# HOW TO CONDUCT AN IRB RELIANCE AGREEMENT

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

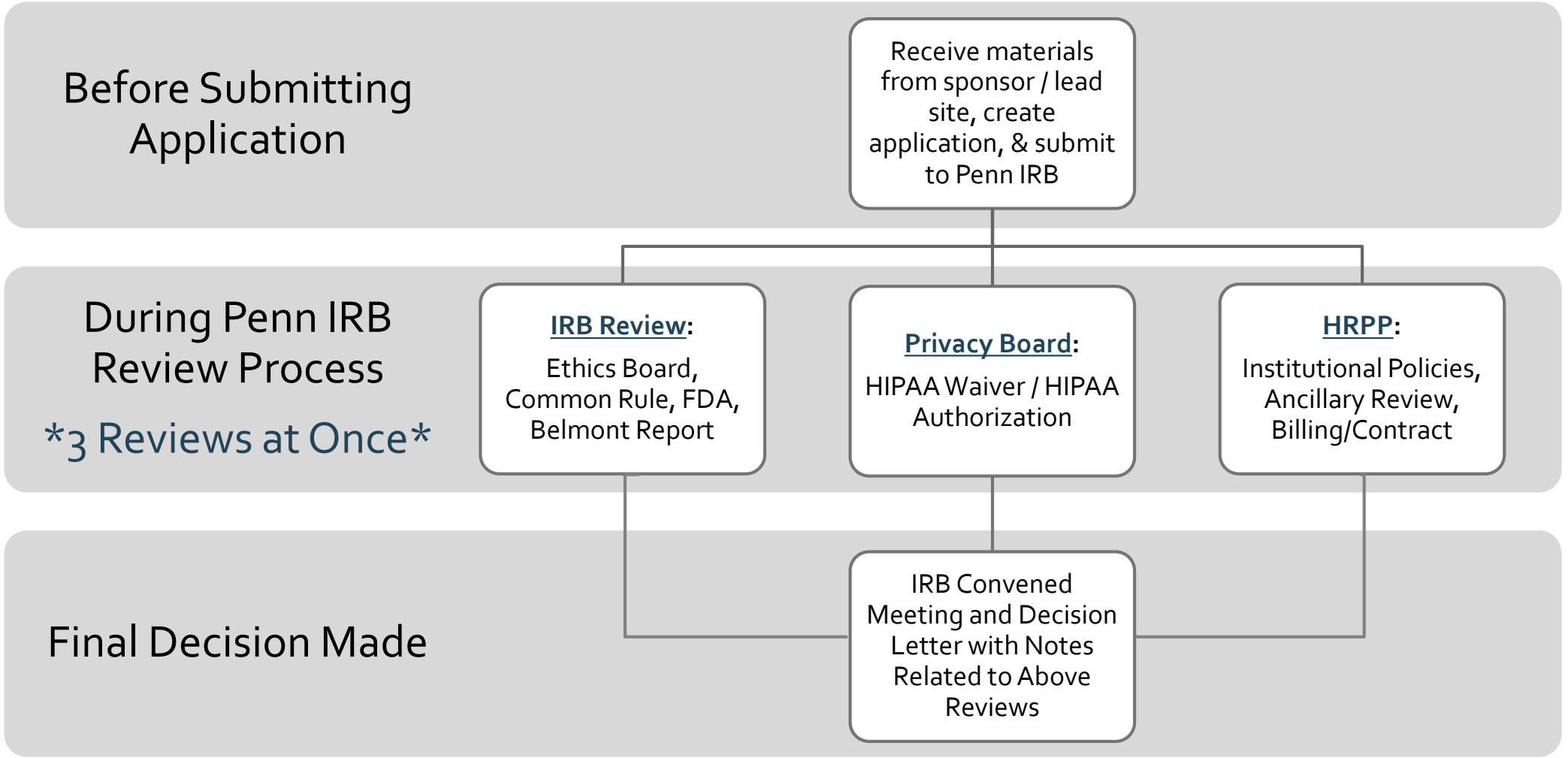
# Agenda for Course: Discuss what reliance agreements are and what it means for you

