

2020 OHRP EXPLORATORY WORKSHOP

PRACTICAL & ETHICAL CONSIDERATIONS FOR SINGLE IRB REVIEW

THURSDAY, SEPTEMBER 17, 2020



OHRP
Office for Human
Research Protections

PROGRAM BOOK

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 for human subjects protection. This OHRP Exploratory Workshop explores the practical and ethical considerations for single IRB review.

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 of this workshop on single IRB review are to:

- Share and discuss ways to ensure quality IRB review under the sIRB model;
- Consider the importance of and ways to incorporate and manage local context concerns in sIRB review;
- Discuss and promote best practices for the sharing of oversight responsibilities and separation of roles in IRB review and oversight of research under sIRB; and
- Spark interest in research, scholarship, and collaboration that could inform future practices for sIRB review to better protect research participants.

AGENDA

Time	Sessions
8:10 AM – 8:25 AM	Welcome and Introduction (OHRP)
8:25 AM – 10:20 AM	<p>Session I: Providing Options and Ensuring Quality in Single IRB Review Moderator: Stephen Rosenfeld, M.D., MBA; <i>Freeport Research Systems, LLC</i></p> <p>Single IRB review of collaborative multi-site research can reduce inconsistencies and improve the quality of reviews. However, the single IRB mandate could result in a small number of IRBs amassing more responsibility and importance over a large proportion of federally funded research. Encouraging more institutions to serve as single IRBs is one way to diversify single IRB options and could promote a culture of quality reviews that inspires confidence. This session will share experience on how institutions create options for single IRB reviews, and explore measures to promote quality ethics review and human research protections.</p>
8:25 AM	<p>Session I Introduction Stephen Rosenfeld, M.D., MBA; <i>Freeport Research Systems, LLC</i></p>
8:30 AM	<p>Ensuring Quality IRB Reviews: Lessons Learned from NCI's CIRB Initiative Linda K. Parreco, RN, M.S.; <i>Nurse Consultant, Office of the Deputy Director, Division of Cancer Prevention, National Cancer Institute</i></p>
8:45 AM	<p>Diversifying Options for Single IRBs: An Institution's Experience With Extending Their IRB Services to Outside Institutions Ann Johnson, Ph.D.; <i>IRB Director, University of Utah</i></p>
9:00 AM	<p>From Relying to Reviewing: Considerations and Lessons Learned When Establishing a Single IRB Joshua Fedewa, M.S., CIP; <i>Associate Director, HRPP, University of Texas Southwestern Medical Center</i></p>
9:15 AM	<p>Evaluating the Quality of Ethics Review and Promoting Transparency and Accountability in the Era of Single IRBs Holly A. Taylor, Ph.D., M.P.H.; <i>Research Bioethicist, Department of Bioethics, Clinical Center, National Institutes of Health</i></p>
9:30 AM	Session I Panel Discussion
10:20 AM – 10:40 AM	Break
10:40 AM - 12:35 PM	<p>Session II: Effectively Managing Local Context Concerns in Single IRB Review Moderator: Liza Dawson, Ph.D.; <i>Chief of Bioethics and IRB Chair, Walter Reed Army Institute of Research</i></p> <p>There are questions about whether local context issues receive adequate consideration in single IRB review of collaborative multi-site research. This session will examine what might constitute legitimate local context concerns and how single IRBs could best ensure that they receive appropriate attention and accommodation.</p>
10:40 AM	<p>Session II Introduction Liza Dawson, Ph.D.; <i>Chief of Bioethics and IRB Chair, Walter Reed Army Institute of Research</i></p>
10:45 AM	<p>Addressing Local Context Issues By Single IRBs in Multi-Site Research Robert Klitzman, M.D.; <i>Professor of Psychiatry, Columbia University</i></p>
11:00 AM	<p>Challenges to Reviewing Clinical Research When Local Context Includes Variation in Infrastructure and Practices Jonathan M. Green, M.D., M.B.A.; <i>Director, Office of Human Subjects Research Protections, National Institutes of Health Intramural Research Program</i></p>

AGENDA

Time	Sessions
11:15 AM	<p>How Might a Single IRB for Multisite Research Address Local Culture, Race and Social Class of Potential Human Subjects?</p> <p>Stephen B. Thomas, Ph.D.; <i>Professor, Health Policy and Management, and Director, Maryland Center for Health Equity School of Public Health, University of Maryland, College Park and IRB member for the All of Us program</i></p>
11:30 AM	<p>Experience With Regionalized Ethics Review Committees in the United Kingdom and Europe</p> <p>Sarah J.L. Edwards, Ph.D.; <i>Professor of Bioethics, Department of Science and Technology Studies, University College London</i></p>
11:45 AM	Session II Panel Discussion
12:35 PM – 1:30 PM	Lunch
1:30 PM - 3:25 PM	<p>Session III: Sharing Responsibilities and Distinguishing Roles in the Single IRB Era</p> <p>Moderator: Megan Kasimatis Singleton, J.D., M.B.E., CIP; <i>Assistant Dean, Human Research Protections and Director, Human Research Protections Program, Johns Hopkins University School of Medicine</i></p> <p>The transition to single IRB review for cooperative research requires institutions to change how they conduct oversight of research. Even when IRBs are no longer the IRBs of record, their institutions continue to have legal and ethical responsibilities for protecting research participants. This session will explore the challenges and adjustments for relying institutions as they implement the single IRB mandate. This may also present opportunities for improving oversight of the conduct of research at the institutions.</p>
1:30 PM	<p>Session III Introduction</p> <p>Megan Kasimatis Singleton, J.D., M.B.E., CIP; <i>Assistant Dean, Human Research Protections and Director, Human Research Protections Program, Johns Hopkins University School of Medicine</i></p>
1:35 PM	<p>Reliance Agreements: Considerations and Responsibilities Beyond IRB Review</p> <p>Emily Chi Fogler, Esq.; <i>Partner, Verrill Dana LLP</i></p>
1:50 PM	<p>Establishing the Role of the Relying Institution in Human Subjects Protection in the Era of Single IRB</p> <p>Kelley O'Donoghue, M.P.H., CIP; <i>Associate Vice President for Human Subject Protection and Director of the Office for Human Subject Protection (OHSP) at the University of Rochester</i></p>
2:05 PM	<p>Working Together to Improve the Single IRB Model: Suggestions from a Multi-Stakeholder Project Team</p> <p>Sara B. Calvert, PharmD; <i>Senior Project Manager, Clinical Trials Transformation Initiative (CTTI)</i></p>
2:20 PM	<p>SMART IRB: Lessons Learned and Opportunities Ahead</p> <p>Barbara E. Bierer, M.D.; <i>Director, Regulatory Policy, SMART IRB and Director, Regulatory Foundations, Ethics, and the Law, Harvard Catalyst (CTSC)</i></p>
2:35 PM	Session III Panel Discussion
3:25 PM	Summary Panel: Where do we go from here?
4:00 pm	Closing

SESSION I

PROVIDING OPTIONS AND ENSURING QUALITY IN SINGLE IRB REVIEW

Single IRB review of collaborative multi-site research can reduce inconsistencies and improve the quality of reviews. However, the single IRB mandate could result in a small number of IRBs amassing more responsibility and importance over a large proportion of federally funded research. Encouraging more institutions to serve as single IRBs is one way to diversify single IRB options and could promote a culture of quality reviews that inspires confidence. This session will share experience on how institutions create options for single IRB reviews, and explore measures to promote quality ethics review and human research protections.

Session I Introduction



Stephen Rosenfeld, M.D., MBA (Moderator)
Freeport Research Systems, LLC

Dr. Rosenfeld is a hematologist who trained at Cornell, Dartmouth, and NHLBI. He spent 19 years at NIH doing basic and clinical research and working in medical informatics and hospital administration. He ended his time at the NIH as the Clinical Center's Chief Information Officer. Dr. Rosenfeld moved from Maryland to Maine, to become the CIO of MaineHealth, a large independent delivery network, before moving to Washington State as the CEO of the Western Institutional Review Board (WIRB). After leaving WIRB he spent 7 years as the Executive Board Chair of Quorum Review. He is currently the President of Freeport Research Systems, LLC. In addition to his medical degree, he holds a master's in business administration from the Georgetown McDonough School of Business. Dr. Rosenfeld is currently the chair of the Secretary's Advisory Committee on Human Research Protections (SACHRP) and on the Boards of PRIM&R and AAHRPP.

SESSION I

PROVIDING OPTIONS AND ENSURING QUALITY IN SINGLE IRB REVIEW

Ensuring Quality IRB Reviews: Lessons Learned from NCI's CIRB Initiative



Linda K. Parreco, RN, M.S.

