



Advancing the Use of Central IRBs for Multicenter Clinical Trials in the United States

Executive Summary of the Expert Meeting held June 12-13, 2014

Hilton Washington DC/Rockville Hotel & Executive Meeting Center, Rockville, MD

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

Meeting materials, including agenda, participant list and presentations, are available on the Clinical Trials Transformation Initiative website at: <https://ctti-clinicaltrials.org/advancing-the-use-of-central-irbs-for-multi-center-clinical-trials-in-the-united-states/>

Publication Date: January, 2017

MEETING OBJECTIVES

(1) Discuss practices, implementation strategies, and solicit additional suggestions for increasing the use of central IRBs for multicenter clinical trials, (2) present findings from the Central IRB Advancement project's collection of IRB authorization agreements (IAAs) and SOPs, and (3) obtain additional feedback to refine the proposed IAA template and tools.

MEETING EXECUTIVE SUMMARY

On June 12-13, 2014, the Central IRB Advancement project team convened an expert meeting involving stakeholders with expertise in this topic. This project was a follow-on to an earlier CTTI project (2011-2013) that addressed barriers to the use of a central IRB (CIRB) for multicenter clinical trials and issued recommendations and a “Considerations” document. Taking further steps to address remaining barriers and encourage implementation of the recommendations was the goal of this current expert meeting. Participants included representatives from academic institutions, institutional review boards, industry, contract research organizations, government agencies, health systems, and the patient advocacy community.

Session topics were designed to elicit stakeholder discussion, beginning with an overview of the current landscape of CIRB use.

In **Session 1**, speakers and participants discussed outcomes from recent examples of implementing a CIRB model at academic, federal, and industry entities. Presenters covered challenges, efficiencies gained, and acceptance by research and IRB staff. Initial discussion identified the need to continue to clarify the definition of a CIRB—that is, *a single IRB of record for all sites participating in a protocol for a multicenter clinical trial*. A range of entities may serve as a central IRB. Key points included:

- Relying on a CIRB for ethical and scientific review takes effort and resources at the institution, so institutions should plan for transition and evaluate resources, policies, and procedures. It is beneficial to identify a CIRB expert/contact(s) at the institution to serve as liaison with the CIRB—noting a single person may be insufficient.
- Guidance is needed for criteria to evaluate the quality of a CIRB during the selection process.
- It is important to specifically delineate the roles and responsibilities regarding the identification and management of financial Conflict of Interest (COI).
- It is useful for the institution to differentiate between “required” (e.g. regulatory requirements) and “suggested” policies or best practices during CIRB review.
- Include international sites in future work since the CIRB model is expanding outside of the United States. In the US, “central” is often assumed to be commercial/independent. Outside the US, a “central IRB” is typically a government board.
- It is crucial to keep communication open among all stakeholders and to prioritize education and collaboration. It is also important to keep the CIRB proceedings transparent to encourage a quality review.

In **Session 2**, panelists discussed aspects of local context that remain problematic to widespread adoption of CIRBs. Perceived barriers include issues around informed consent language, the required signatories, whether the site is appropriate for the study, how differences

in participant populations may be important, and which entity has responsibility for any failures in study conduct. Key points included:

- Good communication plans and repeated experience with CIRBs builds trust and can help increase acceptance at institutions.
- A CIRB will need to rely on sites for knowledge of applicable state laws, policies, or requirements.
- A CIRB’s review decisions affect the entire multicenter study—not just one site.
- In multicenter studies, sites have more commonalities than differences; local exceptions should be minimized. Most informed consent language should be centralized across the entire study in order to ensure all subjects receive the same information.
- Nonacademic sites often do not have a conflict of interest (COI) infrastructure. COI review is required, and has often been handled within IRB offices, but it is not a required function of the IRB. COI is often and can be conducted outside of the local IRB. Establishing who will conduct COI review is necessary.
- A CIRB has the potential to be more objective than a site when reviewing COI or handling cultural sensitivity, as the CIRB may have the ability to serve as a more specialized review board (i.e. a cancer focused CIRB for cancer trials).
- It would be beneficial to have patient advocates with experience in the area of study to serve on the CIRB. Community representatives are already required as part of the IRB roster. However, consideration should be given to additional inclusion of patients or patient advocates in the IRB process.
- If one goal is to accelerate the entire clinical trial process, then more than just ethical review could be centralized.

