University of Vermont

Study Team Meeting Regarding External IRB Reliance

As Principal Investigator at the **Relying Institution** for a study that is 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, you have the following responsibilities:

Attendees:	
Date:	
Protocol:	
External IRB:	

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. External IRB SOPs:

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☐ 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.

☐ Create and maintain a Regulatory Binder and documentation in accordance with Good Clinical Practice and ALCOA-CCEA principles.

☐ 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 UVM and the UVM IRB

☐ Register the study in UVMClick and upload required documents per UVM Policy (Section 13.3):
- Final External IRB approved protocol and local consent document(s)
- Data Management and Security Plan
- Request to Rely Form
- Initial study-wide approval and UVM site approval from External IRB
- Key Personnel
- Funding source and Funding Proposal number
- Other locally relevant documents as required

☐ Ensure all local institutional reviews and sign offs, in addition to IRB approval, are in place before a study is activated, such as billing coverage analysis, department approvals, data use agreements, material transfer agreements, ancillary committee reviews (e.g., , investigational drug services, PRMC, etc).

☐ 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 UVM IRB of any staff or PI 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, protocol deviation, training, and adverse events documentation.

☐ Notify the UVM IRB of ongoing submission requirements, including:
- Any reportable events that occur locally according to regulations and the UVM IRB's policy (Section 18.1). Please note there are specific criteria for reporting to UVM and not all events require local reporting on External IRB studies.
- All changes in local PI or Key Personnel
- Changes in funding
- Protocol changes affecting the required local consent form or HIPAA 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 per Section 18.1

☐ Provide, upon request, access to study records for QualityAssurance post approval monitoring by the UVM IRB per UVM Policy (Section 26.1). Investigators must provide the UVM QA team with:
- All versions of the External IRB-approved protocol and consent documents that have been approved for use at UVM;
- Regulatory determinations made by the External IRB regarding modifications, reportable new information and CAPAs as applicable;
- All local participant records including source documentation and consent;
- Regulatory binder;
- Access to local documentation as necessary, including REDCap, shared drives or local servers;
- Access to the External IRB or Lead Site's regulatory submission platform, eConsent module, EDC, or other platforms as necessary for the QA team.

Signatures attests that each of the items listed above were reviewed, and the PI and relevant KP (those responsible for communications with and regulatory submissions to the External IRB and/or lead site and UVM) have an understanding of their responsibilities in ensuring protection of human subjects in the absence of UVM IRB review.

NAME	ROLE	SIGNATURE	DATE
	IRB Representative		
	Principal Investigator		
	Study Coordinator		