A USA perspective on diversity and inclusion

Barbara E. Bierer, MD
Professor of Medicine, Harvard Medical School
Faculty Director, MRCT Center
Director, Regulatory Foundations, Law and Ethics Program, Harvard Catalyst
bbierer@bwh.harvard.edu

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- We have no personal conflicts of interests with regard to the content of this presentation or discussion.
The MRCT Center is a research and policy center focused on addressing the conduct, oversight, ethics and regulatory environment for clinical trials.

**Vision**

Improve the integrity, safety, and rigor of global clinical trials.

- Academic credibility
- Trusted collaborator
- Independent convener
Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

MRCT Center is affiliated with BWH and Harvard University
Faculty Director, MRCT Center

Director, Regulatory Foundations, Law and Ethics Program, Harvard Catalyst
Agenda

• Political complexities
• The task
• Approaches and questions

Don't Reinvent

Perfect It
Harvard University Faculties and Allied Institutions
(as of 8/16/2019)

President
Provost

Faculty of Arts and Sciences
- Harvard College
- Graduate School of Arts and Sciences
  - School of Engineering and Applied Sciences
  - Division of Continuing Education

Harvard Business School
Harvard Graduate School of Design
Harvard Divinity School
Harvard Graduate School of Education
Harvard Kennedy School of Government
Harvard Law School
Harvard Medical School
Harvard School of Public Health
Radcliffe Institute for Advanced Study

Harvard School of Dental Medicine

Allied Institutions
- American Repertory Theater
- Arnold Arboretum
- Harvard Art Museums
- Harvard University Press
- Nieman Foundation
- Villa I Tatti

Interfaculty Initiatives
- Advanced Leadership Initiative at Harvard University
- Berkman Klein Center for Internet & Society at Harvard University
- Center for Geographic Analysis
- Center on the Developing Child at Harvard University
- David Rockefeller Center for Latin American Studies
- Edmond J. Safra Center for Ethics
- Francisco-Xavier Bakuno Center for Health and Human Rights
- Harvard Brain Science Initiative
- Harvard Center for Population and Development Studies
- Harvard China Fund
- Harvard Data Science Initiative
- Harvard Global Health Institute
- Harvard Humanities Initiative
- Harvard Mind/Brain/Behavior Interfaculty Initiative
- Harvard Stem Cell Institute
- Harvard University Asia Center
- Harvard University Center for African Studies
- Harvard University Center for AIDS Research
- Harvard University Center for the Environment
- Harvard University Native American Program
- Harvard University Origins of Life Initiative
- Institute for Quantitative Social Science at Harvard University
- Lasker-Bell South Asia Institute at Harvard University
- Mahindra Humanities Center
- Microbial Sciences Initiative at Harvard
- Prince Awaisuddin Bin Talal Islamic Studies Program at Harvard University
- Program in Health Policy
- Wyss Institute for Biologically Inspired Engineering at Harvard University
To reduce barriers for PIs, by building on the strength of our institutions, the programs on regulatory foundations has a “bottom-up” approach.
Harvard Catalyst (Harvard Clinical and Translational Center)

Decentralized and Large
Decentralized system of legally separate and financially distinct entities
21 separate 501(c) 3 institutions
24 separate Federal wide Assurances

Diverse Faculty
Investigators are faculty of Harvard, Broad, or MIT; not all Harvard employees
31 institutions and schools

Expertise and Funding
Varying degrees of AAHRPP accreditation
Research revenues from ~$1M to ~$900M
One focus is on the **INVESTIGATOR** over the **ENTIRE LIFESPAN** of a given research study.
NIH CTSA goals

- Goal 1: Train and Cultivate the Translational Science Workforce
- Goal 2: Engage Patients and Communities in Every Phase of the Translational Process
- Goal 3: Promote the Integration of Special and Underserved Populations in Translational Research across the Human Lifespan
- Goal 4: Innovate Processes to Increase the Quality and Efficiency of Translational Research, Particularly of Multisite Trials
- Goal 5: Advance the Use of Cutting-Edge Informatics

The power of a funder: requirements and accountability
Training: Alignment and harmonization of core competencies

1. Identify competency domains

**Competency Domains** are broad categories of knowledge, skills and attitudes which are necessary to successfully function within a field of expertise.

2. Map and define competencies

**Competencies** are specific knowledge, skills and attitudes which comprise Competency Domains.

- Categorize competencies, learning objectives and statements from published efforts
- Define harmonized competency statements for each category

3. Obtain endorsement

Obtain endorsement from major stakeholders and content providers.
JTF Framework – Competency Domains for the Clinical Research Professional

- Standardized role descriptions
- Competency-based training/education
- Level of competency vs level of job
  - Promotion and upward mobility
- Self-assessment & competence
  - Recognize personal training needs
  - Personal portfolio of competencies
- Competence & career development
  - Academic program accreditation
- Continuous process (competence not static, jobs change, gaps appear); lifelong learning

Leveling of the JTF Core Competency Framework (2018)

SKILL LEVELS

- Fundamental level: can perform with coaching/explain
- Skilled level: can perform independently/demonstrate
- Advanced level: can teach/develop
Translating the MRCT Center JTF Framework

We are committed to providing the JTF Core Competency Framework in as many languages as possible. If you are interested in helping with translations, please contact mrct@bwh.harvard.edu.

