Single IRB Updates

VHRPP NEWS YOU CAN USE

JANUARY 22, 2018

Jenni Beadles, MEd, Single IRB Operations Manager (VHRPP)
Bree Burks, RN, MSN, CCRP, Senior Director (VCC)
Emily Serdoz, MPA, Manager of Translational Research (VICTR)
Overview

Review of the NIH policy and terminology

VHRPP updates and requirements
- Study team responsibilities when Vanderbilt is the Reviewing IRB
- Study team responsibilities when Vanderbilt is a Relying IRB

Resources available to study teams at Vanderbilt
- VHRPP
- VCC Services
- RSS and SMART IRB Exchange
Review of NIH Policy + Key Terms
NIH Policy on Single IRB

Grant Applications with receipt dates on or after January 25, 2018

- Ongoing, non-competing awards will not be expected to comply with this policy until grantee submits a competing renewal application

Non-exempt, NIH-funded multi-site studies conducting the same protocol

Domestic awardees and domestic sites only
Terminology

Single IRB (sIRB)
- the IRB of record, selected on a study-by-study basis, which provides the ethical review for all sites participating in a multi-site study.

Central IRB (cIRB)
- the IRB of record that provides the ethical review for all sites participating in more than one multi-site study. *The sites are usually in a network, consortium or particular program.*

Reviewing IRB
- the IRB of record to which authority for IRB review and oversight for a study has been ceded by another institution
Who determines which IRB will serve as the Lead IRB?

May be pre-determined by study sponsor or grant (primary award site)

Previously established by prior arrangement (network or cooperative group)

Primary PI’s home institution may serve as IRB

The decision is based on type of procedures to be performed or study population

The VHRPP will determine if the Vanderbilt IRB can be the single IRB for a study or network, as well as when the Vanderbilt IRB can cede review to another IRB.
Purpose of the Policy is to go from this...
...to this

Central IRB Review

- Relying Site 1
  - Local Review
- Relying Site 2
  - Local Review
- Relying Site 3
  - Local Review
- Relying Site 4
  - Local Review
- Relying Site 5
  - Local Review
Single IRB Resources on the NIH Website

Single IRB Policy for Multi-site Research


Frequently Asked Questions

What does this mean for us at Vanderbilt?
VHRPP Experience

Single IRB review is not new to Vanderbilt’s IRB

As part of the TIN, work with other premier IRBs across the country to develop harmonized processes and systems

Serve as the Central IRB and Relying IRB for multiple national networks

Members and contributors of key national reliance platforms

Designated Single IRB team consisting of 4 people with collectively ~25 years of IRB experience
What will the Single IRB team do?

Coordinate reliance with the Reviewing IRB (*fully executed agreements must exist between IRBs in order for reliance to be valid*)

Communicate with the Vanderbilt PI about study status

Collaborate with other IRBs to ensure protections of human subjects

Provide additional education as we grow

Provide guidance, and tools for general assistance
When Vanderbilt is the Single IRB
How do I request Vanderbilt be the Single IRB?

Step 1: Complete Reliance Interest Form on the Single IRB Help page

Step 2: VHRPP will determine if the Vanderbilt IRB can be the Single IRB

Step 3: If yes, SUBMIT a new study via DISCOVR-e as usual

Note: For all NIH-funded research and where possible for any other research, the SMART IRB Exchange platform will be used as the basis for reliance
Reliance Interest Form
## Reliance Interest Form

Please complete the survey below.

Thank you!

Please complete the following information. A member of the IRB will be in touch with you shortly.

1. Please list the Principal Investigator's name and credentials:  
   * must provide value

2. Please provide the PI's email address:  
   * must provide value

3. Please list the Study Coordinator or Study Contact's name and credentials:  
   * must provide value

4. Please enter the Study Coordinator/Contact's email address:

5. Please enter the study title:  
   * must provide value

6. If you have a protocol, please upload it here.

7. If you are applying for a grant, please provide a copy of the grant.

8. If you have a template consent form, please upload that document here.

9. Please list all known sites participating in this research study:  
   * must provide value

10. Are any of the sites signed on to the SMART IRB Master Agreement?  
    - Yes  
    - No  
    - I don't know

11. Will you be using the Vanderbilt Coordinating Center?  
    - Yes  
    - No

[Submit]
Things to think about...

