Meeting New Challenges in Informed Consent in Clinical Research

FRIDAY, SEPTEMBER 7, 2018

2018 OHRP EXPLORATORY WORKSHOP

PROGRAM BOOK

Office for Human Research Protections
INTRODUCTION

BACKGROUND

The rapidly changing landscape of biomedical and health-related behavioral research continues to present diverse challenges for adequately reviewing and appropriately regulating research to best protect human research subjects. Charged with the mission of providing leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS), the Office for Human Research Protections (OHRP) endeavors to keep abreast of these challenges with the long-term goal of developing meaningful policy guidance that responds to them.

OHRP's Division of Education and Development (DED) promotes education and outreach on the protection of human subjects in research. DED created the OHRP Exploratory Workshop to provide a platform for collegial intellectual exchanges within the research community to promote exploration of a topic of interest that hinges on the Federal regulations or human subjects protection.

This OHRP Exploratory Workshop explores the ethical and regulatory dimensions of informed consent. The recent publication of the revised Common Rule provides an opportunity to explore challenges that arise for different aspects of informed consent. Experts are asked to present their perspectives and discuss concerns, controversies, and potential solutions. OHRP considers constructive communication a vital first step towards finding common ground and creating pragmatic workable solutions that promote the common good.

OBJECTIVES

The purpose of OHRP’s Exploratory Workshop is to provide a platform for open dialogue and exchange of ideas between stakeholders in the regulated community. The objectives for this workshop on informed consent include:

- Discuss the ethical concepts that underlie and motivate the regulations and explore additional ethical considerations relevant to informed consent
- Share evidence-based practices for facilitating informed consent
- Provide a forum for the research community to identify for OHRP challenges encountered when obtaining informed consent, and to share ideas for responding to these challenges
- Spark interest in research and practical applications of scholarship that could inform future policy considerations
# AGENDA

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<td><strong>8:00 AM – 8:15 AM</strong></td>
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| **8:15 AM – 10:10 AM** | **Session A: Laying the Groundwork for Meaningful Informed Consent**  
Moderator: David H. Strauss, M.D.; Austen Riggs Center |
| 8:15 AM | The Ethical Foundations of the Disclosure Requirement  
Danielle Bromwich, Ph.D.; University of Massachusetts  
Joseph Millum, Ph.D., M.Sc.; National Institutes of Health Clinical Center |
| 8:45 AM | The Reasonable Person Standard and Research Disclosure  
Rebecca Dresser, J.D.; Washington University in St. Louis |
| 9:05 AM | Empirical Standards for Informed Consent  
Baruch Fischhoff, Ph.D.; Carnegie Mellon University |
| 9:25 AM | Panel Discussion for Session A (45 minutes) |
| **10:10 AM – 10:25 AM** | Break |
| **10:25 AM – 12:30 PM** | **Session B: Effectively Presenting Information to Facilitate High-Quality Decision-Making**  
Moderator: Christine Grady, RN, Ph.D., FAAN; National Institutes of Health Clinical Center |
| 10:25 AM | Presenting Information for Effective Communication  
Lisa Schwartz, M.D., M.S.; The Dartmouth Institute for Health Policy and Clinical Practice, Dartmouth Medical School  
Steven Woloshin, M.D., M.S.; The Dartmouth Institute for Health Policy and Clinical Practice, Dartmouth Medical School |
| 10:55 AM | Patient Decision Aids to Support Patient Decision Making  
Angie Fagerlin, Ph.D.; University of Utah |
| 11:15 AM | Participant-Centered Design for Informed Consent  
John Wilbanks; Sage Bionetworks  
Megan Doerr, M.S., C.G.C.; Sage Bionetworks |
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<td>11:45 AM</td>
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| 1:15 PM – 2:45 PM | Session C: Pragmatic Clinical Trials (PCT)—Challenges and Innovations in Getting Informed Consent  
Moderator: Gregory E. Simon, M.D., M.P.H.; Kaiser Permanente Washington Health Research Institute |
| 1:15 PM     | Practical Issues with Pragmatic Trials: Challenges with Informed Consent and Lessons Learned from the VA Point-of-Care Program  
Sarah M. Leatherman, Ph.D.; U.S. Department of Veterans Affairs  
Ryan E. Ferguson, Sc.D., M.P.H.; U.S. Department of Veterans Affairs |
| 1:45 PM     | Naked and Afraid: Protecting Research Subjects from Overly Excited Pragmatic Investigators  
George J. Annas, J.D., M.P.H.; Boston University |
| 2:00 PM     | Panel Discussion for Session C (45 minutes)                              |
| 2:45 PM – 3:00 PM | Break                                                                  |
| 3:00 PM – 4:15 PM | Session D: Delivery Room Research and the Challenges for Informed Consent  
Moderator: Sara F. Goldkind, M.D., M.A.; Goldkind Consulting, L.L.C. |
| 3:00 PM     | IRB Chair’s Perspective: Are There Special Considerations for Informed Consent in Delivery Room Research?  
Mark S. Schreiner, M.D.; The Children’s Hospital of Philadelphia |
| 3:15 PM     | Delivery Room Research: Challenges and Opportunities  
Neil Finer, M.D.; Sharp Mary Birch Hospital for Women and Newborns |
| 3:30 PM     | Panel Discussion for Session D (45 Minutes)                              |
| 4:15 PM – 4:45 PM | Closing Session: Moderators Panel                                      |
Informed consent is an ethical requirement for most medical research involving human participants. The consent process typically involves providing potential participants or their surrogates with information about the study—including its purpose, procedures, and possible risks and benefits—as well as documenting their agreement through a signed consent form. Studies of participants enrolled in medical research, however, show highly variable and frequently poor understanding of key informed consent elements. These studies raise ethical concerns, suggesting not only that many participants were unaware of what they consented to, but that some may not have given valid consent at all. This concern prompts the question: what should participants be told, and what do they need to understand, from an ethical standpoint?

