Are You Ready for Mandated Single IRB Review for Multicenter Clinical Trials?

Record of Meeting held Nov. 14, 2017

DoubleTree by Hilton Silver Spring
8727 Colesville Road
Silver Spring, MD 20910

CTTI MISSION: To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials

Workshop meeting materials, including a one-page summary, the agenda, participant list and presentations, are available on the Clinical Trials Transformation Initiative (CTTI) website at: https://www.ctti-clinicaltrials.org/briefing-room/meetings/are-you-ready-mandated-single-irb-review-multicenter-clinical-trials

Publication Date: Feb. 23, 2018
MEETING/WORKSHOP BACKGROUND & OBJECTIVES

Definition:

Central IRB: CTTI defines a central Institutional Review Board (IRB) as a single IRB of record (sIRB) for all clinical trial sites in a multi-center trial. A range of entities may serve as a central/single IRB of record, including another institution’s IRB, a federal IRB, or an independent IRB. Central IRB is used when referring to the CTTI Central IRB Projects conducted from 2010-2015. Single IRB of record (sIRB) is a synonym, and the terminology used by the NIH policy and Common Rule, and therefore is the current term used in all other occurrences in this summary.

Background

Using a single IRB for multi-site trials can improve the quality and efficiency of multi-center clinical trials. Since 2010, CTTI has worked to address barriers to the adoption of sIRBs for multi-center clinical trials through its Central IRB and subsequent Central IRB Advancement projects, and resulting recommendations and resources.

In 2014, the National Institute of Health (NIH) released a draft policy referencing CTTI’s work and recommended the use of sIRBs to increase the efficiency of multi-center clinical trials. Then, in 2016, the NIH issued a final policy requiring the use of a single IRB for multi-center NIH-funded clinical trials effective Jan. 25, 2018. In 2017, the final changes to the Common Rule were announced, including a mandate that U.S. institutions involved in cooperative research in the U.S. (with certain exceptions) use a single IRB. These Common Rule changes are scheduled to take effect on Jan. 20, 2020.

CTTI’s existing recommendations and resources are available to help with implementation of the NIH policy and Common Rule changes. The purpose of the expert meeting outlined in this report was to determine further actions that the U.S. Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), NIH, and/or CTTI can take to ease the transition to mandatory sIRB review for multi-site research.

Objectives

- Review upcoming NIH policy and Common Rule changes regarding single IRB review as well as existing FDA Guidance on Centralized IRB Review Process in Multicenter Clinical Trials
- Discuss the remaining gaps in knowledge, guidance, and tools for implementing a single IRB review model
- Propose solutions regarding implementation of the single IRB model for federally funded (e.g., NIH sponsored), and for FDA-regulated drug and device, multicenter clinical studies
MEETING/WORKSHOP KEY THEMES & HIGHLIGHTS

CTTI convened a meeting involving stakeholders with expertise in the use of single IRBs for multi-center clinical research trials. Participants included approximately 50 representatives from academia, nonprofit organizations, government agencies, IRBs, industry (including pharmaceutical and device companies, and contract research organizations), professional service organizations, and patient representatives.

Over the course of the meeting, sIRB requirements within NIH policy and Common Rule changes, and the 2006 FDA Guidance, were presented and discussed. Tools for addressing many of the challenges associated with the transition to a sIRB were presented, including resources from CTTI Central IRB projects, the Streamlined, Multisite, Accelerated Resources for Trials (SMART) IRB platform and exchange, and the Association for the Accreditation of Human Research Protection Programs (AAHRPP) tip sheet. Attendees also discussed remaining challenges and suggested tools or approaches to facilitate implementation of a sIRB review model. The meeting concluded with attendees offering suggestions for next steps.

Themes that emerged throughout the meeting included:

► Clarity is needed around which studies are required to use a sIRB, as well as definitions of “compelling justification” for exemption from the sIRB mandate in the NIH policy and “cooperative research” in the Common Rule.
► The elements of local context most relevant to sIRB review, and the process for collecting and evaluating local context, remain unclear.
► Quality measures for IRB activities must be developed so that tools for facilitating the transition to a sIRB point institutions and IRB members in the right direction.
► There is a need for examples illustrating successful models for sIRB implementation—specifically, those that include details of the sIRB and reliant institution responsibilities, cost models and best practices, strategies for managing or avoiding additional administrative burden, and management of specialized trials.
► Independent IRBs’ experience with centralizing information from multiple research sites will be helpful for assisting academic and government research organizations.

RECAP OF INTRODUCTION

The meeting began with a presentation that provided an overview of the CTTI mission, methodology, and Central IRB Projects. The purpose of the meeting, to determine how CTTI, FDA, OHRP, and/or NIH can help the transition to mandatory sIRB review for multisite research, was presented.

RECAP OF EACH PRESENTATION & DISCUSSION
Session I: Review Single IRB Policies, Rules, and Guidance

NIH Single IRB Policy

The NIH Policy on the use of a sIRB for multi-site research was published in 2016 with the purpose of reducing clinical trial start-up time without increasing potential subject harm. While existing grants are not yet subject to the policy, the policy is effective for competing grant applications submitted for the January 25, 2018 due date or later and research and development contract proposals published on or after Jan. 25, 2018.

The sIRB policy provisions apply to domestic sites of multi-site studies with the same or shared protocols and include all non-exempt human subjects (not just clinical trials). Exceptions include foreign sites, instances in which local review is required (e.g., tribal communities), and exceptions for new studies ancillary to ongoing parent studies (this is a time-limited exception). The sIRB for new studies does not have to be the IRB of the parent award and can be an existing IRB at a participating site, an independent IRB, or an organized centralized IRB (e.g. NCI Central IRB). The sIRB must be registered with OHRP and have qualified membership to adequately review the proposed study.

The NIH expects investigators to communicate ahead of application submission to select a sIRB best suited to the proposed study, and a multisite study application should name the sIRB and indicate reliance for all participating sites. Often, sIRB costs may be charged as direct costs. The institution is responsible for determining if sIRB costs are appropriately classified as direct or indirect.

Challenges to sIRB implementation include technological challenges of tracking and sharing documents across sites, negotiation of the reliance and authorization agreements, defining roles of sIRBs and local IRBs, and development of a budget that takes into account variation in costs across sites. Willingness to use a master agreement and use of CTTI and/or SMART IRB developed resources can assist in resolution of these issues.

Review of Changes to the Common Rule Regarding Use of sIRB

This presentation provided an overview of the requirements for single IRB review for cooperative research that will go into effect on January 20, 2020 under the revised Common Rule published on January 19, 2017. The requirements apply to any institution located in the United States that is engaged in cooperative research that is conducted in the United States.

The Common Rule revisions stipulate that the sIRB will be selected by the federal department or agency supporting or conducting the research, or proposed by the lead institution (subject to the acceptance of the funding federal department or agency). There are requirements for documenting an institution’s reliance on the sIRB and the responsibilities of each entity, but flexibilities are available on how the documentation can be done, for example, through written agreements,
documentation within the research protocol, or institution-wide policy directives. Exceptions to the sIRB mandate include when the law requires more than single IRB review (e.g., tribal law) and if any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

Though the goals of the revision are compatible with the new NIH sIRB policy, there are some differences in scope and language:

► The NIH policy refers to multisite studies conducting the same protocol, while the revised Common Rule revisions refer to cooperative research (sites do not have to conduct the same protocol to be subject to the mandate)
► The NIH policy may also allow for additional exceptions

In support of the sIRB mandate, the revised Common Rule includes a new regulatory provision that allows OHRP to exercise its compliance authority directly over IRBs not operated by a Federalwide Assurance (FWA)-holding institution.