*Nurse Consultant, Office of the Deputy Director,
Division of Cancer Prevention, National Cancer Institute*

Linda Parreco, RN, M.S., is an advanced practice oncology nurse with over 40 years' experience in cancer clinical trials, including 20 years' experience at the National Cancer Institute where she currently serves as a Nurse Consultant in the Division of Cancer Prevention and provides contractual oversight and coordination of the Cancer Prevention and Control Central Institutional Review Board. Before her current role, she served in the NCI's Office of Communication where she focused on the use of communication and education strategies to support clinical trial accrual, and launched AccrualNet™, an online community of practice to support clinical trial accrual. Before entering government service, she spent twenty years in clinical oncology practice, most recently at the Lombardi Cancer Center at Georgetown University.

Diversifying Options for Single IRBs: An Institution's Experience With Extending Their IRB Services to Outside Institutions



Ann Johnson, Ph.D.

IRB Director, University of Utah

Dr. Johnson is the Director for the University of Utah Institutional Review Board and has been with the organization since 2006. She is an expert in human subjects research requirements and regulations. She has been a leader in establishing a single IRB process for the University of Utah, as well as the NCATS-funded Trial Innovation Network. Dr. Johnson is an active member of the research community, not only reviewing and auditing proposals for the IRB, but also having conducted research and public health interventions in the United States and abroad. She has taught undergraduate- and graduate-level courses and is instrumental in continuing research education for the University of Utah, providing instruction on consent form models, establishing data and tissue repositories, investigator-initiated clinical trials, and managing reportable events.

SESSION I

PROVIDING OPTIONS AND ENSURING QUALITY IN SINGLE IRB REVIEW

From Relying to Reviewing: Considerations and Lessons Learned When Establishing a Single IRB



Joshua Fedewa, M.S., CIP

Associate Director, HRPP, University of Texas Southwestern Medical Center

Joshua Fedewa, M.S., CIP, has worked 10 years in research specializing in research participant protection. He was promoted to leadership at an accredited (AAHRPP) IRB, has worked as a Clinical Research Educator, and most recently as an Associate Director of the HRPP at an Academic Medical Center. He's managed many projects, including: implementing new research software, rewriting a policy manual, and developing a quality review program.

Evaluating the Quality of Ethics Review and Promoting Transparency and Accountability in the Era of Single IRBs



Holly A. Taylor, Ph.D., M.P.H

Research Bioethicist, Department of Bioethics, Clinical Center, National Institutes of Health

Holly A. Taylor, Ph.D., M.P.H., is Research Bioethicist in the Department of Bioethics, Clinical Center, National Institutes of Health. Dr. Taylor is a social scientist by training and has 20 years of experience conducting quantitative and qualitative research in the field of research ethics, including informed consent for research participation, subject selection and recruitment and research oversight. She has experience with research ethics consultation and has served on Institutional Review Boards in the academic, public, and private sectors.

SESSION II

EFFECTIVELY MANAGING LOCAL CONTEXT CONCERNS IN SINGLE IRB REVIEW

There are questions about whether local context issues receive adequate consideration in single IRB review. This session will examine what might constitute legitimate local context concerns and how single IRBs could best ensure that they receive appropriate attention and accommodation.

Session II Introduction



Liza Dawson, Ph.D. (Moderator)

Chief of Bioethics and IRB Chair, Walter Reed Army Institute of Research

Liza Dawson, Ph.D., M.A. is Chief of Bioethics, IRB chair, and Research Integrity officer at the Walter Reed Army Institute of Research (WRAIR) in Silver Spring, MD. WRAIR is a DOD-funded research institution conducting research in infectious diseases and brain and behavioral health in the US and at multiple international sites. Dr. Dawson leads a bioethics consultation service at WRAIR to assist researchers and leaders grappling with ethical issues in research. She also leads a small team which provides training and education on Responsible Conduct of Research for all WRAIR investigators and research staff. Recently during the COVID-19 pandemic, Dr. Dawson's team has initiated a Community Engagement program for WRAIR in the DC metropolitan area. Within bioethics, Dr. Dawson's main interests and publications are in the area of clinical trial design, community engagement, intersection of research and public health activities, and oversight of human research.

Prior to joining WRIAR in 2019, Dr. Dawson worked for 16 years at the National Institutes of Health, including 11 years at the NIAID Division of AIDS (DAIDS). While at DAIDS, she spearheaded a unique grant program for bioethics scholarship in research which funded grants from 2012 to 2016, as well as serving as a bioethics consultant for the Division. She previously worked for three years as a Senior Policy Analyst in the NIH Office of Science Policy, Office of the Director, on human research protections and related policy issues. She also worked as a faculty Research Associate at the Johns Hopkins University Berman Institute of Bioethics, focusing on international research ethics and ethical issues arising in novel scientific areas such as stem cell research.

Dr. Dawson studied molecular microbiology and public health and received a Ph.D. at the Johns Hopkins University Bloomberg School of Public Health, and received a Master of Arts in Philosophy and Social Policy from George Washington University.

SESSION II

EFFECTIVELY MANAGING LOCAL CONTEXT CONCERNS IN SINGLE IRB REVIEW

Addressing Local Context Issues By Single IRBs in Multi-Site Research



Robert Klitzman, M.D.

Professor of Psychiatry, Columbia University

Robert Klitzman, M.D., is a professor of psychiatry at the College of Physicians and Surgeons and the Joseph Mailman School of Public Health, and the Director of the online and in-person Bioethics Masters and Certificate Programs at Columbia University. He has written over 140 scientific journal articles, nine books, and numerous chapters on critical issues in bioethics regarding genetics, neuroscience, doctor-patient relationships and other areas. Klitzman has received numerous awards for his work, including fellowships from the John Simon Guggenheim Foundation, the Russell Sage Foundation, the Commonwealth Fund, the Aaron Diamond Foundation, the Hastings Center and the Rockefeller Foundation. He is a member of the Empire State Stem Cell Commission, and the Ethics Working Group of the HIV Prevention Trials Network, and served on the U.S. Department of Defense's Research Ethics Advisory Panel. He is a Distinguished Fellow of the American Psychiatric Association, a member of the Council on Foreign Relations, and a regular contributor to the New York Times and CNN.

Challenges to Reviewing Clinical Research When Local Context Includes Variation in Infrastructure and Practices



Jonathan M. Green, M.D., M.B.A.

*Director, Office of Human Subjects Research Protections,
National Institutes of Health Intramural Research Program*

Jonathan M. Green, M.D., M.B.A. is Director, Office of Human Subjects Research Protections for the National Institutes of Health. Prior to joining the NIH, Dr. Green was professor of medicine, pathology, and immunology, as well as Associate Dean for Human Studies, and Executive Chair of the institutional review board at Washington University School of Medicine in St. Louis, MO. He received his medical degree from Wayne State University in Detroit followed by residency training in internal medicine at Boston City Hospital. He then completed a fellowship in pulmonary and critical care medicine at the University of Michigan Medical Center, and additional post-doctoral training at the University of Chicago. He received an M.B.A. from Washington University Olin School of Business in 2017. He is board certified in internal medicine, pulmonary diseases, and critical care medicine. Dr. Green continues to serve as an attending physician in the

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EFFECTIVELY MANAGING LOCAL CONTEXT CONCERNS IN SINGLE IRB REVIEW

Medical Intensive Care Unit and Pulmonary Consult Service at the NIH Clinical Center and has conducted both basic science and clinical research on the regulation of the immune response. Dr. Green has had a long standing interest in biomedical ethics. He has been a member of the Barnes Jewish Hospital Ethics Committee since 2000, leading the clinical ethics consultation service from 2001-2005 and serving as Chair of the Ethics Committee from 2005-2009. After joining the Washington University Institutional Review Board in 2008, he assumed the role of committee co-chair in 2009. In 2010, he was appointed Associate Dean of Human Studies and Executive Chair of the IRB at Washington University in St Louis. Dr. Green served on the Secretary's Advisory Committee on Human Research Protections (SACHRP) from 2015-2018, also serving on the Subpart A subcommittee.

How Might a Single IRB for Multisite Research Address Local Culture, Race and Social Class of Potential Human Subjects?



Stephen B. Thomas, Ph.D.

