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U.S. Department of Health and Human Services (HHS)

Title

UC Response to HHS Notice of Committee Establishment, Notice of Intent To Convene, and Call for Nominations for the NIH Human Fetal Tissue Research Ethics Advisory Board for Fiscal Year 2020

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OFFICE OF THE VICE PRESIDENT – RESEARCH AND INNOVATION

OFFICE OF THE PRESIDENT
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March 20, 2020

Executive Secretary
NIH Human Fetal Tissue Research Ethics Advisory Board—FY 2020
Office of Science Policy, NIH
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892
Submitted via email to: SciencePolicy@od.nih.gov

RE: HHS Notice of Committee Establishment, Notice of Intent To Convene, and Call for Nominations for the NIH Human Fetal Tissue Research Ethics Advisory Board for Fiscal Year 2020

Dear Executive Secretary:

I write on behalf of the University of California (UC) system with regard to the HHS Notice of Committee Establishment, Notice of Intent To Convene, and Call for Nominations for the NIH Human Fetal Tissue Research Ethics Advisory Board for Fiscal Year 2020 issued on February 20, 2020.

The UC system is comprised of ten research-intensive campuses, six medical schools, and three affiliated U.S. Department of Energy national laboratories. As a system, UC receives approximately \$6 billion annually in extramural research awards and is the nation's largest academic recipient of federally funded research and other university-based projects. In 2018, UC received more than \$2.95 billion in federal agency research funding.

The UC system nominates Dr. Lawrence Goldstein, UC San Diego (UCSD), Dr. Keith Yamamoto, UC San Francisco (UCSF), and Professor Michele Goodwin, SJD, UC Irvine (UCI) to serve on the NIH Human Fetal Tissue Research Ethics Advisory Board. Requested information about each nominee is provided below.

Dr. Lawrence S.B. Goldstein, UC San Diego

Dr. Goldstein is an internationally-recognized expert in stem cell research, molecular medicine, and neurosciences. He is a Distinguished Professor in the Department of Cellular and Molecular Medicine and the Department of Neurosciences at the University of California, San Diego (UCSD), School of Medicine, as well Scientific Director of the Sanford Consortium for Regenerative Medicine, and Director of the Sanford Stem Cell Clinical Center. He received his

B.A. degree in Biology and Genetics from UCSD and his Ph.D. in Genetics from the University of Washington, Seattle. Dr. Goldstein did postdoctoral research at the University of Colorado, Boulder and at MIT. He was assistant, associate, and tenured professor at Harvard University in the Department of Cellular and Developmental Biology. Dr. Goldstein returned to UCSD as Professor of Pharmacology, Investigator with the Howard Hughes Medical Institute, Professor and then Distinguished Professor of Cellular and Molecular Medicine and then Neurosciences. Dr. Goldstein's laboratory focuses on understanding the molecular mechanisms involved in movement inside neurons and how these systems are affected in Alzheimer's and Huntington's Diseases.

Dr. Goldstein founded and directed the UCSD Stem Cell Program and the Sanford Stem Cell Clinical Center and is founding scientific director of the Sanford Consortium for Regenerative Medicine. He co-chaired the scientific advisory board for California's Proposition 71 that established \$3 billion for stem cell medical research in the state. He served on the ISSCR Board of Directors, the Task Force on Unproven Stem Cell Therapies, and Task Force on Guidelines for the Conduct of Human Embryonic Stem Cell Research; he has been a member of the Public Policy and Ethics Committees.

Throughout his career, Dr. Goldstein has advocated for science before local, state, and national policy makers on issues such as decisions about funding levels, and guidelines and ethical standards for research using stem cells, fetal tissue, and other issues. His awards include a Senior Scholar Award from the Ellison Medical Foundation, and American Cancer Society Faculty Research Award, appointment as the Loeb Chair in Natural Sciences at Harvard University, election to the American Academy of Arts and Sciences, 2009 Public Service Award from the American Society for Cell Biology and the ARCS Scientist of the Year 2015 and ASCB Lifetime Achievement Fellow 2016.

