**Institutional Review Board**

Phone: 215-573-2540

**Exception Request Form**

FULL PROTOCOL TITLE**:**

PROTOCOL #:

PENN PRINCIPAL INVESTIGATOR**:**

**IRB APPROVAL EXPIRATION DATE:**

|  |
| --- |
| *Use this form to request permission of a single protocol exception. A protocol exception is a one time, intentional action or process that departs from the IRB-approved study protocol, intended for one occurrence or applied to a single individual. This action is approved by the sponsor or funding agency, IRB, and the FDA, if applicable, prior to its implementation. An example of an exception may include the enrollment of a research participant who fails to meet all of the protocol eligibility criteria.*  **Before completing this form please see** [**exception request guidance and definitions**](http://www.upenn.edu/IRB/exceptions)  **DOCUMENTS REQUIRED FOR EXCEPTION APPROVAL:** Please provide one copy of the following:  - Completed exception request form  - Documentation of sponsor approval (if applicable)  - Documentation of medical monitor approval (if applicable)  - All IRB submissions for Greater Than Minimal Risk research must include a complete list of documents being submitted for review as they should appear in your determination letter (document name, version #, date) |

|  |  |  |
| --- | --- | --- |
| 1. **Who should the IRB contact with questions?** *Note: If Penn is serving as the Single IRB (IRB of Record) for a multi-site protocol, please list the name and contact information for the designated Point of Contact who is creating and submitting this exception in HSERA.* | | |
| Name: | Telephone: | |
| Penn Email: | | |
| Is this a multi-site study where Penn is serving as the Single IRB or IRB of record for external sites? | | **YES** **NO** |
| ***If Yes,*** please identify the site where the exception will occur in the text box below and provide  the names, email addresses & phone numbers for the site Investigator and Study Contact that  the IRB can contact with questions related to the substance of the modification. | | |
|  | | |

|  |  |
| --- | --- |
| 1. **Additional Approvals:** Please indicate the additional approvals obtained for this exception | |
| 1. Has the sponsor approved this exception request? | YES NO |
| ***If “No,”*** *please provide rationale in the box below:* | |
|  | |
| 1. Has the Medical Monitor approved this exception request? | YES NO |
| ***If “No,”*** *please provide rationale in the box below:* | |
|  | |
| 1. Are other approvals required (FDA, DSMB, etc…)? | YES NO |
| ***If “Yes,”*** *please elaborate and provide approval status in the box below:* | |
|  | |

|  |  |  |
| --- | --- | --- |
| 1. **Exception Summary:** Please provide the following details for the exception being requested. Where applicable, please reference specific pages of the IRB approved protocol where alterations are proposed. | | |
| 1. Date or time frame for the proposed exception   *Please be specific as to when you would need IRB approval by; if the exception is related to an already scheduled study visit, please also include the time of the appointment*. | |  |
| 1. Is this a time sensitive request *(approval needed in < 2 days*)? | YES NO | |
| **If “Yes,”** please provide a rationale to explain the time sensitivity: | | |
| 1. Description of protocol exception: | | |
|  | | |
| 1. Rationale for proposed exception: | | |
|  | | |
| 1. Plans for communicating information about this exception to the affected participant, as applicable.   *Please Note: If an addendum consent form or telephone script has been created to communicate information about the exception to the participant, please note this here and attach a copy of the relevant document(s)*: | | |
|  | | |

|  |
| --- |
| 1. **Assessment:** To determine the level of review required please address the following: |
| 1. Will this exception request pose an additional risk to subjects? Why or Why not? |
|  |
| 1. Is this exception request in the best interest of the subject? Why or Why not? |
|  |

|  |  |
| --- | --- |
| 1. **Protocol Impact:** To determine impact on the protocol, please answer the following questions: | |
| 1. Will this exception request compromise the data obtained from the subject? Why or Why not? | |
|  | |
| 1. Has this exception been requested previously on this protocol? | |
| **YES** | **NO** |
| 1. **If “Yes”:** Please identify the confirmation code(s) under which the exception was previously submitted:      1. **If “Yes”:** Will these exceptions have any potential adverse impact on the data/scientific integrity of the study as a whole? Why or Why not? | 1. **If “No”:** Please provide an explanation as to why this action is a one-time occurrence: |
| 1. Please provide a description of any plans to modify the protocol OR rationale for not revising the protocol: | |

|  |
| --- |
| **Completion of exception: (This section not required if submitting via HSERA)**  By signing this form the principal investigator and the person completing the form (if other than the investigator) certify that he/she has disclosed to the IRB all relevant information that might affect the risk to benefit analysis of this study.  If the PI is unable to sign due to the timing of the exception request, the IRB will accept an email from the PI approving the request. |

Name of person completing this form:

Signature of person completing the form:

Principal Investigator Name:

Principal Investigator Signature:

Date:

|  |
| --- |
| **FOR IRB USE ONLY** |

APPROVED EXPEDITED

REFERRED FOR CONVENED BOARD REVIEW

Final Reviewer notes:

Signature of Final Reviewer: DATE: