|  |
| --- |
| **UVA Study Team Responsibilities &****Relying Site Study Team Responsibilities when the UVA IRB is serving as the Single IRB of Record** |

**UVA Study Team Responsibilities**

* For NIH funded research, obtain a Letter of Support, as required from the UVA IRB to include in the NIH grant submission
* Creating a grant budget that reflects the additional costs associated with UVA acting as the IRB of record. For example:
* The administrative cost of covering IRB oversight for external sites
* Large scale, complex projects should budget to hire a Research Coordinator and/or Project Manager. A program manager may be required to coordinate the project on a national level.
* Submission of initial protocol and consent(s), modifications, continuing review and reportable events to the UVA IRB according to HRPP standards.
* Notify the relying sites of all determinations and communications form the UVA IRB, including those for initial review, continuing review, modifications and reportable events.
* Make available relevant IRB minutes, IRB membership rosters, and standard operating procedures to the relying organization upon request
* Assist the relying sites to ensure consent documents include applicable site-specific required language
* Dissemination of IRB approved study materials to relying sites (e.g. consent, authorizations forms, protocol, and recruitment material).
* Ensuring that all engaged UVA study team members and the relying sites study teams have completed required human subject protection training.
* Ensuring that all engaged UVA study team members have declared any Conflicts of Interest (COI) and implementing any COI management plans required by the UVA Conflict of Interest committee.
* Act as the primary contact for the Relying Site research teams and the UVA IRB.
* Ensuring that all institutional requirements have been met (Data Use agreement, and/or Material Transfer Agreement).
* Provide access, upon request, to study records for audit by the relying site and other regulatory or monitoring agencies.
* Follow all requirements of the Relying Institution with regard to ceded review requirements and acknowledgment, before study activation occurs at a Relying Institution.

**Relying Site Study Team Responsibilities**

The Relying Site Study Teams, are responsible for providing the information or performing the activities described below related to the reliance review process and once IRB review has been ceded and approved by the UVA IRB-HSR:

* Follow all requirements of their home institution with regard to ceded review, such as ensuring other reviews or sign-offs required by the institution have been completed before a study is activated.
* Promptly respond to questions or requests for information from the UVA study team as well as from the UVA IRB through the communication mechanism(s) established.
* Work with the UVA study team to incorporate site-specific required language into the consent to be used at their institution.
* Provide the sponsored programs office at their institution with documentation that IRB oversight for a study has been ceded to and approved by the UVA IRB-HSR.
* Provide the IRB at their home institution with information regarding local Site Investigator or other Relying Site Study Team personnel changes.
* Report to their home IRB, any changes in conflict of interest (COI) disclosures and resulting changes in COI management plans related to the Research (i.e., the specific study or studies ceded to the UVA IRB).
* Promptly report to the UVA study team, any changes (including funding changes and change to PI), reportable events, and continuing review progress reports, for submission to the UVA IRB in accordance with their policies and procedures for timing and content of such submissions.
* Promptly report to the UVA Study team, any unanticipated problems involving risks to subjects or others, subject injuries related to the research, or significant complaints that could impact the conduct of the Research (i.e., the specific study or studies ceded to the UVA IRB) in accordance with the UVA IRB’s policies and procedures for timing and content of such submissions. Significant complaints are defined as those that cannot be resolved by the study team and a) suggest an increased or unexpected new risk or harm or b) change the risk/benefit ratio of the research. Other complaints should be reported in accordance with UVA IRB’s policies and procedures.
* Promptly report to the UVA Study team, any potential noncompliance that occurs in relation to the research (i.e., the specific study or studies ceded to the UVA IRB) in accordance with the UVA IRB’s policies and procedures for timing of submission and content of such submissions.
* Provide, upon request, access to study records for audit by the local UVA study team, the UVA IRB and other regulatory or monitoring entities.