In this presentation, Drs. Bromwich and Millum classify two distinct consent process goals that are facilitated by disclosing information to potential participants; for each goal, they identify ways in which disclosing information about a study can go awry.

The first goal involves obtaining valid consent to the procedures that a study includes, an ethical requirement potentially violated when a person disclosing information to potential participants exercises illegitimate control over participants’ decision-making. To avoid this, researchers should disclose relevant decision information that participants would expect to be told, in a manner that gives participants a reasonable opportunity to understand.

The second goal involves facilitating good decision-making by potential participants. This goal is ethically preferable, though not required; while facilitating good decision-making is a laudable goal of the informed consent process, it can't be a requirement, competent adults maintain their right to make life decisions, however well or poorly they choose to do so. Although the studies that show poor understanding by research participants are troubling, they do not necessarily show that participants failed to give valid consent.

Finally, Drs. Bromwich and Millum close by considering how researchers should prioritize the two goals for different types of research.
THE REASONABLE PERSON STANDARD AND RESEARCH DISCLOSURE

Rebecca Dresser, J.D.
Washington University in St. Louis

Legal authorities adopted the "reasonable person" standard to evaluate the acceptability of individual conduct. The standard instructs those applying it to consider both societal safety and realistic expectations of human actors to determine whether defendants are negligent. In the legal system, the reasonable person standard is traditionally applied by a jury of the defendant's peers.

During the 1970s, however, judges began using this standard to evaluate negligence claims brought by injured patients who said doctors had failed to obtain informed procedural consent. Judges declared that the traditional standard for disclosure—what a reasonable medical professional would disclose—was insufficient with respect to a patient's right to decide. Instead, they stated, professionals should disclose what reasonable patients would need and want to know about their options.

The revised Common Rule adopts the reasonable person standard to guide research disclosure. Some members of the research community contend that the standard is confusing and ill-suited to the research oversight system. Others are more positive and suggest that the rule revision could promote a more ethically defensible and effective study disclosure process.

In this presentation, Ms. Dresser argues that the revised rule is not as radical as it might seem. In its influential Belmont Report, the National Commission recommended application of a "reasonable volunteer standard" to guide IRBs evaluating research disclosures. Evidence also suggests that IRBs often invoke the reasonable person standard in deliberations about consent forms. Past application of the standard, however, has been informal and uneven.