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

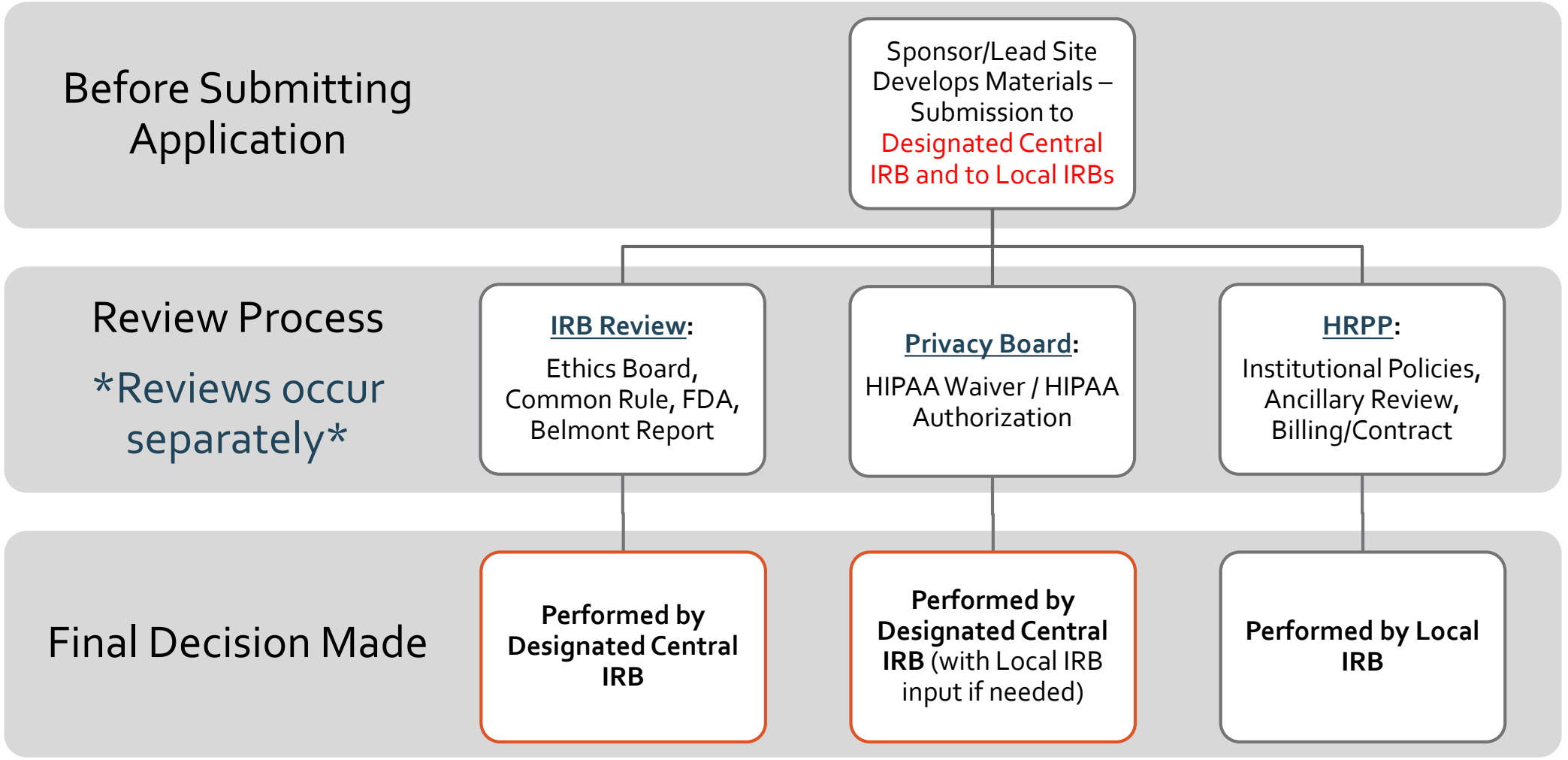
2. **What to Expect when Submitting**: Submissions still involve HS-ERA; Instructions are available; Process takes some practice