Session 3 was a breakout of 4 workgroups to identify the top barriers and potential solutions for transitioning to the CIRB model, including suggestions for who can make the changes happen and what information they need. This was followed by a slide presentation by each group to the followed by full group discussion. Highlights from each workgroup are shown in the following table:

Barrier	Solution
Requiring CIRB could create increased competition for sites and expertise and access to patients. For example, if a site requires local IRB the study could lose access to that site.	<ul style="list-style-type: none"> • Let sites know they may be losing out on exciting research opportunities by not using a CIRB. • All stakeholders can help to make the change by being ambassadors of CIRBs; sponsors can be consistent in their message about supporting CIRBs. • Site performance metrics are needed to show that CIRBs can be efficient. • Sponsors or agencies can mandate or offer financial incentives to institutions to rely on a CIRB.

Barrier	Solution
<p>Perception of quality issues in CIRB review</p> <ul style="list-style-type: none"> • Lack of trust in outside IRB • Lack of quality and operational standards across IRBs, institutions, and provider/clinical sites • Misperceptions about barriers and challenges related to legal liability and regulatory 	<ul style="list-style-type: none"> • Identifying quality standards for CIRBs that are consistent across policies, Guidance, accreditation. • Implement mechanisms for assuring CIRB review quality and transparency; e.g., disclosure of previous findings on a centralized public website. • Institutional officials who oversee the HRPPs need information on success stories from institutions that have used a CIRB; quality metrics and evidence-based research on the CIRB model; and guidance, instruction, and education so that institutions can embrace CIRBs. • Develop SOPs and templates to help institutions get started. • Establish definitions such as how a site is defined and who is engaged in research. • AAHRP and accrediting bodies, regulators, sponsors, consortiums, and multi-stakeholder groups like CTTI can help to produce best practices. • Common definitions are needed. Establish what is common to activities/processes/deliverables/best practices as a baseline. • Disseminate research on existing CIRB use.
<p>How to implement CIRB process within existing HRPP.</p> <ul style="list-style-type: none"> • How to maintain institutional oversight and knowledge of research occurring within institution. • How to manage complexity and challenges of working with multiple external IRBs • Difficulty in detangling processes (both administrative and electronic) currently managed by the local IRB into a well-articulated process for outsourcing to a CIRB 	<ul style="list-style-type: none"> • Provide guidance for establishing relationships between institutions and CIRBs. • Institutional clinical research professionals/Clinical Trial Offices/Human Research Protection Program (HRPP) heads can help with guidance on roles, responsibilities, process, and structure/alignment. • Develop HRPP policies for investigator oversight and training outside of individual protocols • Designate central IRB contact within HRPP for investigators to contact with questions • Institutions should share best practices. • Tools, templates, and SOPs are needed. • Use CTTI Developed Considerations Document
<p>Lack of data standards and regulatory/ethical nomenclature for information technology systems</p>	<ul style="list-style-type: none"> • Data standards for IT systems (such as with CDISC) are needed when transitioning to a CIRB model. • Standard terms and common data elements should be developed with the input of all stakeholders, such as funders (both federal and industry), institutions, or data coordinating centers. Regulators could be advisors. • Start with a manageable group, then roll out to larger group, develop the business case, and have transparent and accessible data. • Develop and use an electronic document submission and a common/standard application system. • System vendors need agreed-upon standards.

Session 4 was a panel and group discussion of the CIRB operations model. Part 1 asked: What operational changes do institutions have to implement, including both start-up and ongoing issues, when relying on a CIRB? Key points included:

- There can be a lack of attention at sites when transitioning to a centralized IRB process. Sites need to remember they are not outsourcing their human research protection program or site management responsibilities, just the IRB review.
- A large metropolitan health system that has both served as a CIRB and relied on a CIRB found it crucial to delineate the responsibilities between the institution and the CIRB. This system has its own HRPP organization and has established system-wide policies independent of the CIRB chosen. Before research begins, both CIRB and institutional approval are required.
- Independent/external CIRBs will need to make a good impression at the institution—collaboration and flexibility are important.
- There needs to be a full-time liaison between the CIRB and institution/sites. It is not “business as usual” when it comes to contracts and invoicing.
- An advantage of using a CIRB is that institutions with HRPP programs can focus their resources/staff on other activities (for example quality assurance) instead of redundant IRB review. You can change the activities of an employee without eliminating the position.
- Questions remain for some institutions about whether there is sufficient expertise at an independent/commercial CIRB to evaluate, for example, early-phase studies. There is a perception that many CIRBs lack clinical researchers or practicing physicians. It is less of concern for phase 3-4 studies. However, others at the meeting noted the opposite experience working with CIRBs with extensive early phase experience. Also noted that many clinical researchers and practicing physicians serve on independent/commercial IRBs.
- Potentially, a CIRB could convene a *stronger* panel of experts than an individual institution could (e.g. boards specializing in a specific type of research like early phase or specific disease state). This characteristic could become the standard for using CIRBs going forward—that is, making the CIRB business model more about improved human subject protection than improved efficiency.
- Who is responsible for handling/monitoring the conduct of the research if the CIRB is handling the protocol? Oversight monitoring can still be done by the CIRB, but an institution does not cede responsibility to the CIRB for routine auditing, patient safety, research compliance, or unanticipated problems at a site. Good quality controls need to be in place “on the ground.”

Part 2 asked: If your institution wants to serve as a CIRB, what needs to be planned for? Key points included:

- It’s important to have a dialog between legal counsel and the institution to ensure full support for becoming a CIRB. Next, consider the resources needed, which will depend on the number of sites involved as well as the complexity of the studies. Often resources and staffing are underestimated.
- The start-up phase includes execution of an IRB reliance agreement, a definition of who is a site (common for one health system to have multiple sites), and SOPs drafted. In the

maintenance phase, site-specific differences will need to be managed. Also consider what IT system is in place to handle the exchange/depositing of documentation.

- Consider where the principal investigators are coming from—a research institution, community health center, etc. Knowing how much experience a site has in doing research will affect the amount of time devoted to start-up.
- Who at the CIRB will collect the local context information (laws, policies, etc.) and who does the information go to? Establish a coordinating mechanism such as a dedicated team that handles submissions from multiple sites. This team could be a separate, collaborating group outside of the CIRB (e.g. the clinical operations staff of a coordinating center where the institutional IRB is also serving as the single IRB of record).
- Institutions should talk to people who have been successful; talk to coordinating centers, who have the most experience in data collection for large research enterprises.

Session 5 was a presentation and group discussion about the rationale for creating a CTTI IRB Authorization Agreement template as a “best practice” foundation for sites and IRBs to build on. The presenter reviewed findings from the team’s data collection and synthesis of IAA elements and SOPs. Key points included:

- Guidance was sought from institutional HRPP/IRB organizations who currently allow reliance on a CIRB or who serve as a CIRB, asking them to share their template/waiver agreements with the study team to determine the kinds of clauses included and the frequency with which those clauses appeared.
- 16 institutions and organizations agreed to be part of the data collection process, 4 did not have template agreements, and 3 had more than 1 kind of agreement. Of the 16 IRB agreements reviewed, 56% were from institutional IRBs, 31% were from independent IRBs, 30% were from federal sponsors, and 30% were from clinical trials networks, with some organizations serving in more than one role.
- The largest proportion (69%) called their agreement an IRB Authorization Agreement (IAA). There was discussion about differences between an IAA and a master services agreement (MSA), the granularity of each, and whether the emphasis is regulatory or legal. It was noted that an MSA and IAA are not equivalent agreements and that some entities have both types.
- Common to all templates evaluated were administrative information, a body, and signatures. Wording varied widely across 72 different clauses, but the following elements were included in all: the name of the reviewing IRB and institution, a general statement of reliance, scope, and signatures for representatives of the reviewing IRB and institution.
- There was consensus that the CTTI template will be called an IAA. To be defined in Day 2 of the meeting will be whether there should be more than 1 template agreement, and if so, how to evaluate appropriateness of use; what clauses the template should contain to represent the best practices; and the suggested/recommended language.
- The resulting template is intended to be a baseline on which to build; the study team wanted to keep it as simple as possible, avoiding overly legal language, to make it easier to adopt at centers and sites that do not have large legal affairs offices.

The CTTI IAA template is not meant to serve as an MSA. There was a concern expressed that the IAA is the lowest level of relationship between a site and a CIRB, whereas MSAs relate to services that address some of the barriers already discussed.

Session 6 (Day 2) was a group discussion of criteria used to determine the type of reliance agreement needed and a refinement of the elements of the IAA template to serve as a baseline document. This session comprised discussions of several topics, described below with key points.

1. In general, what are the considerations for institutions deciding whether to adopt the CIRB model (but not a specific CIRB)?
 - Key considerations included research design, level of risk, funding environment, reputation of the CIRB, number of sites involved, clinical research strategy, risk tolerance, financial analysis, organizational culture and potential loss of control by outsourcing, level of investigator and institutional buy-in, scalability of the CIRB model, information from other entities that have used a CIRB, impact on electronic systems used in data collection, and how to train staff.
2. After deciding to adopt the CIRB model, what do institutions and sponsors want and need to know when selecting a *particular* CIRB?
 - Key considerations included certifications and accreditation, technology, regulatory history, therapeutic expertise, client list, turnaround time, qualifications of board members, quality assurance processes (both internal and external), organization history of working with institutions, ability to step seamlessly into the process (including state laws and local context), cost, vendor analysis, how the CIRB helps the institution manage change, protocol details, and the communication process.
3. What should a CIRB know about the institution before deciding whether to enter into that relationship?
 - Key considerations included compliance history of the institution; goals and drivers of the institution; relevant laws, local regulations, institutional norms and values, requirements; point of contact; level of involvement in unanticipated problems and other problems; lines of communication; the institution's experience working with outside IRBs; the institution's expectations regarding performance and metrics; scope of agreement and specific studies (e.g., one study, all studies, certain subset of studies); and negotiation of protocol/consent disagreements.

Other discussion points included:

- Regarding local context, meeting attendees concurred that this issue has been widely debated by other groups and agreed that Secretary's Advisory Committee on Human Research Protections (SACHRP) Recommendations on Consideration of Local Context with Respect to Increasing Use of Single IRB Review from January 2013 should be followed and endorsed by CTTI rather than have another group make specific recommendations. SACHRP recommends that the reviewing IRB should have access to and consider institutional capacity, commitments and policies. SACHRP also recommends that when an IRB is reviewing research to be conducted at an external site, the IRB should establish mechanisms (e.g., relying on institutional processes) to assess the experience and qualifications of investigator and study staff. The IRB should also

assess relevant information about prior research noncompliance, criminal activities, state board issues, etc.

- There were different views expressed about whether institutions should consider the accreditation status of a CIRB: (1) Accreditation serves a purpose, but a lack of accreditation does not mean the CIRB's program is bad or cannot be relied on to do a good review. (2) Yet accreditation is the only proxy for quality that we have. Even reputable institutions with an FWA that have the best intentions sometimes fail to follow the regulations. The group agreed that institutions may consider CIRB accreditation but that it should not be a requirement for choosing a CIRB.

4. There was discussion about the rationale for MSAs and IAAs and the relationships these agreements enable—recognizing that there is a range from simple to complex. How should we define these agreements, and in what situations are they applicable?

Key points included that the difference between an MSA and an IAA is level of risk and volume of relationship – does the relationship involve minimal risk studies or greater than minimal risk studies, multiple study review or a single study relationship.

An MSA is typically a *general* agreement, not study specific, that outlines the service-level agreements and offerings, and terms and conditions of the relationship between the institution and the CIRB and which involves greater than minimal risk studies or some combination of risk. A MSA often contains items not typically covered in an IAA such as the terms and conditions of payment, limits of liability, and insurance requirements. A MSA typically governs a deeper relationship between a CIRB and institution and often covers multiple studies or relationships. An important point was noted that a MSA should be kept separate, and is for a different purpose, than the Clinical Trials Agreement or Master Trials Agreement between a sponsor and an institution.