Budgeting for IRB Fees when writing your grant

You are the coordinating center! (if no other coordinating center has been designated for your study)

Onboarding sites

Adding participating sites via IRB submissions

Managing other sites’ study documents/materials, including generating consent forms for all sites

Communication with relying study teams
Lines of Communication

- Reviewing IRB
- Lead Study Team or Coordinating Center
- Relying Institution IRB/HRPP
- Relying Site Study Team
When Vanderbilt is the Relying IRB
Why + When to submit

Reminder: the authority to determine whether Vanderbilt’s IRB cedes review to another IRB rests with the Vanderbilt Human Research Protection Program

- The IRB has many factors to consider, like the size and scope of the IRB, funding source, accreditation status, etc

As soon as you are contacted about being a relying site, submit a request via DISCOVR-e via the abbreviated application pathway

These submissions will be assigned to a team as they currently are
NYCU: Single IRB Updates

Study Type and Performance Site Information

Type of study:
- Standard or Expedited
- Exempt
- Grant Review/Umbrella Review for funds release
- Comparative Effectiveness Research
- Non-Human Subject Determination
- Quality Improvement/Non-Research Determination

Study reviewed by another IRB

Please indicate which Committee is most appropriate to review your project:
- Social and Behavioral Sciences
- Health Sciences

What type of arrangement are you requesting?
- Use of IRB choice
- Review by another IRB
- Use of a pre-arranged reliance

Is this project cancer-related?
- Yes
- No

NOTE: All cancer-related studies are required to be reviewed by the VCC Scientific Review Committee (SRC) prior to opening to accrual.

Save

- Initial/new study
- Continuing review
- Amendments to the study
- Local changes (changes to funding, key study personnel, site-specific requests)
- Potential unanticipated problems
What is the difference between Local Review + Local Context?

LOCAL REVIEW
All of the elements of review, except IRB review, required by Vanderbilt to be conducted by the VHRPP (as shown in previous pie chart)

LOCAL CONTEXT
All of the elements specific to our location that may affect the conduct of research at Vanderbilt:
- State and local law
- Institutional policies
What needs to be submitted via DISCOVR-e?

**IF WE ARE THE REVIEWING IRB:**

<table>
<thead>
<tr>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full IRB Application including all study materials, documents and related</td>
</tr>
<tr>
<td>information</td>
</tr>
<tr>
<td>sIRB Team will assist with obtaining local context for relying sites</td>
</tr>
<tr>
<td>All Amendments</td>
</tr>
<tr>
<td>Reportable Events for all sites</td>
</tr>
<tr>
<td>Continuing Review including site enrollment and status information</td>
</tr>
</tbody>
</table>

**IF WE ARE THE RELYING IRB:**

<table>
<thead>
<tr>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbreviated IRB Application for local context (KSP, Funding, Drugs/Devices/Biologics, Radiation, HIPAA, COI, Consent Forms – for local consent language)</td>
</tr>
<tr>
<td>Any forms required by the Reviewing IRB (COMPLETED Local Context Worksheets/Survey)</td>
</tr>
<tr>
<td>Major Amendments</td>
</tr>
<tr>
<td>Continuing Review Submissions</td>
</tr>
</tbody>
</table>
Tools to Facilitate sIRB review

DEVELOPED
- sIRB Team + Team Liaisons
- Reliance Interest Form
- Template Letters of Support
- Template text for grant applications
- Letter of Indemnification (LOI) for SMART IRB agreement
- PI assurance document
- Document outlining required consent language when relying
- In-Person training sessions

IN PROGRESS
- DISCOVR-e enhancements to support sIRB submissions
- Access by external users
- sIRB Fee structure
- sIRB educational tools
- Monitoring Strategy
- Tools to facilitate CIRB review [e.g. consent tool]
Everything in one location
For questions, contact the Single IRB Team

Single IRB page on VHRPP website:
https://wp0.vanderbilt.edu/irb/single-irb-help/

- Jenni Beadles
  - jenni.beadles@vanderbilt.edu
  - 322-3597

- Kari Campbell
  - kari.campbell@vanderbilt.edu
  - 875-8989

- Tyler Hubbard
  - tyler.hubbard@vanderbilt.edu
  - 875-8716

- Jessica James
  - jessica.james@vanderbilt.edu
  - 875-8980
Vanderbilt Coordinating Center

Central IRB Support Options

1.22.2018

Bree Burks, RN, MSN, CCRP
Senior Director
Vanderbilt Coordinating Center
Vanderbilt Institute for Clinical and Translational Research
Agenda

• What’s the VCC?