Robust application of the reasonable person standard will require researchers and IRBs to learn more about what ordinary people want and need to know about the studies they are invited to join. Input from people with personal experience as study participants could be particularly useful to this learning effort. Although the oversight system cannot turn to juries for guidance, experienced participants are peers of prospective subjects, with valuable knowledge of what ordinary people should understand before volunteering for research.

EMPIRICAL STANDARDS FOR INFORMED CONSENT

Baruch Fischhoff, Ph.D.
Carnegie Mellon University

Researchers, ethicists, clinicians, and officials have made great progress in understanding the cognitive, affective, and social issues involved in achieving informed consent for medical treatment, in both clinical trials and normal practice. This talk by Dr. Fischhoff offers a behavioral decision research approach to determining whether the resulting procedures are adequate, in terms of whether: 1) procedures contain the information that patients—or potential trial participants—need; 2) said information exists in places that patients and participants can readily access, and 3) information resides in forms that they can understand.

This talk will propose practical ways to translate these goals into a materiality standard for content, a proximity standard for accessibility, and a comprehensibility standard for understanding. Dr. Fischhoff will suggest infrastructure that DHHS might create to facilitate applying these standards, one of which involves building on FDA's Benefit-Risk Framework for identifying the key benefits, risks, uncertainties, and supplementary protections associated with medical treatments. This cognitively-oriented proposal is meant to complement the social and institutional supports that individuals require to achieve mastery of their medical decisions.
SESSION B

EFFECTIVELY PRESENTING INFORMATION TO FACILITATE HIGH-QUALITY DECISION-MAKING

PRESENTING INFORMATION FOR EFFECTIVE COMMUNICATION

Lisa Schwartz, M.D., M.S.
The Dartmouth Institute for Health Policy and Clinical Practice, Dartmouth Medical School

Steven Woloshin, M.D, M.S.
The Dartmouth Institute for Health Policy and Clinical Practice, Dartmouth Medical School

In this talk, Drs. Schwartz and Woloshin consider strategies—as well as available evidence—for more effective communication about informed consent. Strategies include the key fact summary, presentation, and quantification of side effects: language that explains randomization and acknowledges the inherent uncertainty of drugs that are new or being used in new ways. They will also explore how our current cultural environment challenges communication by creating unrealistic expectations about treatments under study, such as cancer center advertising touting the benefits—and masking the harms—of clinical trials, or regulatory language such as when FDA assigns the "breakthrough" designation to a drug during its research phase.

PATIENT DECISION AIDS TO SUPPORT PATIENT DECISION MAKING

Angie Fagerlin, Ph.D.
University of Utah

Patients want to be involved in their health care decisions, or, at minimum, want to understand their health conditions and the risks and benefits of treatment options. While health care providers play an important role in helping patients understand their condition and treatment options, their support may not be sufficient; patients may not remember what their provider tells them, or providers may speak in convoluted jargon.

In this presentation, Dr. Fagerlin explores patient decision aids as ways to support patient understanding and provide informed consent for any treatment. Decision aids aim to present balanced information in understandable ways, to help communicate key information in medical decisions and help patients clarify their values to their providers regarding treatment choices. The International Patient Decision Aids Standards (IPDAS) Collaboration used a Delphi process to develop a set of standards for the design and evaluation of decision aids to encourage quality decision aids. These standards address the content of information (e.g. balance, accuracy, completeness), literacy, risk communication, conflict of interest, use of testimonials, and values clarification exercises.

A Cochrane review of 115 decision aid trials found that, compared to standard care, decision aids increase patients’ participation in decision-making, increase satisfaction, improve patient-provider communication, and reduce decisional conflict. Evidence, however, is variable about the impact of decision aids on treatment choice. Finally, Dr. Fagerlin observes that while few studies have compared the effectiveness of decision aids in patients’ varying levels of literacy and numeracy skills, some work has suggested that decision aids are effective among lower-literacy populations.
PARTICIPANT-CENTERED DESIGN FOR INFORMED CONSENT