Review of FDA Guidance on Centralized IRB Review Process in Multicenter Clinical Trials

This presentation focused on current FDA guidance for using a centralized IRB review process in multicenter clinical trials. The guidance was issued in 2006 and describes the roles of participants in a centralized IRB review process, offers guidance on how a centralized IRB review process might include local considerations, and provides recommendations for documenting agreements between the local and sIRB to establish respective responsibilities and implement procedures.

The FDA guidance includes examples of cooperative models and suggests methods for obtaining local context, specifying information exchange between the sIRB and site investigators, and defining responsibilities and roles. Updated regulations and guidance can now include device studies because Section 3056 of the 21st Century Cures Act modified the Federal Food, Drug and Cosmetic Act to remove the requirement for review by “local” institutional review committee. FDA is interested in harmonization with the Common Rule and is interested in obtaining input from stakeholders on how to best achieve that goal.

Discussion of Session I

Clarity

The group raised concerns about the specificity of the language in the revised Common Rule and asked that the term “cooperative research” be more clearly defined. Institutions working on different activities within the same study protocol would be considered part of the same study, but the idea that entirely different protocols might be considered part of the same cooperative study is confusing.
There is a need for clarification on whether new platform trials would be subject to the sIRB requirement under the Common Rule.

**Flexibility and Exemption**

Attendees expressed concern surrounding the flexibility of NIH sIRB requirements and asked if a reevaluation one year after implementation could be used to inform the addition of exemptions, modification of requirements, or a plan for low-cost review.

Attendees asked for insight into the types of situations that constitute “compelling justification” for the NIH Policy and “not appropriate for the particular context” for the revised Common Rule. Currently, specific examples are unavailable, and both organizations agree that inclusion of a “compelling justification” exemption is intended to provide the flexibility needed to evaluate situations as they arise. However, it was noted that being unwilling to use a sIRB does not qualify as a compelling justification. Participants expressed that it may be beneficial to align federal departments in terms of what constitutes “compelling justification,” and “not appropriate for the particular context.” There are ongoing harmonization efforts between OHRP and FDA.

There is concern that NIH will not be able to modify requirements once the revised Common Rule is in place. The time period in between when the NIH policy and Revised Common Rule go into effect (Jan. 25, 2018 through Jan. 20, 2020) represents a period of flexibility in which NIH can modify the policy to remedy any unintended negative effects. For this reason, ongoing dialogue to identify and implement needed changes is critical.

**Collaboration with Industry**

One attendee noted a need to have discussions with industry sponsors or contract research organizations (CRO) about policies on sIRBs. Interest was expressed in initiating dialogue between sponsors and the FDA around this issue.

---

**Session II: Discuss Available Resources for Implementation of sIRB for Multicenter Clinical Trials**

**Review of Resources from CTTI Central IRB Projects**

This presentation provided an overview of the CTTI Central IRB Projects and the resources that have resulted from this work. The first CTTI Central IRB Project findings unveiled 1) a need to define “central IRB,” 2) concerns associated with conflation of institution responsibilities with the ethical review responsibilities of the IRB, and 3) a remaining discomfort rooted in lack of experience using centralized review. In response to these findings, CTTI issued recommendations that included a concise definition of a central IRB, as a single IRB or record, and published a Considerations Document as a guide for assigning responsibilities to both institutions and the sIRB. In addition, CTTI recommended that sponsors in a position to require the use of a sIRB do so to in order for relevant stakeholders to
gain experience with sIRB review. Though these documents provide relevant and actionable recommendations, stakeholders voiced a need for additional resources and specific guidance.

In response, the CTTI Central IRB Advancement Project assessed the remaining areas of concern and proposed solutions to address the “How-To” of using a sIRB of record for multicenter clinical trials. The outcome of this project included several new recommendations, an Evaluation Checklist for assessing readiness and facilitating IRB or site selection, and a Template IRB Authorization Agreement. Each of the tools is publicly available on the CTTI’s Central IRB web page.