For member category on the NIH Human Fetal Tissue Research Ethics Advisory Board, Dr. Goldstein is a scientist with substantial accomplishments in biomedical and stem cell research.

Dr. Goldstein can be reached as follows:

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Dr. Keith Yamamoto, UC San Francisco

Three elements of Dr. Yamamoto's expertise, experience and character make him an outstanding candidate for membership on this Board: Science, policy, and ethics.

Science. Dr. Yamamoto is quintessentially a "scientist with substantial accomplishments in biomedical or behavioral research." An active investigator at UCSF for 43 years, Dr. Yamamoto

is an international leader and innovator in the investigation of metazoan transcriptional regulation, using mechanistic and systems approaches to pursue these problems in pure molecules, cells and whole organisms. His transformative work has been recognized with awards, prizes, honorary lectureships, symposium chairmanships, and by election to the National Academy of Sciences, the National Academy of Medicine, the American Academy of Arts and Sciences, the American Academy of Microbiology, and fellowship in the American Association for the Advancement of Science. He is well known and highly respected in the scientific community.

Policy. Dr. Yamamoto is a generalist whose wisdom and judgment are widely sought, both for assessment of the quality and merit of scientific research, and for shaping science policy that fosters and nurtures groundbreaking scientific discovery. His ability to identify highly meritorious research proposals far outside of his own specialty has been on display throughout his career, *e.g.*, as NIH study section chair, chair of NIH Director's Working Group on Enhancing Peer Review, creator of the Transformative R01 funding mechanism (and chair of its first two rounds of review), chair of the National Academies Board on Life Sciences, and member of the National Academies Governing Board Executive Committee. He has been deeply and expansively involved in science policy for four decades, *e.g.*, support for new investigators; career exploration and composition of the scientific workforce; new models for graduate training; federal support of non-citizen trainees; open science publication and practice; conceptualization and implementation of precision medicine at federal, state and institutional levels; oversight of embryonic stem cell research and genomic editing research and regenerative medicine at international, national or state levels. He consulted with NIH and HHS on this human fetal tissue research issue. As UCSF's first Vice Chancellor for Science Policy and Strategy, he is regularly in Washington DC for various policy activities. As a trusted expert, he has testified many times before congressional committees.

Ethics. Dr. Yamamoto is sensitive and proactive in advancing the alignment of scientific research with social and ethical values and standards. He served on the committee that produced the National Academies consensus report Responsible Science. As chair of the NAS Board on Life Sciences, he helped conceptualize, and was a member of the report committees for, A New Biology for the 21st Century, which frames the role of biological research in addressing urgent societal issues, and Toward Precision Medicine, which presents an approach to integration of biomedical research, health and healthcare that promotes access of research and medical breakthroughs to all. He served on the NIH Directors Working Group on Diversity in the Biomedical Workforce. He proposed that the National Academies launch and lead an international effort on the science and social implications of genome editing, and served on the resulting committee that produced Human Genome Editing: Science, Ethics and Governance. He is a member of the Board of Directors and Executive Committee of Research!America, a 420 member alliance that promotes biomedical research and its appropriate applications and access to the public.

For member category on the NIH Human Fetal Tissue Research Ethics Advisory Board, Dr. Yamamoto is a scientist with substantial accomplishments in biomedical and ethics/policy research.

Dr. Yamamoto can be reached as follows:

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Professor Michele Goodwin, SJD, LL.M

Chancellor's Professor Michele Bratcher Goodwin is nominated for the ethicist position. She is the founder and director of the Center for Biotechnology and Global Health Policy. Her expertise is interdisciplinary spanning medical sciences, bioethics, and law. Professor Goodwin has substantial accomplishments in the bioethical, biomedical, and biotechnological fields. As well, she is a law professor. Professor Goodwin is an elected member of the renowned Hastings Center, the world's first bioethics research institute. She is also an elected member of the American Law Institute, the leading independent organization in the United States producing scholarly work for courts and legislatures. Her leadership and recognition as a leading voice in bioethics as well as tissue harvesting and transplant policy is demonstrated through prior appointments.

