SINGLE IRB REVIEW

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Reliance Specialist, HRPO
Disclaimer

• sIRB is a new and evolving process, locally and nationally

• Process is likely to change

• Join our mailing list to receive notices of future sIRB education sessions

• Check Pitt “Single IRB Review” webpage often
Presentation Agenda

• NIH Single IRB policy & upcoming DHHS Regulation

• Preparing a sIRB grant submission

• Requesting the use of a sIRB at Pitt

• Documents needed for Office of Research

• PittPro electronic submission system
Terms you might hear

**Single IRB Review** – a legal arrangement that allows one IRB to review the research on behalf of other engaged institutions
  - Also commonly referred to as “Central IRB”

**Reliance Agreement** – an agreement that outlines the responsibilities of each party when using sIRB
Terms you might hear

**Reviewing IRB** – the IRB that reviews and makes required regulatory determinations
  - Also commonly referred to as “IRB of Record,” “Single IRB” or “Lead IRB”

**Relying Institution** – the institution that cedes IRB responsibilities to the reviewing IRB
  - Ceding site, Relying site
• **SMART IRB** (Streamlined, Multisite, Accelerated Resources for Trials Institutional Review Board) was developed under an NIH grant and is responsive to new NIH policy requiring the use of a single IRB for multi-site research funded by the agency.
A master agreement to support collaboration across the nation

8 CTSAs came together to develop a national IRB reliance agreement
  • Public & private universities
  • Academic healthcare centers

Shared with 72 Institutions
  + 25 CTSAs in 19 states
  + Community hospitals
  + Independent/commercial IRBs

Shared with 115+ Institutions
  + 64 CTSAs in 33 states
  + NIH agencies

Collaboratively developed with broad stakeholder input
NIH Policy

- NIH funded or supported
- Competing grant applications (new, renewal, revision, or resubmission)
- Multi-site research
- Non-exempt research
- Conducted at U.S. domestic sites
- Receipt date on or after January 25, 2018
Roles and Responsibilities
(Final NIH Policy)

**Single IRB:** Conducts the initial and continuing reviews to ensure compliance with regulatory requirements. May also act as the Privacy Board for HIPAA purposes.

**Participating Sites:** Rely on the Single IRB to carry out functions for institutional compliance. Meet other regulatory obligations – obtaining informed consent, reporting unanticipated problems, communicate relevant local context and state regulations.
DHHS Regulation

• Regardless of funding source
• Non-exempt, cooperative research (more than one site)
• Conducted at domestic sites
• IRB determined by Federal agency
• Exclusions:
  • Required by law
  • Determined by Federal department or agency
• Effective date: January 18, 2020
A Note of Caution

- Ceding oversight only covers the IRB review piece
NIH sIRB grant submission

Requires a sIRB plan that includes:

• Name of the sIRB of record

• Indication that all sites, including any added after award, agree to rely on sIRB

• Sites will sign reliance agreement that will include a communication plan

• Indicate who will maintain records of this agreement
Grant – Letter of Support

• The Pitt IRB can provide a letter of support for inclusion with grant applications.

• To request a letter of support, email irb.reliance@pitt.edu and provide the following information

  • Name, title and institution of individual(s) the letter should be addressed to

  • Identify the grant you are applying for (i.e. RFP#, RFA#)

  • Grant title
Grant budget – sIRB Review Costs

• The IRB of Record is permitted to charge Relying sites for IRB Review.

• Inquire with the IRB of Record regarding fee structure when constructing grant budget

• Contact irb.reliance@pitt.edu when formulating a budget where Pitt will act as IRB of Record
Process at Pitt
Requesting Use of a Single IRB

Contact us early in the process!

• Complete sIRB request paperwork

• Request forms available on “Single IRB Review” webpage

• Submit paperwork to irb.reliance@pitt.edu
Weekly sIRB meeting

sIRB requests are reviewed at a weekly sIRB meeting

Determinations to use sIRB made on case–by–case basis

- Funding source
- Site accreditation/expertise
- Number of sites
- Research activities
- Level of risk
Pitt cedes – Outside institution is IRB of Record

• The Pitt IRB will contact the IRB of Record to determine what type of agreement will be executed
  • Drafted from scratch
  • OHRP template
  • SmartIRB Master Reciprocal Agreement
  • Master Service Agreement

• The agreement must be signed by the Institutional Official at both institutions
Pitt cedes – local context

• Lead study site sends materials to collect information about local context
  • Institutional policies and procedures
  • State law

