European Genome-Phenome Archive
c/o European Bioinformatics Institute
Wellcome Trust Genome Campus
Hinxton
Cambridge
CB10 1SD
United Kingdom

To whom it may concern,

This document refers to the H3Africa Consortium data set, <**Study Accession Number>**, which has been submitted to the European Genome Archive (EGA) for the restricted access by legitimate academic institutions that have agreed to comply with the terms of a Data Access Agreement drafted by **<Name of CDAC or individual >**.

There are a number of steps that a researcher must take to obtain access to this data and the process is overseen by ~~our~~ H3Africa Consortium Data Access Committee, called <**NAME and EMAIL ADDRESS OF CDAC>**.

Please be advised that **<INDIVIDUAL NAME and EMAIL ADDRESS>** is authorized to upload data to the EGA for archiving and distribution as part of your submission process, which will enable approved researchers to have encrypted access to the data.

We can confirm that this submission is consistent with the informed consent of the participants of the study or has been granted ethical approval and is in accordance with the applicable laws and regulations. We certify that data submission plans meet the following expectations:

- The data submission is consistent with all applicable laws and regulations as well as institutional policies;
- The appropriate research uses of the data and the uses that are specifically excluded by the informed consent documents are delineated;
- The identities of research participants will not be disclosed to the ~~NIH GWAS data~~ EGA repository; and
- An IRB and/or Privacy Board, as applicable, reviewed and verified that:
    - The submission of data to the ~~NIH GWAS data~~ EGA data repository and subsequent sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;
    - The investigator's plan for de-identifying datasets is consistent with the standards outlined in the H3Africa policy;
    - It has considered the risks to individuals, their families, and groups or populations associated with data submitted to the ~~NIH GWAS~~EGA data repository; and
    - The genotype and phenotype data to be submitted were collected in a manner consistent with 45 C.F.R. Part 46.

Sincerely,

<Representative of study, e.g. Principal Investigator, and their institution>

Comment [EGA1]: Provided by the EGA at the start of the submission process. The format should be: **EGASXXXXXXXXXX**.

Comment [GM([2]: Is data access allowable by industry for research purposes?

Formatted: Highlight

Comment [GM([3]: Should be submission of the data to Eurpoean Genome-Phenome Archive

Comment [GM([4]: Is "it" the institution; I think so and I suggest to from it to Institution.

Comment [DNM5]: Should we change this to H3Africa policies?

Comment [GM([6]: This is US laws and mentioned in NIH GWAS policy but may be too specific here. There is a comment above in green that is more broader than US regulations.

Comment [EGA7]: Individual must have the authority to underwrite the statement. In most cases, the PI associated with the study is sufficient.