Professor, Health Policy and Management, and Director, Maryland Center for Health Equity School of Public Health, University of Maryland, College Park and IRB member for the All of Us Program

Stephen B. Thomas, Ph.D., is Founding Director of the Maryland Center for Health Equity and Professor of Health Policy & Management in the School of Public Health at the University of Maryland. Dr. Thomas is one of the nation's leading scholars on community-based interventions to eliminate racial and ethnic health disparities including obesity, diabetes, hypertension, HIV AIDS and COVID-19. He is Principal Investigator of the Center of Excellence on Race, Ethnicity and Disparities Research funded by the NIH-National Institute on Minority Health and Health Disparities (NIMHD). Dr. Thomas is also Principal Investigator (with Dr. Quinn) on the NIH-NIMHD National Bioethics Research Infrastructure Initiative "Building Trust Between Minorities and Researchers" focused on delivery of scientifically sound and culturally relevant research with racial and ethnic minority populations. He earned certificates in bioethics from Georgetown University (2000) and the University of Washington in Seattle (2001).

Since 2015, he has been supported by the Cigna Foundation with a World of Difference grant that supports mobilization of black barbershops and salons to become portals for delivery of medical and public health services. In 2018, barbershop campaign expanded to a national level with launch of the National Association of Black Barbershops & Salons for Health. Dr. Thomas has served as the Philip Hallen Professor of Community Health and Social Justice at the University of Pittsburgh's Graduate School of Public Health (2000-2010). In 2010, he received the Dorothy Nyswander Social Justice Award from

SESSION II

EFFECTIVELY MANAGING LOCAL CONTEXT CONCERNS IN SINGLE IRB REVIEW

the Society for Public Health Education. He was awarded the 2005 David Satcher Award from the Directors of Health Promotion and Education for his leadership in reducing health disparities through the improvement of health promotion and health education programs at the state and local levels and received the 2004 Alonzo Smyth Yerby Award from the Harvard School of Public Health for his work with people suffering the health effects of poverty.

Experience With Regionalized Ethics Review Committees in the United Kingdom and Europe



Sarah J.L. Edwards, Ph.D.

*Professor of Bioethics, Department of Science and Technology Studies,
University College London*

SESSION III

SHARING RESPONSIBILITIES AND DISTINGUISHING ROLES IN THE SINGLE IRB ERA

The transition to single IRB review for cooperative research requires institutions to change how they conduct oversight of research. Even when IRBs are no longer the IRBs of record, their institutions continue to have legal and ethical responsibilities for protecting research participants. This session will explore the challenges and adjustments for relying institutions as they implement the single IRB mandate. This may also present opportunities for improving oversight of the conduct of research at the institutions.

Session III Introduction



Megan Kasimatis Singleton, J.D., M.B.E., CIP (Moderator)

Assistant Dean, Human Research Protections and Director, Human Research Protections Program, Johns Hopkins University School of Medicine

Megan Kasimatis Singleton, J.D., M.B.E., CIP, is Assistant Dean for Human Research Protection and Director of the Human Research Protection Program at Johns Hopkins University School of Medicine. In this role she is responsible for oversight and direction of JHM's 7 IRBs. Ms. Singleton is a licensed attorney in Pennsylvania. She earned her law degree from Temple University and her Masters in Bioethics from the University of Pennsylvania. In addition to her current role in leading the Johns Hopkins Medicine HRPP, she serves as the director of central IRB (CIRB) activities for the Johns Hopkins/Tufts Trial Innovation Center (TIC), leading the charge for innovations in operationalizing single IRB (sIRB) review. Ms. Singleton serves as a member of the SMART IRB Harmonization Steering Committee and is a member of the Steering Committee for AEREO, a consortium designed to advance effective research ethics oversight through empirical research. Ms. Singleton is co-chair of PRIM&R's Advancing Ethical Research Conference Workshop/ Didactic Subcommittee and is a member of the PRIM&R Board of Directors. She is also an AAHRPP, Inc. site visitor and member of the AAHRPP council.

SESSION III

SHARING RESPONSIBILITIES AND DISTINGUISHING ROLES IN THE SINGLE IRB ERA

Reliance Agreements: Considerations and Responsibilities Beyond IRB Review



Emily Chi Fogler, Esq.

Partner, Verrill Dana LLP

Emily Chi Fogler, Esq., is a partner in the Health Care Group at Verrill Dana LLP. She advises institutions, universities, companies, research organizations, and their IRBs on matters related to the conduct and oversight of clinical research, including human subject protection; FDA clinical investigations; single IRB review arrangements; sponsored research agreements; tissue/data repositories; data-sharing; and national and international privacy regulations. She is currently counsel to one of the NIH grantees that developed SMART IRB. Prior to joining Verrill, Emily served for over a decade as senior counsel for human research matters at Partners HealthCare (Mass General Brigham) in Boston, MA. Before that, she was an associate at Ropes & Gray LLP, and a law clerk to the Honorable Patti B. Saris of the U.S. District Court of MA. Ms. Fogler is a graduate of Harvard Law School, where she was an executive editor of the Harvard Law Review.

