

**Institutional Review Board**

3800 Spruce Street

First Floor Suite 151

Philadelphia, PA 19104-6006

Phone: 215-573-2540

**Closure Request Application**

FULL PROTOCOL TITLE**:**

PROTOCOL **#:**

PRINCIPAL INVESTIGATOR**:**

EXPIRATION DATE**:**

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| ***If IRB Approval Expired****: No research related activities may occur after the protocol expiration date, unless the PI contacts the IRB in advance and it is determined that continuation during expiration is appropriate for subject safety. In the space below please indicate if any activity has occurred during the lapse in approval. If yes, please describe the activity in the space provided:* |
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| 1. **Who should the IRB contact with questions?** | |
| Name: | Telephone: |
| Penn Email: | |

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| 1. **Please indicate the reason for closing the study as well as any additional necessary information:** |
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| 1. **Did the research result in any publications (or are any publications pending)?**   YES NO -if Yes feel free to provide references in the space below |
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| 1. **Please identify your study’s funding source:** |
| Industry Funding Federal Funding Internal Penn Funding Other No Funding |

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| 1. **To assess whether closing is appropriate, please complete the following:** | |
| 1. **For All Studies:** | |
| * + Have all subjects completed all study related visits and procedures?   ***\*If no****, closure with the IRB is not appropriate at this time* | YES NO |
| * + Is any further contact with subjects needed for reasons related to research?   *\*****If yes****, closure with the IRB is not appropriate at this time.* | YES NO |
| * + Is any further access to identifiable subject data required for research purposes (data analysis, manuscript preparations, etc.)?   *\*****If yes****, closure with the IRB is not appropriate at this time.* | YES NO |

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| 1. **For Industry Sponsored Studies Only:** | |
| * + Has the sponsor completed a close out visit at all Penn study sites? | YES NO |
| *\*****If no****, closure with the IRB is not appropriate at this time or clarification is required from the sponsor stating that a site visit will not be conducted.*  *\*****If yes****, please provide a copy of the sponsor’s closeout visit letter or other documentation indicating that closure with the IRB is appropriate at this time.* | |

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| 1. **Outstanding Items Assessment:** | |
| 1. Are there any pending actions related to previously submitted items (Modifications, Exceptions, Deviations, Reportable Events) that have not yet been addressed or any items not previously submitted to the IRB that require submission to the IRB at this time? | YES\* NO |
| *\*****If yes****, closure with the IRB is not appropriate at this time. Please contact an IRB Administrator to rectify any previously submitted items that have not been fully processed prior to submitting for closure.* | |
| 1. **Investigator Initiated Trials ONLY:** Have results been posted to Clinical Trials.gov?   CT.gov posting may be required for any study that meets the NIH definition of a clinical trial: “*A research study in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.”* Please refer to the CT.gov [flow chart](https://irb.upenn.edu/sites/default/files/CT.gov%20registration%20flowchart%20SM.IB.pdf) for more information.  Note: “Interventions” may include but are not limited to a drug or device product, a treatment procedure or surgery, a social-behavioral intervention, etc. | |
| YES: Please submit a copy of the confirmation that results were received.  NO: Closure with the IRB is not appropriate at this time. Please submit results to CT.gov before submitting a closure request to the IRB.  NA: Study oversight is conducted by an industry sponsor who is responsible for CT.gov posting.  NA: Study does not meet the NIH criteria of a clinical trial or it was determined that posting was not required. | |

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| 1. **Closure Form Completion: This section NOT required when 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. [Click to review PI Responsibilities](http://www.upenn.edu/IRB/mission-institutional-review-board-irb/guidance/agreements) |

Name of person completing this form:

Signature of person completing the form:

Principal Investigator Name:

Principal Investigator Signature:

Date:

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| **IRB USE ONLY** |

**Date of Screening:**

* + Are all basic requirements for closure satisfied by this application**:** YES NO

-If No please summarize outstanding issues and responses:

* + If Industry Sponsored:

- Have all additional requirements been satisfied? YES NONA

-If No please summarize outstanding issues and responses:

- Has the business administrator verified payment from the sponsor? YES NONA

-If payment issues exist please note and do not place for final approval until resolved:

* + Screener’s final recommendation and reviewer assignment:

**APPROVED VIA EXPEDITED IRB REVIEW:**

**Issue(s) Identified – Referred to IRB Staff with Instructions**

**Signature of Expedited Approver: DATE:**