Data Request Form

If you are interested in requesting specific collection data from the NIDDK data repository, update and submit the form below and a member of the NIDDK Central Repository staff will contact you within 7-10 days. If desired, you may save the form instead and return to complete it at a later time.

* = Required Field

Data Request

Request Name*

Research Project on DCCT Data

Create a nickname for your reference

Requestor Information

Name*

John Doe

Email*

john.doe@university.edu

Address*

123 Main Street
Anytown, US 12345

Title

Postdoctoral Fellow

Institution

University of Anytown

Phone

111-222-3333

Fax

111-222-4444

Website

www.university.edu/mylabpage/

A URL for the requestor if they have a site.

PI Name*

Dr. Jane N. Charge

PI Institution*

Any Place University

PI Email*

jane.charge@apuniversity.edu

Support Information

Support Type

NIH Extramural Funding Award Number

Other

Grant/PAR Number

Request Details

Study*

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

Select the desired studies. Hold down "Control", or "Command" on a Mac, to select more than one.

Information Security: Please check the information security practices to be used

- [x] Institute supported, controlled access server
- [x] Institute supported, password protected desktop computer
- [x] 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

Study data must be maintained in a secure and controlled environment

Comments

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.

Agreement Form

Title of Research Plan*

Effects of Factors A, B, and C on Outcome1 in Type 1 Diabetics

Other Users*

None

Collaborators

Names of any independent collaborators and their institution(s).

Requested Materials*

DCCT Data Set

Description of Research*

I am requesting the provision and use of the DCCT data sets for my research project at the Anytown University School of Public Health and Health Services. I have submitted a concept paper outlining my intended research, and was approved through the Anytown University Institutional Review Board as exempt from IRB review, as my research will not be involving human subjects and will be using de-identified data sets. I am not planning to use the data sets from the EDIC study. The only variables I intend on using from the DCCT data sets are not sufficient to identify any research participants included in my analyses. Since the data will be de-identified, there will not be any identifying information used in any manuscripts or presentations. Confidentiality and privacy will be maintained by affirming that all DCCT data released by NIDDK will remain de-identified and anonymous, and maintained on a secure medium.

Research Objectives and Design*

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*

I plan to compare the relative hazards of the following factors: A, B, C, D, and E, 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 stratum from the CBL Monthly Analyte2 Values form, Medical History and Physical Examination form, and Patient Identification forms respectively.

Public Use Statement*

The purpose of my research is to analyze the effects of Factors A, B, and C on Outcome1 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, and C 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.

Please include a one-two (1-2) paragraph Research Use Statement which may be made publicly available.