Mobile technologies have the potential to revolutionize both the ways in which individuals monitor their health, as well as the ways researchers collect frequent, yet sparse data on participants in clinical studies. For data from these devices to have maximal impact in a research setting, however, the development of systems to collect, manage, and broadly analyze these data is essential. But informed consent on a mobile device is complex, requiring both careful ethical analysis and attention to user experience design. In this presentation, John Wilbanks and Megan Doerr will present cases and empirical research drawn from their mobile-informed consent experiences to date, including Apple’s ResearchKit and the All of Us Research Program.
PRACTICAL ISSUES WITH PRAGMATIC TRIALS: CHALLENGES WITH INFORMED CONSENT AND LESSONS LEARNED FROM THE VA POINT OF CARE PROGRAM

Sarah M. Leatherman, Ph.D.       Ryan E. Ferguson, Sc.D., M.P.H.
U.S. Department of Veterans Affairs        U.S. Department of Veterans Affairs

The high cost of traditional explanatory clinical trials, a growing appetite for pragmatic comparative effectiveness data, and the emergence of a conceptual ‘rapid learning healthcare system’ (RLHS) collectively account for an increasing interest in embedding research activities into the clinical care ecosystem. The goal of the VA Point of Care (POC) Program is to deliver state of the art treatments to patients, while simultaneously enrolling them as participants in experimental comparative effectiveness research that aims to redefine that care. By institutionalizing a process of statistically sound and efficient learning, and by integrating that learning with automatic implementation of best practices, participating VA health care systems will accelerate improvements in effective veteran care.

Progress in this area requires rethinking all aspects of clinical research, from design—identification of subjects, delivery of interventions, and ascertainment of outcome—to ethical and operational issues of consent and randomization in the clinical care ecosystem. One of the most difficult and complex issues to rethink (and then to operationalize) is that of informed consent. Many models exist for incorporating learning within the clinical care ecosystem, but few models present a ‘one size fits all’ consent solution. In this presentation, Drs. Ferguson and Leatherman will formally present the VA’s POC Program: the models selected to inform participants, challenges and barriers experienced, and lessons learned from implementing pragmatic studies into clinical care.
In this presentation, George Annas argues that we should not modify either IRB review or informed consent rules for pragmatic trials, based on a few core arguments:

- Informed consent is a legal requirement to protect autonomy and dignity. It is mandated by court opinions, statutes, and regulations. IRBs should have a strong presumption against waiving the informed consent requirement. Nonetheless, methods of documenting consent should be the subject of continued exploration, including limiting the size of consent forms to one page, and supplementing forms with audio or video recordings of informed consent discussions.

- The public reasonably takes the Hippocratic injunction to “do no harm” seriously, and values the advice of physicians based on their clinical judgments, evidence-based or not. Replacing the medical judgment of one’s physician with a coin flip should only be done with informed consent. (“Standard of Care” is a legal term used in medical malpractice cases, has created confusion in pragmatic trials, and has no useful role in describing risks.)
From an IRB chair’s perspective, approving delivery room research is not especially problematic. The data supporting the efficacy and safety of many current treatments, as well as choices between competing treatments, are often inadequate. Clinicians and investigators, therefore, are often in a state of clinical equipoise that justifies the conduct of a proposed trial.

In this presentation, Dr. Schreiner notes that unpredictable emergencies that require immediate intervention do not easily lend themselves to a true informed consent process. The IRB's challenge is thus to determine the appropriate requirements for parental permission. Investigators are obligated to provide the IRB with a detailed discussion justifying their plans. Some of the questions investigators must address include:

- Is an “emergency” situation truly unpredictable? Some DR emergencies can be anticipated, and consent obtained beforehand. For a hypothetical trial in the DR involving non-vigorous infants born through meconium stained amniotic fluid, several authors argued that it was impracticable to obtain consent in this setting. Subsequently, Chettri et al. demonstrated that it was indeed possible to obtain consent in a trial identical to the hypothetical one.

- Are interventions no more than minimal risk? There is considerable controversy regarding both the meaning of minimal risk, and which risks are foreseeable. This discussion is frequently raised for comparative effectiveness research involving two or more “standard care” interventions. IRBs adhere to the definitions and conclusions of OHRP’s draft guidance on foreseeable risk to guide their determinations.