• Purpose: used by the IRB of Record to review for the Relying site

• The Pitt study team will need to complete this in conjunction with the Pitt IRB
Pitt cedes – local consent/assent form(s)

- Lead study site sends a template consent form to insert local language

- Pitt Study team inserts local language and emails draft to irb.reliance@pitt.edu for Pitt IRB to review

- The Pitt study team provides the final version of the local consent form to the lead site for submission to the IRB of Record
Pitt cedes – External Pathway (EXT) submission

AFTER the IRB of Record approves Pitt as a site

• A registration application is submitted via “External Pathway” OSIRIS
  • Ensures completion of other institutional requirements (ancillary reviews)
  • Allows tracking of approved studies at institution
• Research cannot begin until we activate this submission
Select the type of application:

- New Research Study
- New Coordinating Center (CC) Application (do not convert approved CC applications)
- External IRB of Record - Selectable only if the University of Pittsburgh has approved this external IRB
- Innovative Practice (not research) - An innovative clinical practice is an intervention designed solely to enhance the well-being of an individual patient or client. The purpose of an innovative clinical practice is to provide diagnosis, preventative treatment, or therapy to particular individuals.
- Quality Assurance Project (not research) - Projects directed at improving patient care or other outcomes within a given institution or environment and are therefore not initiated with the intent to contribute to generalizable knowledge.
- New Emergency Use Application (not research)

Read carefully - Studies are not eligible for NCI Central IRB review if any of the following are required:
- review by the Institutional Biosafety Committee (IBC)
- waiver of HIPAA authorization
- conduct of any research procedures at a site outside of the Commonwealth of Pennsylvania
- enrolling prisoners

Please select the external IRB of record:

<table>
<thead>
<tr>
<th>Name</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Falls Prevention</td>
<td>Falls Prevention</td>
</tr>
<tr>
<td>NCI Central IRB</td>
<td>National Cancer Institute</td>
</tr>
<tr>
<td>NeuroNEXT</td>
<td>Network for Excellence in Neuroscience Clinical Trials</td>
</tr>
<tr>
<td>SPIRIT Consortium</td>
<td>SPIRIT Consortium</td>
</tr>
<tr>
<td>StrokeNet</td>
<td>StrokeNet</td>
</tr>
<tr>
<td>PaTH</td>
<td>Johns Hopkins University</td>
</tr>
<tr>
<td>PETAL Network</td>
<td>Vanderbilt IRB</td>
</tr>
<tr>
<td>Other</td>
<td>Permission granted for single project</td>
</tr>
</tbody>
</table>
External (EXT) Pathway submission

Materials that must be submitted in EXT application:

• Approval letter from IRB of Record that states Pitt has been officially approved as a research site

• IRB–approved protocol

• IRB–approved local consent/assent form(s)

• IRB–approved recruitment materials
After External Pathway Activation

Only limited information is submitted to Pitt IRB

• Time of continuing review (Renewal)

• If the Pitt PI or study staff changes

• If any procedure related to an ancillary review changes (i.e. adding an x-ray)

• If the Reviewing IRB makes a determination of serious or continuing non-compliance or unanticipated risk to subjects or others at the Pitt site
PI/Research Team Responsibilities

• Complying with the IRB of Record’s policies and procedures

• Registering through External Pathway

• Maintaining a current and accurate study regulatory binder
  • Including correspondence from IRB of Record
Pitt as IRB of Record – Agreement

• Pitt IRB contacts the Relying Site IRBs to determine what type of agreement will be executed

• Pitt IRB facilitates obtaining agreement signatures
Pitt as IRB of Record – IRB Submission

• Normal submission through OSIRIS
• Indicate “(sIRB)” after protocol title
• First submit as if Pitt is the only research site
• Do not list other sites in CS15.0
• Upload Pitt–specific consent form in 4.9 of OSIRIS
• Upload consent template in CS11.0
• Do not list external personnel in OSIRIS
Consent template

Areas of the consent template Relying Sites edit:

- Institutional letterhead
- Local staff and contact info
- Compensation for injury language (if may cause physical injury)
- HIPAA language
  - A separate authorization document can be used if required by external site policy
- Data retention policy
Dissemination of materials

Pitt study team disseminates to Relying sites and collects completed materials:

• Initial IRB approval letter
• IRB–approved consent template
• IRB–approved protocol
• Communication Plan
• sIRB Implementation Checklist
• Local context form
Onboarding conference call

If deemed necessary, an all-site phone conference can be scheduled

- All study teams
- All Relying Site IRB Representatives
Onboarding Relying Sites

AFTER the following steps have been completed, Pitt Study team submits a Modification to add site(s).