**SMART IRB Platform Overview**

This presentation introduced the resources available through the National Center for Advancing Translational Sciences (NCATS) SMART platform and provided an overview of how SMART IRB resources can help institutions request, track, and document reliance agreements for a sIRB. To address the emerging challenges of using a sIRB for multisite research, the Clinical and Translational Science Awards (CTSA) program funded investigators and brought together a wide range of stakeholders, including recognized IRB experts, to develop a sIRB reliance platform.

The SMART IRB platform resources include a single, pre-negotiated national authorization (reliance) agreement that is signed by all participating institutions, an electronic system for communicating reliance documentation, and standard operating procedures. SMART IRB is flexible and can accommodate large and small studies as well as those that operate within or outside of a network. Currently, more than 300 entities have signed onto the programs.

The national reliance agreement provides a default allocation of responsibilities that eliminates the need for additional IRB authorization agreements between member institutions, but does allow for adaptations and amendments that delegate responsibilities in a way that best suits the needs of individual studies. Together, these features reduce the time and costs associated with renegotiation while allowing flexibility. The electronic online reliance system tracks data collection and can serve as a portal, eliminating the need for tracking requests via e-mail or other methods. Within the SMART platform, incorporated workflows make it clear when action is required. Together, these tools allow institutions to more easily make the transition to using a sIRB.

**SMART IRB Exchange and the NIH Trial Innovation Network**

The NIH Clinical Trial Innovation Network (CTIN) was launched by NCATS to accelerate clinical trials through leveraging CTSA resources. The CTIN has several complementary tools under development that further support the SMART IRB and aim to reduce the need for individual institutions to adapt and develop practices in parallel. For example, reliance agreements often require an indemnification or exemption for state institutions, and the CTIN has developed a master indemnification letter that has been adopted by 72 institutions.
The SMART IRB exchange is a web-based platform that works as part of the SMART IRB platform. The exchange is used at more than 112 sites by IRB staff, principal investigators, coordinating center staff, and study teams to track the status of reliance relationships.

Currently, the CTIN is working to further develop features of the platform so that it can track site progress towards reliance and centralize submission of institutional and local context review documents (e.g., institutional policies, ancillary reviews, state laws or information on organizational non-compliance). In addition to these developments, the CTIN plans to monitor the transition to sIRBs and identify and address challenges as they emerge.

**AAHRPP Proposed Single IRB Review Standard**

This presentation introduced elements of the tip sheet that accompanies the newly released AAHRP I-9 standard. While AAHRPP has consistently advocated for the use of sIRBs in the past, the I-9 standard combines these separate recommendations into a document that is easily accessible to those new to the sIRB process. Within the I-9 standard, AAHRP does not take a formal position on the nature of implementation: the guidance is non-specific and focused on outcomes. While this may be frustrating to some new to sIRBs, the nature of the guidance is intended to encourage innovation.

The tip sheet is a guide for implementation that includes several tools developed in response to common roadblocks identified by a workgroup that included both experienced institutions as well as those just now initiating the transition to sIRBs. The AAHRPP anticipates that the tip sheet will serve as an evolving commentary on the essential elements of the I-9 standard. Currently, the tip sheet includes general considerations and information on the individual and overlapping roles of both the reviewing IRB and relying organizations. For example, the tip sheet recommends elimination of the IRB “gatekeeper” function and transition of ancillary reviews (i.e., radiation safety) to individual institutions. Resources compiled in the tip sheet include manuals, decision trees, and matrices for researchers; template reliance agreements, initiation checklists, consent forms, and guidance documents; and recommendations for database development to address technological barriers, among others. Importantly, the tip sheet also discusses which elements of local context are essential to IRB ethical deliberations and which are more pertinent to regulatory compliance. While many methods for operationalizing the transition to a sIRB are currently disjointed and ad-hoc, the outcomes-driven nature of the I-9 standard will likely drive an evolution toward more uniform practices.

**Discussion of Session II**

**Local Context**

Attendees discussed the lack of clarity surrounding which elements of local context are most relevant to a sIRB. One attendee noted that while local context is often cited as a reason for using institutional IRBs, there are often no meaningful issues
outside of understanding local laws. Another attendee noted the potential for more sensitive issues in international trials.

For the CTIN, consideration of local context is rooted in the desire to operationalize collection of relevant materials. Local context is generally limited to site-specific participant payment, locally required language, or HIPAA regulations.

Consent

One attendee noted that she is uncomfortable with the idea that informed consent language is subject to local context. Differences in consent documents can be confusing, especially given that patients often communicate with one another online. While there is a general sense among attendees that excessive local demands (e.g., header and font requirements) will fall away over time with sIRB review, one attendee noted that when she served on a sIRB, the IRB refused to modify any consent language without a compelling reason and that sites did not push back to the point of leaving the study. In one instance, the consent language was changed to accommodate a population with low literacy.

Ancillary Reviews

Attendees noted that institutions are struggling with how to separate ancillary reviews from IRB approval. Use of a sIRB is only one part of moving things forward, and there are additional opportunities for increasing efficiency. For example, aligning slightly different hospital policies (e.g., pediatric guidelines on blood-draw volumes) would not only improve trial efficiency but is in the interest of patients.

SMART IRB Resources

Participants discussed the difference between SMART IRB exchange and SMART IRB. SMART IRB is a platform in which investigators can request a sIRB while SMART IRB exchange documents the process of sIRB selection, enrollment of reliant sites, and modifications to flexible parts of the reliance agreement; provides a central location for approval documents; and facilitates notification of approval. Currently, the exchange is unable to track progress for sites that have not signed the reliance agreement.

Accrual

Attendees discussed how a sIRB might monitor or decide to terminate a study based on low accrual. One attendee pointed out that a sIRB has the perspective to intervene and take corrective action prior to terminating a study. One important aspect of a sIRB is that sites can be more easily added. This is important, as there are families with rare-disease patients that must move to a different site for care.

Independent IRB Resources

An independent IRB stakeholder noted that independent IRBs have solved many issues facing academic institutions transitioning to a sIRB and suggested leveraging the experience of the private sector. Today’s meeting is part of that process and it is critically important to not only identify issues, but also for the parties who may already have solutions to share successful practices.
Session III: Breakout Sessions

Attendees were divided into two breakout groups: a regulatory group and operational group. Each group was provided with the following objectives:

► Discuss the remaining gaps in knowledge, guidance, and tools for implementing a sIRB review model.
► Propose solutions regarding implementation of a sIRB model for multicenter clinical trials whether federally funded (e.g., NIH-sponsored) or FDA-regulated drug and device studies.

Highlights from each group’s discussion were presented.

Regulatory Group Highlights

Challenges indicated by the regulatory group include managing sites resistant to using a sIRB, cost, and the ability of the sIRB to understand highly specialized protocols. IRB review may be also conflated with other local institutional reviews or the local IRBs gatekeeping function. There is also anxiety surrounding the level of trust required in the sIRB model—including relying solely on one IRB that has or could have violations or underperformance issues during the study—and the challenges related to synthesizing documents from individual institutions.

Suggestions for overcoming challenges include early engagement with the sIRB during trial planning and creating a culture of transparency from all parties. Industry sponsors generally choose independent IRBs that they are familiar with and will audit them. Allowing sponsor audits of other sIRBs may help maintain the overall quality of sIRBs.

Opportunities for facilitating use of a sIRB include harmonization of FDA guidelines with Common Rule changes, clear guidelines about the nature and extent of communication between local and sIRBs, FDA endorsement of an IRB reliance agreement template similar to SMART IRB reliance agreement, and clarification of when a sIRB is not appropriate for a particular context.

Suggested exceptions from use of an sIRB included studies with only a few sites, studies of certain patient populations, or studies that required sites with unique assessment capabilities or equipment.

The regulatory group also suggested clarifying procedures for enforcement and conflict management and including evidence that the sIRB model works in “specialized” situations (e.g., rare disease, early phase, or pediatrics). Sponsors are concerned about losing key sites that are unwilling to use a sIRB.

Operational Group Highlights
Further training for both investigators and IRB members is needed. Training should include guidance for investigators on when they should meet with their institution’s Human Research Protection Program (HRPP) offices before submitting a grant or planning to use a sIRB for an industry study.

Guidance surrounding acceptable cost models and examples of operating models from NIH, industry, or institutions are needed. Guidance should include strategies for managing or avoiding additional administrative burden, adapting electronic systems and document management, and identifying a central contact. An institution serving as a sIRB may also require additional insurance to mitigate risk in case of errors.

The elements of quality review should be identified and incorporated into a guidance document.

---

**Session IV: Summary of Challenges, Discuss the Path Forward**

In the final meeting session, attendees discussed the following:

► What can FDA, OHRP, NIH, and/or CTTI do to help transition to mandatory sIRB review for multisite research?
► Discuss next steps

Attendees provided the following suggestions:

► **CTTI.**
  ► Provide examples of separating institutional and IRB responsibilities, (i.e., case examples of applying Considerations Document)
  ► Promote SMART IRB’s resources and recommendations for harmonization
  ► Provide stakeholder-specific resources for implementation of sIRB

► **NIH.** Cost models and a statement of best practices or examples of acceptable practices

► **OHRP.** Standardization surrounding what documentation should be included in local context review.

► **SMART IRB.** Consent form templates, cost models, local context, and communication and reporting requirements are projects in development by the SMART IRB harmonization committee.

► **Industry.** Attendees asked if industry sponsors will require a sIRB for all multicenter clinical trials.

**Other Suggestions:**

► **FDA.** Guidance on how Part 11 rules will be applied or enforced
► **OHRP.** Guidance on where and how to post consent forms (Common Rule requires that the grantee institution post a version of the consent
approved consent, but does not provide a timeline for posting revisions or specify how to handle site-specific variation in consent documents).

- Variability between posted consent documents and those presented to patients may damage trust.

---

**RECAP OF CLOSING**

Attendees were thanked for their time and CTTI emphasized that today’s sIRB meeting is a starting point for new projects and/or smaller committees to develop additional supportive tools and strategies. Attendees were invited to submit any ideas and/or indicate interest in participating in future efforts in the post-meeting survey or via email to sara.calvert@duke.edu.

---

**FUNDING STATEMENT**

Funding for this project was made possible, in part, by the Food and Drug Administration through grant 5R18FD005292. Views expressed in written materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government.

---

**ABOUT CTTI**

The Clinical Trials Transformation Initiative (CTTI)—co-founded by Duke University and the U.S. Food and Drug Administration—is a public-private partnership whose mission is to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. The CTTI vision is a high-quality clinical trial system that is patient-centered and efficient, enabling reliable and timely access to evidence-based therapeutic prevention and treatment options. More information about CTTI and its projects is available at http://www.ctti-clinicaltrials.org/.

---

*For more information, contact the IRB Project Manager Sara Calvert at sara.calvert@duke.edu or visit [http://www.ctti-clinicaltrials.org](http://www.ctti-clinicaltrials.org).*
# Appendix A. Meeting Agenda

