

12/5/22

To: ICOC

Fr: CIRM

Re: Consideration of appointment of members to the Standards Working Group

On September 29, CIRM described the <u>process</u> of identifying candidates to serve on the Standards Working Group (SWG), and the ICOC approved the appointment of Dr. Jeff Kahn to serve as co-chair of the working group. The additional SWG candidates below have been recommended for your consideration. The CIRM/ICOC team is continuing the recruitment process with the aim of appointing all 19 members and will bring additional candidates forward for consideration.

### **Recommendation:**

Staff recommends the appointment of the members the members below to the Standards Working Group.

## **Ethics Policy:**

<u>Sharon Terry</u>: Genetics research, patient and participant engagement in research consumer participation in genetic research, services and policy, she serves in a leadership role on many of the major international and national organizations. Consideration of Standard for genetic research is called out in Proposition 14, and Sharon Terry is a recognized policy expert. She was recommend and recruited by co-chair Dr. Kahn.

<u>Karen Rommelfanger</u>: Karen Rommelfanger is the program director of the Neuroethics Program at the Ethics Center and is an associate professor in the Departments of Neurology and Psychiatry at Emory. Rommelfanger also serves as a member of the BRAIN Initiative's <u>Neuroethics Working</u> <u>Group</u> and on the advisory council to the director of <u>NIH for BRAIN 2025</u>. Consideration of neuroethics was deemed a vital subject area given Proposition 14 commits CIRM to \$1.5B to diseases of the brain and CNS. She was recommend and recruited by co-chair Dr. Kahn.

<u>Melissa Lopes</u>: Melissa Lopes serves as a Senior Research Compliance Officer within the Office of the Vice Provost for Research. Lopes combines regulatory policy expertise in stem cell research with operational understanding of how research policy translates in instutional review and oversight. Ms. Lopes advises researchers and department administrators on compliance issues across Harvard University with a specific focus on stem cell research. She is a former Research Fellow in Bioethics with the Harvard Medical School Department of Global Health and Social Medicine. She has previously advised CIRM on issues relating to donor consent for biospecimen donation and the draft NIH Guidelines for Stem Cell Research. She was recommend and recruited by CIRM.

### Scientist:

<u>Rayne Rouce</u>: Rayne Rouce is a physician at Texas Children's Cancer Center where she is a member of the Bone Marrow Transplant/Stem Cell Transplant Program. Her clinical time is spent seeing leukemia and lymphoma patients. Dr. Rouce is board certified in pediatrics and pediatric hematology/oncology by the American Board of Pediatrics. She is the Associate Director for Community Engagement at Baylor Medical College and has performed medical field work in underserved areas. Her combination of stem cell transplant expertise and community engagement will inform CIRM's infrastructure and patient support programs. She has served as a GWG reviewer, and was identified based on this contribution and expertise.

<u>Benhur Lee</u>: Benhur Lee is a Professor of Microbiology at the Icahn School of Medicine at Mount Sinai (ISMMS). He obtained his MD from Yale University School of Medicine (1995). He established new concepts and standards for the HIV entry field that continue to inform current research on HIV vaccines and therapeutics. His current research focus includes gene therapy delivery and genome editing. He has previously served on the Standards Working Group where he bring insight and expertise on in vivo research models and animal welfare.

Krishanu Saha: Krishanu Saha is an associate professor of biomedical engineering, medical history and bioethics. His lab specializes in human stem cell engineering, CRISPR gene editing and epigenetic reprogramming. His scholarship includes an emphasis on science and society. He serves on the ISSCR Ethics Policy Committee and the NIH Somatic Cell Genome Editing Program. He has served as a GWG reviewer, and was identified based his publications, service on national and international science policy committees, and GWG contributions.

<u>Akshay Sharma</u>: Akshay Sharma performs bone marrow transplantation and cellular therapy at St. Jude Children's Hospital. His clinical research interests include Gene therapy and gene editing, bone marrow transplantation for patients with non-malignant hematological conditions, and development of novel reduced intensity and non-myeloablative conditioning regimens. He presented at ISCT in 2022 highlighting his research into methods for enhancing the education and consent process for sickle cell patients considering gene therapies.

John Wagner: John Wagner is a Professor in the Department of Pediatrics, Division of Blood and Marrow Transplant & Cellular Therapy. He is the Founding Director of the new Institute of Cell, Gene and Immunotherapeutics at the University of Minnesota. Co-Director of the Center for Translational Medicine, and holds two endowed chairs—Children's Cancer Research Fund/Hageboeck Family Chair in Childhood Cancer Research, and the University of Minnesota McKnight-Presidential Endowed Chair. Dr. Wagner has frequently addressed riskbenefit considerations in experimental cell and gene therapies and has extensive interactions with research participants in the informed consent process. He has served as a GWG reviewer, and has previously served on the Standards Working Group where he bring insight and expertise in clinical research ethics.

Janet Rossant: Janet Rossant is a world-renowned expert in developmental biology, is the definition of a trailblazer. She started as the Gairdner Foundation's President and Scientific Director on May 4, 2016. Widely known for her studies of the genes that control embryonic development in the mouse, Rossant has pioneered techniques for following cell fate and altering genes in embryos. This work continues to resonate in medical genetic research. Her current research focuses on stem cell development and cell differentiation in the developing embryo, important areas for the study of birth defects as well as regenerative medicine. Dr. Rossant has

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sereved in a number of advisory capacities with CIRM and was recommended by Dr. Lawerence Goldstein to bring expertise in embryology and embryo model development.

# **ICOC Nurse & Patient Advocate Members:**

- Fred Fisher co-chair
- Christine Miaskowski
- Le Ondra Clark Harvey
- Elena Flowers
- Karol E. Watson