**DCEG Data Access Committee: Charter**

**Revised 4/12/24**

**1. Charge to the Data Access Committee**

The Division of Cancer Epidemiology and Genetics (DCEG) Data Access Committee (DAC) provides governorship of data posted to the DCEG Publication Data Repository (PDR).

**2. Composition of the Data Access Committee**

The DCEG DAC will be nominated by the Director of the Trans-Divisional Research Program and approved by the DCEG Director. The DAC will be composed of two DCEG DAC Co-Chairs with appropriate scientific, bioethics, and human subjects' research expertise. An Executive Secretary will be appointed to manage logistics, coordinate data transfer agreements (DTAs) with the NCI Technology Transfer Branch, and triage data access requests (DARs).

**3. Role of the Data Access Committee Chairs**

The DCEG DAC is responsible for the lifecycle of the data sharing process including (1) review of all DARs from the research community for access to controlled-access cancer datasets made available through the DCEG PDR, and (2) the oversight of data access and use by approved users. The DCEG DAC Co-Chairs will coordinate responses to data management incidents and communications with the Institutional Review Boards (IRBs) or other ethical committee that the study is enrolled under (if applicable). The DCEG DAC Co-Chairs are expected to communicate regularly with the DCEG Scientific Director and the Director of the Trans-Divisional Research Program to ensure ongoing communication regarding issues affecting data sharing and management. The DAC will not routinely notify DCEG principal investigators of DARs unless there is a compelling reason.

**4. Scope of Work**

*What the DAC will do:* The DAC will review and approve or disapprove requests from the research community for access to DCEG research datasets. Data Access decisions will be made based on whether the request conforms to the specifications of the NIH Data Management and Sharing (DMS) Policy and any program-specific requirements or procedures. All proposed use of the data must be consistent with the Data Use Limitations (DULs) as stipulated in the Institutional Certification (IC) document. The DCEG DAC will maintain records of data access requests (DARs) to controlled datasets for programmatic oversight, research purposes, and for DCEG researchers to stay informed of how data are being used.

The DCEG DAC will consider requests for access to data through the review of incoming DAR, submitted through the DCEG PDR. Requestors must be registered with login.gov. Prior to DAC review of an incoming access request, the DCEG DAC Executive Secretary will review the application for completeness of administrative elements and appropriateness of credentials for the Requesting Investigator (Requestor) or their institution. Once the DAC approves a DAR, the Requester and their institution must agree to the terms and conditions for data use specified in the Data Transfer Agreement (DTA) for each dataset requested. For example, the DTA may require that Requesters, at a minimum, agree to:

* Abide by the agreed upon research uses of the requested dataset, as stated in the IC,
* Conduct only the research approved by the DAC,
* Not seek to identify individuals within the dataset,
* Not distribute controlled-access datasets and derivatives of controlled-access datasets to any entity or individual not identified in the submitted DAR; collaborators at other institutions must submit their own DAR,
* Keep the data secure according to the current [NIH Security Best Practices](http://www.ncbi.nlm.nih.gov/projects/gap/pdf/dbgap_2b_security_procedures.pdf) for Controlled-Access Data Subject to the GDS Policy and the institutional IT security requirements and policies to protect the confidentiality and integrity of the data, and,
* Acknowledge the Contributing Investigator(s) who submitted data from the original study to the repository, the primary funding organization that supported the Contributing Investigator(s), the DCEG-designated data repository, and the persistent identifier(s) to the specific version of the dataset(s) analyzed, as appropriate in all oral and written presentations, disclosures, and publications resulting from any analyses of controlled-access data obtained through the DAR.

These and other requirements are detailed in the DTA.

*What the DCEG DAC will not do:*

* Evaluate the scientific merit of a DAR, or
* Ensure that the data requester complies with local human subjects' protections, except when documentation of IRB approval is required by the DULs of the requested dataset.

Note that DCEG Investigators, in concert with the applicable NIH IRB or NCI Ethical Review Panel (ERP), are responsible for ensuring that all required ethical approvals and institutional certifications are obtained prior to submitting the data to the DCEG PDR. DCEG DAC’s oversight of the data is based on these ICs.

**5. Operations Administrative Review, DAC Review, and Review Schedule**

Using a DAR review checklist, the DAC Executive Secretary will conduct an administrative review of DARs to determine whether applications are complete and may ask for additional information from the Requester and/or their institution. Following this administrative review, the Executive Secretary will send the DARs to DAC Members for review. DARs will be reviewed as they are received; however, the schedule of DAR review may be adjusted at the discretion of the DCEG DAC.

DARs will be reviewed by DCEG DAC co-chairs who will vote to approve, disapprove, or discuss to resolve any outstanding issues with the request. If the vote is not unanimous for a given DAR, the DCEG DAC Co-Chairs will consult with DCEG leadership, or contact the requestor for further information, etc., to reach consensus.

Once the DAR is unanimously approved, the DCEG DAC Executive Secretary will initiate the DTA process between the requestor’s institution and the NCI Technology Transfer Branch. Once the DTA is fully executed, the DCEG DAC Executive Secretary will grant access to approved data by emailing a link to a Box folder where the data are stored.

**6. Procedures for Reviewing and Responding to Data Access Requests**

Generally, IRB or ethics approval is not required for access to data. By agreeing to the terms of access in the DTA, Requesters and their institutions are certifying that they will adhere to any applicable Federal, State, and Local laws, and if applicable, local human subjects’ protections. The DCEG DAC will not review the Requestor’s or their institution’s IRB or ethics board approval letter unless documentation of local IRB approval is required by the DUL. In these cases, the Requestor must include the documentation with the DAR.

Decisions on requests for access to datasets are relayed by the DCEG DAC Executive Secretary to the Requester. Any decision not to grant access will be conveyed to the Requester with feedback on the reasons behind the determination, for instance, a brief statement that the proposed research use is not consistent with the DUL for the dataset in question.

If a Requester contests the DCEG DAC’s decision regarding the appropriateness of their access to data, the Requester may resubmit their request with additional information and clarification of the research use statement.

All approved users are required to comply with tasks described in the terms of the DTA including project closeout.

**Glossary**

Data Access Committee (DAC)

Data Access Request (DAR)

Data Management Incident (DMI)

Data Management and Sharing (DMS)

Data Transfer Agreement (DTA)

Data Use Limitation (DUL)

Ethical Review Panel (ERP)

Institutional Certification (IC)

Institutional Review Board (IRB)

Information Systems Security Officer (ISSO)

Publication Data Repository (PDR)