The ELSI Advisory Board

GP-write/ The Center of Excellence for Engineering Biology

Background Information on GP-write, with ELSI dimensions

The Genome Project-write (GP-write) is an open, international research project led by a multi-disciplinary group of scientific leaders who will oversee a reduction in the costs of engineering and testing large genomes, including a human genome, in cell lines by over 1,000-fold within ten years. The overarching goal of such an effort is to further our understanding of the blueprint for life provided by the Human Genome Project (HGP-read) by developing new technologies and an ethical framework for genome-scale engineering, as well as transformative medical applications.

GP-write will include whole genome engineering of human cell lines and other organisms of significance to research and development, agriculture, and public health, as well as organoids derived from human cells. A coordinated scientific effort to understand, discuss, and apply large genome editing technologies is timely, and public discourse regarding such an endeavor is both expected and encouraged as GP-write gets underway. However, responsible innovation requires having more than ELSI discussions; it also involves identifying common goals important to scientists and the public through timely and detailed consultation among diverse stakeholders.

The GP-write effort is aimed at technology development and knowledge creation, with the ultimate goal of improving life on Earth. Potential innovations relate to biomedical therapies, food supply management, biofuels, and public health. However, as with many other technology development initiatives, there is potential for misuse, and some risks may be unforeseen. Therefore, security, biosafety, and regulatory and other policies will need to be developed to help ensure that new technology is developed and deployed in ways that are ethically sound.

As such, the project infrastructure will be designed to responsibly support and advance GP-write, with a particular focus on addressing the potential risks and ethical implications of the project as they arise. The GP-write project will devote a percentage of all research funds to address ELSI issues.

Mission of GP-write ELSI Advisory Board

The ELSI Advisory Board of GP-write is tasked with elucidating the ethical, legal and social implications (ELSI) of the project, and formulating recommendations on how to address these dimensions in policies at every level (project, local, state, national and international). At each stage of the project, the GP-write ELSI board will seek input from both the scientists who are driving GP-write, as well as members of our society at large, to comprehensively examine regulatory and policy issues as well as ethical concerns. In addition, it will co-develop ethical, legal, and policy guidelines to ensure that genomic engineering/large-scale DNA synthesis technology development proceeds in a way that adheres to the highest ethical standards. With distinguished and transdisciplinary members from around the world, the GP-write ELSI

Advisory Board envisions that it will play a leading role in addressing the ELSI issues that arise in the context of synthetic biology.

To accomplish its mission, the ELSI Advisory Board will work with project scientists as well as the GP-write Public Communications and Education working groups. Close collaborations between scientists and multidisciplinary experts (e.g., bioethicists, lawyers, etc.) will allow ELSI issues to remain at the forefront of the science and technology development. Public engagement and education will also be priorities, as will the establishment of communication channels to elicit feedback and input on the project from various stakeholders.

The group will lead foresight efforts to clarify and elucidate the ethical, legal, and social dimensions of the project through legal, normative, conceptual and empirical (qualitative/ quantitative) research, including an emphasis on understanding community perspectives, in order to make sound policy recommendations on these issues. In this way, the board will advance the ELSI field from academic and legal/regulatory standpoints, using collaborative, iterative, and transparent methodology.

Members of ELSI Advisory Board (brief bios provided in Appendix A)

- Arthur Caplan, NYU Langone Health
- Carolyn Chapman, NYU Langone Health
- Barbara Evans, University of Houston Law Center (Co-chair)
- Dov Greenbaum, Yale University
- Gigi Gronvall, Johns Hopkins Center for Health Security
- Todd Kuiken, North Carolina State University
- Rosario Isasi, University of Miami School of Medicine
- Jeantine Lunshof, Harvard Medical School
- Jonathan Moreno, University of Pennsylvania (Co-chair)
- Pilar Ossario, University of Wisconsin
- Robert Smith, Kings College London
- Stephan Zuchner, University of Miami School of Medicine

Work Accomplished To Date

GP-write, through its affiliated scientists and ethicists, has already made substantial contributions to addressing the ELSI issues of synthetic biology. This work will remain an important focus of the project. Notable accomplishments are highlighted below:

- *Science* Commentary, "The Genome Project-write"[1], published June, 2016 with 25 participating authors that included both scientists and ethicists, called for the establishment of GP-write and included many references to ELSI issues:
    - "there should be equitable distribution of any early and future benefits in view of diverse and pressing needs in different global regions." [1]
    - "the highest biosafety standards should guide project work and safety for lab workers and research participants, and ecosystems should pervade the design process." [1]
    - "The project could encourage broad intellectual property access via patent pooling." [1]
    - "The broad scope and novelty of the project call for consideration of appropriate regulation alongside development of the science and societal debates. National and international laws differ, and as in stem cell research, a major burden of responsibility for setting standards rests with the scientists and their community. Existing stem cell research guidelines may serve as a useful template." [1]
    - "Responsible innovation…involves identifying common goals important to scientists and the wider public through timely and detailed consultation among diverse stakeholders." [1]

- Jef Boeke and collaborators developed a Statement of Ethics and Governance, to which all participants in the Sc2.0 project must consent.[2] The statement addresses four areas including societal benefit, intellectual property, safety and self-governance. The GP-write ELSI Advisory Board intends to create a similar statement. [2]

- Development of "Lab-based ethics:" ELSI issues have been identified from the ground up, through close collaborations between ethicist-philosophers and scientists in an approach pioneered by Jeantine Lunshof in the laboratory of Dr. George Church at Harvard Medical School
    - In collaboration with the consortium partners in GP-write, Dr. Lunshof developed a model for interactive ethics collaboration in the synthetic biology lab, and she is continuing her work in this area.
    - Her work has led to a number of both academic and mainstream publications that demonstrate the value of close interactions between ethicist-philosophers and bench scientists.[3,4]

- Leadership of successful international workshops/conferences: GP-write has already held two international workshop/conferences attended by scientists and ethicists. Many of the sessions focused on the ELSI dimensions of the project. Below we have highlighted some

the ELSI sessions; video recordings and meeting summaries of these sessions are publically available on the Center of Excellence for Engineering Biology website.

