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| IRB#      [ ]  Initial Report[ ]  Follow-up Report | IND#       | IDE#       | IRB ONLY |
| **Part A – Demographic Information** |
| Study Title:       |
| Principal Investigator  |
| Name:       | Title:       |
| School:       | Department:       | Division:       |
| Email:       | Phone:       | Fax:       |
| Study Coordinator (list the person to be contacted) |
| Name:       |  |  |
| Email:       | Phone:       | Fax:       |
| **Part B – Study Site Information** |
| Indicate all sites where research procedures will be performed |
| [ ] University of Pittsburgh  | [ ] Center for Emergency Medicine of Western PA, Inc. |
| [ ] UPMC Presbyterian  | [ ] UPMC Center for High-Value Healthcare |
| [ ] UPMC Children’s Hospital  | [ ] UPMC Passavant | [ ] Sherwood Oaks UPMC |
| [ ] UPMC Magee Women’s  | [ ] UPMC McKeesport | [ ] The Heritage-Shadyside UPMC |
| [ ] UPMC Western Psychiatric Institute  | [ ] UPMC Northwest |  |
| [ ] UPMC Mercy  | [ ] UPMC Horizon | [ ] UPMC Cancer Centers: List all sites       |
| [ ] UPMC Shadyside  | [ ] UPMC Bedford |
| [ ] UPMC East | [ ] UPMC Cranberry Place | [ ] Other (specify):       |
| [ ] UPMC St. Margaret | [ ] UPMC Seneca Place |
| **Part C – Source of Support** |
| Indicate all sources of support |
| [ ]  Federal | Name of Sponsor:       |
|  | Awardee Institution:       |
|  | Grant #:       |
|  | Grant Title:       |
| [ ]  Commercial | Name of Sponsor:       |
| [ ]  Foundation | Name of Sponsor:       |
| [ ]  Other | Name of Sponsor:       |
| [ ]  No support |
| **Part D – Event Information** |
| 1. Date initially observed:
 | 1. Date reported to PI:
 |
| 1. If applicable, identify the subjects involved, using initials or case # (no names!):
 |
| 1. Is it your intention to create a modification in response to this unanticipated problem? [ ]  Yes [ ]  No

If **Yes**, submit with this report or indicate when it will be submitted:       |

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| 1. Describe the event which occurred during the conduct of the research (e.g., subject ID and characteristics, timeline of events, persons involved). Provide a detailed description of the event. It is very important that you submit a **comprehensive summary** of the event to facilitate IRB review.
 |
| 1. Explain the reason the problem occurred:
 |
| 1. Indicate whether the described unanticipated problem involves risk to human subjects or others (for each problem, indicate the risk to each individual person or to the study population in general):
 |
| 1. If the unanticipated problem was a deviation from the protocol, explain why you did not prospectively obtain the approval from the University of Pittsburgh IRB. Indicate in the textbox if not applicable:
 |
| 1. What steps have been taken to resolve the problem and procedures implemented to avoid future occurrences:
 |
| 1. Do you feel that the currently enrolled subjects should be notified of this unanticipated problem? [ ]  Yes [ ]  No

If **Yes**, provide a rationale and describe how you plan to provide notification:      [Note that the University of Pittsburgh IRB will make the final determination as to whether subjects should be notified and all communications must first be approved by the IRB before dissemination to the subjects.] |
| 1. To what other groups has this unanticipated problem been reported:

|  |  |
| --- | --- |
| [ ]  Sponsor | [ ]  Coordinating Center |
| [ ]  FDA | [ ]  Office for Human Research Protections (OHRP) |
| [ ]  DSMB | [ ]  Other |
| [ ]  Institutional Biosafety Committee (rDNA) | [ ]  No External Report |
| [ ]  Office of Biotechnology Activities (OBA) | [ ]  RCCO Education and Compliance Office |

If Other, indicate to whom it has been reported and attach a copy of the report sent:       |

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| **Part E – Certification of Investigator Responsibilities** |

1. I have reviewed this protocol submission in its entirety and that I am fully cognizant of, and in agreement with, all submitted statements.
2. I have adequate resources and facilities to carry out the proposed research.
3. I will conduct this research study in strict accordance with all submitted statements except where a change may be necessary to eliminate an apparent immediate hazard to a given research subject.
4. I will notify the IRB promptly of any change in the research procedures necessitated in the interest of the safety of a given research subject.
5. I will request and obtain IRB approval of any proposed modification to the research protocol or informed consent document(s) prior to implementing such modifications.
6. I will ensure that all co-investigators, and other personnel assisting in the conduct of this research study have been provided a copy of the entire current version of the research protocol and are fully informed of the current (a) study procedures (including procedure modifications); (b) informed consent requirements and process; (c) potential risks associated with the study participation and the steps to be taken to prevent or minimize these potential risks; (d) adverse event reporting requirements; (e) data and record-keeping requirements; and (f) the current IRB approval status of the research study.
7. I will not enroll any individual into this research study: (a) until such time that the conduct of the study has been approved in writing by the IRB; (b) during any period wherein IRB renewal approval of this research study has lapsed; (c) during any period wherein IRB approval of the research study or research study enrollment has been suspended, or wherein the sponsor has suspended research study enrollment; or (d) following termination of IRB approval of the research study or following sponsor/principal investigator termination of research study enrollment.
8. I will respond promptly to all requests for information or materials solicited by the IRB or IRB Office.
9. I will submit the research study in a timely manner for IRB renewal approval.
10. I will not enroll any individual into this research study until such time that I obtain his/her written informed consent, or, if applicable, the written informed consent of his/her authorized representative (i.e., unless the IRB has granted a waiver of the requirement to obtain written informed consent).
11. I will employ and oversee an informed consent process that ensures that potential research subjects understand fully the purpose of the research study, the nature of the research procedures they are being asked to undergo, the potential risks of these research procedures, and their rights as a research study volunteer.
12. I will ensure that research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the research study.
13. I will maintain adequate, current, and accurate records of research data, outcomes, and unanticipated problem reports to permit an ongoing assessment of the risks/benefit ratio of research study participation.
14. I am cognizant of, and will comply with, current federal regulations and IRB requirements governing human subject research including unanticipated problem reporting requirements.
15. I will make a reasonable effort to ensure that subjects who have suffered an adverse event associated with research participation receive adequate care to correct or alleviate the consequences of the adverse event to the extent possible.
16. I will ensure that the conduct of this research study adheres to Good Clinical Practice guidelines.
17. I will ensure that all listed investigators and research staff have the appropriate credentials to conduct the portion of the study in which they are involved.

Principal Investigator:

Principal Investigator Signature:

Date Signed:

**Submission Instructions**

Submit (1) copy of the required documents by email or deliver directly to the IRB Office

1. E-mail askirb@pitt.edu

or deliver to:

1. University of Pittsburgh
Human Research Protection Office
3500 Fifth Avenue

Suite 106

Pittsburgh, PA 15213

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| **For IRB Use Only** |
| [ ]  Additional information Required |
| [ ]  Refer to IRB Committee |
|  [ ]  may represent unanticipated problem involving risk to human subjects or others (unanticipated, serious, and possibly or definitely related to the research) |
|  [ ]  may represent serious non-compliance |
|  [ ]  may represent continuing non-compliance |
| [ ]  File only |

Chair/Vice Chair Signature:

Date Signed: