

## **9 Research overseen by a non- UVA IRB of Record**

### **9.1 UVA Investigator Responsibilities**

Prior to submitting the application to the non-UVA IRB, the UVA investigator must satisfy University of Virginia requirements for the research. Even though the UVA IRB will not serve as the IRB of Record, they are responsible for verifying that other compliance and educational requirements are met.

### **9.2 UVA IRB Responsibilities**

- When the submission packet is received, the IRB Director or designee reviews the application materials. The following is reviewed:
- Eligibility to use external IRB review
- Review of investigator and study staff (confirmation of training, COI etc.)
- Review of non- IRB Compliance reviews/ approvals (e.g. Radiation safety, pharmacy, etc.)
- UVA Departmental Chair certification of scientific merit
- HIPAA compliance if the IRB-HSR will serve as the HIPAA Privacy Board

Once the above are reviewed by the IRB Director or designee and determined to be acceptable, the investigator will be notified that they may move forward with their submission to the non-UVA IRB. This approval will also be shared with other UVA offices via HSR Workflow, IRB online or ?? SBS PROCESS. The UVA IRB will provide the UVA PI with training certification for all UVA study personnel. If not included with the IRB Reliance Agreement the UVA study team will also be provided with the UVA local language to be included in the IRB approved consent from the IRB of Record.

### **9.3 Responsibilities after the study is open to enrollment at UVA**

After the research has begun any reports of UVA site monitoring activities which have any findings that potentially impact human subject protections must be shared with the UVA IRB.

Changes in study personnel must be submitted to University of Virginia IRB with the continuation status report. No personnel may begin study responsibilities prior to completing human subject research protection training.

UVA retains responsibility for Post Approval Monitoring. The study team will be required to submit PAM reports to the IRB of Record per their policies and procedures.

Additional responsibilities:

IRB-HSR: [CIRB Procedures](#)

IRB-SBS: