell bank set up by California's stem cell agency, the California Institute for Regenerative Medicine (CIRM). The governing Board of the agency today voted to approve nine applications to create the cells that will go in that bank and to run it.

The applicants will work together to collect tissue samples from people who have different diseases, turn those samples into high quality stem cell lines - the kind known as induced pluripotent stem cells (iPSC) - and create a facility where those lines can be stored and distributed to researchers who need them. The cells will be genetically identical to the people who donated the samples, and will provide a way for researchers to study those diseases.

"Access to high fidelity iPSC lines from a wide range of complex diseases will be an important accelerator of research," says Alan Trounson, PhD, President of the stem cell agency. "This initiative will provide scientists with access to multiple cell lines that should have much of the genetic variations that represent the variety within any human disease such as Alzheimer's, heart disease, lung fibrosis and autism. Scientists and companies can use these cells to discover the nature and causes of the underlying human diseases in a way not feasible before. We are hopeful these cells will be an incredible resource for scientists in their quest for understanding the origins and causes of human pathologies."

Altogether nine different groups and organizations are involved in the collection, creation, storage and distribution of the cell lines. The initiative expects to create and store 9,000 cell lines, from 3,000 individuals, representing 11 diseases at a total cost of \$32.3 million.

The stem cell agency's Board, the Independent Citizens Oversight Committee (ICOC), also approved several amendments to its bylaws. The amendments were needed following the Board's decision in January to endorse a series of changes in response to a report from the Institute of Medicine. The changes include:

- Who can vote on funding issues
- How scientific appeals are to be reviewed
- The role of patient advocates in programmatic review – where the agency tries to ensure it funds a diverse and balanced research portfolio that meets its overall goals – and the movement of programmatic review from the Grants Working Group to the Board
- The further delineation of the roles of the Chair and the President
- The establishment of a Scientific Advisory Board
- Streamlining IP revenue sharing requirements for companies
- Consider holding workshops and producing initiatives on ethics for research involving people

"We feel these changes address the recommendations from the IOM," says Jonathan Thomas, PhD, JD, Chair of the ICOC. "Our goal now is to have the focus be on the work that we do, work that the IOM had great praise for, saying it had helped establish California as a world leader in stem cell research. There is so much progress being made, and so many promising developments in stem cell research and we want that to be the center of attention from now on."

The Board also approved an Extraordinary Supplement Award of \$3 million to Dr. Mark Humayun and his team from the University of Southern California. Dr. Humayun has a Disease Team award to develop a stem cell therapy for dry Age Related Macular Degeneration (AMD), one of the leading causes of vision loss in older adults. The team has been making great progress and is on track to file an Investigational New Drug (IND) application with the FDA but because this is such a pioneering approach the precise regulatory requirements that it has to meet were not clear when the original budget was drawn up. This supplementary award is to help them work through those additional requirements and move this promising therapy closer to a clinical trial.

CIRM Human Induced Pluripotent Stem Cell (hiPSC) Initiative Awards

Application Number	Researcher	Institution	Funds committed
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hPSC Repository Award			
IR1-06600	Steven James Madore	Coriell Institute for Medical Research	\$9,999,834
hiPSC Derivation Award			
ID1-06557	Thomas J Novak	Cellular Dynamics International	\$16,000,000
Tissue Collection for Disease Modeling Award			
IT1-06611	Joseph Gleeson	University of California, San Diego	\$874,135
IT1-06596	Joseph C Wu	Stanford University	\$1,435,371
IT1-06589	Douglas Galasko	University of California, San Diego	\$643,693
IT1-06571	Joachim Franz Hallmayer	Stanford University	\$530,265
IT1-06601	Kang Zhang	University of California, San Diego	\$1,034,452
IT1-06563	Jacquelyn J Maher	University of California, San Francisco	\$865,370
IT1-06570	Brigitte N. Gomperts	University of California, Los Angeles	\$934,515
Total			\$32,317,635

About CIRM: CIRM was established in November 2004 with the passage of Proposition 71, the California Stem Cell Research and Cures Act. The statewide ballot measure, which provided \$3 billion in funding for stem cell research at California universities and research institutions, was overwhelmingly approved by voters, and called for the establishment of an entity to make grants and provide loans for stem cell research, research facilities, and other vital research

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