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| --- | --- | --- | --- |
| IRB#       | IND#       | IDE#       | IRB ONLY |
| **Reason for Submission** | **Review Requested** |
| Modification | [ ]   | Expedited [ ] Full Board [ ]  |
|  |
| **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 – Ancillary Reviews** |
| 1. Do the proposed modifications substantially alter the specific aims or scientific design of the research study? [ ]  Yes [ ]  No
2. If **Yes**, attach the new scientific review approval letter
 |
| 1. Do any of the proposed modifications materially affect an assessment of the risks and benefits of the research study or substantially change its specific aims or methodology? [ ]  Yes [ ]  No
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| 1. Do the proposed modifications add/remove/change any procedures performed in a UPMC facility during the conduct of your research study? [ ]  Yes [ ]  No
2. If **Yes**, you must obtain approval from The UPMC Office of Sponsored Programs and Research Support (OSPARS) for the requested changes ( IRB review can occur without the OSPARS approval letter)
 |
| 1. Do the proposed modifications include the addition of investigators or research coordinators who will be involved directly in the performance of research-related medical procedures or tests? [ ]  Yes [ ]  No
2. If **Yes**, has it been verified that all new members of the research team have the appropriate expertise and credentials to perform those research procedures that are their responsibility as outlined in the IRB protocol?[ ]  Yes [ ]  No
 |
| 1. Have there been any changes to an investigator status which result in a change to the current **Conflict of Interest** questions? Refer **to Part G** for the series of COI questions.[ ]  Yes [ ]  No
2. If **Yes**, attach the new COI approval letter
* Review the current COI questions carefully before responding
* For example, has any investigator recently obtained a financial interest in the study sponsor or in the technology being evaluated, or has a new investigator been added who has a reportable conflict?
* To prevent delays in processing, do not answer ‘yes’ unless the responses to the questions have changed
 |
| 1. Was this research study previously approved by the HUSC (i.e., the Human Use Subcommittee of the Radiation Safety Committee) and, if so, do any of the proposed modifications alter the radiation dose that will be received by the study participants; or, if this research study was not previously approved by the HUSC, do any of the proposed modifications incorporate;
* the use or evaluation of an investigational radioactive drug or an investigational radiation-emitting device;
* an experimental intervention that involves radiation exposure; or
* any standard radiation-emitting procedures (e.g., chest X-rays, CT scans, FDG-PET studies) that are being performed for screening and/or follow-up purposes at a substantially greater frequency than what would be encountered in routine clinical practice*?* [ ]  Yes [ ]  No

(Note: “investigational” means not currently approved by the FDA for commercial marketing; “experimental intervention” means the drug or procedure being specifically evaluated in the research study)1. If **Yes**, attach the new HUSC approval letter
 |
| 1. Do any of the proposed changes to an experimental gene transfer study include the following? [ ]  Yes [ ]  No
* Inclusion/Exclusion criteria
* Primary/Principal Investigator (does not apply to co-investigators)
* Dose/dosages of experimental agents that fall under the Institutional Biosafety Committee (IBC) review
* Route or method of administration of experimental agents that fall under IBC review
* Follow-up or post-procedural tests that are directly related to the administration of experimental agents that fall under IBC review
* FDA or IND required modifications due to safety concerns related to the administration of experimental agents that fall under IBC review
1. If **Yes**, attach the new IBC approval letter
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| **Part E – Current Status** |
| Select your options carefully: If any of the "Permanently closed to additional enrollment" options are selected, enrollment cannot be re-initiated unless a New Study is submitted |
| [ ]  R**emains ongoing** (***open to additional enrollment***) |
| [ ]   **Remains ongoing** (***permanently closed to additional enrollment but subjects continue to undergo research-related activities*** |
| [ ]  **Remains ongoing (*permanently closed to additional enrollment and subjects have completed all research activities but the research remains active for long-term follow-up of subjects\**).** Renewal may be expedited**\***Note that the IRB considers long-term follow-up to be limited to review of medical records (i.e., information collected for clinical purposes) and checking for survival status either through contact with the subject or by a review of the National Death Index). |
| [ ]  **Remains ongoing (*the ONLY research activity is data analysis*).** Renewal may be expedited |
|  |
| **Part F – Subject Activity** |
| 1. How many subjects have been entered into this research study since initial IRB approval?
 |
| 1. What is the total number of subjects to be enrolled at this site, including subjects to be screened?
 |
| 1. Will currently enrolled subjects be re-consented? [ ]  Yes [ ]  No
2. If Yes, describe in detail the re-consent process in the IRB protocol
3. Explain the rationale for your response:
 |
|  |
| **Requested wording to be displayed in approval letter:**      * Provide any language or name of documents to be displayed in the approval letter
* List only those items submitted for review with this submission
* Language may include items such as versions of investigator brochures, consent forms, and advertisements
 |

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| **Part G – Conflict of Interest** |
| **Is this study funded in part or whole by a** [**Public Health Service Agency**](http://www.coi.pitt.edu/PHS/faq.htm#PHS) **(PHS )?** **[ ]  YES, complete Section 1** **[ ]  NO, complete Section 2** |
| Contact the [Conflict of Interest Office](http://www.coi.pitt.edu) directly if you have any questions ([www.coi.pitt.edu](http://www.coi.pitt.edu)) |
| **Section 1A– PHS funded study** |
|  If **YES**, does any investigator**\*** involved in this study (select all that apply): |
| [ ]  A. Have a financial interest (aggregated value of equity and remuneration**\*\*** during the past or next twelve months) in a **publicly-traded entity** that either sponsors**\*\*\*** this research or owns the technology being evaluated or developed that exceeds **$5,000 but not $10,000**? |
| [ ]  B. Have a financial interest (aggregated value of equity and remuneration during the past or next twelve months) in a **publicly-traded entity** that either sponsors this research or owns the technology being evaluated or developed that exceeds **$10,000**? |
| [ ]  C. Receive remuneration (during the past or next twelve months) from a **non-publicly traded entity** that either sponsors this research or owns the technology being evaluated or developed that exceeds **$5,000 but not $10,000**? |
| [ ]  D. Receive remuneration (during the past or next twelve months) from a **non-publicly traded entity** that either sponsors this research or owns the technology being evaluated or developed that exceeds **$10,000**? |
| [ ]  E. Have equity in a **non-publicly traded entity** that either sponsors this research or owns the technology being evaluated or developed? |
| [ ]  F. Receive reimbursement or sponsorship of travel expenses (for one trip or a series of trips during the past or next twelve months) by an outside entity that either sponsors this research or owns the technology being evaluated or developed that exceeds **$5,000**? |
| [ ]  G. Have rights the author or inventor of **intellectual property** being evaluated or developed in this research that is the subject of an issued patent, or has been optioned or licensed to an entity? |
| [ ]  H. Have an officer or management position **\*\*\*\*** with a **Licensed Start-up Company** overseen by the COI Committee that either sponsors this research or owns the technology being evaluated or developed? |
| [ ]  I. Receive compensation of any amount when the value of the compensation would be affected by the outcome of this research, such as compensation that is explicitly greater for a favorable outcome than for an unfavorable outcome or compensation in the form of an equity interest in the entity that either sponsors this research or owns the technology being evaluated or developed? |
| [ ]  **None** of the above options apply and there are no other financial conflicts of interest in the conduct of this research. |
| **\***Investigator means the PI, co-investigators, and any other member of the study team, regardless of title, who participates in the design, conduct, or reporting of this research, as well as his/her spouse, registered domestic partner, dependents, or other members of his/her household. **The PI is responsible for ensuring that s/he and all other relevant members of the study team review the above questions describing Significant Financial Interests.** **\*\***such as salary, consulting fees, honoraria, or paid authorship**\*\*\***through the provision of funds, drugs, devices, or other support for this research**\*\*\*\***such as serving on the Board of Directors or Board of Managers or a position that carries a fiduciary responsibility to the company (e.g., CEO, CFO, CTO, or CMO) |
| **Section 1B** - If you selected any of the checkboxes other than **None**, address the following:* If you selected **B, D, E, or H**, attach a completed Standard COI Management Plan for Human Subject Research and submit it with this application.
* For all other financial interests (**A, C, F, or** **G**), the COI Office will work with you to develop an appropriate COI Management Plan.
 |
| Provide the name of the investigator(s) and describe the nature of the Significant Financial Interest(s):       |

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| **Section 2A – Not a PHS funded study** |
| If **NO**, does any investigator**\*** involved in this study (select all that apply): |
| [ ]  A. Have equity in a publicly-traded entity that either sponsors**\*\*** this research or owns the technology being evaluated or developed that exceeds a **5% ownership interest** or a current value of **$10,000**? |
| [ ]  B. Have equity in a **non-publicly-traded entity** that either sponsors this research or owns the technology being evaluated or developed |
| [ ]  C. Receive salary, consulting fees, honoraria, royalties or other remuneration from an entity that either sponsors this research or owns the technology being evaluated or developed that is expected to exceed **$10,000** during the past or next 12 months? |
| [ ]  D. Have rights as the author or inventor of **intellectual property** being evaluated or developed in this research that is the subject of an issued patent, or has been optioned or licensed to an entity? |
| [ ]  E. Have an officer or management position **\*\*\*\***with a **Licensed Start-up Company** overseen by the COI Committee that either sponsors this research or owns the technology being evaluated or developed? |
| [ ]  F. Receive compensation of any amount when the value of the compensation would be affected by the outcome of this research, such as compensation that is explicitly greater for a favorable outcome than for an unfavorable outcome or compensation in the form of an equity interest in the entity that either sponsors this research or owns the technology being evaluated or developed? |
| [ ]  **None** of the above options apply and there are no other financial conflicts of interest in the conduct of this research. |
| **\***Investigator means the PI, co-investigators, and any other member of the study team, regardless of title, who participates in the design, conduct, or reporting of this research, as well as his/her spouse, registered domestic partner, dependents, or other members of his/her household. **The PI is responsible for ensuring that s/he and all other relevant members of the study team review the above questions describing Significant Financial Interests.** **\*\***such as salary, consulting fees, honoraria, or paid authorship**\*\*\*\***such as serving on the Board of Directors or Board of Managers or a position that carries a fiduciary responsibility to the company (e.g., CEO, CFO, CTO, or CMO) |
| **Section 2B** - If you selected any of the checkboxes other than **None**, address the following:* If you selected **B, D, E, or H**, attach a completed Standard COI Management Plan for Human Subject Research and submit it with this application.
* For all other financial interests (**A, C, F, or** **G**), the COI Office will work with you to develop an appropriate COI Management Plan.
 |
| Provide the name of the investigator(s) and describe the nature of the Significant Financial Interest(s):       |

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| **Part H – Changes Requested** |
| * **Document to be edited** (e.g., protocol, consent, instrument)
* **Change from:**
* **Change to:**
* **Rationale/Justification for each requested change:**
* **Delete any unused sections below before submitting**
 |
| 1. Document to edited:      Changed From:

Changed To:      Justification:       |
| 1. Document to edited:      Changed from:

Change to:      Justification: |
| 1. Document to edited:      Changed from:

Change to:      Justification: |
| 1. Document to edited:      Changed from:

Change to:      Justification:       |
| 1. Document to edited:      Changed from:

Change to:      Justification:       |
| 1. Document to edited:      Changed from:

Change to:      Justification:       |
| 1. Document to edited:      Changed from:

Change to:      Justification:       |
| 1. Document to edited:      Changed from:

Change to:      Justification:       |
| 1. Document to edited:      Changed from:

Change to:      Justification:       |
| 1. Document to edited:      Changed from:

Change to:      Justification:       |

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| **Part F – 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 to askirb@pitt.edu

or deliver to:

1. University of Pittsburgh
Institutional Review Board (IRB)
3500 Fifth Avenue

Suite 106

Pittsburgh, PA 15213