

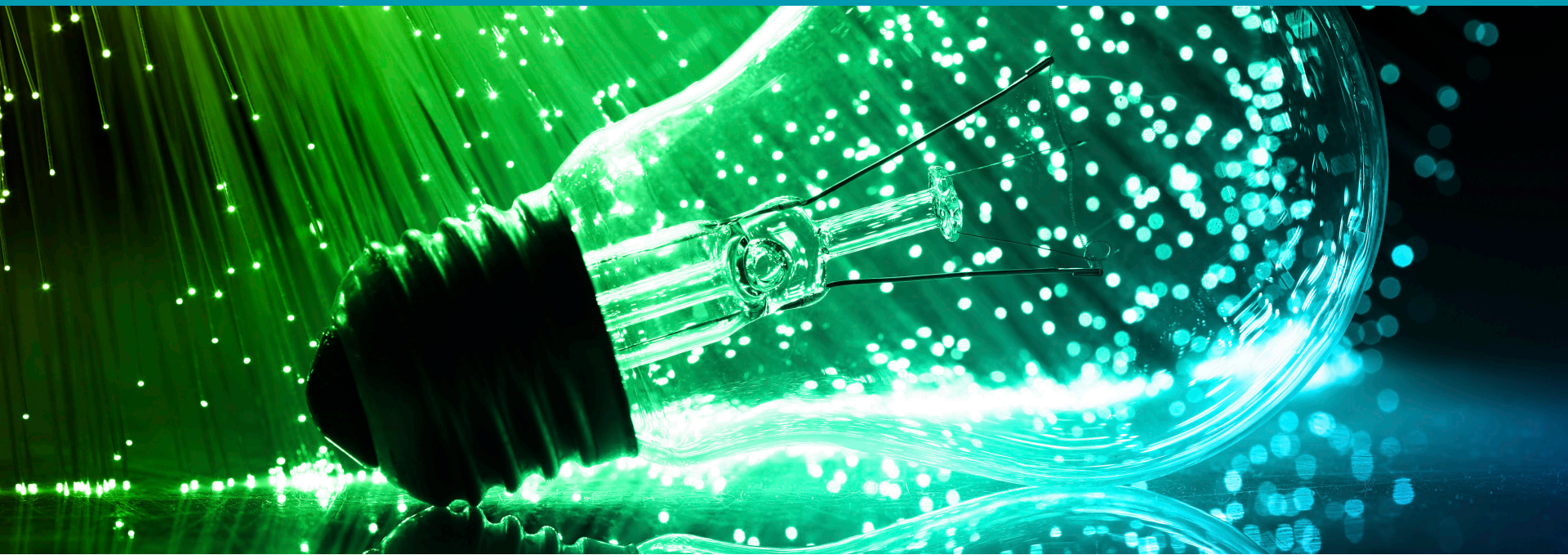
Advancing the Use of Central IRBs for Multicenter Clinical Trials in the United States: Expert Meeting: Day 1

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Disclaimer

The views and opinions expressed in this presentation are those of the individual presenter and do not necessarily reflect the views of the Clinical Trials Transformation Initiative or the North Shore-LIJ Health System.

Cynthia Hahn is an employee of North Shore-LIJ Health System and is a co-team lead on the CTTI Advancing Central IRB project. She has no conflicts to disclose.

How did we get here?



What do we need?



What have we done?

- ▶ We asked for help, we sought guidance from the community whose work and workload would be most affected by changes in the business model: Institutional Human Research Protection Programs and Central IRBs.



Survey/Call for Templates

➤ A request was made on the IRBforum List serve in July 2013 asking for members of the Institutional Review Board Community who allow reliance on or who serve as Central IRBs to share their template agreements with the study team.

- 16 institutions and organizations agreed to be part of the initial data collection process,
- 4 did not have template agreements, and 3 organizations had more than 1 kind of agreement.
- 16 template IRB agreements/waivers were reviewed to determine the kinds of clauses included and the frequency which those clauses appeared.

Summary of the Response

➤ What kinds of IRBs and HRPPs responded?

- Institutional IRBs: 56%
- Commercial/Independent IRBs: 31%
- IRBs associated with a federal sponsor: 30%
- IRBs associated with a Clinical Trial Network: 30%

➤ What did the IRB or HRPP call their agreement?

- Of those with template agreements, the most common were
 - Waiver: 13%
 - IRB Authorization Agreement: 69%
 - Services Agreement: 13%

Summary of the Response

- ▶ **Are there domains included in 100% of agreements?**
 - Yes, all agreements include Administrative Information, a Body of the Agreement, and Execution/Signatures.
 - However, there is wide variability in the clauses included within those domains.



Summary of the Response

➤ Are there any clauses included in 100% of agreements?

➤ Yes, all agreements include

- Name of the Reviewing IRB
- Name of the Institution
- General Statement of Reliance
- Scope of the Agreement
- Signature of an Institutional Representative
- Signature of an IRB Representative



➤ This is out of a possible 72 clauses.

Next Steps (aka Day 2)

- Consider whether there should be 1 or more template agreements, if more than one template agreement, should we develop criteria for evaluating appropriateness of use?
- Consider/Define/Recommend what our template agreement should be called.
- Review the domains and clauses to validate whether they should be considered for inclusion in our template agreement(s).
- Assess whether there are any potential clauses missing from the data collected
- Define suggested/recommended language to be included in the template IRB Authorization Agreement

What is our goal?



Thank you.



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