HOW TO CONDUCT AN IRB RELIANCE AGREEMENT

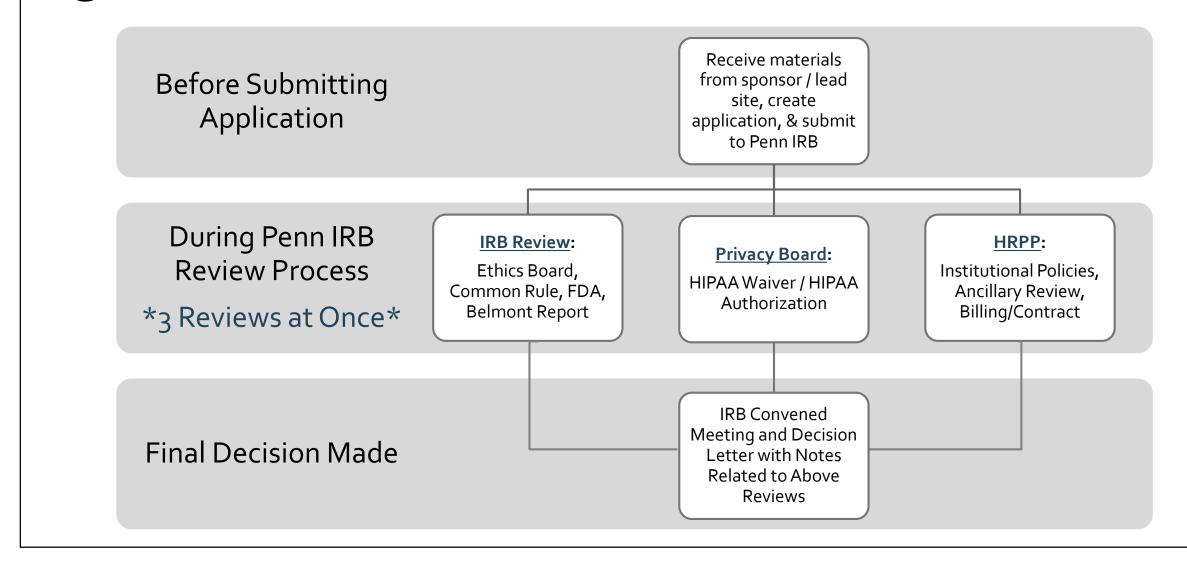
What Reliance Agreements Are, How They Are Reviewed, and What It Means for Submitting Research

Agenda for Course: Discuss what reliance agreements are and what it means for you

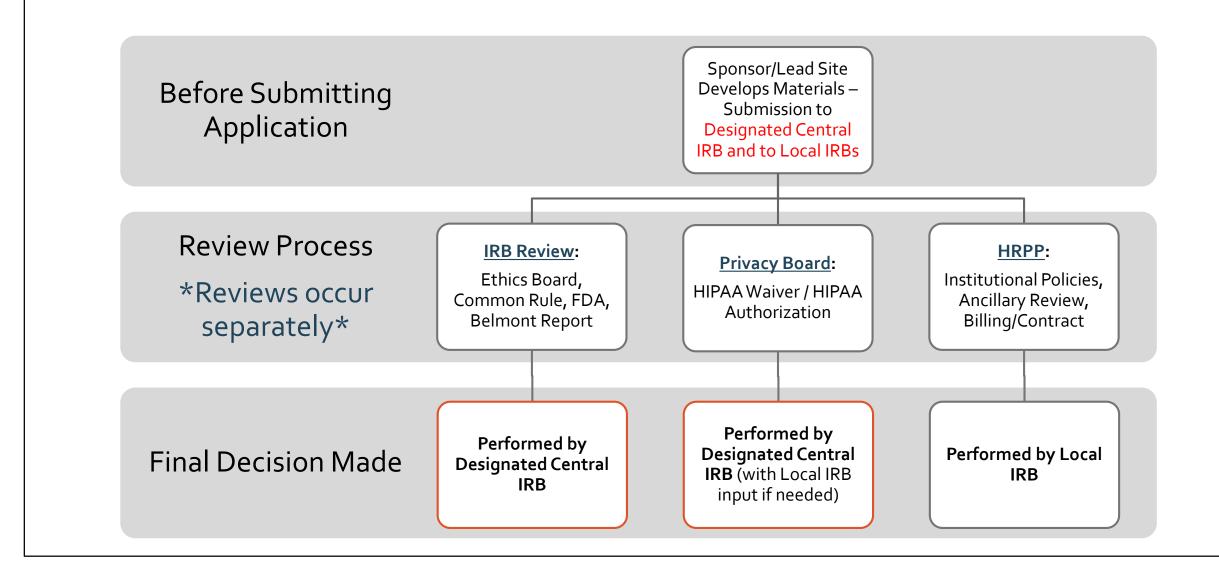
How Reliance Agreements Work in General: Local IRBs are still involved; Process looks very different from your normal experiences with the Penn IRB

- 2. What to Expect when Submitting: Submissions still involve HS-ERA; Instructions are available; Process takes some practice
- 3. What it means to have Penn be the Central IRB: Additional steps in the process and additional requirements for ongoing review

Penn IRB Review Process without a Reliance Agreement



IRB Review Process with a Reliance Agreement



This is Not a New Procedure.

Reliance agreements have been around since the Common Rule was put into effect.

Penn has already been actively piloting different reliance agreement processes since October 2015.

Here are the **key takeaways** for how it will affect the overall study and the submission process...

Effect on Overall Study: Minimizes the number of Convened IRB Reviews across sites

For Initials:

May not shorten time to site activation

For Continuing Reviews & Modifications:

Large impact on Ongoing Reviews

Effect on Submitters: Expect it to Require Practice

First Time Submitting can be Frustrating, but Easier as You Get Used to the Process

More Labor-Intensive for You when Penn IRB is the Designated Central IRB

This Isn't Required Right Now, but May Be Soon for Your Studies.

NIH Requirement:

September 2017

Common Rule/ FDA Requirement:

January 2020

Penn IRB has Extensive Guidance, Including:

Instructions: http://www.upenn.edu/IRB/2016-forms-revision-overview/reliance-agreements

- FAQs when conducting a reliance agreement
- Instructions on how to submit via HS-ERA
- Guides for Consent Forms & Templates

Feel Free to Ask Questions:

- Primary Contact: Patrick Stanko (pstanko@upenn.edu; 215-573-2197)
- Secondary Contacts: Emily Wirtanen, Stephanie Lesage, Timothy Kenealy, Tracy Ziolek

Your questions could result in changes to FAQs and Instructions.

What This Means: What It Looks Like When Penn Relies on Another IRB

- Sponsor/Lead Site gets protocol approved by Designated Central IRB
- Sponsor/Lead Site gives you approved materials & requests reliance agreement
- You create & submit an HS-ERA Reliance Application

Prior to Penn Local Review

During Penn Local Review

- IRB & Ancillary Committees review and request any necessary changes
- Penn IRB Does a Local Context Review. Things We Look For Include: inclusion of Penn-required template language, CITI Training, ancillary review, prospective billing analysis
- Authorization Agreement signed & contracts executed

- Submit revised documents to Designated Central IRB
- Designated IRB approves the addition of Penn as a study site
- Ongoing review done by Designed Central IRB; Penn only involved if changes involve local consent issues

After Penn Local Review

What This Means: What It Looks Like When All Other Sites Rely on Penn

- You obtain initial review and approval of the protocol from the Penn IRB
- Create consent form template & send it, as well as other documentation, to other sites with request to rely on the Penn IRB

Penn Reviews First

Sites' Local Review Occurs

- Local context review takes place at each site
- Local Context Review May Include: similar considerations as Penn, questions or requests for added documentation, & signature of Authorization Agreement
- Site send you local-specific materials when review complete

- You submit a modification adding site & their materials
- Penn IRB reviews & approves modification; receive an approval letter & stamped consent form
- Submit additional modifications as site materials are received

Penn Approval of Other Sites

What Ongoing Submissions Look Like When Sites Rely on Penn

Modifications

- Protocol-wide amendments via HS-ERA must have all site-specific consent forms & other site specific documents as needed
- Site-specific modifications need to be submitted via HS-ERA

Continuing Reviews

- Progress report will require information on progress both at Penn and at all other relying sites
- Penn IRB has two CR forms – an overall study CR form and site specific CR forms

Deviations / Reportable Events

- Events at other sites need to be reported via HS-ERA if they meet the Penn IRB reporting criteria
- Other sites need to be aware of Penn IRB reporting requirements

Agenda for Course: Discuss what reliance agreements are and what it means for you

How Reliance Agreements Work in General: Local IRBs are still involved; Process looks very different from your normal experiences with the Penn IRB

- 2. What to Expect when Submitting: Submissions still involve HS-ERA; Instructions are available; Process takes some practice
- 3. What it means to have Penn be the Central IRB: Additional steps in the process and additional requirements for ongoing review