Steps involved to Rely on another IRB

(Reliance Agreements / Institutional Authorization Agreements)

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Step 1: Establishing who is the IRB of Record

- *IRB of Record*: The IRB that provides approval for Initial & subsequent submissions for all relying sites.

- For federally-funded, multi-site studies, this should be discussed when writing the grant.
  - Some IRBs charge for being the IRB of Record
  - Temple generally will not act as the IRB of Record

- Industry-sponsors generally dictate the IRB of Record
  - Usually, it is either WCG or Advarra

- Another IRB can be the IRB of Record*, even if not required
  - *Depending on IAA constraints discussed later

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Step 2: Executing the agreement

- Reliance agreements and Institutional Authorization Agreements (IAAs) are different words for the same thing.

- The process for executing an IAA differs based on institution.
  - Temple has existing agreements with Fox Chase, WCG, and Advarra. All other IRBs will require a new reliance agreement to be signed.
  - Most IRBs require an additional local context questionnaire (or equivalent).
  - Most Universities use the SMART IRB Agreement (likely will refer to it as an LOA (Letter of Agreement)).
  - Have your collaborator talk with their IRB about their specific process.
  - Connect with Temple IRB early to coordinate.

- Signing the agreement can happen in parallel to the local context review.

- **Temple IRB must conduct a local context review before the IRB of Record can review our site, regardless of if there is an existing agreement.**

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Step 3: Submit for local context review

- Note: Most IRBs will not fully execute a reliance agreement until the IRB of Record has approved the base study (i.e., without external sites).
- After the main site is approved, submit the study via ERA (era.temple.edu).

- Create a new study as you normally would, and include a clearly labeled memo stating:
  - Who will be the IRB of Record and if the IAA will use SMART IRB.
  - Variations in how Temple will conduct the research, compared to the protocol (e.g., not enrolling minors, only handling identifiable data, etc.).

- Include any documents associated with the IAA (e.g., local context forms, LOIs, LOAs, ancillary committee checklists, etc.).

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Step 4: Local context review

- When conducting the local context review we will look for:
  - Can the PI be a PI?
  - Do research personnel have required CITI trainings and are in the route?
  - Is there a known fCOI, and is the required language in the consent?
  - Ancillary committee (e.g., MRC, IBC, IDS, etc.) notification or approval, as appropriate.
  - Has TUHS IT approved (generally only required for registries where we're sharing significant amounts of PHI)?

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Step 4: Local context review (cont'd)

- Consent form checks:
  - PI contact information
    - We are testing phone numbers after several instances dead numbers
  - Injury statement is consistent with template language and funder?
  - Reference to the separate HIPAA Authorization is included (if accessing our EMR)
  - Temple IRB, Temple University, and Temple University Hospital System and its affiliates are listed as entities that have access to the study records
  - Compensation conforms w/ TU policies (e.g., ClinCard, cash exemptions, gift cards, tax language, etc.)
  - Are LAR signature blocks appropriate given what Temple is doing?
  - Is the Temple protocol number included?
- HIPAA Authorization checks:
  - Using the new (harmonized with FCCC) HIPAA Authorization?
  - Are the study-specific sections (in blue) filled out correctly?

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Step 5: Submitting to the IRB of Record

- The local context review is complete when the TU IRB sends the PI (via ERA) the signed IAA, a cede letter (titled as such), and the approvable versions of the consent(s) and HIPAA Authorization (as applicable).

- These documents should be submitted to the IRB of Record
  - Likely via an Amendment
  - Likely through your collaborator (if IRB of Record is another university IRB)
  - By the research team (if using a for-profit IRB like WCG, Advarra, and BRANY).

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Step >5: Everything post local context review

- Provide the approval letter (it should explicitly reference Temple being added as a site or otherwise indicates that Temple is approved to start the research) to the TU IRB either via an email to IRB@temple.edu or via a Reportable New Information (RNI).

- TU IRB will needs to be informed of:
  - Personnel (TU and TUHS personnel) additions
    - Via Personnel Amendments)
  - Major problems (serious/continuing noncompliance, Suspension, Termination, Unanticipated Problems involving Risks to Subjects or Others).
    - Via RNI
  - When Temple is closed as a site (this can also be if the study, as a whole, is closed).
    - Via RNI or email to IRB@temple.edu
- Everything else should only be submitted to and reviewed by the IRB of Record

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