For example, Professor Goodwin was appointed a member of the United States National Academy of Sciences, Engineering, and Medicine Committee on Issues in Organ Donor Intervention Research. This committee was responsible for researching, analyzing, and recommending kidney transplant policy. Prior to that, Professor Goodwin was appointed an observer by the United States National Conference of Commissioners on Uniform State Laws (for the revision of the Uniform Anatomical Gift Act). The Uniform Anatomical Gift Act (UAGA) is the law that governs tissue transplant policy in the United States. For two years, Professor Goodwin guided and advised commissioners on how best to formulate tissue harvesting and transplant policing, including decisions regarding altruistic donations, compensated donation, presumed consent, and other important legal and ethical matters.

Professor Goodwin's medical and ethical research has forged important new directions in organ and tissue transplant policy. She is the author of *Black Markets: The Supply and Demand of Body Parts* (2006, Cambridge University Press) as well as the leading casebook on biotechnology and bioethics: *Biotechnology & Bioethics* (2015, Carolina University Press). Collectively, she is the author of six books and over eighty articles and book chapters. We note, Professor Goodwin's analysis on tissue and organ transplantation policy is hailed as "exceptional" in the *New England Journal of Medicine*.

Professor Goodwin holds cross-disciplinary appointments in Law; Medical Sciences; Gender & Sexuality Studies; Criminology, Law, and Society; and Stem Cell Research. This reflects her academic qualifications, which include two terminal degrees: a *juris doctorate* and *doctorate of juridical sciences*. The focus of her Master's Thesis was cornea transplant policy in the United

States. Her doctorate focused on organ transplant policy, with a particular analysis on barriers to transplantation as well as organ donation, especially from low-income and communities of color.

Over the span of her career, Professor Goodwin has conducted field research in Asia, Africa, Europe, and the United States on human trafficking. She is a widely cited legal authority in constitutional law, health law, bioethics and biotechnology, as well as women's rights. Professor Goodwin's writings have been consulted by courts, legislators, government agencies, and civil society organizations. She has advised or given testimony before state and federal governments as well as the United States' Uniform Law Commission on ethics, privacy, the regulation of the human body, and reproductive health. She has conducted policy research for state-level departments of health and human services.

A thought leader in academia, she has chaired several sections of the Association of American Law Schools, including its Health Law Section and was the co-founder of the Bio Law Section. She served as a Trustee of the United States Law and Society Association, and was elected Secretary General of the International Academy of Law & Mental Health. She has been featured in *Politico*, *Salon.com*, *Forbes*, the *New York Times*, *L.A. Times*, *Boston Globe*, *Chicago Sun Times*, NPR, and *Ms. Magazine* among others. Her scholarship, which threads ethics, history, and law, is published in the most elite law journals: the *Yale Law Journal*, *Harvard Law Review*, *Cornell Law Review*, *NYU Law Review*, *California Law Review*, *Georgetown Law Journal*, and *Northwestern Law Review* among others. A prolific author, her publications include six books and over 80 articles, essays, and book chapters.

For member category on the NIH Human Fetal Tissue Research Ethics Advisory Board, Professor Goodwin is a scientist and ethicist with substantial accomplishments in bioethics, constitutional law, family law, and health law.

Professor Goodwin can be reached as follows:

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The UC system fully endorses the nomination of Dr. Lawrence Goldstein, Dr. Keith Yamamoto, and Professor Michele Goodwin to serve on this important committee. Thank you for your consideration.

Sincerely,



Theresa A. Maldonado, Ph.D., P.E.
Vice President, Research & Innovation
University of California Office of the President