EXAMPLE TEMPLATE – FOR INFORMATIONAL PURPOSES ONLY

This form is an EXAMPLE only and should not be filled out and sent to the NIDDK Central Repository. If you are interested in requesting data stored at the NIDDK Central Repository, please navigate to the 'Requests' tab from the NIDDK-CR Homepage and select "Data Request".

NIDDK Central Repository – Resources for Research (R4R)

Data Request Form

The following example responses are shown for informational purposes only. Do not copy any of the example responses to populate the request fields.

* = Required Field

General

Request Name*

Research Project on DCCT Data

Study*

(DCCT/EDIC) Diabetes Control and Complications Trial / Epidemiology of Diabetes Interventions and Complications

Select the desired studies.

Research Team Information

Requestor Information

Name (*auto-populated*)

John Doe

Institution Name (*auto-populated*)

University of Anytown

Email Address (*auto-populated*)

john.doe@university.edu

Institution Location (*auto-populated*)

State, US

Phone (*auto-populated*)

111-222-3333

Principal Investigator Information

Email Address*

jane.charge@university.edu

First Name* | M.I. | Last Name*

Jane | *N.* | *Charge*

Job Title/Position*

Professor

Other Researchers Under the PI

Provide the names of other researchers in the same institution as the PI that will have access to the data (or its derivatives).

+ Add Researcher

Authorized Organization Representative Information

Please provide the name, title, and email address of the official from your institution who will act as the Authorized Signatory on the Agreement. The Authorized Signatory (aka Signing Official) is described on the Frequently Asked Questions page as follows:

A Signing Official (SO) from your institution should provide this signature. An SO has institutional authority to legally bind the institution in grants administration matters. The individual fulfilling this role may have any number of titles in the grantee organization. For most institutions, the Signing Official (SO) is located in its Office of Sponsored Research or equivalent.

Email Address*

authorized.signatory@university.edu

First Name* | M.I. | Last Name*

John | *A.* | *Sign*

Job Title/Position*

Contract Manager

Independent Collaborators

Provide the names and institutions of collaborators in a different institution than the PI that will have access to the data (or its derivatives); a secondary agreement is required for Independent Collaborators and their institutions.

+ Add Collaborator

Research Project Information

Title of Research Plan*

EXAMPLE: *Effects of Factors A, B, C, and D on Outcome1 and Outcome2 in Type 1 Diabetics*

Description of Research*

The Research Description must convey the relevant background to justify the request. This should include the following information:

- Scientific premise, including the importance of the research question and the potential impact of the project
- Explanation on how the data being requested will accomplish the aims of the proposed research project

EXAMPLE: *The incidence of type 1 diabetes (T1D) is increasing at alarming rates worldwide, but the etiology of T1D remains unknown. Studies have identified several environmental factors as potential triggers for autoantibody development and T1D diagnosis. However, these studies investigate single exposures and do not account for the interplay between the timing of multiple environmental triggers for T1D. A clearer understanding of the temporality and interactions between environmental exposures in triggering autoantibody development is needed to inform strategies to prevent or delay T1D diagnosis.*

Through access to de-identified data from the DCCT study, I will use statistical methods to elucidate environmental triggers for T1D. Factors A, B, C, and D will be included in the analysis to investigate the impact on Outcome1 and Outcome2. Confidentiality and privacy will be maintained by storing the DCCT data in a secure, encrypted, and password-protected analysis environment at Anytown University School of Public Health and Health Services. My proposed research does not involve the use of any other data sources other than the DCCT data.

Research Objectives and Design*

Please provide a description of your Research Objectives and Design. The description should include the hypothesis that will be tested, research methodology and analysis procedures, and justification for the use of the specific data for your research project.

EXAMPLE: *Statistically, the principal predictor variables will be Factors A, B, C, and D, while the dependent outcome variable is time to Outcome1. The main research objective will be to examine any relationships between participant Variable1 and the related risk to Outcome2. My primary statistical methods will include using Cox proportional hazards models for separate survival analyses for each factor and the time to Outcome1, if reached. I also plan to use Pearson correlation analyses and simple linear regression to determine whether there are relationships between the Factors A, B, C, and D, the potential confounding variables, and the ClinicalMeasure1 levels. I will be stratifying my analysis between the trial cohorts, primary prevention and secondary intervention, as disease progression will likely affect the time to Outcome1. All necessary power calculations will be performed using the R statistical package.*

Analysis Plan*

The Analysis Plan must describe a detailed plan for data analysis. This should include:

- A brief summary of the team's expertise and experience to perform the analysis proposed
- Specifics on how the data will be held, managed, and processed

EXAMPLE: *I plan to compare the relative hazards of the following factors: A, B, C, and D, with ClinicalMeasure2 among DCCT participants. These will be measured by the baseline Factor A and B Intake questionnaire. The primary outcome event will be DCCT-defined Outcome1 >40mg per 24 hours, confirmed by urine Analyte1 excretion rate data from the Central Biochemistry Laboratory forms. As possible confounding variables of interest, I will also be analyzing Analyte2 values, Analyte3 levels, participant age, and baseline study stratumfrom the CBL Monthly Analyte2 Values form, Medical History and Physical Examination form, and Patient Identification forms respectively.*

Public Use Statement*

The Public Use Statement should be a standalone summary (1 to 2 paragraphs) of the proposed research project in layman's terms to be made publicly available and featured in the List of Approved Requestors on the NIDDK-CR website.

EXAMPLE: *The purpose of my research is to analyze the effects of Factors A, B, C, and D on Outcome1 and Outcome2 in type 1 diabetics. The general study design for my project is a secondary analysis of DCCT data. I will be comparing baseline levels of Factors A, B, C, and D with the time to onset of ClinicalMeasure1 throughout the DCCT Study period. All participants throughout the entire DCCT study will be included, except for the subset of participants who presented ClinicalMeasure1 at baseline, who will be excluded from my analyses.*

Support Information

Support Type	Other
NIH Extramural Funding Award Number	

Grant Number, if NIDDK funded

Policy Compliance and Documentation

Data Security

Please select the information security practices that will be used*

- [✓] Institute supported, controlled access server
- [✓] Institute supported, password protected desktop computer
- [✓] Encrypted, password protected laptop computer
- [ ] Encrypted portable media (encrypted external hard drive, encrypted thumb drive)
- [ ] Unencrypted portable media backup (CD, DVD, thumb drive) stored in locked file cabinet

Additional Comments

EXAMPLE: *The Anytown University Division of Information Technology has set up an agreement with me to use an AU- supplied encrypted, password-protected laptop that has all safeguards specified for NIDDK data for my data analyses in my research. I have developed a data security and management plan with AU, in order for the university to sign off on my DUA, and they will be responsible for any IT support with the encrypted equipment. The laptop will be stored at my office at the AU Biostatistics Center, which has many physical safeguards of an office that supports other NIDDK studies. I will be the sole user with access to the NIH data.At the conclusion of my analyses, AU IT will ensure that all data has been removed from the system.*

Attachments

IRB Approval*

For access to the data, you must have your institution's IRB approval or waiver. If you do not have an IRB, you must use an external IRB. This IRB step is required whether or not you publish your findings. Since the data has been de-identified and provided as a Limited Datasets according to the HIPAA definition, your IRB may consider issuing a waiver.

Other Documents