Selecting an Alternate Single IRB

This is a new responsibility for VT investigators, who will be the lead site or coordinating center for a multi-site study. There are many issues to consider. See the NIH FAQ Guidance and consult with the VT Institutional Review Board (IRB) Office by contacting irb@vt.edu.

Who decides?

In some cases, NIH (or another funding sponsor) may specify the sIRB in the FOA or RFP funding announcement. However, for most grants, NIH expects the lead PI to identify a specific sIRB in the grant application. *Note that NIH has explicitly stated in its sIRB FAQ that "The proposed single IRB will not be evaluated as part of the peer review process and will not affect the overall assigned score of an application/proposal or the overall rating of the acceptability of the Protection of Human Subjects section".*

The decision-making process should include the study leadership and the VT IRB. Agreement of the following parties is essential:

- VT Institutional Review Board – ***The IRB in the VT Office of Research Compliance is the only VT entity authorized to prepare, and recommend I.O. approval of inter-institutional IRB reliance agreements.***
- The IRB selected to serve as the sIRB
- The lead PI's institution (if not VT)
- All domestic participating sites

What are the options?

Any IRB with a Federalwide Assurance (FWA), or federal registration can serve as an sIRB. This includes the "independent" or commercial IRBs such as WIRB, Schulman, Quorum, Chesapeake, etc. not affiliated with any institution.

Factors to consider include the history and experience of the IRB as well as its capacity and expertise for serving as the IRB of record for the study.

At this time, the Virginia Tech IRB will not agree to serve as the sIRB for multi-site studies. The IRB will work with Virginia Tech PIs (and NIH, as needed) to choose from these options:

- **A NIH IRB**
  This option is available only if NIH has specified its use in the FOA or RFP.
- **An IRB specifically set up for an already-established-and-funded research network or consortium**
  This option is available only if the study you are proposing will be conducted under the auspices of the network/consortium.
- **An Independent or commercial IRB, approved by the VT IRB and in accordance with VT research contracting policies and procedures.**
- **The IRB of one of the other institutions** participating in the research

The VT IRB will monitor the activity of the NIH sIRB policy. The VT IRB will gather information about costs, workloads, and research teams' experience. This will be the basis for deciding whether or not the VT IRB will serve as a sIRB in the future.

How do you approach the alternate single IRB?

If the specific IRB is named in the funding FOA or RFP
You do not need to communicate with the alternate IRB prior to submitting your grant unless the FOA or RFP directs you to do so.

All other scenarios
You should approach the alternate IRB before submitting your grant application, to:

- Ensure that the IRB is willing to be the sIRB;
- Determine whether the IRB charges fees, and obtain cost estimates for your grant budget. See the NIH FAQ on NIH Grant Application/Contract Proposal Preparation for more information about costs.

You may wish to consult with the VT IRB about how to approach the alternate IRB, by sending a consultation request to irb@vt.edu. The VT IRB will assist you with the most efficient and direct way to communicate with the IRB. In some cases, the VT IRB can approach the alternate IRB on your behalf.

What do you need for your grant application?

The name of the single IRB
An estimate of the direct costs (if any) for IRB review, in the grant budget
A Letter of Support from the sIRB (strongly recommended)
A Letter of Support from each participating site, indicating its willingness to rely on a single IRB (strongly recommended)