University of Richmond IRB

**Multisite Research: Personnel and Data Safety and Monitor Procedures**

Studies conducted at multiple research sites, with each site managed by a site-specific investigator, are considered to be multisite projects. Research activities may include, but are not limited to, storing or distributing study data, identifying or enrolling subjects, administering the study protocol, and/or carrying out the informed consent process. Individuals who are not engaged in research (e.g., they announce a study or provide possible subjects with information about the project, they collaborate on the design of research but do not interact with participants) are not considered study personnel.

1. List the sites where the research will be conducted and the principle investigators at each site.

2. Identify the lead investigator with primary responsibility for cross-site communication and monitoring protocol compliance and adverse event reporting. Briefly describe the lead PI will communicate with and disseminate information to other sites/personnel (e.g., regularly scheduled conference calls or meetings, email, Open Science Framework, etc.).

3. Describe the cross-site data and safety-monitoring plan, including the protocol that will be followed for data storage and maintaining data security.

4. Describe any aspects of the study, if any, that vary from one site to another (variations in consent, in subject populations, in protocol, etc.).

5. If the study involves extramural investigators (researchers who are not affiliated with the University of Richmond), provide confirmation that each identified investigator has completed training in human subjects research from their respective institutions and that these individuals agree to comply with conditions mandated by the University of Richmond’s research review process. Please note:

* In most cases the project should be reviewed and approved by the IRB at each investigator’s University or institution since approval of a protocol by URIRB may not be sufficient to meet the regulatory requirements of extramural investigators’ employing universities or institutions.
* If any of the project’s external researchers are NOT affiliated with an organization with an IRB they are eligible to complete that training using the University of Richmond’s account with CITI.
* Depending on the nature of the research, a letter of support from the external researcher’s organization may be required.
* Multisite research supported by certain federal agencies (e.g., NIH) and all human research (beginning January 19, 2020) must identify a single IRB as the IRB of record for research review. The review of the study must be conducted only at that IRB, with other IRBs ceding responsibility for review to that IRB. That process requires an IRB Authorization Agreement (IAA) identifying one of the sites as the IRB of Record.