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PROBLEM STATEMENT

Academic institutions struggle with how to support Sponsor-Investigators (SIs), individuals who serve as both the clinical investigator and the sponsor, when conducting investigational drug and device research. In response to this challenge we sought to:

1. Understand how disparate institutions support their SIs
2. Identify needs (personnel, expertise and capabilities)
3. Develop shared and accessible tools and resources
4. Create a pathway for institutions with limited or no resources to access tools and share education and learning

SOLUTION

Establishing a contributory network to share in the development of policy, forms, tools, and educational resources can offer compelling benefits to SIs and institutions. Extending services to, and expanding education and assistance for, employees benefits small, medium, and large sized institutions, and enables both staff and faculty to be more productive, proactive, and responsive to SI needs.

INDIDE SUBCOMMITTEE

The Harvard Catalyst IND/IDE Subcommittee includes recognized IND/IDE compliance leaders, IRB personnel and QA/QI professional:

• Bruno Rodriguez, CIP, Dana Farber Cancer Institute
• Robert Thorne, CIP, Joslin Diabetes Center
• Jennifer Hirsh, CIP, Harvard Medical School
• Joseph Wilford, CIP, Harvard School of Dental Medicine
• Fellowship Program

IND/IDE SUBCOMMITTEE

COLLABORATION STRATEGY:

PROCEDURE FOR INSTITUTIONS TO COLLABORATIVELY CREATE BASIC TOOLS AND SHARE EDUCATION AND LEARNING

Form Committee

Identify Needs & Challenges

Develop Materials & Improve Transparency

Implement/Adopt/Deploy Best Practices, Tools & Materials

1. Identify Broad Needs and Challenges
2. Identify and Recruit Contributors (Membership) and Collaborators – to provide content expertise and best practices; go outside of your own institution
3. Identify, Define and Appoint Leadership – bring together; keep together
4. Create and Foster Community – together identify needs; develop feasible deliverables
5. Support Contributors – identify a team or person accountable to research, draft, project manage; together share education
6. Develop Durable Resources – integrate into individual roles and responsibilities at home institutions
7. Utilize, Distribute and Share - utilize your commonly and readily accessible deliverables, present and publish broadly
8. Review Tools – perform continuous quality improvement; convene, review and update past deliverables

NEW TOOLS AND DELIVERABLES

1. Education and Guidance
   • Host symposia: i.e. “IND/IDE on a shoestring” panel of experienced investigators
   • Create specific curriculum (1 class/month) leading to certificate
   • Draft best practices guidance for SI IND/IDEs
2. Tools and Templates
   • Create IND/IDE Binder
   • Develop Protocol Information for IRB submissions
   • Develop SI-specific FAQs
   • Document job responsibilities and define core competencies
   • Develop monitoring plan templates and resources
   • Identify internal and external consultants
   • SI Audit-ready checklists for compliance maintenance
3. Services
   • Identify and develop a mentor network
   • Determine if Monitoring Services can be offered
   • Support for FDA investigations and respond to findings

BRING INSTITUTIONS TOGETHER

Small (0 – 50 SI)

Medium (51 –100 SI)

Large (101+ SI)

SI Support Focus: Education
Personnel: Non-specific job function: function of another job such as IRB or QA/QI professional
Capabilities:
• Reactive individual, consults and meetings
• Assist in interpreting/applying IND/IDE requirements and SI responsibilities
• Ad hoc education and training
• Goodwill reliance on and partnership with experts outside of institution

SI Support Focus: Customization
Personnel: Specific job and/or non-specific job function: function of another job with identified IND/IDE duties
Capabilities:
• Individual consults and meetings
• Mandatory education and training for SIs
• Embedded into IRB and QA/QI
• Customized services such as regulatory strategy, help with FDA submission, ancillary reviews, correspondence, binders, etc.
• Auditing

SI Support Focus: Compliance & Education
Personnel: Specific job and/or job duty with specific IND/IDE duties
Capabilities:
• Individual consults and meetings
• Mandatory IND/IDE certification and/or new sponsor-investigator training
• Integration with IRB, QA/QI and Clinical Trial Offices
• Access to mentors
• Targeted SI education and training
• Standardized templates, checklists & binders
• Auditing, Support for FDA inspections

Questions/Comments? Contact the IND/IDE Subcommittee

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About the IND/IDE Subcommittee:

The Harvard Catalyst IND/IDE Subcommittee includes recognized IND/IDE compliance leaders, IRB personnel and QA/QI staff as well as those who offer fresh perspectives and novel approaches to assist IRBs and faculty who are sponsors. Participation in the Subcommittee provides an opportunity to collaborate with and learn from area experts around IND/IDE issues.

The institutions contributing to this poster and represented on the subcommittee are as follows:

• Boston Children’s Hospital
• Brigham and Women’s Hospital
• Dana-Farber Cancer Institute
• Harvard Medical School
• Harvard School of Dental Medicine
• Harvard School of Public Health
• Joslin Diabetes Center
• Massachusetts General Hospital
• McLean Hospital

We give thanks and appreciation to all of the institutions that participated in our survey and gave their time for the interviews and follow-up.

This work was conducted with support from Harvard Catalyst | The Harvard Clinical and Translational Science Center NIH Award #UL1 TR001102, as well as 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.

To learn more about the IND/IDE Subcommittee and to download available materials:
http://catalyst.harvard.edu/programs/regulatory/indyide.html