An IAA is typically study-specific or governs a specific group or risk level of studies, although it may apply more broadly.

5. The last part of this session was a clause by clause refinement of the proposed IAA template. Meeting attendees evaluated whether a clause was required or optional as well as commenting on specific language of the template agreement.

Conclusion and Next Steps

The meeting was closed by thanking the experts for their thoughts and ideas, which will be summarized and utilized to refine the IAA template. The template and meeting proceedings will be made publicly available on the CTTI website to facilitate further advancement of the use of central IRBs for multicenter clinical trials.

FUNDING STATEMENT

Financial support for this project is provided by grant #U19 FD003800 from the U.S. Food and Drug Administration (FDA) and CTTI membership fees.

ABOUT CTTI

The Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the U.S. Food and Drug Administration, seeks to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. Comprised of more than 80 member organizations, CTTI is transforming the clinical trials landscape by developing evidence-based solutions to clinical research challenges. Learn more about CTTI at www.ctti-clinicaltrials.org

Advancing the Use of Central IRBs for Multicenter Clinical Trials in the United States

Expert Meeting Agenda · June 12-13, 2014

Hilton Washington DC/Rockville Hotel & Executive Meeting Center
1750 Rockville Pike
Rockville, MD 20852

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

CTTI Definition of Central IRB: A single IRB of record for all sites participating in a multicenter clinical trial. A range of entities may serve as a central IRB (e.g. another institution's IRB, a federal IRB, or an independent IRB).

Meeting Objectives:

- ▶ Discuss practices, implementation strategies, and solicit additional suggestions for increasing the use of central IRBs for multicenter clinical trials
- ▶ Present findings from the CTTI Central IRB Advancement project's collection of IRB authorization agreements and standard operating procedures
- ▶ Obtain additional feedback to refine proposed IAA template and tools

DAY 1 – JUNE 12, 2014

- 8:45 AM Welcoming Remarks**
Introduction to the Clinical Trials Transformation Initiative
Bray Patrick-Lake (CTTI)
- 8:55-10:30 Session I**
Landscape of the Use of Central IRBs for Multicenter Clinical Trials
Session Facilitator: Soo Bang (Celgene Corporation)
Session Objectives:
- Discuss past, present, and future of the use of central IRBs for multicenter clinical trials (including the outcomes of previous CTTI activities)
 - Review industry, federal, and academic examples of changing to centralized IRB review model
- 8:55 AM History of the Use of Central IRBs for Multicenter Clinical Trials
Soo Bang
- 9:10 AM Academic Institution Example
David Borasky (University of North Carolina – Chapel Hill)
- 9:30 AM Federal Central IRB Example
Jacquelyn Goldberg (National Cancer Institute – Central IRB)
- 9:50 AM Industry Sponsor Example
Soo Bang
- 10:10 AM Q&A and Discussion
- 10:45-11:45 Session II**
Why Are We Still Talking About Local Context as a Barrier?
Session Facilitator: Cynthia Hahn (North Shore-LIJ Health System)
Session Objectives:
- Identify and discuss the aspects of local context that remain problematic for central IRBs
 - Discuss how local context is handled by all parties when a central IRB is used for a multicenter clinical trial
- 10:45 AM Panel:
- Patrick McNeilly (FDA)
 - Kerrie Flynn (Neurological Clinical Research Institute)
 - Jane Perlmutter (Patient Representative)
 - David Forster (WIRB-Copernicus Group)
- 11:15 AM Q&A and Discussion (All Meeting Attendees)