- Agreement fully executed between sites
- Local context form completed and returned
- Local consent template vetted by Relying Site’s IRB
Rolling or Batched Onboarding

Pitt Study team can decide:

- Submit Mods to onboard sites one at a time, as they are ready
- Batch sites to onboard
PI/Research Team Responsibilities

• Primary contact for all Relying Sites & Pitt IRB

• Disseminating and collecting all study materials to/from Relying Sites

• Submitting study into OSIRIS

• Following provisions of agreement
Office of Research (OOR) – Pitt Cedes

OOR will require the following documents to be submitted:

• Fully executed agreement or Letter of acknowledgement (if SmartIRB is used)

• External Pathway Activation letter
Office of Research (OOR) – Pitt IRB of Record

OOR will require the following documents to be submitted:

- Initial IRB approval letter
- Modification approval letter that on-boarded the Relying Site
COMING ATTRACTIONS
Expansion of Reliance Team

Allison Gerger will be joining the Reliance team as a Reliance Specialist.

Welcome, Allison!
Visual representation of how Michelle feels about the expansion of the Reliance team:
PittPro

• New System to replace OSIRIS coming Spring 2018!

• Simplified submission system

• Improved questions

• Built with sIRB needs in mind
Example of Home Page
Basic Information

1. Title of study:
   Demo-CReate a New Study

2. Short title:
   Demo-siIRB for grant

3. Brief description:
   Learn how to create a new study in PittPRO when Pitt will be the IRB-of-Record for all participating sites

4. Principal investigator:
   Patty Pi

5. Does the investigator have a financial interest related to this research?
   Yes  No  Clear

6. Will an external IRB act as the IRB of record for this study?
   Yes  No  Clear

7. What kind of study is this?
   Multi-site study (More than one site will conduct the entire study)
   Collaborative study (each site will conduct a portion of the study)
   Single-site study

8. Will your IRB act as the single IRB of record for other participating sites?
   Yes  No  Clear

9. Attach the protocol?
# Study Sites and Current State

<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
<th>SmartForm Institution</th>
<th>Principal Investigator</th>
<th>State</th>
<th>FWA Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>SITE18010017-03</td>
<td>NeuroNEXT - Partners Human Research Committee Participating Site for Pitt IRB for Multi-site study</td>
<td>NeuroNEXT (Partners Human Research Committee)</td>
<td>Alex Adesina</td>
<td>Active</td>
<td>22222</td>
</tr>
<tr>
<td>SITE18010017-02</td>
<td>University of Michigan IRB Participating Site for Pitt IRB for Multi-site studyX</td>
<td>University of Michigan IRB</td>
<td>Tim Coleman</td>
<td>Active</td>
<td>45567</td>
</tr>
<tr>
<td>SITE18010017-01</td>
<td>University of Utah Participating Site for Pitt IRB for Multi-site study</td>
<td>University of Utah</td>
<td>Mary Brown</td>
<td>Awaiting Site Materials</td>
<td>1234</td>
</tr>
</tbody>
</table>

3 items
### Report Continuing Review Data

1. **Specify enrollment totals:**

<table>
<thead>
<tr>
<th>Subjects Enrolled</th>
<th>Total</th>
<th>Since Last Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

At this investigator's sites: 

- [ ]

2. **Check the items that are true for this site since the last IRB approval:**

- [ ] NO subjects experienced unexpected harm
- [ ] Anticipated adverse events have NOT taken place with greater frequency or severity than expected
- [ ] NO subjects withdrawn from the study
- [ ] NO unanticipated problems involving risks to subjects or others
- [ ] NO complaints about the study
- [ ] NO publications in the literature relevant to risks or potential benefits
- [ ] NO interim findings
- [ ] NO multi-center trial reports
- [ ] NO data safety monitoring reports
- [ ] NO regulatory actions that could affect safety and risk assessments
- [ ] NO other relevant information regarding this study, especially information about risks
- [ ] In the opinion of the PI, the risks and potential benefits are unchanged
- [ ] All modifications to the protocol have been submitted to the IRB
- [ ] All problems that require prompt reporting to the IRB have been submitted

3. **Supporting documents:**

(include an explanation of each item left unchecked above)

- [ ] Add

Name

There are no items to display

4. **Comments:**


Common Rule – 2018

• Did you know that the Federal policy for the protection of human subjects (The common rule, subpart A) has major changes coming?


• HRPO will keep you posted on the revisions and policies
When in Doubt…

Call us: 412–383–1480

Set up a consultation appointment

Email us: irb.reliance@pitt.edu