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| IRB# | Principal Investigator: | | | |
| **Part A – 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 B – Summary of Subject Enrollment** | | | | |
| *If your protocol involves any IRB-approved method of obtaining informed consent, please complete the following enrollment summary to provide an accurate breakdown of the total number of enrolled subjects. The IRB considers subjects to be enrolled if they signed a written consent or entered under an IRB approved waiver. This includes those who did not complete the study for any reason such as ineligibility, loss-to-follow-up, or withdrawal.* | | | | |
| Total number of subjects approved by the IRB for entire duration of study (including screened subjects) | | Total number of eligible subjects approved to undergo research related procedures (target enrollment) | | |
|  | | | **Activity since last Renewal Report submitted** | **Activity since Initial IRB approval to present** |
| Total number of subjects enrolled | | |  |  |
| Subjects deemed ineligible after signing consent | | |  | **\*** |
| Subjects currently active on study or in follow-up | | | n/a | **\*** |
| Subjects withdrawn at their own/family request (e.g. subject signed consent and then changed mind or stopped at their request) | | |  | **\*** |
| Subjects withdrawn by PI due to toxicity or adverse events | | |  | **\*** |
| Subjects withdrawn by PI due to other reasons (e.g., lack of compliance, pregnancy, death due to disease progression) [address in textbox below] | | |  | **\*** |
| Subjects lost to follow-up | | |  | **\*** |
| Subjects who completed the study | | | n/a | **\*** |
| **\***Sections with an asterisk should equal the TOTAL NUMBER ENROLLED  If subjects were withdrawn by the PI due to reasons not listed above, explain:  **Review the previous Renewal Report** to ensure subject activity is correct, if a discrepancy is noted, explain: | | | | |

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| **Part C – Activity Report** |
| **All responses below should be based on activities performed during the past renewal period** |
| 1. Based on the current rate of subject accrual and your planned enrollment, will the total enrolment objective be met? If no subjects were enrolled during the past renewal period and study is open to enrollment, select No.   Yes  No   If you answer **No**,   1. provide a justification for continuing this research study: 2. address the steps that will be taken to increase subject enrollment: |
| 1. Has subject accrual reflected the racial/gender/ethnic subgroups as outlined in your protocol?  Yes  No   If you answer **No**, address the steps that will be taken to correct this deficiency: |
| 1. Were any children in foster care at the time of enrollment?  Yes  No   If **Yes**, indicate who provided consent for each child’s participation: |
| **Based on your Local Data and Safety Monitoring Plan** |
| 1. Which research personnel, based on role or position, participated in the monitoring? |
| 1. How often did the monitoring take place? |
| 1. Has the frequency or severity of the adverse event profile differed from that expected?  Yes  No If **Yes**, describe: |
| 1. Has the adverse event profile changed the risk/benefit assessment?  Yes  No   If **Yes**, describe: |
| 1. Have there been any other unanticipated problems, not previously reported, that meet the University of Pittsburgh IRB reporting guidelines (e.g., adverse events, medication or laboratory errors, unintended disclosure of confidential information or privacy issues, etc.)?  Yes  No   **If Yes, you must submit an Unanticipated Problem Report which must be available for review at the time of this renewal review.** |
| 1. Have there been any concerns or complaints by subjects or others?  Yes  No   If Yes, describe the events and explain how they were resolved: |
| 1. Have all the original signed consent forms been retained?  Yes  No   If **No**, describe: |
| 1. Are there any new preliminary findings, pertinent scientific literature reports, therapeutic developments, or results of related studies that may have an impact on the subject safety or the ethical conduct of the study?   Yes  No   If **Yes**, explain: |
| 1. Has there been any change in the risk/benefit assessment?  Yes  No   If Yes, explain: |
| 1. Have there been any changes in the financial relationship of any investigator based on the Conflict of Interest questions listed in this document (e.g., has an investigator acquired a financial relationship with the entity that either sponsors the research or owns the technology being evaluated)?   Yes  No  **If Yes, you must immediately submit a Modification which must be reviewed and approved by the Conflict of Interest Office before IRB review will occur.** |
| 1. Has this study been monitored/reviewed/audited by an outside monitor, sponsor, or agency?  Yes  No 2. If **Yes**, specify the entities that performed the review, attach summary reports, and address any deficiencies identified: 3. Attach the summary report to this submission |
| 1. Does this study have a local and/or external Data and Safety Monitoring Board (DSMB) or other Data Monitoring Committee (DMC) providing oversight of this study?  Yes  No 2. If **Yes**, specify the entity that performed the review, attach summary reports, and address any deficiencies identified: 3. Attach the summary report to this submission |
| **Drug and Device Studies** |
| 1. Does your study involve drug or device research?  Yes  No   If **Yes**, address the next series of questions:   1. Since the time of the last continuing review, has this study been inspected by the FDA?  Yes  No   If **Yes**, attach a copy of the FDA report and response provided with this submission   1. Does the research involve a University of Pittsburgh based sponsor-investigator IND/IDE application?  Yes  No 2. Have there been any problems or concerns related to drug and/or device accountability?  Yes  No   If **Yes**, and previously reported, you must submit an Unanticipated Problem Report with this submission |
| **rDNA and Industry Sponsored Studies** |
| 1. Does this research study involve an experimental gene transfer intervention?  Yes  No   *The most current versions of supporting documentation must be available for review. These include but are not limited to Appendix M for gene transfer studies, sponsor protocols and IND/IDE brochures. You may need to create a Modification which must be submitted at the same time as this Renewal Report.* |
| 1. Is this research study industry sponsored?  Yes  No   If **Yes**,   1. Are you requesting a waiver of the industry fee for IRB continuing review of this research study?  Yes  No 2. If Yes, provide a justification for the request: |
| **Part D - Renewal Report Conclusion** |
| 1. Based on your review of all data and safety information, should this study continue unchanged?  Yes  No   If **No**, describe your plans: |
| 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 E** 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 |

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| **Part E – 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): |

**Submission Instructions**

The following documents are required for all Renewal Report Submissions:

1. Renewal Report for Paper Submissions
2. Protocol
3. Consent
4. Industry sponsored – attached the current version of the sponsor clinical protocol and investigator brochure