Re: Institutional Review Board verification concerning data sharing with the Platform for Accelerating Genetic Discovery for Cerebrovascular Disease

COHORT:
Principal Investigator: __________________________________________________________
Institution: ___________________________________________________________________
Title and Protocol #: ____________________________________________________________
____________________________________________________________________________
Cohort name (if applicable):______________________________________________________

The regional IRB/Ethics Committee at the aforementioned mentioned Institution has reviewed the relevant aspects of the proposal including the consent form, and verified that:

PART I:

a. Data collected under the aforementioned protocol may be sent to and analyzed by investigators registered with the Platform for Accelerating Genetic Discovery for Cerebrovascular Disease.
b. De-identified data will be stored at The Broad Institute on servers designated to the Platform for Accelerating Genetic Discovery for Cerebrovascular Disease for future use as determined by the Steering Committee.

_______________________________   Date _____________
IRB/Ethics Committee Chair

_______________________________  Date_____________
Principal Investigator

PART II:

a. The submission of data to the Platform for Accelerating Genetic Discovery for Cerebrovascular Disease and subsequent sharing for research purposes are not inconsistent with the informed consent of study participants from whom the data were obtained. Data will remain in the controlled access Platform and never distributed to users of the Platform. A results file will be generated at completion of each analysis for distribution to the end user.
b. Data Sharing Category (as described in consent form(s)):

- **Health/Biomedical**: The use of the data is restricted to health/biomedical purposes, and does not include the study of population origins and ancestry.

- **Disease-specific-list disease(s)**: The use of the data must be related to the specified disease(s).

- **General Research Use**: The use of the data is limited only by the terms or the Data Use Agreement. The data may be used for all research use including the study or population origins and ancestry.

The use of aggregate-level data for general research use is not inconsistent with the informed consent. **Yes/No.** *(Please note: In general, the PHRC will approve the aggregate use of the data unless there is a specific consent form limitation.)*

c. Restrictions for data use (considering the consent form)

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____________________________________________________________________

d. The proposed submission of data, to the general NIH data repository for subsequent sharing for research purposes as described in the NIH Policy is consistent with the informed consent of study participants from whom the data were obtained.

Sincerely,

____________________________________________________________________

IRB/Ethics Committee Chair Date _____________

____________________________________________________________________

Principal Investigator Date _____________

Institution

1 For studies using data or specimens collected before the effective date of the Genomic Data Sharing Policy, the Partners IRB, will review informed consent materials to ensure that data submission is not inconsistent with the informed consent provided by the research participants.