Single IRB (SIRB) Submission Tip Sheet for Lead Study Teams/Coordinating Centers When Vanderbilt is the SIRB

VANDERBILT

Human Research Protections Program - HRPP

Supporting the work of the IRB and Providing HRPP Oversight

Initial Review (New Study)

For the initial review of a new study, the VUMC SIRB reviews the overall study **with the Lead Site only**. All global, study-wide documents that may pertain to the conduct of the study at all sites are reviewed with this initial review, as well as the lead site's consent form and local considerations, and include, but are not limited to:

- Protocol
- IRB Application
- Part 1 Master Informed Consent Documents (ICDs) (when applicable)
- Part 2 Study Site Information ICDs **for lead site only** (when applicable)
- Assent Forms (when applicable)
- Investigator's Brochure or package inserts (when applicable)
- Device Manual (when applicable)
- Recruitment materials (when applicable) – recruitment materials should be written as templates at the study-wide level so that they may be used by any participating site
- Study Measures (e.g., questionnaires, surveys, interviews)
- Reliance documentation for lead site (when the lead site is NOT Vanderbilt)
- Short Form ICDs for non-English speaking participants – these should be reviewed with the initial submission and should include all languages approved by VUMC or the lead site

References:
HRPP III.E. IRB Review of Human Subjects Research - Full Committee
HRPP III.E.1. Procedure for IRB Review of Human Subjects Research - Full Committee
HRPP III.E.2. Procedure for Initial Application Materials to be Reviewed by the Full IRB Committee

Site Additions

Site Additions are expected to be submitted AFTER the SIRB's initial approval of the overall study and local review by the relying sites. Site Additions should include the following information PER RELYING SITE – all of the following items are exported from IREx and checked for completion by the Study Coordinator or Coordinating Center prior to submission to the VUMC SIRB:

- Institutional Profile – complete with responses to all questions
- Human Research Protection (HRP) Survey – should include:
  - Responses to all questions
  - Uploaded Part 2 ICD (when applicable) complete with respective site's required local language
  - Signature of HRP Representative
- Principal Investigator (PI) Survey – should include:
  - Responses to all questions
  - Signature of respective site's PI
- Study-Specific Reliance Plan (SSRP)
- Part 2 ICD (when applicable)
- Site-specific Assent Form (when applicable)

- Stand-alone HIPAA forms: these are accepted with the site's information, but are not approved/stamped by the VUMC SIRB

Note: incomplete surveys will not be accepted. Sites with incomplete surveys will be considered 'not ready' for review and removed from the submission to facilitate review of the sites that are ready. Site Additions are limited to 5 'ready' sites per submission to accommodate the SIRB Reviewers. Upon fulfillment of all of the above requirements, a VUMC IRB analyst must mark the site as "Ready" in DISCOVR-e before it can be added as a Site Addition. For remaining questions about the Site Addition process, contact the Single IRB Operations Manager, Jenni Beadles at jenni.beadles@vumc.org.

References:
HRPP I.D. Knowledge of Local Research Context
HRPP I.D.1. Procedure for Knowledge of Local Research Context
HRPP I.G. Use of Single IRB Models to Facilitate Review Time and Effort
HRPP I.G.1. Procedure for Use of Single IRB Models to Facilitate Review Time and Effort

Amendments

Study-wide Amendments: amendments to documents that may pertain to the conduct of the study at all sites. Changes to any of the following documents constitute a study-wide amendment:

- Protocol
- Part 1 Master ICD
- Recruitment Materials

Site-Specific Amendments: amendments to documents that pertain to specific sites and not the overall study.

- Examples of site-specific amendments that require SIRB review and will be accepted by the VUMC SIRB:
    - Site PI or Study Coordinator Changes
    - Rare changes to the Part 2 consents (e.g., compensation, subject injury, HIPAA language that is incorporated into the Part 2)
    - Short forms in languages that ARE NOT available at the lead site (Note: when processing a new SIRB study, the team may opt to use VUMC's short forms OR the lead site's short forms. All available languages should be reviewed/approved as global documents for all sites to use – see Initial Review (New Study) section above)
- Examples of site-specific amendments that do not require SIRB review and will not be accepted by the VUMC SIRB (these may still require local review at the respective site):
    - Adding barcode and/or logo to master ICD
    - Adding barcode and/or logo to part 2 after site add has been approved
    - Site-specific ads/recruitment materials to add local contact information (approval of ads should be at global level – see Initial Review (New Study) section above)
    - Adding page numbers and consent labels in the footer per site request
    - Stand-alone HIPAA forms – these will not be 'approved'/stamped by the VUMC SIRB, as they are local documents
    - Short forms in languages that are already approved globally

In accordance with the above guidance:

- Study-wide amendments are submitted as a single submission for all sites
- Site-specific amendments are submitted as single submissions for each site unless the change is exactly the same for all sites in which case, a single submission for multiple sites is preferred

References:
HRPP III.J. Amendments to Previously Approved Applications, Claims for Exemption, or Non-Human Subjects/Non-Research Determinations
HRPP III.J.1. Procedure for Amendments to Previously Approved Applications, Claims for Exemption, or Non-Human Subjects/Non-Research Determinations

Continuing Reviews

The annual review information for SIRB studies should be submitted to theVUMC SIRB NO LATER than 8 weeks prior to the study's expiration date to allow time for review and dissemination of approval to all sites (this is 4 weeks sooner than noted in the policy to accommodate study teams' need to disseminate approval to multiple sites). The Continuing Review (CR) documentation should include, but is not limited to, the following information as applicable:

- Continuing Review or Study Closure Application completed in DISCOVR-e
- Currently approved IRB Application
- Currently approved Part 1 ICD in Word format – clean for date stamping (when applicable)
- Currently approved Part 2 ICDs in Word format – clean for date stamping (when applicable)
- Currently approved Assent Forms in Word format – clean for date stamping (when applicable)
- Progress Report of the research that includes:
    - Any adverse events and a profile of what differed from initially expected including causality;
    - Any Data and Safety Monitoring reports;
    - Any events requiring reporting to the IRB (e.g., serious adverse events);
    - Any unanticipated problems involving risks to participants or others and reports of non-compliance, even at sites in which the Investigator is not responsible for the conduct of the research;
    - Any participant withdrawals;
    - Any participant complaints;
    - Any recent relevant literature;
    - Any interim findings;
    - Any progress reports;
    - Any mulitcenter reports;
    - Any other relevant information, especially that may impact the risk/benefit ratio;
    - Any problems recruiting potential participants; and
    - Any benefits from the research.
- Use this table as a resource for what information is needed per site, and what is needed in aggregate:

Per site	In Aggregate
Max # of participants approved (if available)	Adverse event report
# enrolled within the last SIRB approval period	Protocol Deviation report
# enrolled since the beginning of the study (in Y1 this and the one above will match)	Summary of DSMB reports Is a DSM or DSMB assigned? How often do they review? Are any reports provided?
# withdrawals (including PI-initiated, dropped out, lost to f/u)	Summary of interim findings
	Progress reports that cover the previous approval period
	Any participant complaints *(optional)*

References:
HRPP III.K. IRB Continuing Review
HRPP III.K.1. Procedure for Conducting IRB Continuing Review
HRPP III.K.2. Procedure for Notification of IRB Continuing Review
HRPP III.K.3. Retired
HRPP III.K.4. Procedure for the Processing of IRB Continuing Review

Adverse Event and Non-Compliance Reports

Adverse Event (AE) and Non-Compliance (NC) reports are submitted to the VUMC SIRB via DISCOVR-e according to IRB Policy and Procedures. **The identity of the site must accompany the report.**

References:
HRPP III.L. Reporting of Adverse Events, Serious Adverse Events, and Unanticipated Problems Involving Risk to Participants or Others
HRPP III.L.1. Procedure for Reporting of Adverse Events, Serious Adverse Events, and Unanticipated Problems Involving Risk to Participants or Others

2-Part ICDs

The VUMC SIRB utilizes a 2-part consent form to facilitate SIRB review. The two parts are used together to constitute one legally effective informed consent document.

- **Part 1 – Master Consent:** This section of the ICD contains the overall information about the study as it pertains to all participating sites. There are no site or investigator names, and no site-specific text included in this section. The Part 1 Master Consent is approved by the SIRB at the study-wide level at the time of initial review, study-wide amendment, and continuing review.
- **Part 2 – Study Site Information:** This section of the ICD contains the site-specific information for each site. The VUMC SIRB expects this template to be used by all relying sites without exception. Section headings and page numbers must be observed as indicated, and specific instructions are provided in blue text within the template for guidance. (The pagination for Part 2 intentionally restarts with p.1 to accommodate potential amendments to Part 1 that may change the number of pages of the consent form. For example, if the Part 1 Master Consent is initially approved with 6 pages, but an amendment revises it to 7, restarting the Part 2 ICD with p. 1 eliminates the need to revise every site's Part 2 for updated pagination).

Note: The 2-part consent template is updated regularly, so it is recommended that the current version be obtained from the Single IRB Help page (https://www.vumc.org/irb/node/28) prior to each use with a new study. It is the responsibility of the study team or coordinating center to combine Part 1 and Part 2 prior to use with research participants.

All SIRB submissions are initiated, and reviewed/approved by the VUMC SIRB via the **DISCOVR-e** online submission portal. **DISCOVR-e** is ALWAYS the primary source for IRB-approved documents for the lead study team or coordinating center.