TOPMed BRAVO variant server:
ELSI discussion summary (unofficial version)

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Over the past six months, the TOPMed ELSI Committee engaged in a series of discussions regarding the WGS project, return of results from incidental findings, contribution of TOPMed genomic data to the variant server (BRAVO), and contribution of TOPMed genomic data to an imputation engine. The ELSI Committee would like to acknowledge the assistance of Goncalo Abecasis in discussions regarding the variant server and the imputation engine.

With respect to all aspects of the project, the ELSI Committee recognizes the importance of adhering to the guiding principles of the informed consent for use of participant phenotypic and genotypic data. The Committee also recognizes that the context under which consent was granted may be quite different from the current (and future) state of genomic science. Thus, it is important for the study investigators to be engaged with their participants to maintain and enhance understanding and consent for ongoing studies. This area is not as clear for historical (legacy) studies.

A key concept for consideration is that of the "publication analogy". The "publication analogy" is the concept that once data are published in a journal article, they are in the public domain and are available for use by other researchers, for any purpose. Thus, the limits imposed by the original consent no longer apply.

The ELSI Committee is in general agreement that, for the TOPMed Variant Server,

(a) the publication analogy is a reasonable one;

(b) as there is no link between aggregated variant summary data and individual participants, there is minimal to no risk of identification for an individual;

(c) the TOPMed Variant Server scope (*i.e.*, amount of data) and ease of use in searching the server are factors that generate scientific value, with minimal risk to participants whose data are used for the server; and

(d) it is likely that the concept of consent for specific projects, followed by publication of results and subsequent public access of data, has not been discussed with study participants, either from the minimal risk or from the uncontrolled access perspective. Going forward, the value of their contribution should be explained to study participants as part of the informed consent process.

The ELSI Committee is continuing to discuss the imputation engine and has not yet reached conclusions about appropriate access to this TOPMed function.