AN INNOVATIVE APPROACH TO MULTI-SITE IBC REVIEW AND OVERSIGHT: THE HARVARD CATALYST MASTER IBC RELIANCE AUTHORIZATION AGREEMENT

Harvard Catalyst: Sabune J. Winkler, JD; Ted Myatt, Sc.D; Joanna Greene, Barbara Bierer, MD; **IBC representatives**: Despina A. Felis, MS, RBP; Rebecca R. Caruso, MPH, RBP, CBSP, SM (NRCM); Karen B. Byers, MS, RBP, CBSP; Kathy Eklund, RDH, MHP; Leslie Hofherr, MPH, MS, CBSP; Robert Rasmussen, PhD

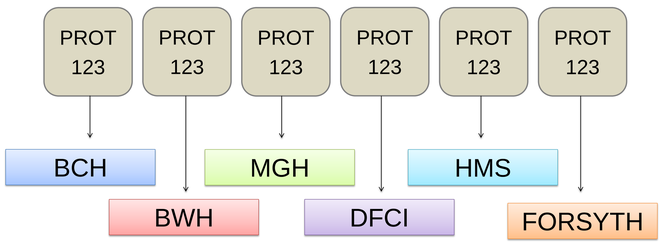
THE HARVARD CLINICAL AND TRANSLATIONAL SCIENCE CENTER

HARVARD MEDICAL SCHOOL · MASSACHUSETTS GENERAL HOSPITAL · BRIGHAM AND WOMEN'S HOSPITAL · Forsyth Pioneering Discoveries Profound Change · Boston Children's Hospital Until every child is well™ · DANA-FARBER CANCER INSTITUTE

PROBLEM STATEMENT

The close proximity of 16 institutions in the Boston area and the dual appointments of faculty, has allowed for reliance on resources across institutions conducting both clinical gene transfer studies and laboratory research projects. Projects conducted across multiple institutions currently require IBC review at each individual institution.

DUPLICATIVE REVIEW OF COLLABORATIVE RESEARCH BURDENS IBCs & INVESTIGATORS



RESULT = DELAYS IN THE CONDUCT OF MULTICENTER PROTOCOLS

GOAL

Reduce the burden on investigators and institutions by simplifying the review process for multisite clinical or laboratory research involving recombinant or synthetic nucleic acid molecules, biological agents, and/or the biological materials of concern.

CHALLENGES

- Acknowledge legal and operational autonomy of signatory institutions
- Allow case-by-case decisions on protocol review
- Develop a system that enables involved institutions to meet reporting requirements
- Limit to local institutions to ensure fulfillment of OBA requirement for inclusion of an unaffiliated community member representing the interests of the surrounding community

PROCESS

5 IBC committees covering 16 Harvard Catalyst institutions came together → **Formed working committee representing leadership of affiliated IBCs** → **Bi-weekly meetings over nearly 2 years to define agreement requirements** → **Selected topic areas; developed supporting policies and procedures** → **Agreed upon 16 key standards for framework to reduce duplicative IBC review** → **Harvard Catalyst Master Common Reciprocal IBC Reliance Authorization Agreement**

Multiple stakeholders include: NIH Office of Biotechnology Activities (OBA), local municipalities, institutional officials, biosafety officers, general counsels, and compliance officers.

IBC AGREEMENT

THE IBC RELIANCE AGREEMENT

A master agreement among Harvard-affiliated institutions that allows for ceding IBC review to one designated IBC for clinical or laboratory-based research that will take place across two or more institutions.

A formal, signed document permits an institution to cede responsibility and authority for IBC review and approval, on a protocol-by-protocol basis, to another institution with a duly authorized and constituted IBC.

AGREEMENT CHARACTERISTICS:

- **Allows Single and Consolidated IBC Review** among 5 IBCs covering 16 institutions
- **Creates a Cede Review Process** using shared forms and server access
- **Delineates Duties and Responsibilities** of REVIEWING and RELYING IBCs
- **Allows for ongoing evaluation** of the standardized processes

Key Standards for Review including:

- Cede Review Application
- Laboratory inspections
- Training
- Occupational Health and Medical Surveillance plan

Reviewing IBC provides:

- Review of the application
- Access to minutes
- Approval notification and updates
- Communication re: suspension, termination, accidents, spills and exposures

Collaborating Institutions comply with:

- IBC Registration with NIH Program on Biosecurity & Biosafety Policy
- Process for reporting requirements to NIH, state and local officials
- Procedures for injuries, accidents, illnesses and emergencies
- Access to annual reports / records
- Procedures for reporting adverse events
- Access to determinations of non-compliance; corrective actions for major/minor non-compliance
- Evaluation of contested findings
- Scientific misconduct follow-up
- Assurance of insurance
- Continuing review of IBC reliance processes

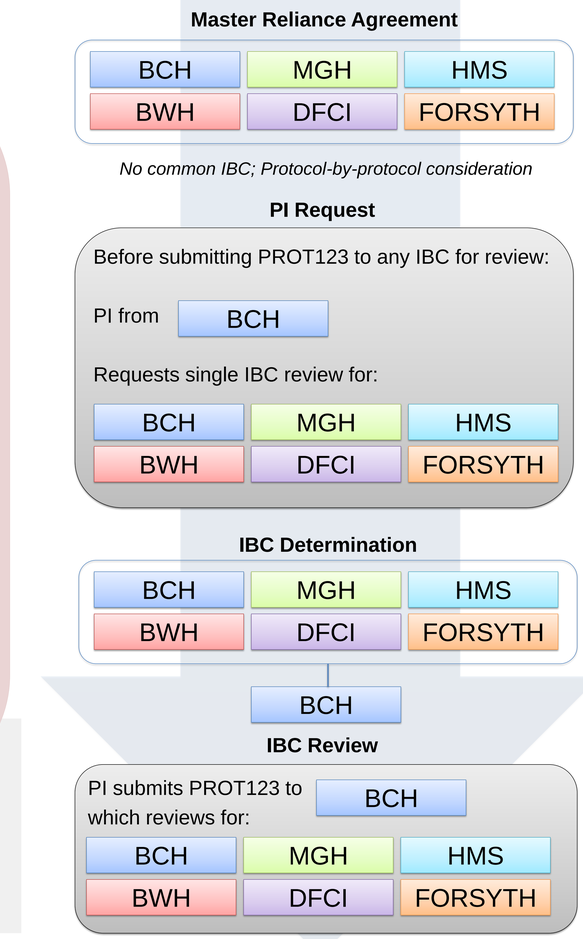
EXPECTED OUTCOMES

- Reduction in duplicative IBC review
- A proof of concept model for streamlining IBC review and enabling accelerated collaborative research
- A flexible and replicable framework adaptable by other institutions that share geographic location.

SOLUTION

- Develop an inter-institutional framework for IBC reliance that addresses institutional and regulatory requirements
- Enable reliance through practical tools such as shared policies, forms, reporting mechanisms, and access to resources via shared server access
- Create a flexible, scalable, and adaptable model

IBC RELIANCE ENABLES STREAMLINED REVIEW FOR IBCs AND INVESTIGATORS



The IBC working group is coordinated by Harvard Catalyst, founded in 2008 to provide investigators with the tools for collaborative research efforts. Biosafety professionals from the 5 IBCs that oversee 16 institutions participated in drafting the agreement. To request a copy of the IBC Agreement and forms, please contact: Sabune Winkler, JD, Director, Regulatory Affairs Operations, Email: Sabune_Winkler@hms.harvard.edu Tel: 617-432-7811

This work was conducted with support from Harvard Catalyst | The Harvard Clinical and Translational Science Center NIH Award #1UL1 TR001102-01 and by contributions from Harvard University, Harvard Medical School, Harvard School of Public Health, Beth Israel Deaconess Medical Center, Boston Children's Hospital, Brigham and Women's Hospital, Dana-Farber Cancer Institute, and Massachusetts General Hospital. The content is solely the responsibility of the authors and does not necessarily represent the official views of Harvard Catalyst, Harvard University and its affiliated academic health care centers, the National Center for Research Resources, or the National Institutes of Health.