- 11:45-Noon** **Session III**
Challenges and Solutions for Implementing Use of a Central IRB for Multicenter Clinical Trials: Breakout Sessions
- 11:45 Introduction to post lunch breakout group activities
Sara Calvert (CTTI)
- 1:00 PM Workgroup Activity: Discuss biggest challenges to using centralized review and propose solutions to those challenges. Who are the people who are in a position to make changes? What information do they need? How do we get the required information to those who can make changes?
- 2:00 -3:00** **Session IV**
Challenges and Solutions: Feedback
Session Objective: Presentation and discussion of the challenges and solutions from each working group
- 2:00 PM Report out by breakout groups (10 minutes each group)
- What were the top 3 challenges discussed by your group?
 - What are the proposed solutions to these challenges?
- 2:30 PM Full group discussion
- 3:15- 4:15** **Session V**
Process of Implementing Central IRB: Operations Model
Session Facilitator: Petra Kaufmann
Session Objectives:
- Discuss changes in institutional business model when transitioning from using in-house institutional IRB only to outside central IRB(s) for multicenter clinical trials
 - Consider strategies to overcome institutional challenges of accepting ethical review from multiple outside IRBs
- 3:15 PM Panel:
- Hallie Kassan (North Shore-LIJ Health System)
 - George Gasparis (Peer Consulting Group)
 - Carol Pech (University of Wisconsin-Madison)
 - Eric Mah (University of California, San Francisco)
- 3:45 PM Q&A and Discussion
- 4:15-5:00** **Session VI**
IRB Authorization Agreement Data Collection
Session Facilitator/Presenter: Cynthia Hahn (North Shore-LIJ Health System)
Session Objectives:
- Discuss rationale for IRB Authorization Agreement template creation
 - Review findings from data collection and synthesis of IAA agreements and standard operating procedures
- 5:00 PM** **Day 1 Wrap Up**

