Single IRB (sIRB) Review:
Guidance for Investigators + Study Teams When Vanderbilt is Relying on Another IRB

Purpose: This document provides guidance for Vanderbilt Investigators using single IRB review where Vanderbilt is relying on (or ceding review to) another IRB.

Initial Study Submission

1) The Vanderbilt Investigator/Study Coordinator will submit an abbreviated IRB Application via DISCOVR-e **after the IRB of Record has approved the initial study**. Information submitted should include, but is not limited to, the following as it applies to the study.
   a) Abbreviated IRB Application as designated by the following selections within DISCOVR-e:
      i) Study Type: Study reviewed by another IRB
      ii) Type of Reliance: Use of a pre-arranged reliance (if applicable) OR select Other (selecting Other will populate an additional field for data entry)
      iii) The Application should address the following sections as they apply to a particular study and will be conducted at Vanderbilt:
         (1) data and safety monitoring plan
         (2) recruitment plan
         (3) Radiation for research purposes
         (4) Drugs, Devices, and Biologics
         (5) consenting plan/PHI authorization
         (6) conflict of interest
      iv) Key study personnel
   b) Consent form(s) with Vanderbilt local consent language included (see Local Context Language document on the Single IRB Help page)
   c) Any Vanderbilt-specific study documents (e.g. recruitment materials applicable to only Vanderbilt)
   d) Current study approval letter from the IRB of Record
   e) Approved study documents from the IRB of Record (as applicable):
      i) Protocol
      ii) Investigational Brochure(s)
      iii) Grant face page/funding documentation
      iv) Study Measures and Materials
      v) Recruitment materials and Advertisements
2) VHRPP will identify any ancillary reviews that are required pursuant to the reliance agreement in place. Ancillary reviews are those reviews that do not fall under the purview of IRB review, but still meet the institutional requirements for VHRPP review. When applicable, such reviews include but are not limited to:
   a) conflict of interest (COI)
   b) study personnel qualifications
   c) requests for waivers of authorization to use and disclose PHI
   d) radiation safety
   e) Medicare Qualifying Clinical Trial (QCT) analysis
3) Upon completion of the review process, an Analyst will distribute verification of local review via DISCOVR-e with the study documentation. Please note that the notification does not provide IRB approval for the research activities as VANDERBILT is not the IRB of Record; therefore, the Vanderbilt Consent Form(s) will not include the IRB Approval stamp.

4) The Vanderbilt Investigator/Study Coordinator should provide the local review documentation to the IRB of Record. Only the IRB of Record can approve the initiation of research activities at the site.

Amendments

The Vanderbilt Investigator/Study Coordinator is responsible for submitting amendments that affect study documents to the IRB of Record as per the protocol. Upon approval from the IRB of Record, the Vanderbilt Investigator/Study Coordinator will submit Amendments to the VHRPP via DISCOVR-e. The submission should include the approved documents provided by the IRB of Record, including the letter of approval from the IRB of Record. The documents will be distributed via DISCOVR-e in order to retain the most currently approved versions.

Continuing Review (Annual Enrollment Report)

The Vanderbilt Investigator/Study Coordinator is responsible for submitting Continuing Review (CR) information to the IRB of Record. Within 30 days of receipt of CR approval from the IRB of Record*, the Vanderbilt Investigator/Study Coordinator will submit a CR form via DISCOVR-e with Vanderbilt specific study information as an annual enrollment report. The submission should include, as applicable:

- CR approval letter from IRB of Record
- Study status at Vanderbilt
- Enrollment figures at Vanderbilt
- Deviations or adverse event reports from Vanderbilt
- Participant withdrawals or complaints at Vanderbilt
- Recruitment issues at Vanderbilt
- Other information relevant to review of research at Vanderbilt
- Currently approved consent form(s)

Upon acceptance, a letter of acknowledgement and the approved documents from the IRB of Record will be distributed via DISCOVR-e in order to retain the most current approved study documents.

*Please note you will receive an email notification from DISCOVR-e to submit a CR based on the timing of Vanderbilt CR submissions. For the purposes of the sIRB review model, these notifications serve as a reminder to submit the approved CR from the IRB of Record.

Reportable Events

The Vanderbilt PI is responsible for submitting unanticipated problems as described by IRB Policy III.L in addition to reporting requirements outlined in the study protocol.

The Vanderbilt Investigator/Study Coordinator is responsible for reporting to the IRB of Record within 7 calendar days of the Investigator's knowledge of any serious event that occurs at Vanderbilt and is unanticipated or unexpected, involves risks to participants or others and was possibly related to the research procedures or any noncompliance that increases risk or affects the participant's rights, safety or welfare. Please note that the IRB of Record may have differing reporting timelines and requirements for documentation.