- When the risks of a proposed intervention are greater than minimal, and the newborn would be in a “life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary…” The research might qualify for an exception from the requirements for informed consent (EFIC). Approval of a waiver under EFIC, however, does not remove all obligation to obtain consent or confirm permission. When there is enough time, investigators are still obligated to obtain informed consent; when there is not, investigators still must try to contact the family to allow them the opportunity to opt-out. Since at least one parent (at a minimum) is always present in the DR, investigators must allow the parent(s) to opt-out.
Research conducted in the delivery room is unique for several reasons: 1) there are always at least two patients (and sometimes more), each of whom are considered especially vulnerable, and 2) the actual circumstances of the delivery and support requirements for the mother and infant(s) cannot be accurately predicted beforehand. Thus, research studies, especially randomized interventional trials which would require consent from the parent(s) before the intervention, present challenges.

Approaching a mother in labor to discuss a trial consent is an added stress at an already stressful time, especially if the mother is in preterm labor or about to deliver an infant about whom there is significant concern. In addition, previous studies have determined that infants born to mothers approached for consent had better overall outcomes than mothers who were not available for consent. This suggests that such trials may favor advantaged populations and miss the most vulnerable infants. Many trials are presently attempting to determine best practice from current approaches; where these alternate approaches are both considered to be of minimal risk, waiver of consent is an option. With the ability to use waivers comes novel and infrequently used design possibilities.

In this presentation, Dr. Finer describes one such approach, the randomized cluster cross-over (RCC) study. The RCC studies attempt to evaluate optimal initial oxygen concentrations for premature newborn infants requiring resuscitation, and have now been funded for a comparative study of immediate cord clamping versus cord milking for non-vigorous term and near-term infants utilizing the RCC approach. Dr. Finer argues that there is a need for using more pragmatic study designs and waivers of consent, where appropriate, to encourage participation of both physicians and potential study subjects. Moreover, the definition of risk, which is both pragmatic and clinically relevant, is a key consideration in any comparative trial, and requires significant deliberation.
SPEAKER BIOS

GEORGE J. ANNAS, J.D., M.P.H.
Boston University

George Annas, Warren Distinguished Professor at Boston University, is the director of the Center for Health Law, Ethics, & Human Rights of Boston University School of Public Health, and a professor in Boston University's School of Medicine and School of Law. He is the cofounder of Global Lawyers and Physicians, a transnational professional association of lawyers and physicians working together to promote human rights and health. Professor Annas has authored or edited 20 books on health law and bioethics, including Worst Case Bioethics, American Bioethics, The Rights of Patients (3d ed. 2004), and Standard of Care. He has written a bioethics-themed play, Shelley's Brain, and is Boston's "oldest new stand-up comic." Professor Annas is a fellow of the American Association for the Advancement of Science, member of the National Academy of Medicine, and former member of the National Academies' Human Rights Committee.

DANIELLE BROMWICH, Ph.D.
University of Massachusetts

Dr. Danielle Bromwich is an associate professor of philosophy at the University of Massachusetts Boston, and a former postdoctoral fellow in the Clinical Center Department of Bioethics at the National Institutes of Health (NIH). Her research interests include moral motivation and the ethics of consent. She has published, in collaboration with Dr. Joseph Millum from NIH, a series of articles on the ethics of consent, including: “Disclosure and Consent to Medical Research Participation,” Journal of Moral Philosophy, 2012; “Informed consent to HIV Cure Research,” Journal of Medical Ethics, 2016; “Understanding, Communication, and Consent,” Ergo, 2018; and “Lies, Control, and Consent: A Response to Dougherty and Manson,” Ethics, 2018. Dr. Bromwich is currently in the process of working on a book with Dr. Millum on what consent is, and how it goes wrong.