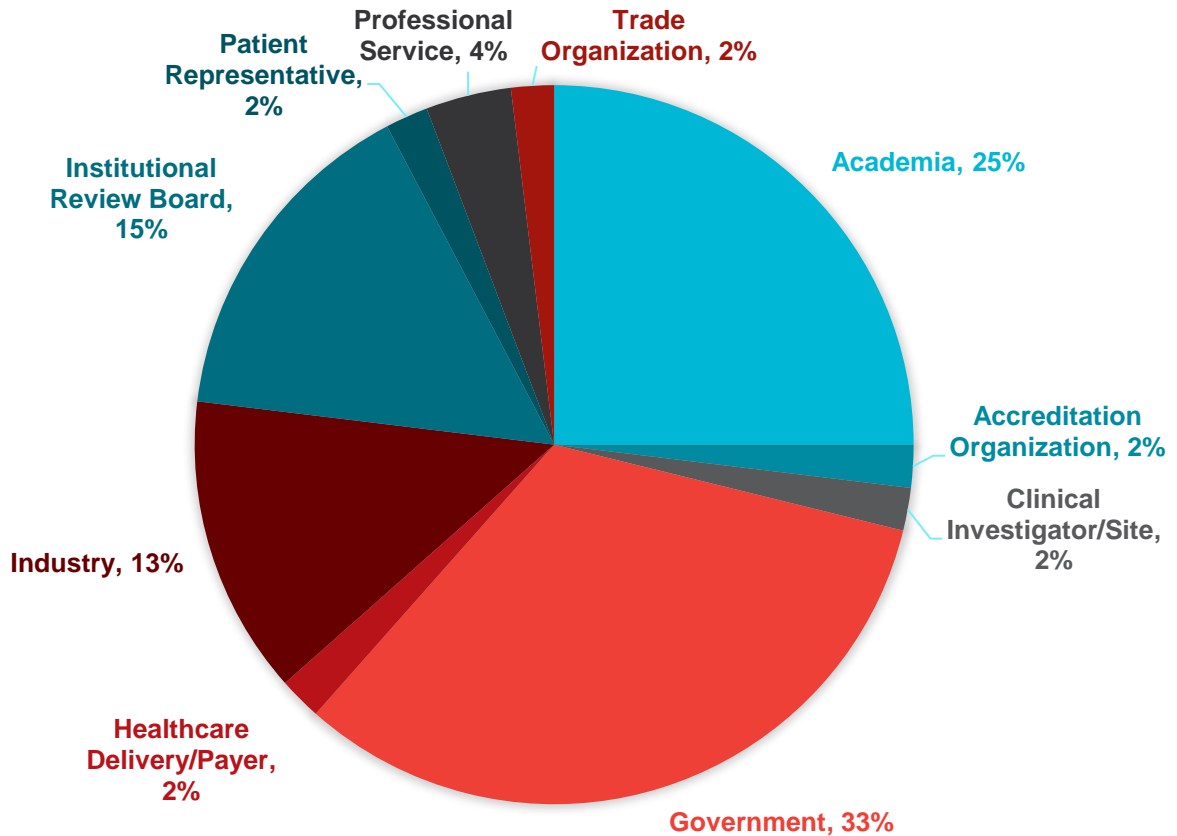
DAY 2 – JUNE 13, 2014

- 9:00-1:00** **Session VII**
Feedback and Refinement of IRB Authorization Agreement (IAA) Template
Session Facilitator: Cynthia Hahn (North Shore-LIJ Health System)
Session Objectives:
- Present and solicit feedback on proposed IAA Template
 - Discuss what criteria are used to determine the type of reliance agreement (i.e. simple vs. complex) is required in different situations
- 9:00 AM Presentation and feedback on IAA template and propose criteria for selecting reliance agreement type
- 10:00 AM Q&A and Discussion
- 10:45 AM Group discussion and decisions on IAA template and complexity criteria
- 12:00 PM** **Working Lunch**
Summarize decisions and next steps
- 1:00 PM** **Adjourn**

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 ATTENDEES

NAME	AFFILIATION
Priscilla Adler	MedStar Health Research Institute
Eli Alford	Schulman Associates IRB
Soo Bang	Celgene Corporation
Barbara Bierer	Brigham and Women's
Peter Blaisdell	Amgen
David Borasky (TC)	University of North Carolina
Karim Calis	Food and Drug Administration
John Clore	Virginia Commonwealth University
Elaine Collier	National Institutes of Health
Owen Faris	Food and Drug Administration
Michael Ferrell	PRA International
Kerrie Flynn	Massachusetts General Hospital
Emily Fogler	Partners Healthcare System
David Forster	WIRB-Copernicus Group
Maria Fotiu	PPD
George Gasparis	Peer Consulting Group
Cami Gearhart	Quorum IRB
Nitin Gogtay	National Institutes of Health
Jacquelyn Goldberg	National Institutes of Health
Felix Gyi	Chesapeake IRB
Cynthia Hahn	North Shore- LIJ Health System
Sharon Hamp	National Institutes of Health
Raffaella Hart	BRANY IRB
Stuart Horowitz	WIRB-Copernicus Group
John Isidor	Human Subject Protection Consulting
Karen Jeans	Department of Veterans Affairs
Julie Kaneshiro	Office for Human Research Protections
Hallie Kassan	North Shore- LIJ Health System
Petra Kaufmann	National Institutes of Health
Caitlin Koris	Food and Drug Administration
Joanne Less	Food and Drug Administration
Michael Linke	University of Cincinnati IRB
Eric Mah	University of California San Francisco

NAME	AFFILIATION
Jill McGuinn	AstraZeneca
Patrick McNeilly	Food and Drug Administration
Jerry Menikoff	Office for Human Research Protection
Tara Ollinger	Bristol-Myers Squibb
Pearl O'Rourke	Partners Healthcare
Bray Patrick-Lake	Clinical Trials Transformation Initiative
Carol Pech (TC)	University of Wisconsin
Jane Perlmutter	Gemini Group
Jennifer Peterson	INC Research
Ivor Pritchard	Office for Human Research Protection
Stephen Rosenfeld	Quorum IRB
Emily Sheffer	Vanderbilt University Medical School
Priscilla Short	Consortium of Independent Review Boards (CIRB)
Robert Silbergleit	University of Michigan Medical School
Doug Silverstein	Food and Drug Administration
Julia Slutsman	National Institutes of Health
Elyse Summers	AAHRPP
Rose Tiernan	Food and Drug Administration
Sabune Winkler (TC)	Harvard Catalyst
Andrew Womack	Biotechnology Industry Organization

For more information, contact the Single IRB Project Manager Sara Calvert at sara.calvert@duke.edu or visit <http://www.ctti-clinicaltrials.org>