• cIRB Support Options
  • “Light-Touch”
  • Support for Implementation
  • Comprehensive Implementation
VCC-Background

• Provides comprehensive, central support for a diverse platform of clinical and translational research projects

• Dedicated divisions support VUMC local enrollments, Investigator Initiated Trials, Clinical Research Navigation, and Auditing, Compliance and Education

• Currently oversee 157 active projects, 16 of which are investigator initiated

• Oversee 204 enrolling centers

• Support over 28 departments/divisions at VUMC
Large Departments
- Section 15%
- Medicine 31%
- Pediatrics 28%

VCC Support Areas
- DBMI
- Cardiac Surgery
- Health Policy
- Allergy, Pulmonary, Critical Care (7/8)
- Cardiology (6)
- Clin Pharm (9/10)
- Dermatology
- Endocrine
- Intern Medicine/Public Health
- Geriatric
- Hematology/Onc (9/10)
- Infectious Disease (4)
- Rheumatology/Immunology
- Neurology (2)
- Neurological Surgery
- Plastic Surgery
- Surgery (3)
- Thoracic Surgery
- Urology
- OBGYN
- Ortho
- Pathology (7/8)
- Pediatrics (1)
- Psych (5)
- Radiology
- VU
Details

- Review resources on DISCOVR-e Webpage
- NIH
- Initial funding after 1/25/18
- Multicenter
cIRB Pathways

1. sIRB Apply?
2. Complete sIRB Request
3. “Light-Touch” OR VCC cIRB Support OR VCC as Coordinating Center
   - 4. Education/Resources
5. sIRB Support Quote
6. Grant Text/LOS

Details
- Request through central portal on DICSCOVER-e COMING SOON!
- Provide study information
  - # of Sites
  - Contact information
  - Coordinating center selected
  - Prior cIRB experience
  - RFA
- Select support type
- TIN Project?

TRIAL INNOVATION NETWORK
cIRB Pathways

1. sIRB Apply?

2. Complete sIRB Request

3. "Light-Touch"
   - VCC cIRB Support
   - OR
   - VCC as Coordinating Center

4. Education/ Resources

5. sIRB Support Quote
   - OR
   - Full Budget Quote

6. Grant Text/ LOS
   - OR
   - Grant Text/LOS

**Light-Touch**

- Education/Resources/Checklists will be provided supporting a “DIY” approach
- Investigator will provide resources/personnel to facilitate cIRB process
- Study Project Manager/Coordinating Center will:
  - Serve as contact to PI’s and their Coordinating Teams at sites
  - Facilitate continued progress of agreements, initial approval, and ongoing amendments
Pre-Award cIRB Pathways

1. sIRB Apply?
2. Complete sIRB Request
3. "Light-Touch" OR VCC cIRB Support OR VCC as Coordinating Center
4. Education/Resources
5. sIRB Support Quote
6. Grant Text/LOS

VCC cIRB Support
- Education/Resources/Checklists will be provided supporting an “Ongoing, Facilitative” approach
- Investigator/team will utilize Project Coordinator from VCC to provide ongoing support as needed
- VCC cIRB Project Coordinator **will**:  
  - Support Coordinating Center Project Manager/Team  
  - Provide consistent updates on overall cIRB status across sites  
    - Examples: weekly meetings, consistent email communication, ongoing education/presentations; reports with status updates  
  - Provide in-depth support if barriers/questions arise
- VCC cIRB Project Coordinator **will not**:  
  - Complete IRB application/submissions on behalf of sites  
  - Serve as a content expert on the study design
cIRB Pathways

1. **sIRB Apply?**
   - Complete sIRB Request

2. **VCC cIRB Support OR VCC as Coordinating Center**
   - **"Light-Touch"**
   - Education/Resources
   - sIRB Support Quote
   - Grant Text/LOS

3. **IRB + VCC**

4. **VCC as Coordinating Center**
   - **“Comprehensive”** approach
   - Investigator will utilize VCC Project Manager to perform all cIRB duties and support all cIRB needs
   - VCC cIRB Project Manager **will**:
     - Serve as the study design content expert and lead cIRB contact for research teams/PI’s at participating sites
     - In partnership with the VUMC HRPP, provide education and training to sites (initial and ongoing)
     - Complete all cIRB applications and amendments
     - Provide consistent updates on overall cIRB status across sites and ensure cIRB processes are on track
cIRB Pathways

1. sIRB Apply?

2. Complete sIRB Request

3. “Light-Touch” OR VCC cIRB Support OR VCC as Coordinating Center

4. Education/ Resources

5. sIRB Support Quote

6. Grant Text/ LOS

Education and Resources

- DISCOVRe: Central area where education and resources are located
- Provided with resources and tools that fit your individual needs
  - Not “one size fits all”

CTSA Clinical & Translational Science Awards

VUMC IRB TRIAL INNOVATION NETWORK
**sIRB Support Quote**
- Support provided to Coordinating Center Project Manager
- VCC will not give feedback on study design/science
- Federal Charge-back Core
  - Rates are actual costs
  - Rates change as actual costs change
- Hourly rates charged for support (~$70/hour)

**Full Budget Quote**
- Comprehensive coordinating center support provided, including sIRB submissions and processes
- Federal Charge-back Core
  - Rates are actual costs
  - Rates change as actual costs change
- Hourly rates charged for support (~100/hour)
cIRB Pathways

1. sIRB Apply?

2. Complete sIRB Request

3. **Light-Touch**
   - VCC cIRB Support
   - VCC as Coordinating Center

4. **Education/Resources**
   - VCC cIRB Support
   - VCC as Coordinating Center

5. sIRB Support Quote
   - Full Budget Quote

6. Grant Text/LOS

---

**Grant Text/Letters of Support**

- VCC will provide specific language to highlight resources and expertise provided for cIRB assistance
  - Support for the Coordinating Center Team
  - Full project management of study
    - Including cIRB implementation

- **Central portal on DISCOVRe will provide ready grant text for “Light-Touch” pathway**

- **TIN submissions will have tailored, customized language provided**

- **SMART IRB EXCHANGE grant text is also available to support submissions**
VCC-Get in Touch

- Request support for a new project
- View our teams
- Get information on our services
- Identify active studies in your area
- Get grant text

vcc.vumc.org

proud to provide comprehensive support for clinical discovery
Vanderbilt Institute for Clinical and Translational Research: Research Support Services

Emily Serdoz, MPA
Manager of Translational Research
Vanderbilt Institute for Clinical and Translational Research
VICTR-RSS sIRB Consultation Services and Support

Grant Preparation Toolkit

SMART IRB Exchange
What are the NIH grant requirements?

- Name of the sIRB of record
- Indicate ALL of the following
  - 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
- Exceptions, if applicable, (sites that will not be using the single IRB)

Grant Preparation Toolkit Components

- Grant text template
- Help determining site’s sign-on to the reliance-related agreements
- Budget preparation
- Template letters of support for participating sites, if needed
- Help getting institution signed onto the reliance-related agreements

How to request VUMC serve as the single IRB of record?

- Central portal on VUMC HRPP Single IRB website: [https://www.vanderbilt.edu/irb/single-irb-help/](https://www.vanderbilt.edu/irb/single-irb-help/)
Sample Communication Plans

General Lines of Communication

Reviewing IRB  
→  Lead Study Team or CCC  
↓  Relying Institution IRB/HRPP  
↓  Relying Site Study Team

CIRB Workflow Using SMART IRB Exchange

COMMUNICATION PLAN GUIDING PRINCIPLES:
IRBs communicate with IRBs.
AND,
Study Teams communicate with study teams.
Study Teams only communicate directly with their local IRB.
All Study Teams communicate with the CIRB via the Lead Study Team/Coordinating Center.

Initial CIRB Approval for Participating Sites

SMART IRB Exchange

PRBs ensure all required agreements are complete

Participating Site PI

NIHPRPs confirm HRPPs considered whether to rely.

Participating Site HRPP

NIHPRPs confirm HRPPs considered whether to rely.

SMART IRB Exchange

PI completes local context.

Exchange notifies participating sites.

Relying Site Study Team

CIRB submits participating site local context to CIRB.

CIRB reviews and approves participating sites' local context.

CIRB submits participating site local context to Exchange.

Exchange captures local context from participating sites.

Exchange notifies participating sites of IRB approval.

Lead Study Team (LST)/Coordinating Center (CC)

CIRB enters confirmation of reliance.

CIRB uploads Lead Site Approval to Exchange.

Exchange stores approval.

Exchange notifies NIHPRPs about study.

NIHPRPs confirm site engagement.

Relying Institution IRB/HRPP

An IRB notification sent.

LST/CC monitors site progress signing agreements and completing local context in exchange.

LST/CC notifies participating sites of next steps.

Via SMART IRB Adapted from Lines of Communication – Madison (Wisconsin)
VICTR-RSS sIRB Consultation Services and Support

Grant Preparation Toolkit

SMART IRB Exchange
A national policy and reliance agreement are necessary, but not sufficient, to support single IRB review.

The Reliance Agreement is a 1st step.

IT solutions are needed to support single IRB documentation and communication across institutions.
SMART IRB Exchange: An Evolving IT Platform

IRBshare and IRBchoice platforms consisted of the reliance agreement + the IT platform user agreement. Exchange is an IT platform user agreement that can be used with any reliance agreement.
What is SMART IRB Exchange?

A web-based portal that helps facilitate the implementation of a single IRB from initiating the reliance process thru study close.

SMART IRB Exchange is a tool for...

- IRBs to document and track IRB reliance relationships
- Coordinating centers/Lead Study Teams to monitor study start up and manage approvals
- IRBs and study teams to centralized the capture of local considerations
- IRBs and Coordinating centers/Lead Study Teams to manage all IRB approval documents for Participating Sites
- IRBs to streamline and automate study-related notifications to Participating Sites

SMART IRB Exchange is NOT...

- Not a reliance agreement
- Not a Reviewing IRB
Initial Interactions with SMART IRB Exchange

sIRB creates study in Exchange

[optional]
Participating Sites (HRPP + PI) submit local context in Exchange, if applicable

CCC/Lead Study Team exports local context and submits it to sIRB, if used to capture local context

sIRB uploads site approval to Exchange

Exchange emails approval notification to participating site study team + HRPP approval

Participating Site Study Team logs in to access approval documents
Lead Study Teams/CCCs use Exchange to track the steps to reliance

<table>
<thead>
<tr>
<th>Site</th>
<th>SMART IRB</th>
<th>SMART IRB Exchange</th>
<th>Reliance Decision</th>
<th>Approval Status</th>
<th>Local Context</th>
<th>Is the agreement complete?</th>
<th>Has the site entered local context?</th>
<th>Has the HRPP/IRB agreed to rely?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albert Einstein College of Medicine</td>
<td>✓</td>
<td>✓</td>
<td>Complete</td>
<td></td>
<td>Not Approved</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Boston University Medical Center</td>
<td>✓</td>
<td>✓</td>
<td>Pending</td>
<td></td>
<td>Not Ready</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Columbia University</td>
<td>✓</td>
<td>x</td>
<td>Incomplete</td>
<td></td>
<td>Not Ready</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dartmouth College</td>
<td>x</td>
<td>x</td>
<td>Incomplete</td>
<td></td>
<td>Not Ready</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harvard University</td>
<td>✓</td>
<td>✓</td>
<td>Complete</td>
<td></td>
<td>Not Ready</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oregon Health &amp; Science University</td>
<td>✓</td>
<td>✓</td>
<td>Complete</td>
<td></td>
<td>Not Ready</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>University of California, San Francisco</td>
<td>✓</td>
<td>✓</td>
<td>Complete</td>
<td></td>
<td>Not Ready</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yale University</td>
<td>x</td>
<td>x</td>
<td>Incomplete</td>
<td></td>
<td>Not Ready</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Export the information to submit to DISCOVR-E (as it is completed)
Relying Site Study Teams: (1) enter local context into Exchange

Confirm contact information and any differences in consent, recruiting, DSMB at the local site.
Relying Site Study Teams (2) use Exchange to receive notifications of approval

Dear All,

Vanderbilt University Medical Center has shared IRB approval for your institution, Harvard University Medical Center, for the following study: Zoster Eye Disease Study (ZEDS): A multi-center, randomized, double-masked, placebo-controlled study for one year in immunocompetent study participants with a history of dendriform papules and/or iritis due to Herpes Zoster Ophthalmicus (HZO) in the year prior to enrollment.

This was an Initial Study: Full Board approval by the Reviewing IRB. The expiration date is 12/03/2018.

Principal Investigators & Study Contacts: Your approval documents are available in SMART IRB Exchange. Please refer to the site for future submissions and reporting of events.

Access the study at: https://sirb.trialinnovationnetwork.org/study/index/?proj=32

Thank you,
The SMART IRB Exchange Team

and login to access approval documents
- admin@SMARTIRBExchange.org
- About SMART IRB Exchange
- Resources: Coming to the VUMC HRPP Single IRB website

SMART IRB Exchange Team

Adoma Manful
System & Materials Development

Emily Serdoz, MPA
Project Manager

Bridget Swindell, RN, CCRP
Study Support

Linda Tan
Onboarding & User Support
Questions?