Date:

To: **NHGRI IRB**

From:

Subject: Continuing Review Cover Memo

Protocol ID#:

Protocol Title:

Expiration Date of Continuing Review:

*This cover memo only applies to expedited Continuing Review submission requirements because the protocol activities are limited to data analysis. It is not necessary to complete the CR application in PTMS.*

The only remaining human subjects research activity is the analysis of data that includes identifiable private information and the research involves no more than minimal risk. This cover memo is being submitted in compliance with SOP 9, version 3, dated 3-6-2016.

*Please address all of the following:*

1. Project Progress Summary:
2. Confirm that no subjects were enrolled during the previous twelve months.
3. Confirm that all subjects have completed all protocol visits or otherwise have withdrawn from the study.
4. Confirm that no new data are being collected.
5. Confirm there have been no adverse events, unanticipated problems, deviations, breaches of confidentiality, and no loss of specimens or data or other protocol-related problem during the previous 12 month review period, that require reporting to the IRB at the time of continuing review.
6. Is there any information in the literature, or emerging from similar research that might affect the IRB’s analysis of risk/benefit for the protocol.

\_\_\_\_yes \_\_\_\_no Comments:

If such information is obtained before the time of CR, it should be reported to the IRB at the time that it becomes known, and summarized at the time of CR.

1. The IRB may require additional information by stipulation.