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| **Study Information** | |
| Principal Investigator: |  |
| Study Title: |  |
| IRB Control Number: |  |

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:

You should contact the IRB personnel at Jefferson to:

Discuss whether ceding IRB oversight to an external IRB is appropriate.

Provide them with details about the study (including your study team’s role), the proposed reviewing IRB, and the lead investigator’s name and institution.

* + - Obtain a copy of the studywide protocol and template consent documents(s), which will help facilitate the discussion with the Jefferson IRB.

If Jefferson IRB agrees to cede review to an external IRB, you will be asked to:

Provide the Jefferson IRB with:

* + - The names and roles of all key study personnel on the local study team
    - Any management plans for potential conflicts of interest (COI) relevant to the study that will be ceded to the external IRB, including any new or altered management plans put in place throughout the lifespan of the study.

Submit the study in iRIS and upload all required documents.

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 the Jefferson IRB.

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.

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).

Work with the Lead Study Team and the Jefferson IRB to incorporate locally required language into the consent template to be used by the local study team, such as institutionally required compensation for injury language, HIPAA language, MCARE language, local study team contact information, and additional costs that subjects may incur that differ from those identified in the template consent form.

For externally funded studies, provide your sponsored programs office with documentation that IRB oversight for a study has been ceded to and approved by an external IRB.

Notify the Jefferson 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.

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 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 Jefferson, the Reviewing IRB’s institution, and other regulatory or monitoring entities.

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| Investigator Signature | Date |
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