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



# 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

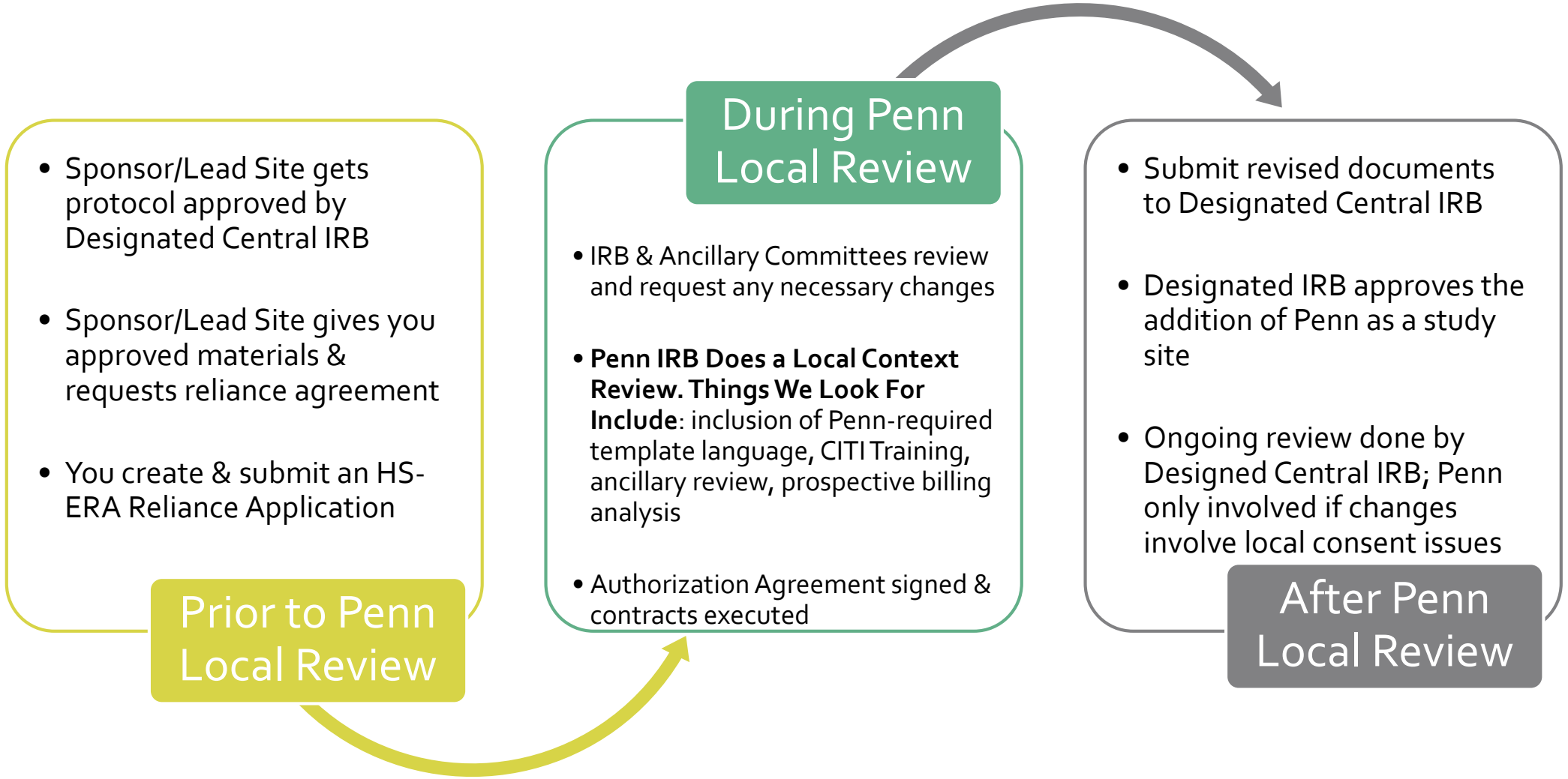
- FAQs when conducting a reliance agreement
- Instructions on how to submit via HS-ERA
- Guides for Consent Forms & Templates

## Feel Free to Ask Questions:

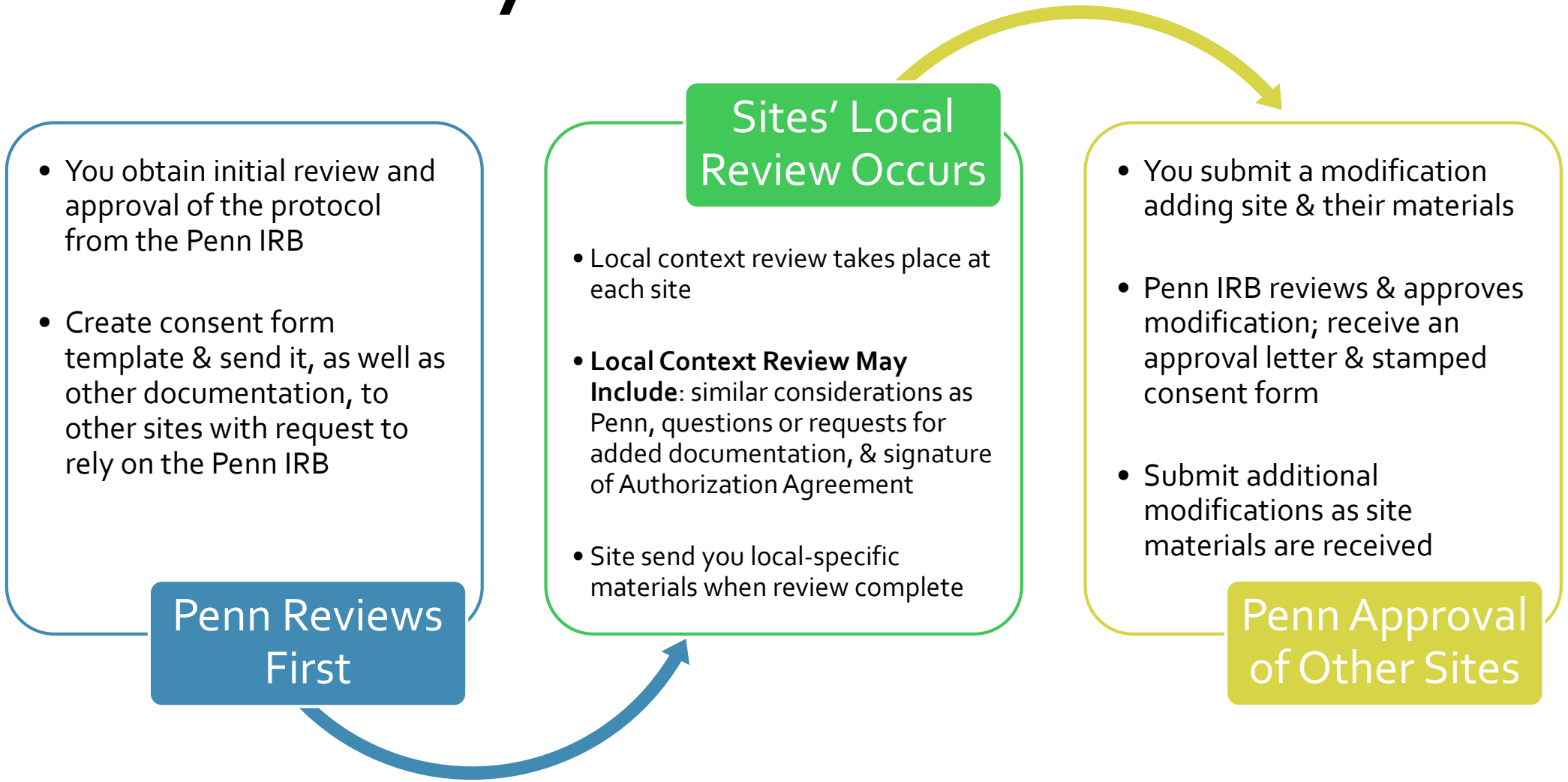
- *Primary Contact*: Patrick Stanko (pstanko@upenn.edu; 215-573-2197)
- *Secondary Contacts*: Emily Wirtanen, Stephanie Lesage, Timothy Kenealy, Tracy Ziolek

*Your questions could result in changes to FAQs and Instructions.*

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



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



# 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

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