This form should be completed by external sites ceding IRB review to Jefferson. This form must be updated and submitted to Jefferson IRB for review during initial onboarding, late onboarding of a site(s) or continuing review. Please check below as appropriate.

|  |
| --- |
| **General Information** |
| External Site Name |  |
| External Site PI |  |
| Jefferson PI |  |
| Study Title |  |
| Jefferson IRB Control Number |  |

**Please select One:**

[ ]  Initial Onboarding

[ ]  Late Onboarding

[ ]  Continuing Review

**Please complete section at time of onboarding only:**

|  |
| --- |
| Ethical Concerns |
| [ ]  The following ethical concerns have been identified pertaining to the community from which research participants will be recruited: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |
| --- |
| Biosafety Review |
| [ ]  Biosafety review is not necessary [ ]  Biosafety Review has been completed by Relying Institution. |

|  |
| --- |
| Radiation Safety Review |
| [ ]  Radiation Safety review is not necessary[ ]  Radiation Safety Review has been completed by Relying Institution. |

|  |
| --- |
| Local Review |
| Applicable state or local laws, regulations, policies, and ancillary review processes are relevant to this study.[ ]  Yes (provided in Local Context Questionnaire) [ ]  No |

**Please complete section at time of onboarding only:**

|  |
| --- |
| Conflict of interest (COI) certification for study personnel at the external site |
| * This form must be signed during initial onboarding by an official of the institution’s Research Compliance Office or with the authority to make these certifications on behalf of the institution who can certify that researchers on this study have been investigated for conflicts of interest, and, if applicable have developed and proposed a management plan according to that institution’s requirements for the Jefferson IRB to consider when reviewing the study.
* The institutional official signing this form also certifies that they will monitor for future conflicts to ensure that investigator’s COI disclosure is current according to their requirements.
* The institution is responsible for promptly notifying the Jefferson IRB of any potential conflicts for any of the investigators on this study.
* This certification must be provided for all personnel on the study performing research with human subjects.
* In lieu of providing proof of COI investigation, research personnel may complete Jefferson’s COI disclosure to meet requirements.
* Make sure this form is updated at time of late onboarding or continuing review

 [ ] The investigators have not identified any secondary financial interests related to this study [ ] The Investigator have identified secondary financial interests related to this study. Please find attached the  approved Conflict of Interest Management Plan. |

**Please complete section at time of onboarding and at time of Continuing Review:**

|  |
| --- |
| Training certification for study personnel at the external site |
| * Training certification will only be accepted from sites that have an FWA registered Human Research Protection Program (HRPP).
* This form must be signed by an official of the institution’s Research Compliance Office or with the authority to make these certifications on behalf of the institution who can certify that researchers on this study meet the requirements for performing this study with human subjects according to that institution’s requirements.
* The institutional official signing this form also certifies that they will monitor training to ensure that investigator’s training is current according to their requirements.
* The institution is responsible for promptly notifying the Jefferson IRB of any lapses in training for any of the investigators on this study.
* This certification must be provided for all personnel on the study performing research with human subjects
* Make sure this form is updated at time of late onboarding or continuing review
 |

**Please complete section at time of onboarding and at time of Continuing Review:**

|  |  |  |  |
| --- | --- | --- | --- |
| PI/Study Team Member | Role | Email | Involvedin consent |
|  |  |  | ☐ |
|  |  |  | ☐ |
|  |  |  | ☐ |
|  |  |  | [ ]  |
|  |  |  | [ ]  |
|  |  |  | [ ]  |
|  |  |  | [ ]  |
|  |  |  | [ ]  |
|  |  |  | [ ]  |

|  |  |
| --- | --- |
| Name of Certifying Official |  |
| Title |  |
| Email |  |
| [ ]  I certify that the study personnel have been investigated for potential conflicts of interest and that if required, management plans for identified conflicts have been developed and submitted to the Jefferson IRB for review, and that their COI disclosure will be monitored for compliance for the duration of their participation on this study. |
| [ ]  I certify that the study personnel are qualified and have been properly trained according to our Human Research Protection Program to carry out their duties, as described for this study, and that their training will be monitored for compliance for the duration of their participation on this study. |
| Signature | Date |
|  |  |