

UVA IRB-HSR TIP SHEET for RELYING SITES

For external sites relying on the University of Virginia IRB for Health Sciences Research (IRB-HSR) as the Single IRB of record.

- 1. UVA IRB-HSR General Contact: IRB Office Staff Contact Information
- 2. <u>Reviewing and Relying Site Responsibilities</u>
- 3. University of Virginia Human Research Protection Program Policies: Refer to HRRP Standard Operating Procedures on our website

4. Education Requirements

All relying site study team members must complete their institution's education requirements **OR** UVA's mandatory <u>CITI education requirements</u>. In addition, ensure any other required education has been completed, for example blood-borne pathogen training.

5. Communication

The UVA PI/study team will communicate UVA IRB determinations, including those for initial review, continuing/annual review, modifications, and reportable events directly to the relying site.

6. Relying Site study teams will work with the UVA study team to submit the following:

(see <u>website</u> for additional information)

- 1. All local changes of protocol
- 2. Information for any applicable continuing reviews for your site
- 3. Reportable events (e.g., noncompliance, unanticipated problems) that occur at your site and meet the Reviewing IRB's requirements for reporting
- 4. Significant subject complaints that you receive (e.g., those that could affect the conduct of the ceded research)
- 5. Subject injuries that you are informed of related to the research
- 6. New or updated management plans for any potential financial conflicts of interests relevant to the ceded research
- 7. Closure report for your site

7. Continuing Review

Each relying site will provide the local UVA study team with information regarding enrollment at the time of the continuation. The UVA study team will submit one protocol status report that will detail relying site(s) study information.

8. Recruitment

The UVA study team will submit recruitment material on behalf of all or some of the relying participating sites as requested. Materials must include the local investigator-specific contact information of the relying site. The UVA IRB may directly contact the relying site study team to discuss site-specific brand issues if necessary. The UVA IRB will review and approve the recruitment material, and the UVA study team will disseminate the approved recruitment material.