**TUESDAY, NOV. 14, 2017**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:00 a.m.</td>
<td><strong>Welcoming Remarks</strong></td>
</tr>
</tbody>
</table>
| 9:00 a.m.| Introduction to the Clinical Trials Transformation Initiative and Central IRB Projects  
*Sara Calvert, Clinical Trials Transformation Initiative (CTTI)* |
| 9:15 a.m.| **Session I: Review Single IRB Policies, Rules, and Guidance**  
*Session I Facilitator: Bridget Foltz, Food and Drug Administration, OCP*  
*Session I Objective:*  
► Review upcoming NIH policy and Common Rule changes regarding single IRB review as well as existing FDA Guidance on Centralized IRB Review Process in Multicenter Clinical Trials. |
| 9:15 a.m.| NIH Single IRB Policy  
*Petrice Brown-Longenecker, National Institutes of Health* |
| 9:30 a.m.| Review of Changes to the Common Rule Regarding Use of Single IRB  
*Yvonne Lau, OHRP* |
| 9:45 a.m.| Review of FDA Guidance on Centralized IRB Review Process in Multicenter Clinical Trials  
*Bridget Foltz, FDA* |
| 10:00 a.m.| Questions and Group Discussion |
| 10:30 a.m.| **Session II: Discuss Available Resources for Implementation of Single IRB for Multicenter Clinical Trials**  
*Session II Facilitator: Cynthia Hahn, Integrated Research Strategy*  
*Session II Objectives:*  
► Review available resources for implementation of single IRB model for multicenter clinical trials.  
► Discuss successful practices for implementation of a single IRB model. |
| 10:30 a.m.| Review of Resources from CTTI Central IRB Projects  
*Cynthia Hahn, Integrated Research Strategy* |
| 10:45 a.m.| SMART IRB Platform Overview  
*Petra Kaufmann, National Center for Advancing Translational Sciences, NIH* |
| 10:55 a.m.| SMART IRB Exchange and the NIH Trial Innovation Network  
*Emily Serdoz, Vanderbilt University Medical Center* |
| 11:10 a.m.| Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) Proposed Single IRB Review Standard  
*Robert Hood, AAHRPP* |
| 11:25 a.m.| Group Discussion of Successful Practices |
12:45 p.m.  Session III: Breakout Sessions

12:45 p.m.  *Breakout Session Instructions: Sara Calvert, CTTI*

*Session III Objectives:*

► Discuss the remaining gaps in knowledge, guidance and tools for implementing a single IRB review model.
► Propose solutions regarding implementation of single IRB model for multicenter clinical trials whether federally funded (e.g., NIH-sponsored) or FDA-regulated drug and device studies.

Regulatory Breakout Group
*Facilitator: Amy Corneli, CTTI*

Operational Breakout Group
*Facilitator: Brian Perry, CTTI*

2:45 p.m.  Session IV: Summary of Challenges, Discuss the Path Forward

2:45 p.m.  *Session IV Facilitator: Amy Corneli*

*Session IV Objectives:*

► Share highlights from breakout groups.
► What can FDA, OHRP, NIH, and/or CTTI do to help transition to mandatory single IRB review for multisite research?
► Discuss next steps.

3:30 p.m.  Adjourn and Departures
Appendix B. Meeting Participants

Our meeting participants include representatives from a broad cross-section of the clinical trial enterprise including regulators, government sponsors of clinical research, academia, industry, patient advocates, clinical investigators, and other interested parties. Participants are actively engaged in dialogue both days.

STAKEHOLDERS REPRESENTED

MEETING/WORKSHOP ATTENDEES

<table>
<thead>
<tr>
<th>Attendee</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tianna Aronson</td>
<td>Medtronic, Inc</td>
</tr>
<tr>
<td>Caryn Barnett</td>
<td>Eli Lilly and Company</td>
</tr>
<tr>
<td>Debbie Basset</td>
<td>Abbott</td>
</tr>
<tr>
<td>David Borasky</td>
<td>WIRB-Copernicus Group</td>
</tr>
<tr>
<td>Helen Bristow</td>
<td>Duke Clinical Research Institute, Duke University</td>
</tr>
<tr>
<td>Chris Browe</td>
<td>Boehringer Ingelheim</td>
</tr>
<tr>
<td>Morgan Brown</td>
<td>Texas Medical Center</td>
</tr>
<tr>
<td>Petrice Brown-Longenecker</td>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>Karim Calis</td>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>Doreen Chaitt</td>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>Lauren Cohen</td>
<td>Duke Clinical Research Institute/PCORnet</td>
</tr>
<tr>
<td>Dan Delaney</td>
<td>CR Bard</td>
</tr>
<tr>
<td>Janet Donnelly</td>
<td>Food and Drug Administration, OGCP</td>
</tr>
<tr>
<td>Fanny Ennever</td>
<td>Boston University</td>
</tr>
<tr>
<td>Don Ertl</td>
<td>Medtronic, Inc</td>
</tr>
<tr>
<td>Tara Federici</td>
<td>AdvaMed</td>
</tr>
<tr>
<td>Attendee</td>
<td>Organization</td>
</tr>
<tr>
<td>--------------------</td>
<td>-------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Emily Flag</td>
<td>University of Rochester</td>
</tr>
<tr>
<td>Molly Flannery</td>
<td>Food and Drug Administration, CDER</td>
</tr>
<tr>
<td>Bridget Foltz</td>
<td>Food and Drug Administration, OGCP</td>
</tr>
<tr>
<td>Kaitlin Gillette</td>
<td>INC Research/inVentiv Health</td>
</tr>
<tr>
<td>Cynthia Hahn</td>
<td>Integrated Research Strategy, LLC</td>
</tr>
<tr>
<td>Robert Hood</td>
<td>AAHRP</td>
</tr>
<tr>
<td>Stuart Horowitz</td>
<td>WIRB-Copernicus Group</td>
</tr>
<tr>
<td>Minerva Hughes</td>
<td>Food and Drug Administration, CDRH</td>
</tr>
<tr>
<td>Hallie Kassan</td>
<td>Feinstein Institute for Medical Research, Northwell Health</td>
</tr>
<tr>
<td>Petra Kaufmann</td>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>Yvonne Lau</td>
<td>OHRP, OS</td>
</tr>
<tr>
<td>Joanne Less</td>
<td>Food and Drug Administration, OGCP</td>
</tr>
<tr>
<td>Barbara LeStage</td>
<td>Individual Patient/Caregiver</td>
</tr>
<tr>
<td>Diane Maloney</td>
<td>Food and Drug Administration, CBER</td>
</tr>
<tr>
<td>Korin Martin</td>
<td>Merck and Company, Inc</td>
</tr>
<tr>
<td>Tara McDonough</td>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>Sherry Mills</td>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>Mary Ellen Monahan</td>
<td>Merck &amp; Company, Inc</td>
</tr>
<tr>
<td>Janet Norden</td>
<td>Food and Drug Administration, OGCP</td>
</tr>
<tr>
<td>Jane Perlmutter</td>
<td>Individual Patient/Caregiver</td>
</tr>
<tr>
<td>Jody Power</td>
<td>Duke University</td>
</tr>
<tr>
<td>Maria Rape</td>
<td>University of North Carolina, CTSA</td>
</tr>
<tr>
<td>James Riddle</td>
<td>Qorum Review IRB, Kinetiq</td>
</tr>
<tr>
<td>John Roberts</td>
<td>University of North Carolina, NCTracs</td>
</tr>
<tr>
<td>Jorge Rodriguez-Larrain</td>
<td>Alexion Pharmaceuticals, Inc</td>
</tr>
<tr>
<td>Shirley Rojas</td>
<td>National Institutes of Health, Intramural Program</td>
</tr>
<tr>
<td>Michele Russell-Einhorn</td>
<td>Schulman IRB</td>
</tr>
<tr>
<td>Seth Schulman</td>
<td>Pfizer, Inc</td>
</tr>
<tr>
<td>Emily Serdoz</td>
<td>Vanderbilt University</td>
</tr>
<tr>
<td>Brandy Stoffel</td>
<td>University of Wisconsin</td>
</tr>
<tr>
<td>Erika Vento-Gaudens</td>
<td>Amgen, Inc</td>
</tr>
</tbody>
</table>