- May 2018 (Boston, MA)
  - ELSI panel
  - Carolyn Chapman, Jeantine Lunshof, Robert Smith, Gigi Gronvall

1.

- May 2017 (NY, NY)
  - Reflecting on the key scientific and technical aspects of GP-write, experts addressed issues related to the ethical, legal and societal impacts (ELSI) of GP-write and responsible innovation with the goal of identifying common objectives and moral concerns of diverse stakeholders. Guided by ESLI experts, the GP-write project will prioritize a culture of safety, together with a two-way dialogue with the public, as core project goals by establishing an inclusive decision-making partnership with humanities scholars, bioethicists, legal scholars and scientists and members of the lay public.
  - Panel/Group Discussion: Required Elements of an Ethical, Social, and Legal Roadmap for GP-write
    - Jonathan Moreno, University of Pennsylvania, Co-Moderator; Barbara Evans, Co-Moderator; Nicole Lockhart, National Human Genome Research Institute; Robert Smith, King's College London; Jeantine Lunshof, Harvard Medical School and University Medical Center, Groningen
  - Overview of Project: From Reading to Writing Genomes –Ethical Frameworks for GP-write
    - Jonathan Moreno & Barbara Evans
  - Concepts & Ethics in GP-write: Understand, Question & Advance "Lab-based ethics work"
    - Jeantine Lunshof
  - Understanding and Anticipating Governance Systems (Local, State, National and International)
    - Gigi Gronvall

- May 2016 (Boston, MA)
  - Regulatory and Bioethical Implications of the 1% Pilot Projects (Panel Discussion)
    - Eleonore Pauwels, Wilson Center, Moderator; Jeantine Lunshof, Harvard Medical School; Matthew Porteus, Stanford University;

Barbara Evans, University of Houston Law Center; Nicole Lockhart, National Human Genome Research Institute

- Is "HGP-write: Testing Large Genomes in Cells" a wise choice? (Panel Discussion)
  - Moderator: Marc Vidal, Harvard Medical School Department of Genetics;
    Debra Mathews, Johns Hopkins Berman Institute of Bioethics; Scott Fahrenkrug, Recombinetics; Nicole Lockhart, National Human Genome Research Institute

Additional Work Includes:

- White Paper dated November 30, 2016, "Genome Project-write: A Grand Challenge Using Synthesis, Gene Editing and Other Technologies to Understand, Engineer and Test Living Systems"[5]
- GP-write ELSI Advisory Board has met monthly from June 2017 through present; transcripts of meetings are available
- Carolyn Chapman, Postdoctoral Fellow in Division of Medical Ethics at NYU School of Medicine, will spend 30% of her time on GP-write initiative, collaborating with members of Jef Boeke's laboratory to identify and analyze ELSI issues that arise in the context of synthetic biology, and working on projects with the ELSI Advisory Board.

Short-term Work: GP-write Pilot Projects

- The ELSI Advisory Board will continue to review all GP-write Pilot Projects as part of the evaluation and approval of such projects by the Scientific Executive Committee.

- Continue the integrated bioethics approach developed by Jeantine Lunshof, an ethicist-philosopher, of proactive, interactive collaboration with scientists in GP-write laboratories. This approach has already demonstrated the potential of producing meaningful progress on the identification and analysis of ELSI issues relating to large-scale genome engineering.

  - Approach is being implemented in the first two funded Pilot Projects approved by the Scientific Executive Committee
    - "Synthesizing a Prototrophic Human Genome," Harris Wang, Columbia University and Jef Boeke, NYU Langone Medical Center. Chronic malnutrition is a global health challenge that leads to a variety of systemic diseases, mortality and negative life outcomes, afflicting especially children and adults in underdeveloped and developing countries. Humans cannot produce all of the necessary metabolites needed for growth and

maintenance and only some vitamins. As a result, they require significant dietary supplementation often not available in underdeveloped countries. Amino acid and vitamin deficiencies as a result of chronic malnutrition and food shortage can potentially be addressed using synthetic biology approaches. This project is exploring the possibility of introducing the missing biosynthetic pathways necessary for production of these essential metabolites in humans from simple sugars from diet.

- "Ultra Safe Cell Line," Jef Boeke, NYU Langone Medical Center and George Church, Harvard Medical School and the Wyss Institute. There is an unmet need for an "Ultrasafe human cell line" designed to serve as a platform for many biomedical applications, from production of biologics, to modeling cell and tissue behaviors, to actual ex vivo and ultimately in vivo applications. This project will engineer a human cell line for use as a basic and potentially universal platform for human biotechnology. This can be done by altering roughly 1% of the genome, including the exons of all of the genes, and nearby sequences, leaving the vast majority of the noncoding regions, which are at this point far less well understood, untouched. This cell line will be engineered to be ultrasafe from many distinct perspectives, including virus resistant, prion resistant, retroelement/transposon free, triplet repeat resistant, germ line negative, radiation resistant, with multiple self-destruct circuits, cancer resistant, immune-negative, with multiple safety targetable sites, a major allele for every SNP and indel, scramble-able which allows rapid evolutionary optimization for desirable traits.

- Pilot project deliverable: co-written academic paper between GP-write member(s) of ELSI Advisory Board and scientists, identifying and elucidating ethical aspects of the scientific endeavors, as well as pieces in popular / mainstream outlets to raise awareness of the issues

- GP-write ELSI Principles and Workshops

  - Develop Ethics and Governance Framework for the GP-write Consortium members to adhere to (akin to Sc2.0 statement mentioned above)

- Lead a landscape review of:
    - Existing governance approaches to large-scale collaborative projects in the life sciences
    - Existing developments within whole genome engineering and their potential ethical, social, legal and political significances vis-à-vis existing governance frameworks
    - There is significant ELSI literature on many of these technologies; therefore, ELSI implications of GP-write can build from this foundation, and contribute to it.

- Develop and hold first workshop to involve scientists, social scientists, legal scholars and bioethicists to collaboratively analyze how GP-write science and technology is similar to and distinct from other genetic, molecular and cellular technologies such as Genome Editing, Stem Cells, Recombinant DNA, Biosafety/ biosecurity, etc. Collaborative landscape and gap analysis.
    - Deliverable: Generate press coverage, and "Sutherland Style" academic paper written post-workshop; share findings in mainstream press as well. First workshop within 6 months.

- Develop and hold second workshop aimed at using framework developed in first meeting to present and discuss with public stakeholders and elicit feedback
    - Deliverable: Generate press coverage/ academic paper written post-workshop/ share findings in mainstream press as well; Second workshop within 12 months

2.

- Pursue funding sources for ELSI projects and work
    - GP-write is currently seeking funds for consortium level support (a portion of which would go towards ELSI work), but GP-write science is progressing via decentralized funding sources (i.e., grant and other financial support of associated, independent laboratories)
    - Similarly, the ELSI group plans to pursue funding that is specific to its work on the ethical, legal and social implications of the large scale DNA synthesis and genome engineering technology development that defines GP-write

Longer-term Roadmap

- Build on the GP-write ELSI foundational work started by pilot projects and workshops, and extend the research and dialogue of the broader field
    - Continue "landscape survey" of the ELSI literature, policies and regulations regarding large-scale genome engineering and "gap" analysis of issues that need to be addressed or explored further
    - Continue ELSI normative, conceptual and empirical research
    - Plan and organize regular meetings for the broader scientific and ELSI communities
    - Formulate policy recommendations on ELSI issues relating to synthetic biology, and advocate for policy changes if needed
    - Establish communication channels to elicit ongoing feedback and input on the project from various stakeholders
    - Educate the broader community, foster and engage in an informed dialogue with the public
    - Develop a curriculum to both inform scientists as well as the lay public about innovations (true potential, as well as myths in genomics)

- The mission and goals of the GP-write ELSI Advisory Board require sustained collaboration and interactive work between board members (which also includes policy experts), the scientific teams, the GP-write Communications and Education Working Groups, as well as the broader public.

1. Boeke JD, Church G, Hessel A, Kelley, N et al. The Genome Project-Write. *Science* 2016; **353**(6295): 126-7.
2. Sliva A, Yang H, Boeke JD, Mathews DJ. Freedom and responsibility in synthetic genomics: the synthetic yeast project. *Genetics* 2015; **200**(4): 1021-8.
3. Aach J, Lunshof J, Iyer E, Church GM. Addressing the ethical issues raised by synthetic human entities with embryo-like features. *Elife* 2017; **6**.
4. Lunshof J. Gene editing is now outpacing ethics. The Washington Post. December 12, 2017.
5. Boeke JD, Church G, Hessel A, Kelley NJ, and the GP-write Consortium. Genome Project-write: A Grand Challenge Using Synthesis, Gene Editing and Other Technologies to Understand, Engineer and Test Living Systems. November 30, 2016.

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Appendix A

GP-write ELSI Advisory Board

Arthur Caplan is the Drs. William F. and Virginia Connolly Mitty Professor and founding Director of the Division of Medical Ethics in the Department of Population Health at New York University Langone Medical Center in New York City. Prior to coming to NYU, he was the Sidney D. Caplan Professor of Bioethics at the University of Pennsylvania Perelman School of Medicine in Philadelphia, where he created the Center for Bioethics and the Department of Medical Ethics. Dr. Caplan has also taught at the University of Minnesota (where he founded the Center for Biomedical Ethics), the University of Pittsburgh, and Columbia University. He was the Associate Director of The Hastings Center from 1984-1987. He has served on a number of national and international committees including as Chair of the National Cancer Institute Biobanking Ethics Working Group; Chair of the Advisory Committee to the United Nations on Human Cloning; Chair of the Advisory Committee to the Department of Health and Human Services on Blood Safety and Availability; member of the Presidential Advisory Committee on Gulf War Illnesses; member of the advisory committee to the Wellcome Trust on research in humanitarian emergencies; and the special advisory panel to the National Institutes of Mental Health on human experimentation on vulnerable subjects. He served as the Co-Director of the Joint Council of Europe/United Nations Study on Trafficking in Organs and Body Parts. He is currently the ethics advisor to DOD/DARPA on synthetic biology. Dr. Caplan is an internationally recognized authority on research ethics and research involving vulnerable populations. He has written extensively on transplantation ethics including donation, allocation, eligibility, trafficking and cost. He is one of the leading authorities in the world on vaccine ethics. He has conducted empirically based normative analyses of issues regarding transplantation, vaccines, research ethics, rationing, and compassionate use. Dr. Caplan received his PhD in Philosophy from Columbia University.

Selected articles

"Lessons from the genome" in G Marcus, ed., The Future of the Brain, Princeton, Princeton University University Press, 2014: 194-204 (with N Kunzler)

"Chloe's law: a powerful legislative movement challenging a core ethical norm of genetic testing", PLOS Biology, 13, 8, 2015:e1002219. doi:10.1371/journal.pbio.1002219.