MEGAN DOERR, M.S., C.G.C.
Sage Bionetworks

Meg Doerr is Principal Scientist at Sage Bionetworks. A former botanist and middle school teacher, she joined the genetic counseling community in 2006. She previously led the clinical development and implementation of Cleveland Clinic’s family history and risk assessment tool before joining the Governance team at Sage Bionetworks in 2015. At Sage, Ms. Doerr’s efforts concentrate on supporting innovative, participant-centric approaches in open science. Her work has a strong focus on app-based research, including the ethical, legal, and social implication (ELSI) issues associated with informed consent, research participation, and data sharing for secondary use in entirely remote, mobile platform-based research studies, including for the All of Us research program.
SPEAKER BIOS

**REBECCA DRESSER, J.D.**
*Washington University in St. Louis*

Since 1983, Ms. Rebecca Dresser has taught medical and law students about legal and ethical issues such as end-of-life care, biomedical research, genetics, assisted reproduction, and other related topics. She has been a member of the Washington University in St. Louis faculty since 1998; before that, Ms. Dresser taught at Baylor College of Medicine and Case Western Reserve University. Today, she is a contributing editor and “At Law” columnist for the Hastings Center Report. Her 2017 book, Silent Partners: Human Subjects and Research Ethics, calls for including experienced study subjects in research ethics deliberations. Ms. Dresser is also the author of When Science Offers Salvation: Patient Advocacy and Research Ethics (2001) and editor of Malignant: Medical Ethicists Confront Cancer (2012). From 2002-2009, she was a member of the President's Council on Bioethics and, from 2011-2015, a member of the National Institutes of Health Recombinant DNA Advisory Committee.

**ANGIE FAGERLIN, Ph.D.**
*University of Utah*

Dr. Angie Fagerlin is a professor and chair of the Department of Population Health Sciences at the University of Utah and a Research Scientist at the Salt Lake City Veterans Affairs office. Her training is in experimental psychology, primarily in the areas of cognitive and social psychology. Dr. Fagerlin's research focuses on testing methods for communicating medical data to patients and providers—such as the risks and benefits of cancer treatment—and the development and testing of decision support interventions. Her recent work involves testing the impact of patient decision aids on patient-physician communication, and she is also currently testing multiple methods for communicating about genetic testing and infectious diseases such as the Zika virus, Ebola, and influenza. Dr. Fagerlin's research has been funded by the VA, NCI, NIH, and the European Union.

**RYAN E. FERGUSON, Sc.D., M.P.H.**
*U.S. Department of Veterans Affairs*

Dr. Ryan Ferguson is the director of the VA Cooperative Studies Program Coordinating Center in Boston, MA, where he specializes in designing and conducting large multi-center randomized clinical trials. Dr. Ferguson joined the Cooperative Studies Program in 2001 and has since focused on clinical trial methodologies for conducting pragmatic comparative effectiveness trials. He currently serves as a co-principal investigator for the VA's Point of Care (PoC) Research Program, which focuses primarily on pragmatic clinical trials and innovation in translational science. Dr. Ferguson is a research assistant professor in the Section of General Internal Medicine at the Boston University School of Medicine and a member of the Society for Clinical Trials, the Society for Epidemiologic Research, and the American Statistical Association.
NEIL FINER, M.D.
Sharp Mary Birch Hospital for Women and Newborns

As an Emeritus Professor of the Pediatrics Department at the University of California San Diego (UCSD), Dr. Finer has spent his career caring for premature and/or unstable newborn infants, attempting to define the most significant clinical problems that lack high quality evidence or best practices. He has helped develop clinical trials to discover such evidence, targeting neonatal resuscitation and evaluating interventions that may improve delivery room environments and optimize neonatal team performance. Through these trials, Dr. Finer has concluded that transitional care and neonatal resuscitation should begin during delivery, and that clinicians must determine best approaches through randomized trials. Since retiring from active clinical work at UCSD, Dr. Finer joined the recently-created Neonatal Research Institute at Sharp Mary Birch Hospital for Women & Newborns—the largest delivery service in California—as a senior research associate, where he continues to help design trials that will provide essential evidence for better practices.

