Required Credentials to Submit a Request for Controlled-Access Data

Data Access Requester

Data Access Requests must be submitted by a **Data Access Requester** who meets all the following criteria:

1. Is a permanent employee of their institution or corporation at a level equivalent to, but not limited to that of an academic professor (e.g., assistant, associate, or non-tenure or tenure-track professor) or senior researcher. This does <u>not</u> include lab technicians or trainees, e.g., post-docs or graduate students.
2. Uses an email address affiliated with their self-identified institution or corporation.
3. Has direct oversight of any laboratory staff and/or trainees indicated in the Data Access Request, if applicable.
4. Is accountable for ensuring that the terms of access (through agreements such as the Data Use Certification) and the Institutional Requester's institutional policy(ies) are followed.
5. Only occupies one role at a time. Requests in which the Data Access Requester, or any other Key Personnel, occupy more then one role (e.g., Principal Investigator, Institutional Signing Official, or IT Director) are not allowed.

Institutional Signing Official (SO)

Requests must be certified by the **Institutional Requester** as represented by an **Institutional Signing Official (SO)** who meets all the following criteria:

1. Is affiliated with the **Data Access Requester's** institution or corporation.
2. Has the institutional authority to legally bind the institution or corporation in administrative matters.
3. Uses an email address affiliated with the Data Access Requester's institution or corporation.

<u>Controlled Access Data Requests – Key Definitions</u>

Approved User: A user approved by the relevant Data Access Committee(s) to access one or more datasets for a specified period of time and only for the purposes outlined in the <u>Principal Investigator</u> (PI)'s approved Research Use Statement. The <u>Information Technology</u> (IT) Director indicated on the Data Access Request, as well as any staff members and trainees under the direct supervision of the <u>PI</u> are also Approved Users and must abide by the terms laid out in the Data Use Certification Agreement.

Collaborator: An individual whose identity has been validated and who is a permanent employee of their institution at a level equivalent to, but not limited to, that of an academic professor (e.g., assistance, associate, or non-tenure or tenure-track professor) or senior researcher, who is not under the direct supervision of the Principal Investigator, who assists with the research project involving controlled-access data. This cannot be a lab technician or trainee, e.g., post-docs or graduate students. Internal collaborators are employees of the Institutional Requester and work at the same institution as the Data Access Requester. External collaborators are not employees of the Institutional Requester and do not work at the same location as the Data Access Requester.

Cloud Computing: The National Institute for Standards and Technology defines cloud computing as a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction. For more information see <u>NIST Special Publication 800-145</u>.

Cloud Service Provider (CSP): A company or institution that offers some component of <u>cloud computing</u> to other businesses or individual, typically Infrastructure as a Service (IaaS), Software as a Service (SaaS) or Platform as a Service (PaaS), as defined by the National Institute of Standards and Technology. For more information see <u>NIST Special Publication 800-145</u>.

Data Access Request (DAR): A request submitted to an NIH Data Access Committee for a specific research use specifying the data to which access is sought, the planned research use, and the names of collaborators.

Data Access Requester: The individual who prepares and submits requests, Project Renewals, and Project close-outs. A Data Access Requester is a permanent employee of their institution at a level equivalent to, but not limited to, that of an academic professor (e.g., assistance, associate, or non-tenure or tenure-track professor) or senior researcher; has oversight responsibility for others named on the request who will be granted access to the data; and can be accountable for ensuring that all aspects of data usage align with the terms of the agreement. This cannot be a lab technician or trainee, e.g., post-docs or graduate students.

Data Derivative: Data derived from controlled-access datasets obtained from NIH-designated data repositories. Examples of derived data include imputed datasets and single nucleotide polymorphisms, or any data explicitly designated as <u>Data Derivatives</u> by NIH.

Data Use Certification (DUC) Agreement: Terms of access that include how the data accessed should be secured and used by the Data Access Requester, those they directly supervise, and any collaborators. The Institutional Requester, through the Institutional Signing Official (SO), and the Data Access Requester, are each signatories to the agreement and agree to adhere to terms of access.

Genomic Data User Code of Conduct: Key principles and practices agreed to by all research investigators requesting access to controlled-access data subject to the NIH GDS Policy. The elements within the Genomic Data User Code of Conduct reflect the terms of access in the Data Use Certification Agreement.

Institutional Requester: The home institution or corporation of the Data Access Requester.

Information Technology (IT) Director: An Approved User who is generally a senior IT official of the Institutional Requester with the necessary expertise and authority to affirm the IT capacities at the Requester. The IT Director is expected to have the authority and capacity to ensure that the NIH Security Best Practices for Users of Controlled-Access Data and the Institutional Requester's IT security requirements and policies are followed by all of the Institutional Requester's Approved Users.

Institutional Certification: Certification by the Submitting Institution that delineates, among other items, the appropriate research uses of the data and the uses that are specifically excluded by the relevant informed consent documents. Further information may be found here.

Institutional Signing Official: The label, "Institutional Signing Official" refers to the individual that has institutional authority to legally bind the institution in administrative matters. The individual fulfilling this role may have any number of titles in the institution but is typically located in its Office of Sponsored Research or equivalent.

Principal Investigator (PI): An investigator who is a permanent employee of their institution at a level equivalent to a tenure-track professor or senior scientist with responsibilities that most likely include laboratory administration and oversight. Additionally, the investigator has the authority to ensure that whom they directly supervise adhere to the terms of access in this agreement.

Progress Update: Information included with the annual Data Access Request (DAR) renewal or Close-out providing a summary of research progress and citing any presentations of publications resulting from use and/or analysis of the approved controlled-access data.

Project Close-out: Termination of a research project that used controlled-access data from an NIH controlled-access data repository and confirmation of data destruction when the research is completed and/or discontinued.

Project Renewal: Renewal of a Data Access Requester's access to controlled-access datasets for a previously approved project with options to add or remove datasets, collaborators, or Key Personnel.

Research Use Statement: A summary of research intent submitted by the Data Access Requester that includes information about at least the following: research objectives, study design, and analysis plan.

Submitting Institution: The individual responsible for assuring to NIH that the data are appropriate to share as signatory to the data submission form or certification.

Submitting Investigator: The home institution or corporation of the Submitting Investigator responsible for assuring to NIH that the data are appropriate to share as a signatory to the data submission form or certification.

Third-party IT system: A collection of computing and/or communications components and other resources that support one or more functional objectives of an organization.