Project name:

Requested data (accession number(s)):

Institute affiliation:

Request date:

Collaborators:

**Applicant organization**

Legal name:

Department:

Street:

City

State:

Zip:

Country:

**Principal Investigator (PI)**

Name:

Position:

Organization:

Street:

City

State:

Zip:

Country:

Phone:

e-mail:

**Institutional Signing Official**

Name:

Position:

Organization:

Street:

City

State:

Zip:

Country:

Phone:

e-mail:

**IT Director**

Name:

Position:

Organization:

Street:

City

State:

Zip:

Country:

Phone:

e-mail:

**Project plan and description of the research project**

Objective:

Study Design:

Preliminary Results:

Analysis plan:

Non-technical summary:

The Data access application needs to be signed by the PI requesting the data and her/his Institutional Signing Official.

Project name:

Requested data (accession number(s)):

Date:

Principal Investigator Signature:

Institutional Signing Official Signature:

**Conditions**

The Lund University Diabetes Centre (LUDC) has generated a LUDC data repository for securely storing and sharing controlled-access human data submitted to LUDC. Because the human data maintained in this repository is potentially sensitive (e.g., data related to the presence or risk of developing particular diseases or conditions and information regarding family relationships), data must be shared in a manner consistent with the research participants’ informed consent, and the confidentiality of the data and the privacy of participants must be protected. Access to human data will be provided to investigators who, along with their institutions, have certified their agreement with the expectations and terms of access described in this document. LUDC expects that, through the data access application process, approved users of datasets recognize any restrictions on data use established by the submitting Institutions through the Institutional Certification, and as stated on this document/agreement. The parties to this agreement include: the Principal Investigator (PI) requesting access to the dataset, the PI’s home institution as represented by the Institutional Signing Official and the LUDC.

The applicant agrees that if access is approved, the PI and those named in the request form, working on the proposed research project under the direct oversight of the PI, shall become approved users of the requested dataset(s). Research use will occur only in connection with the approved research project described in the data access application, which includes a description of the proposed research. Investigators interested in using Cloud Computing for data storage and analysis must request permission to use Cloud Computing that describes the type of service and how it will be used to carry out the proposed research as described in the project plan. If the approved users plan to collaborate with investigators outside the applicant’s university, the investigators at each external site must submit an independent data access application using the same project title and research plan. New uses of these data outside those described in the data access application will require submission of a new data access application and modifications to the research project will require submission of an amendment to this application. Access to the requested dataset(s) is granted for a period of one (1) year, with the option to renew access or close-out a project at the end of that year.

The applicant agrees through the submission of the data access application that the PI named has reviewed and understands the principles for responsible research use and data management of the datasets as defined in this form. The applicant and approved users further acknowledge that they are responsible for ensuring that all uses of the data are consistent with national and state laws and regulations as well as relevant institutional policies and procedures for managing sensitive genomic and phenotypic data.

The applicant certifies that the PI is in good standing (i.e., no known sanctions) with the institution, relevant funding agencies, and regulatory agencies and is eligible to conduct independent research (i.e., is not a postdoctoral fellow or student). The applicant and any approved users may use the dataset(s) only in accordance with the parameters described in the project plan above, as described in the data access application, and as required by law.

Through submission of the data access application, the PI and applicant agree to submit a Project Renewal or Project Close-out prior to the expiration date of the one (1) year data access period. The PI also agrees to submit an annual Progress Update prior to the one (1) year anniversary of the project, as described under *Reporting* below.

By approving and submitting the attached data access application, the Institutional Signing Official provides assurance that relevant institutional policies and applicable local, state and national laws and regulations, as applicable, have been followed, including institutional review board (IRB) and/or ethical review board (ERB) approval, if required. Approved users may be required to have IRB/ERB approval if they have access to personal identifying information for research participants in the original study at their institution, or through their collaborators. The Institutional Signing Official also assures, through the approval of the data access application, that other institutional departments with relevant authorities (e.g., those overseeing human subjects research, information technology, technology transfer) have reviewed the relevant sections of this application.

The PI agrees that information about themselves and the approved research use can be posted publicly on the LUDC website. The information includes the PI’s name and applicant, project name and plan. Citations of publications resulting from the use of controlled-access datasets obtained through this data access application may also be posted on the LUDC website.

Approved users agree not to use the requested datasets, either alone or in concert with any other information, to identify or contact individual participants from whom data and/or samples were collected. Approved users also agree not to generate information that could allow the identities of research participants to be readily ascertained.

The applicant and approved users agree to retain control of LUDC controlled-access datasets obtained through the data access application, and any data derivatives of controlled-access datasets, and agree not to distribute controlled-access datasets to any entity or individual not identified in the submitted data access application. Each approved user will follow all data security practices and other terms of use defined in this agreement and the applicant’s IT security requirements and policies. The applicant acknowledges responsibility for ensuring the review and agreement to the terms within this Agreement and the appropriate research use of data obtained through the attached data access application by research staff associated with any approved project. Applicants agree that datasets obtained through the attached data access application and any data derivatives of controlled-access datasets, in whole or in part, may not be sold to any individual at any point in time. The PI agrees that if they change institutions during the access period they will complete a project close-out process before moving to their new institution. A new data access application must be approved before controlled-access data may be reaccessed.

The applicant and approved Users, including the applicant’s IT Director, acknowledge LUDC’s expectation that they have reviewed and agree to manage the requested controlled-access dataset(s) and any data derivatives of the datasets according to LUDC’s expectations and the applicant’s IT security policies. The applicant, including the applicant’s IT Director, agree that the applicant’s IT security requirements are sufficient to protect the confidentiality and integrity of the LUDC controlled-access data.

The applicant and PI agree to notify the data access committee through the LUDC contact person indicated within this document of any unauthorized data sharing or breaches of data security, that may compromise data confidentiality. Notifications should include any known information regarding the incident to define and remediate the situation fully. The applicant also agrees to submit to the data access committee a detailed written report including the date and nature of the event, actions taken to remediate the issue(s), and plans to prevent further problems. Repeated violations or unresponsiveness to LUDC requests may result in further compliance measures affecting the applicant. All notifications and written reports of data security incidents and policy compliance violations should be sent to the data access committee through the LUDC contact person indicated in this agreement.

It is LUDC’s intent to promote the dissemination of research findings from use of controlled-access dataset(s) through scientific publication or other appropriate public dissemination mechanisms. Approved users are encouraged to publish their results in peer-reviewed journals and to present research findings at scientific meetings. Approved users agree to acknowledge the submitting investigator(s) who submitted data from the original study to a LUDC-designated data repository, the primary funding organization that supported the submitting Investigator(s), and the LUDC-designated data repository, in all oral and written presentations, and publications resulting from any analyses of controlled-access data obtained through the attached data access application. Approved users agree that the acknowledgment shall include the LUDC accession number to the specific version of the dataset(s) analyzed.

The PI agrees to provide annual progress updates, prior to the expiration of the one (1) year data access period. This should be sent to the data access committee through the LUDC contact person. The PI who is seeking renewal or close-out of a project agree to provide specific information such as how the data have been used, including publications or presentations that resulted from the use of the requested dataset(s), a summary of any plans for future research use (if seeking renewal), any violations of the terms of access described within this agreement.

The applicant and approved users acknowledge that although all reasonable efforts have been taken to ensure the accuracy and reliability of controlled-access data obtained through the attached data access application, the LUDC and submitting Investigator(s) cannot warrant the results that may be obtained by using any data included therein. LUDC disclaim all warranties as to performance or fitness of the data for any particular purpose.

Upon project close-out, the applicant and approved users agree to destroy all copies, and data derivatives of the dataset(s) retrieved from LUDC-designated controlled-access databases, on both local servers and hardware, and delete the data and cloud images from cloud computing provider storage, and databases. However, the applicants may retain these data as necessary to comply with any institutional policies (e.g., data retention policy), law, and scientific transparency expectations for disseminated research results, and/or journal policies. An applicant who retains data for any of these purposes continues to be a steward of the data and is responsible for the management of the retained data in accordance with any institutional policies. Any retained data may only be used by the PI and applicants to support the findings (e.g., validation) resulting from the research described in the data access application that was approved by the LUDC. The data may not be used to answer any additional research questions. If an applicant retains data for any of these purposes, the terms within this application remain in effect until the data is destroyed.

**Definitions**

**Approved user:** A user approved by the data access committee(s) to access one or more datasets for a period of time and for the purposes outlined in the Principal Investigator (PI)’s approved research plan and data access application. The Information Technology (IT) Director indicated on the Data access application, as well as any staff members under the direct supervision of the PI are also approved users and must abide by the terms laid out in the data access application.

**Collaborator:** An individual who is not under the direct supervision of the PI (not a member of the PI’s laboratory) who assists with the PI’s research project involving LUDC derived data.

**Data derivative:** Data derived from controlled-access datasets obtained from LUDC-designated data

repositories. Examples of derived data include DNA methylation, gene expression and single nucleotide polymorphisms data sets.

**Information Technology (IT) Director:** An approved user who is generally a senior IT official of the Applicant. The IT Director is expected to have the authority and capacity to ensure that the applicant’s IT security requirements are followed by all of the applicant’s approved users.

**Institutional certification:** Certification by the submitting Institution that delineates the appropriate research uses of the data and the uses that are specifically excluded by the relevant informed consent documents.

**Institutional signing official:** The label, "Signing Official," refers to the individual that has institutional authority to legally bind the institution in grants administration matters. The Signing Official for the applicant reviews Data access application, project renewal, and close-out applications submitted by Principal Investigators and legally binds the applicant to agree to adhere to the terms described in this agreement submitted to LUDC. The Institutional Signing Official for the Submitting Institution enters into the Institutional Certification and signs on behalf of the submitting Investigator(s).

**Principal Investigator (PI):** The investigator who prepares data access application, project renewals, and close-outs. The Principal Investigator plays a lead role in ensuring that management and use of controlled-access data remains consistent with the terms in this agreement. A Principal Investigator must be designated as such by their institution and be a permanent employee of their institution at a level equivalent to a tenure-track professor or senior scientist.

**Progress update:** Information included with the annual Data access application renewal or closeout, summarizing the analysis of datasets obtained through the data access application and any publications and presentations derived from the work.

**Project Close-out:** Termination of a research project that used data from the LUDC repository and confirmation of data destruction when the research is completed.

**Project Renewal:** Renewal of a PI’s access to datasets for a previously-approved project.

**Applicant:** The home institution or organization of the approved user that applies to LUDC repository for access to controlled-access data.

**Submitting Institution:** An organization who submitted a dataset to the LUDC repository.

**Submitting Investigator:** An investigator who submitted a dataset to the LUDC repository.

**The data access application and any reporting should be sent to the LUDC data access committee’s contact person:** [**charlotte.ling@med.lu.se**](mailto:charlotte.ling@med.lu.se)

**A CV and publication list for the PI should be attached with the data access application**