Guidelines for Accessing MIDUS/MIDJA Genomic Data

Genomic data from DNA is available for MIDUS Core and Refresher participants who also completed the Biomarker Project at MIDUS 2 (M2) or MIDUS Refresher (MR), as well as those individuals who completed the MIDJA 2 Biomarker protocol. Genomic data from RNA is also available for Refresher Biomarker participants.

Publicly Available Data

The following data are publicly available via the MIDUS Colectica Portal (http://midus.colectica.org/) which houses interactive codebooks for all the publicly available MIDUS projects.

- Polygenic Risk Scores derived from imputed SNP data
- Gene Expression Scores for Conserved Transcriptional Response to Adversity (CTRA) from RNA

Restricted Data

Data about individual genes from DNA (imputed SNPs) and RNA (expression values for CTRA indicator genes) are restricted. Interested users can obtain access to these data via the following process:

1. Complete and submit the access request form via the link available here (http://midus.wisc.edu/midus_restricted_data.php).
2. The request is reviewed by designated members of the MIDUS team.
3. Upon approval, the individual requesting data access will be asked to submit a Data Sharing Agreement (DSA) that has been signed by the requestor and the designated Institutional signer at their institution.
4. Upon receipt of the signed DSA instructions for accessing/downloading the data will be provided.

The remainder of this document specifies the MIDUS policy for accessing restricted data as well as information regarding project details that must be provided.

Policy for Accessing Restricted Data

Please note the following information and requirements prior to submitting the data access form:

1. Requests will be reviewed individually for appropriate research use only. We will not prioritize access, or assess overlap with other projects, or apply any other criteria. The intent is to review each request within two weeks of submission.

2. Data access will be granted only to individuals who are permanent employees of their institution at a level equivalent to a tenure-track professor, or senior scientist/researcher with responsibilities that likely include laboratory administration and oversight. Laboratory staff and trainees, such as graduate students, and postdoctoral fellows are not permitted to submit requests, but may be included in the study team.

3. Institutional Review Board (IRB) and institutional requirements for secure storage and management of genomic data vary across institutions. That said, applicants will be required to attest to that they are aware of, and will comply with:
    a. Institutional Review Board (IRB) requirements at their institution.

b. Institutional requirements regarding secure storage and management of genomic data at their institution.

4. Approved Applicants will be expected to submit a Data Sharing Agreement (DSA), that has been signed by themselves, as well as the appropriate institutional designee. The terms of the DSA include, attestation of compliance with institutional policy (see above), as well as affirmation of the following requirements:
    a. Permission to use the genomic data is granted to requestor at their current institution. Only the requestor and members of the study team (staff, trainees) staff will have access to any MIDUS genomic data.
    b. If requestor, graduate students, or other staff members, leave their current institution, they must reapply for permission for continued access to these data.
    c. No attempt will be made to identify individual respondents for any purpose. Any such attempt may void permission to use the data.
    d. The genomic data, and any data sets derived from it, will be stored and used in a secure computing environment. The data files with this information will be maintained in a secure manner, with access restricted to authorized persons according to NIH guidelines (https://osp.od.nih.gov/wp-content/uploads/NIH_Best_Practices_for_Controlled-Access_Data_Subject_to_the_NIH_GDS_Policy.pdf).

5. Accessing Additional Datasets After Initial Approval: Investigators who would like to access additional genomic dataset(s) for use in an existing approved project should
    a. Revise the existing approved project request to include the new datasets and
    b. Update the Research Use Statement as appropriate. Investigators do not need to submit a new project request unless the dataset will be used for research outside of the scope of the approved Research Use Statement.

Restricted Data Access Request Form: Overview of Components

The following information must be included in the Data Access Request Form.

1. Primary Investigator:
    a. Name, institution, email address, business address, and current CV
    b. Research background and rationale (no more than 3 paragraphs/1 page) – This information will be kept confidential. Inclusion of PubMed links to publications, in lieu of a citation list, is encouraged.
2. Study Team: name, institution, email address, and mailing address for each additional user.
    a. Provide the full legal names and contact information for internal collaborators as well as trainees and staff directly supervised by the PI.
    b. Will there be a designated Study Team member accessing the data on behalf of the PI? If so, they must be identified and their role in the project must be described.
    c. Identify any external collaborators, including institution, and their role in the project. If the external collaborator needs access to the data to fulfill their role, they will need to apply separately for data access. Applications from all collaborators will be processed together. Review of any will be delayed until all requests are received.
    d. Data exchange between all collaborators must be consistent with the (https://osp.od.nih.gov/wp-content/uploads/NIH_Best_Practices_for_Controlled-Access_Data_Subject_to_the_NIH_GDS_Policy.pdf
3. Description of the Project including:

a. Project title
b. Abstract
    i. This should be a non-technical summary of the proposed research uploaded as a separate document
    ii. If the project is approved, this statement may be included in public documents such as grant progress reports
c. Specific MIDUS data resource requested, including the MIDUS sample (e.g., RNA Expression values, Imputed SNP data)
d. Study design – This information will remain confidential
    i. Hypothesis (1-2 sentences)
    ii. Outcome/s (1-2 sentences; may include a specific subset of genes, a composite score, or genome-wide scan)
    iii. Predictor/s (1 paragraph list; may include a specific predictor variable, or a set of variables related to a specific theme, or a combination of variables such as an interaction)
    iv. Control variables/covariates (if any; 1 paragraph)
    v. Statistical analysis model (1 paragraph)
    vi. Approach to multiple testing of gene-level data (e.g., single integrated test statistic; single composite score; multiple parallel tests with control of false discovery rate or family-wide error rate; etc.)

4. Cloud Use Statement and Cloud Servicer Provider Information (if applicable).
    a. Investigators who wish to use cloud computing for storage and analysis of dbGaP data must request permission to do so. They will also need to:
        i. Identify the cloud service provider or providers that will be employed.
        ii. Describe how the cloud computing service will be used to carry out their proposed research.