Date:

To: **NHGRI IRB**

From:

Subject: Continuing Review Cover Memo

Protocol ID#:

Protocol Title:

Expiration Date of Continuing Review:

Confirm that all fields are completed in the PTMS Continuing Review Form and if the field is not answered, provide an explanation as to why. In addition, complete all sections of this memo as numbered, using “n/a” for sections that do not apply to this protocol.

1. Participant enrollment data
   1. Provide a participant Enrollment summary:

|  |  |  |
| --- | --- | --- |
| ***Note:* *If this is the first continuing review application, you need only complete the Column “Since Initial IRB Approval.” Otherwise, complete both columns*** | **Since Initial IRB Approval** | **Since Last IRB CR Report Submission** |
| **Total** Number of enrolled participants:  *(Enrolled means participants who signed an informed consent form, gave verbal consent under an IRB approved waiver of documentation of informed consent, or are participants under a waiver of informed consent.* ***This includes screen failures after consent and participants who have withdrawn or were withdrawn by the study team.)*** |  |  |
| Number of enrolled participants who failed screening if applicable:  Check here if your project does not have screening procedures after consent. |  |  |
| Number of enrolled participants who withdrew or were withdrawn:  *(withdrawn by PI; self-withdrawal; lost to follow-up)*  **If there were withdrawals, indicate reasons and totals** |  |  |

Note: The IRB recognizes that the study team may not have recorded these participant numbers since initiating the study. The expectation is that this information is being collected and reported moving forward.

* 1. Total number per cohort or subpopulation who started study (for example: pediatric subjects, number of patients/index cases vs. number of relatives/healthy volunteers).

1. If there has been no or less than expected enrollment (either overall or in specific subcategories, such as race, ethnicity, sex, or catergories described in 1.b.), please explain. If necessary, what is the plan to enhance enrollment?

*Questions 3-6 may be provided in a narrative summary or table summary format*

1. Provide a summary of Serious and Non-Serious Unanticipated Problems (UPs) that have already been submitted to the NHGRI IRB since the initial approval or the last CR submission as applicable. Submit any new UPs (including external if study is under an IND) through the PTMS Problem Report pathway.
2. Provide a summary of Serious and Non-serious Adverse Events (AEs) since the initial approval or the last CR submission as applicable.
3. Provide a summary of Serious and Non-Serious Protocol Deviations that have been reported to the IRB since the initial approval or the last CR submission as applicable.
4. Provide a summary of Serious, Continuing, and Minor (not serious and not continuing) Non-Compliance since the initial approval or the last CR submission as applicable.
5. If the protocol has a Data Safety Monitoring Board (DSMB) or a safety monitoring committee and it convened during this review cycle, please provide a summary of the meeting; otherwise, explain why the DSMB/SMC has not convened since the last review or indicate N/A.
6. What was the IRB risk determination resulting from the initial review or last continuing review?
   1. Has the risk changed since the last review?
   2. If yes, explain why.
7. Based on any previous IRB stipulations, report on any activities where follow up information was requested (e.g. disclosure of secondary findings, sedation on children, etc.).
8. Is this study in compliance with the NIH Human Data Sharing Policy? <https://oma1.od.nih.gov/manualchapters/intramural/3016/> (this is applicable to new studies initiated after October 1, 2015).
9. Do you need and/or have an approved Genomic Data Sharing Plan? <http://inside.genome.gov/20009049>
10. Is the protocol approved to use the short-form process to enroll non-English speakers?
    1. If yes, has the short-form consent process been used in the past year?
    2. If yes, state number of participants enrolled with short form process.

*(If the CC Short Written Consent Form has been used three times for the same language since the start of the study, the informed consent document must be translated to that language.)*

1. Any other information about which you would like to inform the IRB or IRB Office Staff.
2. Confirm that all of those working on this protocol who are required to take HRPP training under OHSRP SOP 25 (Training requirements for the NIH Human Research Protections Program) have completed all required training.
3. If NHGRI IRB is the IRB of oversight for multiple enrollment sites for this study, provide answers to questions 1-6 and 12 for each site as a supplement to this cover letter.
4. Provide the name, email address, and phone number for the primary research contact for the IRB for this protocol.