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

1. **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

Before Submitting Application

- Receive materials from sponsor / lead site, create application, & submit to Penn IRB

During Penn IRB Review Process

*3 Reviews at Once*

- **IRB Review:** Ethics Board, Common Rule, FDA, Belmont Report
- **Privacy Board:** HIPAA Waiver / HIPAA Authorization
- **HRPP:** Institutional Policies, Ancillary Review, Billing/Contract

Final Decision Made

- IRB Convened Meeting and Decision Letter with Notes Related to Above Reviews
IRB Review Process with a Reliance Agreement

Before Submitting Application
- Sponsor/Lead Site Develops Materials – Submission to Designated Central IRB and to Local IRBs

Review Process
*Reviews occur separately*
- IRB Review: Ethics Board, Common Rule, FDA, Belmont Report
- Privacy Board: HIPAA Waiver / HIPAA Authorization

Final Decision Made
- Performed by Designated Central IRB
- Performed by Designated Central IRB (with Local IRB input if needed)
- Performed by Local IRB
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](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**:  
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- **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

Prior to Penn Local Review

- 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

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

After Penn Local Review

- Submit revised documents to Designated Central IRB
- Designated IRB approves the addition of Penn as a study site
- Ongoing review done by Designated Central IRB; Penn only involved if changes involve local consent issues
What This Means: What It Looks Like When All Other Sites Rely on Penn

**Penn Reviews First**
- 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

**Local Context 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

**Penn Approval of Other Sites**
- 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
What Ongoing Submissions Look Like When Sites Rely on Penn

<table>
<thead>
<tr>
<th>Modifications</th>
<th>Continuing Reviews</th>
<th>Deviations / Reportable Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Protocol-wide amendments via HS-ERA must have all site-specific consent</td>
<td>• Progress report will require information on progress both at Penn and at all</td>
<td>• Events at other sites need to be reported via HS-ERA if they meet</td>
</tr>
<tr>
<td>forms &amp; other site specific documents as needed</td>
<td>other relying sites</td>
<td>the Penn IRB reporting criteria</td>
</tr>
<tr>
<td>• Site-specific modifications need to be submitted via HS-ERA</td>
<td>• Penn IRB has two CR forms – an overall study CR form and site specific CR forms</td>
<td>• Other sites need to be aware of Penn IRB reporting requirements</td>
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