

Data Sharing Plan

GenoMEL has an interest in sharing data with other interested and qualified research groups or individual researchers who may wish to contribute analyses for the benefit of the scientific and health care communities, in the best interests of the patients and their families from whom these data are derived. In general, data that are still in the process of analysis and not yet published may be considered by some or all of the GenoMEL membership to be not yet ready for sharing, and this will apply especially to data that have not yet been fully reviewed, cleaned and subjected to sufficient analysis to ensure that they are reliable and appropriate. Especially in the case of complex datasets, a plan for data sharing will often of necessity include collaborative agreements with groups that have generated all or some of the data to be shared. No warranty condition is made, given or to be implied as to the sufficiency, accuracy or fitness for purpose of the data that is transferred by GenoMEL to other researchers. The recipient researchers shall therefore in any event be entirely responsible for any use whatsoever of such data.

Applicants wishing to use data should use the following procedure:

1. An application form with required preliminary information will be placed on the GenoMEL web site. Using this form, a brief expression of interest should be submitted to the GenoMEL Analysis Group (using contact information supplied on the web site).
2. The Analysis Group will initially review the proposal and may seek clarification of issues in order to determine whether or not the data existing in GenoMEL are likely to satisfy the request, or whether other data sources may be more appropriate.
3. The proposal will then be circulated to the entire GenoMEL membership with a brief (e.g. one month) opportunity given to highlight major issues, especially duplication of, or complementarity to, existing projects.
4. A full application is then submitted and checked by the GenoMEL Analysis Group against criteria that include evidence of external peer review, and ethics (IRB) approval. Depending on local

- conditions, ethics approval may also be required from individual IRBs of member groups of GenoMEL that have contributed data.
5. Proposals will include a discussion of mechanisms for informing subjects (if necessary) and IRBs about the plans, preserving subject confidentiality, and honoring HIPAA and other national and international privacy requirements
 6. The plan will also include an assessment made by GenoMEL for recovery of costs associated with delivery of the data, including costs of preparation of any ethical or regulatory reviews that may be required in any locality, and the requesting organization must commit to cover these costs in their grant proposals. GenoMEL will provide applicant organizations with an estimate of costs for use in such proposals, or in other funding deliberations.
 7. Given that these conditions are met, approval is given contingent upon continuation of necessary support, and on submission of annual progress reports.
 8. Data may be shared by direct transfer of data files or, especially in circumstances in which there is risk of subject identification or when security or other legal restrictions apply to the data, a data enclave may be provided as a physical location where the user may go to access shared data under controlled conditions (e.g., supervision by the PI or designated agent).
 9. Data will be provided with necessary documentation, including explanations regarding complex shared data, assuming that costs are covered and that appropriate collaborative agreements are reached regarding for example the level of involvement of the appropriate GenoMEL group in the proposed analyses.
 10. To further enrich the GenoMEL resource, the researchers are required to supply their research data to GenoMEL after publication, and/or 12 months after completion of their project. In addition, data sharing requests will be tracked over time by the Analysis Group and described in the progress and final grant reports.