Establishing the Role of the Relying Institution in Human Subjects Protection in the Era of Single IRB



Kelley O'Donoghue, M.P.H., CIP

Associate Vice President for Human Subject Protection and Director of the Office for Human Subject Protection (OHSP) at the University of Rochester

Kelley O'Donoghue is the Associate Vice President for Human Subject Protection and the Director of the Office for Human Subject Protection (OHSP) at the University of Rochester. She is responsible for directing and managing the University of Rochester's AAHRPP-accredited Human Research Protection Program. She is currently a member of the Council for Certification of IRB Professionals (CCIP) and an AAHRPP Site Visitor.

Kelley obtained a Master in Public Health from the University of Rochester in 2006 and certification as an IRB professional in September of 2010. Kelley has worked in the field of research for 23 years, holding various positions, including Clinical Research Coordinator, Human Subject Protection Specialist, Clinical Research Associate, Project Manager, and RSRB Director.

SESSION III

SHARING RESPONSIBILITIES AND DISTINGUISHING ROLES IN THE SINGLE IRB ERA

Working Together to Improve the Single IRB Model: Suggestions from a Multi-Stakeholder Project Team



Sara B. Calvert, PharmD

Senior Project Manager, Clinical Trials Transformation Initiative (CTTI)

Sara B. Calvert is a senior project manager at the Clinical Trials Transformation Initiative. She is responsible for managing the development and implementation of multiple projects in collaboration with multi-stakeholder project teams. This includes current and prior projects on the use of single IRBs for multi-center clinical trials, a multi-national observational study on the risk factors for nosocomial pneumonia, characterizing the clinical trials enterprise using data in ClinicalTrials.gov, pregnancy testing in clinical trials, and conducting clinical trials using registries. Prior to joining CTTI, she was clinical pharmacist and project leader at the Duke Clinical Research Institute, managing projects on medication adherence and anticoagulation management. She completed a Doctor of Pharmacy from the University of Pittsburgh and a primary care pharmacy specialty residency at Duke University Medical Center and Health System.

SESSION III

SHARING RESPONSIBILITIES AND DISTINGUISHING ROLES IN THE SINGLE IRB ERA

SMART IRB: Lessons Learned and Opportunities Ahead



Barbara E. Bierer, M.D.

Director, Regulatory Policy, SMART IRB and
Director, Regulatory Foundations, Ethics, and the Law, Harvard Catalyst (CTSC)

Barbara Bierer, M.D., is the faculty director of the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center), a Professor of Medicine, Harvard Medical School and Brigham and Women's Hospital, Boston and a hematologist/oncologist. She is the Director of the Regulatory Foundations, Ethics and the Law Program of the Harvard Clinical and Translational Science Center and the Director of Regulatory Policy, SMART IRB. Previously she served as senior vice president, research at the Brigham and Women's Hospital for 11 years, and was the institutional official for human and animal research, for biosafety, and for research integrity. She initiated the Brigham Research Institute and the Innovation Hub (iHub), a focus for entrepreneurship and innovation. In addition, she was the Founding Director of the Center for Faculty Development and Diversity at the BWH.

In addition to her academic responsibilities, she currently serves on the Board of Directors of Vivli, Inc., a non-profit organization founded by the MRCT Center dedicated to global clinical trial sharing; Management Sciences for Health (MSH), an international organization working in partnership globally to strengthen health care, local capability, and access; and the Edward P. Evans Foundation, a foundation supporting biomedical research. Previously she has served as the chair of the Board of Directors of the Association for Accreditation of Human Research Protection Programs (AAHRPP), on the Board of Public Responsibility in Medicine and Research (PRIM&R), and as chair of the Secretary's Advisory Committee on Human Research Protections, HHS. She has authored or co-authored over 240 publications and has served on the editorial boards of a number of journals including Current Protocols of Immunology, Blood, and Therapeutic Innovation and Regulatory Science.

Dr. Bierer received a B.S. from Yale University and an M.D. from Harvard Medical School.



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