**University of Vermont**

**Study Team Meeting Regarding External IRB Reliance**

As Principal Investigator at the **Relying Institution** for a study that may be overseen by an external IRB, you should be aware of your responsibilities. Once you have agreed to collaborate with an investigator at another institution and intend to use an external IRB for oversight of this study:

|  |  |
| --- | --- |
| Attendees: |  |
| Date: |  |
| Protocol: |  |

**Your Responsibilities to the External IRB**

Promptly respond to questions or requests for information from the Lead Study Team (or their designee) as well as from the Reviewing IRB.

Participate, as required, in conference calls regarding a study as requested by the Lead Study Team, Reviewing IRB, or your local IRB/HRPP.

Become familiar with the reportable event policy of the Reviewing IRB to ensure that you appropriately report protocol deviations, noncompliance, significant subject complaints, subject injuries, unanticipated problems, or other events required by the Reviewing IRB to be reported and within the timeframes required. Does PI have access to the Reviewing IRB’s policies and procedures?

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For externally funded studies, provide Sponsored Projects Administration (SPA) with documentation that IRB oversight for a study has been ceded to and approved by an external IRB.

Notify the lead PI of:

* Any reportable events that occur locally, according to regulations and the Reviewing IRB’s policy.
* Any changes (including those related to funding and personnel) in accordance with the Reviewing IRB’s policies and procedures for timing and content of such submissions.
* Any conflict of interest management plans, including any updates to these plans, as relevant to the study.
* Any applicable information for continuing review progress reports in accordance with the Reviewing IRB’s policies and procedures for timing and content of such submissions.

Follow all determinations of the Reviewing IRB.

Only implement changes of protocol, including local variations, after the Reviewing IRB has approved them, except in cases where a change is required to avoid an apparent immediate hazard to participants.

Provide, upon request, access to study records for audit by the Reviewing IRB’s institution, and other regulatory or monitoring entities.

**Your Responsibilities to the UVM IRB**

Ensure that all local reviews and sign offs that, in addition to IRB approval, are in place before a study is activated, such as coverage analysis, department approvals, data use agreements, material transfer agreements, ancillary committee reviews (e.g., radiology, nursing, and pharmacy).

Register the study at your institution according to local processes, such as creating a shell study in the local electronic system and uploading documents received.

* Final approved protocol and consent document
* Data Management and Security Plan
* Key Personnel

Notify UVM IRB of any staff changes so they can confirm their training is current and help ensure any relevant COI management plans are communicated to the Reviewing IRB.

Develop and maintain delegation of responsibility document.

Notify the UVM IRB of:

* Any reportable events that occur locally, according to regulations and the UVM IRB’s policy.
* Any changes in PI or Key Personnel.
* Noncompliance
* Protocol changes affecting the required consent form language
* Protocol Closure Locally
* Protocol Closure on National level

Notify the UVM IRB if you are requested to provide access to study records for audit by the External IRB’s institution and other regulatory or monitoring entities as per the institutional Audit Policy.

Discuss level of risk and whether monitoring visits will be required.

Signatures attests that each of the items listed above were reviewed, and that the study team has an understanding of their responsibilities in ensuring protection of human subjects in the absence of UVM IRB review.

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PI Signature and Date

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IRB Representative and Date