BARUCH FISCHHOFF, Ph.D.
Carnegie Mellon University

Dr. Baruch Fischhoff is the Howard Heinz University Professor in the Department of Engineering and Public Policy and Institute for Politics and Strategy at Carnegie Melon University. A Detroit Public Schools graduate, he holds a dual B.S. in mathematics and psychology from Wayne State University and a Ph.D. in psychology from the Hebrew University of Jerusalem. Dr. Fischhoff is a member of the National Academy of Sciences and the National Academy of Medicine, and former president of the Society for Judgment and Decision Making and the Society for Risk Analysis. He has chaired the Food and Drug Administration Risk Communication Advisory Committee and been an active member of Oregon’s Eugene Commission on the Rights of Women. Additionally, Dr. Fischhoff has served as a member of the Department of Homeland Security Science and Technology Advisory Committee and the Environmental Protection Agency Scientific Advisory Board, in which he chaired the Homeland Security Advisory Committee. His books include Acceptable Risk, Risk: A Very Short Introduction, and Counting Civilian Casualties.
SARA F. GOLDKIND, M.D., M.A.
Goldkind Consulting, L.L.C.

Dr. Goldkind is a bioethics consultant with a background in both research and clinical ethics issues. In 2014, she left the Food and Drug Administration (FDA), where she served as the Senior Bioethicist in the Office of the Commissioner for over ten years. Dr. Goldkind’s clinical research consultations include: innovative clinical trial designs and product development (e.g., novel therapies, vulnerable populations), regulatory compliance, and policy development, principally related to Good Clinical Practice and human “subjects” protections. Prior to working at the FDA, Dr. Goldkind focused on clinical medical ethics. She is a board-certified internist, having completed her internship and residency at Boston City Hospital and her M.D. at the University of Maryland School of Medicine. She obtained an M. A. in religious studies with a concentration in comparative religious ethics and completed a fellowship in clinical ethics at the University of South Florida. She has served as adjunct faculty at the George Washington University School of Medicine, and at the University of South Florida, School of Medicine, Department of Internal Medicine. She has also been a member of institutional review boards and data monitoring committees.

CHRISTINE GRADY, RN, PH.D., FAAN
National Institutes of Health Clinical Center

Dr. Christine Grady is chief of the Department of Bioethics at the National Institutes of Health Clinical Center. Her research focuses on the ethics of clinical research, especially subject recruitment, incentives, vulnerability, informed consent, and international research ethics. She was a member of the Presidential Commission for the Study of Bioethical Issues, senior research fellow at the Kennedy Institute of Ethics, and an elected fellow at the American Academy of Nursing and at the Hastings Center. Dr. Grady has authored more than 125 papers, authored or edited several books, and has lectured widely on ethical issues in clinical research and clinical care, HIV disease, and nursing. She is a leader of the Bioethics Consultation Service, Institutional Review Board (IRB) and Data Safety Monitoring Board (DSMN) member, and member of several editorial boards. She holds a B.S. in nursing and biology from Georgetown University, a M.S.N. in community health nursing from Boston College, and a Ph.D. in philosophy from Georgetown.
SARAH M. LEATHERMAN, Ph.D.
U.S. Department of Veterans Affairs

Dr. Sarah Leatherman is the associate director of the VA Cooperative Studies PoC Program in Boston, MA, where she oversees the design and conduct of embedded pragmatic clinical trials. Dr. Leatherman joined the Cooperative Studies Program in 2010 and has since focused on implementing pragmatic comparative effectiveness trials and promoting a learning healthcare system within the VA. As a trained biostatistician, she oversees the analytical integrity of the multiple databases required to execute these activities. Dr. Leatherman’s published work includes first-authored publications, abstracts, and presentations on pragmatic trials. She is also a member of the Society for Clinical Trials, the American Statistical Association, and the Caucus for Women in Statistics.

JOSEPH MILLUM, Ph.D., M.Sc.
National Institutes of Health Clinical Center

Dr. Joseph Millum is a bioethicist with the Clinical Center Department of Bioethics and the Fogarty International Center at the National Institutes of Health (NIH). He studied philosophy at Edinburgh University and the University of Toronto, where he received his doctorate, and economics at Johns Hopkins University. Dr. Millum’s research focuses on the rights and responsibilities of parents, the ethics of international research, informed consent, and priority setting for health care and research. He is co-editor of the book Global Justice and Bioethics (2012) and author of The Moral Foundations of Parenthood (2018), both with Oxford University Press.