The following translations are currently available:

- Spanish
- French (in process)
- Japanese (in process)
- Portuguese (in process)
Training materials

DIAMOND Portal Offers Research Training for All

Staff who work on clinical studies can improve their skills with high-quality training materials on the DIAMOND portal. The goal of the DIAMOND project is to create well-run clinical trials through well-trained staff.

What is Research Essentials?

Research Essentials is a unique research training resource that has been designed to deliver a world class program to meet the specific needs of all those involved in research while also enabling learners to pick and choose from a diverse range of subjects so that they can design a training program that best meets their needs.

SMART IRB

Supporting the implementation of single IRB review

GROW
A national IRB reliance network

SUPPORT
Use of SMART IRB

EDUCATE & TRAIN
Institutions & Investigators

HARMONIZE
sIRB review processes across the nation

A Roadmap to Single IRB Review

Funded by NCATS beginning in July 2016
As of July 2018, led by Harvard University and University of Wisconsin-Madison, along with a team of Ambassadors from across the U.S.
A Platform for Single IRB Review

SMARTIRB.org
Resources and supportive services freely available to support sIRB review

Joinder platform
Allows institutions to join the SMART IRB Agreement

Online Reliance System
Provides a central system and process to request, track, and document reliance arrangements for each study

SMART IRB Agreement
Sign once and implement

SOPs
Clear roles and responsibilities for investigators and institutions
Flexibility to use other SOPs as agreed upon or required

Ambassadors
Help institutions join and implement SMART IRB

Education & Training
Tools, templates, FAQs, checklists, guidance, peer consultations, and webinars support adoption of SMART IRB

Harmonization
Steering Committee
Leaders in the field promote best practice

Expertise Across the Nation
Allow SMART IRB Participating Institutions to work together to establish reliance arrangements on a study-by-study basis.

1. With and without significant reliance experience
2. Familiar or unfamiliar with one another
3. With limited or substantial infrastructure to support single IRB review

Request, Track, and Document Arrangements

SMART IRB Online Reliance System

Launched in May 2017

Single point of entry standardizes reliance processes

Communication portal eliminates tracking via email or other methods

Guided workflow makes clear when action is required

The system works for institutions:

Get started at smartirb.org/reliance.
Standard operating procedures (SOPs) for establishing and implementing reliance provide clarity during the review and conduct of research using the SMART IRB Agreement.

- Provide clarity on key roles and responsibilities
- Use of SMART IRB SOPs is not mandated
- SMART IRB supports networks with existing SOPs
- Institutions communicate whether other policies or procedures apply

How to find out who’s joined SMART IRB

- Visit smartirb.org to find the full list of SMART IRB Participating Institutions.
- Once an institution’s joinder is activated, they are listed on the Participating Institutions page.
Streamline efficiencies

• Training
• IRB/EC
• Contracting
Example: Accelerated Master Agreements

- Confidential Disclosure Agreement
- Clinical Trial Agreement
- Data Transfer Use Agreement
- Fixed Price Clinical Trial Subaward Agreement

- The exchange of research materials under material transfer agreements (MTAs).
- Collaborative research conducted under cooperative research and development agreements (CRADAs).
- Clinical studies to determine the safety and efficacy of new agents under clinical trial agreements (CTAs).
- Exchange of confidential information under confidential disclosure agreements (CDAs).
- Informal collaborations that involve the transfer of materials and data under a Research Collaboration Agreement (RCA).

https://www.ara4us.org
Forms & Model Agreements

Licensing Application and Agreements
Used when the industry is interested in licensing a technology.

- Inter-Institutional Agreements
- Public Health Service License Agreements
- License Application

Confidential Disclosure Agreements (CDAs)
Used to exchange confidential information.

- NCATS Model 2-Way CDA (Word - 23KB)
  For two parties sharing confidential information.

- NCATS 1-Way Out CDA (Word - 28KB)
  For an outside party receiving confidential information from NIH.

- NCATS 1-Way In CDA (Word - 27KB)
  For an outside party providing confidential information to NIH.

Research Collaboration Agreement (RCA)
Used in a collaborative project where confidential information and materials may be exchanged hands.

- RCA Template (Word - 31KB)

Employee Invention Report
Used when NCATS employees create new technologies.

- PHS Employee Discovery and Invention Report (Word - 113KB)

Cooperative Research and Development Agreements (CRADAs)
Used when NIH and industry collaborate to further develop a technology for commercialization.

- Model NIH Materials CRADA (Word - 27KB)
  For collaborative studies of basic research.

- Model PHS CRADA (Word - 49KB)
  For collaborative studies of basic research.

- Intramural Clinical Trial CRADA (Word - 47KB)
  For collaborative studies that include a clinical trial conducted at NIH.

- Extramural Clinical Trial CRADA (Word - 49KB)
  For collaborative studies that include a clinical trial conducted at NIH-funded sites.

Research Collaboration Agreement (RCA)
Used in a collaborative project where confidential information and materials may be exchanging hands.

- RCA Template (Word - 31KB)

Material Transfer Agreements (MTAs)
Used to exchange research materials.

- NCATS Provider MTA (Word - 27KB)
- NCATS Recipient MTA (Word - 29KB)

https://ncats.nih.gov/alliances/forms
Streamline efficiencies

• Training
• IRB/EC
• Contracting
• Recruitment
  – Makes clinical trials slow and more costly;
  – Limits the validity of trial results and, in turn, researchers’ ability to apply the findings broadly to the general population; and
  – Stops a trial prematurely or prevents it from taking place at all.

Technology Platforms

The CTSA ACT technology platform has two major components:

1. Informatics for Integrating Biology and the Bedside (i2b2), a software package that converts raw records into de-identified and searchable participant information stored in a central database.
2. Shared Health Research Informatics Network (SHRINE), a search engine for i2b2. With appropriate agreements in place, an ACT investigator can use SHRINE to search de-identified records using a customized set of participant criteria. SHRINE queries all network institutions and provides an approximate number of participants at each site who meet the criteria.
Accrual to Clinical Trials (ACT) Network

- Discovery, exploration, and validation of patient cohorts for investigator-initiated multi-site or single-site clinical trials
# NETWORK PROPOSAL SUBMISSIONS

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# SIRB (more metrics)

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# STANDARD AGREEMENT (in FDP-CTSA)

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**TRIAL INNOVATION NETWORK**

Operational innovation, excellence, and collaboration.

The Trial Innovation Network continues to accept new proposals! Click the button below to get started.

**Get Started now!**

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212 Proposals Submitted

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[https://trialinnovationnetwork.org](https://trialinnovationnetwork.org)
International resources

https://clinregs.niaid.nih.gov
Support the individual investigator

One focus is on the INVESTIGATOR over the ENTIRE LIFESPAN of a given research study

New Idea

Develop Concept

Find Collaborators

Obtain Funding

Study Design Protocol Development

Identify and Recruit

Collect Data

Develop Implementation Plan

Analyze Data

Interpret Results

Communicate Results

Close-out

Complete Clinical Research Study
Support across the clinical trial enterprise

- New Idea
  - Develop Concept
  - Find Collaborators
  - Obtain Funding

- Study Design
  - Protocol Development

- Identify and Recruit

- Collect Data

- Analyze Data
  - Interpret Results

- Communicate Results

- Close-out
  - Complete Clinical Research Study

- Project Management • Study Dashboard

- MRO
  - Research Nurses
  - Research Coordinators
  - Biostatistics
  - Protocol Review

- I2b2/SHRINE
  - Engagement & Communication

- IRB & Other Regulatory Requirements

- Develop Implementation Plan

- Protocol Review
  - Cede Review • Reliance Agreements
  - Regulatory Binder
  - IND/IDE Consult Service

- MRO QA/QI Consult Service
  - Research Nurses
  - Research Coordinators
  - Close-out

- MRO Admin Staff

- Research Nurses

- Biostatistics

- Bioinformatics
Making the case

• Research is not the primary concern of most hospitals and academic institutions

• Frame the case:
  – Financial
  – Care improvement (and therefore financial)
  – Market share, referrals, visibility
  – Public good

• If object of clinical research is attracting industry trials → speed, IRB/EC, contract execution, recruitment (first patient on trial, number of patients on trial), data integrity, oversight

• If object is academic trials, must have clinical significance and impact → develop care pathway, business model

• Ideally, (re)engineer IT system and EHR to incorporate outcomes research as an outgrowth of clinical care
Where there’s a will...

• Political will to proceed ... and to compromise
  – Common goals, vision
  – Trust
  – Time in planning
• Common resources and interdependencies
• Financial alignment (and resources)
• Metrics and measurement
• Accountability
• Governance
Thank you

14 Story Street, 4th Floor, Cambridge, MA 02138, USA
Telephone: (617) 496-9807
Email: mrct@bwh.harvard.edu

Barbara E. Bierer, MD
bbierer@bwh.harvard.edu

Sarah White, MPH
sawhite@bwh.harvard.edu

www.mrctcenter.org
Everything should be made as simple as possible – but not one bit simpler”

Albert Einstein