PI WORKSHEET: Continuing Review when Relying on an External IRB

Use for both continuing review and as a final report to close a protocol. If modifications are being requested, submit a separate request for a modification.

 1. STUDY OVERVIEW

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| --- | --- |
| **1.1 Basic Information** | **Submission Details** |
| **1.1.1 IRB Number:** | Click or tap here to enter text. |
| **1.1.2 Short Title:** | Click or tap here to enter text. |

 2. UCI ENROLLMENT STATUS

|  |  |
| --- | --- |
| **2.1 Enrollment Status** | **Site Enrollment Details** |
| **2.1.1 Number of subjects enrolled at this site in total:** | Click or tap here to enter text. |
| **2.1.2 Number of subjects enrolled at this site since last approval:** | Click or tap here to enter text. |

 3. CURRENT UCI STATUS[[1]](#endnote-2)

**3.1 Protocol Status:** Check all that are true or not applicable.

[ ]  The protocol is permanently closed to enrollment OR was never open for enrollment.

[ ]  All subjects enrolled at this institution have completed all study related interventions OR not applicable (e.g., study did not include interventions, no subjects were enrolled).

[ ]  Collection of private identifiable information is complete OR not applicable (no subjects were enrolled).

[ ]  Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled). *(This can be checked even if a statistical center at another institution will analyze private identifiable data from subjects enrolled at this institution.)*

**If all the above are checked, this will be the last continuing review of this protocol.**

[ ]  Remaining study activities are limited to data analysis.

[ ]  Study remains active only for long-term follow-up of subjects.

**3.2 New Information:** Check all that are true or not applicable.Provide an explanation below for any items which cannot be checked.

[ ]  NO subjects have experienced unexpected harm.

[ ]  Anticipated Adverse Events have NOT taken place with greater frequency or severity than expected.

[ ]  NO subjects have withdrawn from the protocol.

[ ]  There have been NO unanticipated problems involving risks to subjects or others.

[ ]  There have been NO complaints about the protocol.

[ ]  There have been NO publications in the literature relevant to risks or potential benefits.

[ ]  There have been NO interim findings.

[ ]  There have been NO multi-center trial reports.

[ ]  There have been NO data safety monitoring reports.

[ ]  There have been NO modifications to the protocol that have not been submitted to and approved by the IRB.

[ ]  There have been NO regulatory actions that could affect safety and risk assessments.

[ ]  There has been NO other relevant information regarding this protocol, such as information about risks.

[ ]  In the opinion of the principal investigator, the risks or potential benefits are unchanged.

[ ]  All problems that require prompt reporting to the IRB have been submitted.

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|  Click or tap here to enter text. |

 4. UCI INFORMATION

**4.1 Study Team:** Review the Study Team section and specify if there have been any changes in the study team's related financial disclosable interests.

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| --- |
|  Click or tap here to enter text. |

* 1. **Study Progress:** Provide a brief summary of the progress of the protocol.

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|  Click or tap here to enter text. |

 5. INVESTIGATOR ACKNOWLEDGEMENT

[ ]  I will conduct this protocol in accordance with Reviewing IRB’s requirements and any relevant UCI requirements.

1. This refers to the status of the protocol under the supervision of the investigator, not the status of the protocol at all centers. [↑](#endnote-ref-2)