MARK S. SCHREINER, M.D.
The Children’s Hospital of Philadelphia

Dr. Mark Schreiner has been a member of the Department of Anesthesiology and Critical Care Medicine at The Children’s Hospital of Philadelphia since 1984. He received his medical degree from St. Louis University Medical School before completing residencies, as well as a fellowship in pediatric anesthesiology and critical care medicine, at the Children’s Hospital of Philadelphia and University of Pennsylvania Hospital, respectively. From 1998-2005, Dr. Schreiner served as Executive Medical Director of CCRi, an academic CRO conducting multicenter clinical trials. He first served as a member of the Institutional Review Board (IRB) as a pediatric resident and has served on the committee for over 30 years, notably as committee chair for more than a decade and as the current Executive Vice Chair. Dr. Schreiner has published scholarly articles related to IRB function, research bioethics, and comparative effectiveness trials.
LISA SCHWARTZ, M.D., M.S. / STEVEN WOLOSHIN, M.D., M.S.

The Dartmouth Institute for Health Policy and Clinical Practice, Dartmouth Medical School

Drs. Lisa M. Schwartz, M.D., M.S., and Steven Woloshin, M.D., M.S., are professors of Medicine and Community and Family Medicine at the Geisel School of Medicine at Dartmouth, as well as co-directors of the Center for Medicine and the Media at the Dartmouth Institute for Health Policy and Clinical Practice. Together, they have worked to improve how medical evidence is communicated to physicians, journalists, and the public, with a focus on prescription drugs and screenings. Drs. Schwartz and Woloshin have co-authored two books, Know Your Chances: Understanding Health Statistics and Overdiagnosed: Making People Sick in the Pursuit of Health, and their essays have appeared in the New York Times and Washington Post.

GREGORY E. SIMON, M.D., M.P.H.

Kaiser Permanente Washington Health Research Institute

Dr. Gregory Simon is an investigator at Kaiser Permanente Washington Health Research Institute, psychiatrist in Kaiser Permanente’s Behavioral Health Service, and co-chair of the Scientific Advisory Board of the Depression and Bipolar Support Alliance. Dr. Simon completed residency training in internal medicine at the University of Washington, residency training in psychiatry at the Massachusetts General Hospital, and fellowship training in the Robert Wood Johnson Clinical Scholars program at the University of Washington. His research focuses on improving access to and quality of mental health care, especially for mood disorders. Specific areas of his research include improving treatment adherence, increasing the availability of effective psychotherapy, effectiveness of peer support, identifying and reducing risk of suicidal behavior, and comorbidity of mood disorders with chronic medical conditions. Dr. Simon currently leads the Mental Health Research Network, a National Institute of Mental Health (NIMH)-funded consortium of research centers embedded in 13 large health systems.
DAVID H. STRAUSS, M.D.
Austen Riggs Center

Dr. David Strauss is the Director of Research at the Austen Riggs Center in Massachusetts, and a special lecturer at Columbia University. There, he serves on the steering committee and heads the Ethics Unit of a federally funded center grant entitled “Optimizing and Personalizing Interventions for People with Schizophrenia Across the Lifespan.” As Senior Advisor to the Multiregional Clinical Trials Center at Brigham and Women’s Hospital and Harvard, Dr. Strauss co-leads a project aimed at promoting diversity in clinical trials. He is an Executive Council member of PRIM&R Board of Directors, co-chairs its Public Policy Committee, and is member of the Subpart A Subcommittee of SACHRP. Dr. Strauss maintains a private practice of psychotherapy and psychopharmacology and teaches, lectures, and consults widely on matters of human subjects protections and applied research and professional ethics.

JOHN WILBANKS
Sage Bionetworks

John Wilbanks is the Chief Commons Officer at Sage Bionetworks. He previously worked as a legislative aide to former California Congressman Fortney “Pete” Stark and served as the first assistant director of Harvard University’s Berkman Center for Internet & Society. He founded and led the acquisition of bioinformatics company Incellico, Inc., and was executive director of the Science Commons project at Creative Commons. In February 2013, in response to a “We the People” petition spearheaded by Wilbanks and signed by 65,000 people, the U.S. government announced a plan to open taxpayer-funded research data and make it freely available. He holds a B.A. in philosophy from Tulane University and studied modern letters at the Sorbonne University in France.