Neuhaus CP, Caplan AL (2017) Genome editing: Bioethics shows the way. PLoS Biol 15(3): e2001934. https://doi.org/10.1371/journal.pbio.2001934

'Ethical lessons from a tale of two genetically modified insects'. Nature Biotechnology. 35(8) 2017:713-716 (with C. Neuhaus)

"The Council of Europe should not reaffirm the ban on germline genome editing in humans," EMBO Reports, 2017:1-2 (with P Sykora)

Carolyn Riley Chapman, PhD MS, is currently a Postdoctoral Fellow in the Division of Medical Ethics in the Department of Population Health in NYU School of Medicine. She has a wide range of academic, professional, and volunteer experiences, in addition to spending a number of years as a stay-at-home mother. At NYU, she serves as Deputy Chair for the CompAC Infectious Disease committee, which advises Janssen Pharmaceuticals on complex single patient expanded access requests for investigational drugs. Prior to joining NYU, she was Associate/ Lecturer in the Columbia University Bioethics program from July 2016 through August 2017. From February through June 2016, she served as Interim Associate Director for the Columbia Bioethics program. Dr. Chapman has also worked as a freelance science/medical writer, and has published articles in *MedPage Today, Voices in Bioethics, Start-Up, Drug Discovery & Development*, and *Genetic Engineering News*. In the past, Dr. Chapman worked at L.E.K. Consulting as a business strategy consultant in the biotech/pharma industry. She also contributed to the growth of a biopharmaceutical company from its earliest stages, as the third employee at Aton Pharma, a start-up that developed a cancer drug discovered in Columbia University and Memorial Sloan Kettering laboratories. She received an MS Bioethics from Columbia University. As part of an independent study while in the program, she assisted Columbia University's Human Research Protection Office with editing template informed consent forms for Whole Genome and Whole Exome Sequencing research. Dr. Chapman has also participated in creative writing classes at Sarah Lawrence College Writing Institute, and completed two years of a four-year Christian certificate program: Education for Ministry (Episcopal). She earned a Ph.D. in Genetics at Harvard University (studying cell cycle checkpoints in the fission yeast *S. pombe*), after graduating from Dartmouth College *summa cum laude* with high honors in Biology.

Select articles, related to genetics:

Chapman, C.R. Submission for Nuffield Council on Bioethics Open Call for Evidence: Perspectives on the Ethics of Genome Modification using CRISPR-Cas 9. Submitted January 13, 2016. http://nuffieldbioethics.org/wp-content/uploads/genome-editing-evidence-Carolyn-Riley-Chapman.pdf

Chapman, C.R. Is There Value in This Test for Certain Breast Cancer Patients?, *MedPage Today*, January 24, 2017.

Chapman, C.R. Genetic Risk Factors Specific for Psoriatic Arthritis Identified, *MedPage Today,* May 19, 2015.

Chapman, C.R. Race to Cut Whole Genome Sequencing Costs, *Genetic Engineering News*, Volume 25, Number 5, March 1, 2005, p.48, 66.

Chapman, C.R., Evans, S.T., Carr, A.M., and Enoch, T. (1999) Requirement of sequences outside the conserved kinase domain of fission yeast Rad3p for checkpoint control. *Mol. Biol. Cell*, 10 (10): 3223-38.

Stewart, E., Chapman, C.R., Al-Khodairy, F., Carr, A.M., and Enoch, T. (1997) *rqh1*$^{+}$, a fission yeast gene related to the Bloom's and Werner's syndrome genes, is required for reversible S phase arrest. *EMBO J.*, 16 (10): 2682-92

Barbara Evans is the Alumnae College Professor of Law and Director of the Center for Biotechnology & Law at the University of Houston Law Center, a member institution of the Texas Medical Center, and she holds a joint appointment as Professor of Electrical and Computer Engineering at the University of Houston Cullen College of Engineering. Her research interests include citizen science and citizen-led bioethics standard-setting, health information systems and data privacy, and FDA, USDA, and EPA regulatory issues with genome sequencing and gene editing. She was named a Greenwall Foundation Faculty Scholar in Bioethics for 2010-2013 and is an elected member of the American Law Institute. Her recent activities have included serving on the U.S. National Academies' Committee on Future Biotechnology Products; participating in the Oxford Union's history 2016 debate about the morality of gene editing; serving on the U.S. Food and Drug Administration's Sentinel System Privacy Panel and Patient Engagement Working Group and on the U.S. National Committee for Vital and Health Statistics from 2015-2017. She holds an electrical engineering degree from the University of Texas at Austin, an M.S. and Ph.D. in Earth Sciences from Stanford University, a J.D. from Yale Law School, and she completed a postdoctoral fellowship in clinical ethics at the University of Texas M.D. Anderson Cancer Center. She is licensed to practice law in New York and Texas.

Dov Greenbaum is affiliated with the Department of Molecular Biophysics and Biochemistry at Yale University, and is the Director of the Zvi Meitar Institute for Legal Implications for Emerging Technologies at the Interdisciplinary Center (IDC) Herzliya. Dr. Greenbaum completed postdoctoral fellowships at Stanford and Eidgenössische Technische Hochschule Zürich (ETH Zürich), via the Branco Weiss Society in Science Fellowship, where he focused on bioethical issues in personal genomics and other issues related to science in society. In addition to his many legal and scientific papers he has also written non-technical lay pieces relating to the ethical legal and social implications of science in general and genomics in particular. Dr. Greenbaum has his law degree from the University of California, Berkeley where he also received a Law & Technology Program Certificate from the Berkley Center for Law and Technology. Dr. Greenbaum has a PhD in Genetics/Bioinformatics from Yale University. He is licensed to practice law in the State of California and before the United States Patent and Trademark Office.

Gigi Gronvall is a Senior Scholar at the Johns Hopkins Center for Health Security and an Associate Professor in the Department of Environmental Health and Engineering at the Johns Hopkins Bloomberg School of Public Health. She is an immunologist by training.

Dr. Gronvall is the author of the book *Synthetic Biology: Safety, Security, and Promise*, published in fall 2016 (Health Security Press). While the synthetic biology discipline is poised to revolutionize important sectors for national security, there are technical and social risks. Dr. Gronvall describes what can be done to minimize risks and maximize the benefits of synthetic biology, focusing on biosecurity, biosafety, ethics, and US national competitiveness. *Dr. Gronvall is also the author of the book Preparing for Bioterrorism: The Alfred P. Sloan Foundation's Leadership in Biosecurity*. By describing the major grants that represented Sloan's investments in civilian preparedness, public health law, law enforcement, air filtering in buildings, influenza preparedness, and business preparedness, Dr. Gronvall constructed, for a nontechnical audience, a chronicle of early gains in US efforts to confront the threat of bioterrorism.

Dr. Gronvall is a member of the Threat Reduction Advisory Committee (TRAC), which provides the Secretary of Defense with independent advice and recommendations on reducing the risk to the United States, its military forces, and its allies and partners posed by nuclear, biological, chemical, and conventional threats Dr. Gronvall received a BS in biology from Indiana University, Bloomington. She subsequently worked as a protein chemist at the Memorial Sloan-Kettering Cancer Center and received a PhD from Johns Hopkins University for work on T-cell receptor/MHC I interactions. She was a National Research Council Postdoctoral Associate at the US Army Medical Research Institute of Infectious Diseases (USAMRIID) in Fort Detrick, Maryland.

Todd Kuiken is a Senior Research Scholar with the Genetic Engineering and Society Center at NC State University where he explores the scientific and technological frontier, stimulating discovery and bringing new tools to bear on public policy challenges that emerge as science advances. He has numerous projects evaluating and designing new research and governance strategies to proactively address the biosafety, biosecurity and environmental opportunities/risks associated with emerging genetic technologies. He previously was the principal investigator on the Woodrow Wilson Center's Synthetic Biology Project.

In September 2016 he received a grant from the Robert Wood Johnson Foundation to enable the fast-growing ecosystem of "DIY" health innovators to develop a culture of responsibility that reflects its pluralistic and open-source ethos. In addition, he has received a grant from the Open Philanthropy Foundation for a project to ensure safety and security within the rapidly expanding community of amateur biologists and the growing network of community laboratories and maker spaces. The initiative is evaluating the current capabilities of the community and developing programs around the potential biosafety and biosecurity threats associated with such a diffuse community.

Dr. Kuiken is a member of the United Nations Convention on Biological Diversity Ad-Hoc Technical Expert Group on Synthetic Biology. He has also worked with the United Nations Treaty for Plant Genetic Resources for Food and Agriculture to assess how changes in science

and technology, mainly de-materialization and digitization of data, will affect the structure, function and viability of the Treaty. He is also a member of the human practices committee of the International Genetically Engineered Machines competition and a founding member of its biosafety/biosecurity committee.

Dr. Kuiken has provided expert testimony in front of the U.S. National Security Agency Advisory Board, the U.S. National Academies of Science, the United Nations Bioweapons Convention, the Organization for Economic Co-operation and Development, has been featured on NPR's Science Friday, and is a regular speaker on public policy issues related to nanotechnology and synthetic biology.

After completing his B.S. in Environmental Management and Technology at Rochester Institute of Technology he worked directly with renowned scientists on the biogeochemical cycling of mercury at the Oak Ridge National Laboratory. He earned an M.A. in Environmental and Resource Policy from The George Washington University concentrating on the scientific, economic and community development aspects of environmental issues. While there he worked at various environmental non-profits including the National Wildlife Federation where he worked within the Clean the Rain campaign that dealt with the environmental and public health threats associated with mercury pollution. Dr. Kuiken earned his Ph.D. from Tennessee Tech University where his research focused on the air/surface exchange of mercury associated with forest ecosystems. As part of his dissertation he synthesized these results with other studies associated with mercury cycling, public health threats and policy alternatives to bring attention to the threats and need for an improved public policy dealing with mercury pollution.

Citations:

Kuiken, T. Welch, E. Bagley, M.; Louafi, S. 2017. Potential implications of new synthetic biology and genomic research trajectories on the International Treaty for Plant Genetic Resources for Food and Agriculture. http://www.fao.org/fileadmin/user_upload/faoweb/plant-treaty/GB7/gb7_90.pdf

Wintle, B.C. et al. 2017. A transatlantic perspective on 20 emerging issues in biological engineering. eLife. 6:e30247. DOI: https://doi.org/10.7554/eLife.30247

Kuiken, T. 2016. Governance: Learn from DIY biologists. Nature. Vol. 531, 167-168.

Kuiken, T., Quadros, M., McGinnis, S., Hull, M. 2015. Public's Understanding, Perceptions, and Acceptance of Nanotechnology through the Lens of Consumer Products. In: Nanoengineering: Global Approaches to Health and Safety Issues, Edited by Patricia I. Dolez. Elsevier. ISBN: 9780444627476.

Kenneth A Oye, Kevin Esvelt, Evan Appleton, Flaminia Catteruccia, George Church, Todd Kuiken, Shlomiya Bar-Yam Lightfoot, Julie McNamara, Andrea Smidler, James P Collins. 2014. Regulating Gene Drives. Science. Vol. 345(6197).

Rosario Isasi, J.D., M.P.H., is a Research Assistant Professor at the Dr. John T. Macdonald Foundation Department of Human Genetics at the University of Miami Miller School of Medicine. She holds multiple appointments, including at the Institute for Bioethics and Health Policy, within which she serves as Director of their Genetics, Ethics, and Policy Program, as well as the John P. Hussman Institute for Human Genomics and the Interdisciplinary Stem Cell Institute.
Prof. Isasi's research is devoted to identifying and analyzing the social, ethical and policy dimensions of novel and disruptive genetic technologies. She has built an international reputation as a scholar with particular expertise in the area of international comparative law and ethics regarding genomics and regenerative medicine.

She holds many leadership roles in major international initiatives. Prof. Isasi was recently named the President's International Fellow of the Chinese Academy of Sciences (CAS). She is Co-Investigator and ELSI/Communications lead for the SouthEast Enrollment Center (SEEC) a consortium member of NIH's All of Us Research Program. In addition, she serves as the Ethics/ Policy Advisor of the European Commission's European Human Pluripotent Stem Cell Registry (hPSC^{REG}), is a member of the Ethics Advisory Board of the "Vanderbilt-Miami-Meharry Center of Excellence in Precision Medicine and Population Health" and the American Society for Human Genetics (ASHG) Task Force on "Gene Editing". Finally, she is a member of the Ethics & Policy Committee of the International Society for Stem Cell Research (ISSCR) and is the Chair of the International Stem Cell Forum (ISCF) Ethics Working Party, a consortium of funding agencies for regenerative medicine.

