Project Viva Genetic Data Policy

Viva Genetic Data

This policy applies to use of de-identified, genetic data from Project Viva. Individual-level data will be coded with Project Viva study ID and will only be available to IRB-approved Viva analysts and key project staff. Viva analysts will tabulate individual-level data into summary statistics for analysis by approved investigators and consortia. In genetics, results of associations between genetic variants and phenotypes of interest are aggregated (usually expressed as betas or odds ratios) and presented as a "summary statistic" for each genetic variant analyzed in that population. Any proposals requiring PHI or other identifiers (including dates) will be governed by a separate policy (see *Project Viva Policies for Grant Applications, Analyses, Ancillary Studies and Publications/Authorship*).

Data Requests

Requests from Viva investigators: All Viva investigators proposing a genetic study are required to present an analysis plan at a monthly Viva Co-Investigator meeting for scientific review and approval. To protect our participants and the quality and integrity of Project Viva data, Project Viva Principal Investigators and/or designated co-investigators must approve all requests.

Requests from consortia and non-Viva investigators: Independent, non-Viva investigators and colleagues from external cohorts and multiple-cohort consortia may also request Project Viva genetic data to conduct replication analyses or meta-analyses. The lead or proposing investigator provides a data request and analysis plan to the Viva consortium liaison or Project Manager for approval by Project Viva's PI, Dr. Emily Oken or Co-PI, Marie-France Hivert. The Viva PIs review the proposal for scientific merit and determine whether Project Viva has the required data elements and resources necessary to contribute to the analysis.

The Viva Project Manager will maintain a database of all requests and determinations.

Required Documentation: Once a request for genetic data has been approved by the Viva Principal Investigators, the Project Manager will request the following items from the proposing investigator:

1. Acknowledgement of and agreement to abide by the *Project Viva Genetic Data Policy* (this document).
2. A copy of IRB or equivalent approval of the proposed project by the investigator's home institution (if required by that institution), or a determination that approval is not required.
3. A copy of the investigator's human subjects training certification, if required by his/her home institution.
4. A copy of the investigator's C.V. (for Viva co-investigators only).

Once the above requirements are met, the investigator may request and receive summary results from the designated, IRB-approved Viva analyst; the Viva Project Manager should be copied on all requests.

Upon receiving Project Viva genetic summary results, the proposing investigator agrees to follow all policies as outlined in this document.

Use of Data

Investigators may view summary results that are provided by an approved Project Viva analyst. Investigators may only use the data for the purpose originally requested. Approval must be granted by Project Viva investigators and the Harvard Pilgrim Health Care Institutional Review Board, as required, for additional use of the data. Sharing or analyzing Viva data sent by another investigator, lab, or any other individual or entity is against Project Viva's policies. In addition, investigators should not use old datasets or summary data for newly proposed analyses.

Viva analysts do not have access to electronic locator files, medical record text files, or operational folders that may contain any identifiable information or access to the linking code. Given these access limitations, they are unable to link genetic data to individual participants. Viva's Project Manager, Data Manager and other Viva staff members may not disclose identifiable information or the linking code to analysts or outside investigators.

Project Viva IRB-approved analysts are responsible for creating summary results from genetic data and phenotypic data stored in the Viva Data Repository, in accordance with the analytic plan provided by the lead investigator and approved by the Viva PIs. The data shared with investigators for analysis will be in the form of summary data only; there will be no individual-level data. Analysts may also assist investigators with non-genetic analyses if necessary. Analyst(s) providing summary results may be included as author(s) on papers as appropriate.

The investigator shall destroy Project Viva summary files created and distributed by the Viva analyst within one year after resulting manuscripts are accepted for publication. This timeframe allows the investigator to respond to any changes or request for additional results based on the initial manuscript review.

To further safeguard participant privacy and confidentiality, the Viva analyst will:

- Only include necessary results in summary data.
- Analysts will share tabulated (summary) results using secure technology (secure emails, SFTP sites, or other secure data transfer technology available).
- Emails containing results or data will be encrypted and will include the following message:

  "The recipient has read Project Viva's Policies and agrees to abide by them. The recipient agrees to use or disclose the data only for the

purpose requested, and for no other purpose. The recipient agrees to use appropriate safeguards to prevent any use or disclosure of the data. The recipient will report to Project Viva's Project Manager any violation of this agreement or Viva policies."

Manuscript Review

1. All manuscripts – including those from consortia—must be sent to the Project Viva PI Emily Oken or Co-PI Marie-France Hivert, the Project Manager, and to the designated Viva analyst, for review. Manuscripts may also require review by the Chair of the Department of Population Medicine (DPM) and the Director of Research at Atrius' Office of Clinical Research. Viva's Senior Statistical Analyst will coordinate sending out the manuscript for these institutional reviews as needed. Authors should allow seven working days for DPM/Atrius reviews before submitting any manuscripts for publication; no response after seven days can be considered approval. To promote collaboration within the group and shared knowledge of ongoing work, we will circulate publications with the Viva team and other faculty and staff via the internal newsletter of the Division of Chronic Disease Research Across the Lifecourse (CoRAL).

2. All manuscripts involving Viva data or including summary results must have a technical review to ensure that the data are presented accurately. In most cases, this will be done by the designated Viva analyst. The technical reviewer will:
    a. Check for consistency and plausibility of numbers of Viva results.
    b. Double-check tabulated numbers with primary SAS or R output.

NOTE: This policy provides general guidance. Each proposal will be considered individually by Project Viva's operational leadership; specific requirements may differ from what is listed above.

Project Viva Staff Contact Information

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