Prof. Isasi has extensive expertise in providing socio-ethical and legal (ELSI) consultation to multidisciplinary research consortia, particularly in the context of highly disruptive technologies (regenerative medicine, genome editing, synthetic biology, etc.). Her work centers on the prospective identification and management of actual, perceived or emerging ELSI issues and challenges. It also focuses on societal attitudes towards scientific innovation and the factors shaping technological uptake, public engagement and support. As her record of scholarship reflects, Prof. Isasi has unique expertise in international comparative policy. As such, her work is devoted to analyzing whether national regulatory frameworks are fit-for-purpose and, as such, if they promote or hinder innovation. Prof. Isasi's scholarship has contributed to policy reform and the development of evidence-based professional and ethical guidelines. Moreover, her work has

contributed to the development of novel approaches for consenting, data security/sharing, governance models (biobanking, bioinformatics), amongst others. In addition, she has significant experience in both educational and academic research on responsible innovation frameworks and the ELSI implications surrounding the use of novel genomic technologies in research and clinical applications together with their impact on individuals and society.

(Selected) Publications:

Ormond KE, Mortlock D (Co-Chairs), et. al. (Isasi R) Jointly written by: Association of Genetic Nurses and Counsellors (AGNC, UK), International Genetic Epidemiology Society (IGES), National Society of Genetic Counsellors (NSGC, US). Affirmed by the British Society of Genetic Medicine and the, European Society of Human Genetics. American Society for Human Genetics (ASHG) Position Statement on: "Human Germline Genome Editing" (2017). *Am J Hum Genet.* 2017 Aug 3;101:167-176. http://dx.doi.org/10.1016/j.ajhg.2017.06.012. PMID: 28777929.

Isasi R. "Justice in Genomics", (2017) Nature Nov. 16, 551):296-7

Isasi R., Kleideman E. Knoppers B.M. ***"Editing Policy to Fit the Genome?"*** Science. 2016 Jan 22;351(6271):337-9. doi: 10.1126/science.aad6778

Knoppers BM, Leader A, Hume S, Shoubridge EA, Isasi R, Noohi F, Ogbogu U, Ravitsky V, Kleiderman E. "Mitochondrial Replacement Therapy: The Road to the Clinic in Canada". *J Obstet Gynaecol Can.* 2017 July 18. pii S1701-2163(17)30498-X. https://doi.org/10.1016/j.jogc.2017.05.007. PMID: 28733061.

Illes J, Sipp J, Kleiderman E, Benjaminy S, Isasi R, Lomax G., Master Z, McCormick J, Ogbogu U, Ravitsky V, Robillard J, Rossi F, Wilson B, Zarzeczny A. "A Blueprint for the Next Generation of ELSI Research, Training, and Outreach in Regenerative Medicine". *NPJ Regen Med.* 2017 July 5;2:21. doi:10.1038/s41536-017-0026-z.

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- Award # 1OT2OD025285-01 08/26/2017 – 05/31/2018
  NIH/NCATS (Züchner S. (Contact), Carrasquillo O., Hogan WR, Pemu P.E., Pericak-Vance M., Shenkman E.A., Zwick M.E; PIs)

"SouthEast Enrollment Center" (SEEC)" (National Institutes of Health "All of Us Research Program")
We propose to create the South-East Enrollment Center (SEEC) which will provided data from 150,000 volunteers in Florida and Georgia in support of the NIH's Precision Medicine Initiative. Nearly one-third of the SEEC cohort will be Hispanic/Latino and another third black/African American. Our team's combined expertise in genomics, development of robust bio-repositories, outreach and ethics will help ensure that the required novel regulatory, governance and ethical approaches are developed and implemented across all SEEC sites**.**
Role: Co-Investigator, Lead ELSI and Communications.

- Project Number 723620 01/01/2017 – 02/01/2020
(Andreas Kurtz)
European Commission/Seventh Framework Programme (FP7) "European Human Pluripotent Stem Cell Registry (EU-hPSCreg)"
The objective of the EU-hESCreg is to promote access to human pluripotent stem cell (hPSC) lines and to provide transparency about their characteristics, to contribute to the harmonization of hPSC usage and develop it into an international hub.
Role: Ethics & Policy Advisor (sub-contract)

- Project Number N/A (Rosario Isasi) 01/03/2017 – 12/31/2018
Chinese Academy of Science - CAS President's International Fellowship Initiative
"From Stem Cells to Genomic Medicine: Fostering USA-China Partnerships through science, policy and ethics".
The purpose of this fellowship is (i) to facilitate collaborative research projects and develop best practices on regulatory and ELSI issues across host institutions in the field of genomics and regenerative medicine, (ii) to foster training of researchers, with particular focus on ethics and policy; and, (iii) Identify research gaps and address them by capitalizing on national strengths.
Role: Principal Investigator

Jeantine Lunshof is a philosopher and ethicist. She is a Research Scientist at MIT Media Lab, Ethics Consultant to the Church Lab at Harvard Medical School, and Assistant Professor at the Department of Genetics, University Medical Center Groningen, The Netherlands. She obtained her Bachelor's degree in Philosophy with a minor in Tibetan Language & Culture at Hamburg University (Germany) and graduated in Philosophy with a minor in Health Law at the University of Amsterdam. She obtained her PhD degree at VU University with a thesis concerning the impact that developments in genomic sciences have on practical ethics and normative theory. Jeantine was awarded a prestigious Marie Curie Fellowship by the European Commission in 2013. She is ethics consultant with the Harvard Personal Genome Project since 2006, and with the past and the current Center for Excellence in Genomic Science: *Causal Consequences of*

Variation (CCV, 2010-2015), and *Center for Genomically Engineered Organs* (CGEO, 2015-present) at Harvard Medical School. In 2006, she developed the innovative model of *Open Consent* that forms the normative backbone of the Personal Genome Project. Dr. Lunshof has been Ethics Advisory Board Member for two large European Commission-funded research consortia, and is Affiliate Faculty of the Harvard Center for Bioethics.

Dr. Lunshof has been involved with the Genome Project-write from its inception and is an active member of the Ethics Advisory Board. In collaboration with the consortium partners in GP-write, she is currently developing a model for interactive ethics collaboration in the synthetic biology lab.

Recent public outreach:

https://dewerelddraaitdoor.bnnvara.nl/media/381550 (on the Chinese macaque cloning experiments; prime time national public television, Netherlands)

https://www.washingtonpost.com/news/theworldpost/wp/2017/12/12/bioethics/?utm_term=.18611502d8b6

https://www.statnews.com/2017/02/23/bioethics-harvard-george-church/

Selected publications:

From genetic privacy to open consent. Jeantine E Lunshof, Ruth Chadwick, Daniel B. Vorhaus and George M. Church. Nature Reviews Genetics 2008;9:406-411

GENOME ENGINEERING. The Genome Project-Write. Boeke JD, Church G, [...] Lunshof J, [...] Way JC, Yang L. Science 2016;353:126-127. doi:10.1126/science.aaf6850

Addressing the ethical issues raised by synthetic human entities with embryo-like features Aach J, Lunshof J, Iyer E & Church GM eLife 2017;6:e20674. doi: 10.7554/eLife.20674.

Revisiting the Warnock rule Is it time to reassess the 14-day rule for human embryo research? Hurlbut JB, Hyun I, Levine AD, Lovell-Badge R, Lunshof JE, et al Nat Biotechnol 2017;35(11): 1029-1042. doi: 10.1038/nbt.4015

Jonathan Moreno is a Penn Integrates Knowledge university professor at the University of Pennsylvania, holding the David and Lyn Silfen chair. He is also Professor of Medical Ethics and Health Policy, of History and Sociology of Science, and of Philosophy. His most recent book, *Impromptu Man: J.L. Moreno and the Origins of Psychodrama, Encounter Culture, and the Social Network,* the life and times of his father the psychiatrist J.L. Moreno, was named a "#1 new release" by Amazon.com. It has been translated into Portuguese and is scheduled to be published in Chinese by the Beijing Normal University Press. Moreno's previous book, *The Body Politic: The Battle Over Science in America*, was named a Best Book of 2011 by Kirkus Reviews. A revised and updated edition of his book *Mind Wars: Brain Science and the Military in the 21st Century*, which has been published in Japanese, is available in paperback. His co-authored book on neuroscience is under contract with Columbia University Press. He is

currently working on a book for W.W. Norton on the history and philosophy of bioethics with Penn president Dr. Amy Gutmann.

In 2008-09 Moreno served as a member of President Barack Obama's transition team. His work has been cited by Al Gore and was used in the development of the screenplay for "The Bourne Legacy." His online neuroethics course drew more than 36,000 registrants in 2013. Moreno's writings have been translated into Chinese, German, Japanese and Portugese. The *American Journal of Bioethics* has called him "the quietly most interesting bioethicist of our time."

Moreno is an elected member of the National Academy of Medicine and is a National Associate of the National Research Council. He has served as a senior staff member for three presidential advisory commissions, including the bioethics commission under President Obama, and has given invited testimony for both houses of congress. Moreno is the U.S. member of the UNESCO International Bioethics Committee. From 2005 to 2017 he was a senior fellow at the Center for American Progress.

Moreno received his Ph.D. in philosophy from Washington University in St. Louis, was an Andrew W. Mellon post-doctoral fellow, holds an honorary doctorate from Hofstra University, and is a recipient of the Benjamin Rush Medal from the College of William and Mary Law School and the Dr. Jean Mayer Award for Global Citizenship from Tufts University. In 2014 he was named to a three-year term as Visiting Professor in History at the University of Kent in Canterbury, England. In 2016 with the support of the Wellcome Trust he collaborated with Kent's Professor Ulf Schmidt on human research ethics in Central-Eastern Europe during the cold war.

Notable Accomplishments:

The National Academies Consensus Study on Human Gene Editing, Report Review Coordinator, 2016-17

Gutmann A. and Moreno J.D. "Keeping CRISPR Safe," Foreign Affairs, May/June 2018, pp. 171-176

Moreno J.D., "Human Gene Editing: Where Does the 2017 National Academy of Sciences Report Bring Us?" Annals of Internal Medicine 10(166):2017

Committee for Ethical and Societal Implications of Advances in Militarily Significant Technologies that are Rapidly Changing and Increasingly Globally Accessible, Committee on Science Technology and the Law, National Academy of Sciences, 2011-13

Advisory Committee on Human Embryonic Stem Cell Research, Institute of Medicine/National Academy of Sciences, 2006-09

Moreno J.D. Mind Wars: Brain Science and the Military in the 21st Century. New York: Bellevue Literary Press, 2012 (revised and updated from Mind Wars, 2006).

Moreno J.D. The Body Politic: The Battle over Science in America. New York: Bellevue Literary Press, 2011.

Pilar Ossario is Professor of Law and Bioethics where she is on the faculties of the Law School and the Department of Medical History and Bioethics at the Medical School. In 2011 she became the inaugural Ethics Scholar-in-Residence at the Morgridge Institute for Research, the private, nonprofit research institute that is part of the Wisconsin Institutes of Discovery. She also serves as the co-director of UW's Law and Neuroscience Program, as a faculty member in the UW Masters in Biotechnology Studies program, and as Program Faculty in the Graduate Program in Population Health. Prior to taking her position at UW, she was Director of the Genetics Section of the Institute for Ethics at the American Medical Association, and taught as adjunct faculty at the University of Chicago Law School.

Dr. Ossorio received her Ph.D. in Microbiology and Immunology in 1990 from Stanford University. She went on to complete a post-doctoral fellowship in cell biology at Yale University School of Medicine. Throughout the 1990's Dr. Ossorio also worked as a consultant for the federal program on the Ethical, Legal, and Social Implications (ELSI) of the Human Genome Project, and in 1994 she took a full time position with the Department of Energy's ELSI program. In 1993, she served on the Ethics Working Group for President Clinton's Health Care Reform Task Force.

She received her JD from the University of California at Berkeley School of Law in 1997. While at Berkeley she was elected to the legal honor society Order of the Coif and received several awards for outstanding legal scholarship.

Throughout her career, Dr. Ossorio has participated in numerous advisory committees and boards that aid governments in setting science policy. She has advised the U.S. National Institutes of Health and the FDA, Genome Canada, and Health Canada. In 2012 she was appointed to a four year term on the Secretary's Advisory Committee on Health Research Protections, a committee to advise the Secretary of Health and Human Services on how to improve protections for people who participate in biomedical and behavioral research. She recently completed a term on the National Advisory Council for Human Genome Research, and she has served on or chaired numerous committees and working groups that advise large-scale genome research initiatives, such as the 1000 Genomes Project and the Human Microbiome project. She has also served as a member of, or liaison to, several Boards and Committees for the Institute of Medicine and the National Research Council (both part of the National Academies of Science), including the National Cancer Policy Board, the Human Embryonic Stem Cell Advisory Committee, and the

Committee on Intellectual Property Rights. She is an elected fellow of the American Association for the Advancement of Science (AAAS).

Since 2005, Dr. Ossorio has worked helping American Indian communities to develop research governance and oversight processes. For five years she consulted on the Havasupai tribe's research-related litigation, which settled in 2010.

Dr. Ossorio's research interests revolve around research ethics and the protection of research participants, including: governance of large bioscience projects; data sharing in scientific research; the use of race in biomedical and social science research; ethical and regulatory issues in human subjects research; and the regulation and ethics of online research. She is also quite interested in novel ethical, regulatory, and policy issues raised by research aimed at moving scientific and engineering findings from the laboratory to the product development and medical/ therapeutic applications (translational research).

Robert Smith works in the field of science and technology studies. He uses methods from the interpretative social sciences to study the social, political and policy dimensions of the life sciences. He is a research associate at the Department of Global Health & Social Medicine, King's College London, and visiting fellow in Science, Technology & Innovation Studies, University of Edinburgh. He completed his PhD (2015), *Constructing 'the ethical' in the development of biofuels*, at the University of Nottingham.

Since 2016, and with Professor Nikolas Rose, he has lead a programme of research within the UK EPSRC-funded project, 'An Infrastructure for Platform Technology in Synthetic Biology' and is a collaborator on the ERC-funded *Engineering Life Project*. His research programme explores the development of large scale genome synthesis infrastructures, the use of synthetic biology technologies to address societal challenges in resource poor settings, and novel methods for the governance of emerging technologies in democratic societies. Over a five-year period, he has developed considerable knowledge of UK research funding organisations, collaborating with the UK's public funder for biotechnology and biological sciences, BBSRC, in a national bioenergy dialogue (2013) and later developing a pilot to operationalise responsible innovation at a funder level (2015/16). He is currently advising a consortium of European funders on the development of a responsible innovation framework for a five-year programme in systems biology, synthetic biology and industrial biotechnology.

Significant Accomplishments

Recognised UK expert in the governance of synthetic biology and the biosciences, demonstrated by invited membership to BBSRC advisory group on responsible innovation in the context of

systems biology, synthetic biology and industrial biotechnology and King's College London Co-director of Virtual Institute for Responsible Innovation (co-ordinated by Arizona State University) and Deputy Director of Biotechnology and Society Research Group, King's College London.

Active collaborations with UK synthetic biology community at Imperial College London and University of Edinburgh. Demonstrated through co-authored report on Synthetic Biology in Global Health and advisor to 2016 iGEM Grand Prize winning team (Imperial College London).

Published articles in *Science and Engineering Ethics*, *Science and Public Policy*, and *Biomass and Bioenergy* on the topics of governance and responsible innovation. Articles currently under review in *Research Policy* and *Issues in Science and Technology.*

One of a small number of UK experts on responsible innovation approaches as applied to research funding policy, demonstrated by past successful projects with the UK Biotechnology and Biological Sciences Research Council and awarding of competitively awarded consultancy work to develop a framework for responsible research and innovation in the context of ERA CoBioTech, a large five-year European synthetic biology research programme.

Publications

Ribeiro, B., Smith, R. & Millar, K. (2017) A mobilising concept? Unpacking academic representations of responsible research and innovation. *Science and Engineering Ethics.* 23(1) 81-103. doi:10.1007/s11948-016-9761-6

Smith, R., Marris, C., Berry, D., Sundaram, L., Rose, N. (2017) *Biosensors for Global Health? A Report of the Flowers Consortium*. Department of Global Health & Social Medicine, King's College London.

Stephan Züchner, M.D., Ph.D., is a Professor and Chair for the Dr. John T. Macdonald Foundation Department of Human Genetics at the University of Miami Miller School of Medicine. He is a trained neurologist and molecular geneticist with research interests in identifying genetic variation associated with disease. His lab has identified dozens of genes for Mendelian neurodegenerative disorders and also evaluated risk factors for complex genetic conditions, including Alzheimer disease, Parkinson disease, and obsessive-compulsive disorder. His team is amongst the pioneering groups that have promoted genome sequencing methods for disease gene identification and gene editing in humans, mice, fish, and drosophilia. His gene editing work is currently focused on zebrafish studies of brain disorders and has a goal of creating higher throughput disease modeling pipelines. He is currently pursuing large-scale exome and genome analysis in multiple neurodegenerative disorders and develops innovative

new software tools that allow real time-shared analysis of large amounts of genomic data. Specifically for ELSI, as Department Chair he has built an ELSI track and recruited Prof Rosario Isasi from McGill University, which has resulted in several ELSI classes now taught to Miami to Medical and Genomic Medicine Master students. He further has built an ELSI platform within The Genesis Project foundation, a charity that promotes genetic data sharing and genomic matchmaking. Further Dr. Zuchner is the Contact PI for one of the 10 national All of US Precision Medicine Research Centers; the SEEC consortium covers all of Florida and Georgia for recruitment and engagement activities for this large-scale project with the ultimate goal of including 1 million Americans into one study.