

**DCCT-EDIC Data Archive**

**Version 19.0**

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The highest level of study archive (Version 16) for DCCT and EDIC appears as follows:

DCCT  
 DCC\_EDIC Ancillary  
 DCCT\_EDIC Documents  
 EDIC

Each of these directories is described in detail in this document. However, the order of appearance in this document differs from appearance in the actual file. First, we present all information related to the Diabetes Control and Complications Trial (DCCT). The Epidemiology of Diabetes Interventions and Complications (EDIC) is presented second, followed by Ancillary studies related to both studies.

## **\DCCT\_EDIC Documents\**

The root directory contains “Publication List Dec2014.pdf”, which is a list of DCCT-EDIC publications.

### **Diabetes Control and Complications Trial (DCCT)**

Information about DCCT is contained in these directories and subdirectories:

DCCT\_EDIC Documents\DCCT  
 DCCT\_EDIC Documents\SAS Formats  
 DCCT

**\DCCT\_EDIC Documents\DCCT** directory contains four files:

- DCCT Protocol.pdf - DCCT Study Protocol
- DCCT MOOP\_rev\_12-23-08.pdf - DCCT Manual of Operations (formerly called MOOP\_rev\_12-23-08.pdf).
- DCCT\_Forms-to-Datasets\_REV\_2.xls - spreadsheet cross-referencing forms, datasets, numbers of variables and observations
- DCCT Primary Analysis Documentation.pdf – analysis documentation accompanying the first primary results paper documenting the effect of intensive therapy in the DCCT trial, *The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. The DCCT Research Group. NEJM 1993, 329(14):977-986* (formerly called Documentation\_NEJM2.pdf) <http://content.nejm.org/cgi/content/abstract/329/14/977>

**\DCCT\_EDIC Documents\SAS Formats** directory contains five SAS format files submitted by the data coordinating center to assist with the labeling of data values in DCCT/EDIC raw or analysis datasets. Limited description of formats may be found at the top of each program. The NIDDK Repository has not verified the utility of these programs; they are simply provided here for the possible benefit of the user:

- fmt.SAS
- fmt\_base.sas
- fmt\_dcct.sas
- fmt\_ee.sas
- fmt\_mnsi.sas

**\DCCT** directory contains four subdirectories, as described below:

### **\DCCT\DCCT Analysis Datasets**

The archive contains 9 subdirectories: Adverse Events, Baseline, Family Clustering, Glycemic Exposure, Macrovascular, Nephropathy, Neurobehavioral, Neuropathy, and Retinopathy. Unless otherwise indicated, all documentation was previously released by the National Technical

- \Documents – May contain the following types of documents:
  - Analysis documentation in pdf format - The detailed statistical results used in the paper publishing the analysis. The document may contain a reprint of the publication.
  - Codebook files - a codebook or data dictionary for the data used in the analysis. Most codebooks also contain an “Appendix A” containing SAS contents of the analysis datasets and an “Appendix B” containing summary statistics. These appendices may reference TRANSPORT or EXPORT files that are NOT part of the distributed archive. These files were extracted into one or more SAS datasets which are included in the archive.
- \SAS\_DATA – Contains the data used in the analysis in sas7bdat format, usually comprising only one dataset.

\DCCT\DCCT Analysis Datasets \DCCT Adverse Events

- \Documents - AdverseEvents\_DOC\_rev.pdf, AdverseEventCODEBOOK\_REV.pdf, M9EXEVET\_dictionary\_rev7-2008.pdf.
- \SAS\_DATA - (9 datasets) m9exall.sas7bdat, m9excaif.sas7bdat, m9exdeth.sas7bdat, m9exdka.sas7bdat, m9exevet.sas7bdat, m9exhpcs.sas7bdat, m9exhpra.sas7bdat, m9exmorb.sas7bdat, m9exnhds.sas7bdat. The dataset “m9exevet.sas7bdat” was re-released by the study data coordinating center in July 2008, along with a corresponding dictionary.

\DCCT\DCCT Analysis Datasets \DCCT Baseline

- \Documents - BaselineCODEBOOK.pdf
- \SAS\_DATA - baseline.sas7bdat

\DCCT\DCCT Analysis Datasets. \DCCT Family Clustering

- \Documents - FamilyClustering\_DOC\_rev2.pdf, Family Clustering Quasi-CODEBOOK.pdf
- \SAS\_DATA - dtfamcls.sas7bdat

\DCCT\DCCT Analysis Datasets \DCCT Glycemic Exposure

- \Documents - GlycemicExposure\_DOC.pdf, GlycemicExpCODEBOOK\_REV.pdf
- \SAS\_DATA - ms12expt.sas7bdat

\DCCT\DCCT Analysis Datasets \DCCT Macrovascular

- \Documents - MacrovascularCODEBOOK\_Rev5.pdf
- \SAS\_DATA - ms5event.sas7bdat, ms5exprt.sas7bdat

\DCCT\DCCT Analysis Datasets \DCCT Nephropathy

- \Documents - Nephropathy\_DOC.pdf, NephropathyCODEBOOKnew.pdf
- \SAS\_DATA - ms3exprt\_c.sas7bdat. This dataset was modified to eliminate a privacy concern.

\DCCT\DCCT Analysis Datasets \DCCT Neurobehavioral

- \Documents - Neurobehavioral\_DOC.pdf, NeuroBehavCODEBOOKrev\_fixed.pdf

- \SAS\_DATA - ms7exf10.sas7bdat, ms7exgee\_fixed.sas7bdat. The latter dataset was modified from a previous release (ms7exgee.sas7bdat, dated 12/7/2006) to eliminate nine duplicate observations.

*\DCCT\DCCT Analysis Datasets\DCCT Neuropathy*

- \Documents - Neuropathy\_DOC\_REV.pdf, NeuropathyCODEBOOK.pdf
- \SAS\_DATA - ms4exprt.sas7bdat

*\DCCT\DCCT Analysis Datasets\DCCT Retinopathy*

- \Documents - Retinopathy\_DOC.pdf, RetinopathyCODEBOOK.pdf
- \SAS\_DATA - ms2exprt.sas7bdat

***\DCCT\DCCT Forms***

The “DCCT Forms” directory contains the 53 study forms in pdf format. See Appendix 2 for a list of the DCCT forms.

***\DCCT\DCCT Raw and Analysis Variable Summary***

The “DCCT Raw & Analysis Variable Summary” directory contains one document, Describe\_All\_Datasets\_REV.pdf, which describes the variables in the datasets collected using DCCT case report forms (CRFs) and the DCCT analysis datasets. The descriptions were created using Stata describe (263 pages).

***\DCCT\DCCT Raw Datasets***

The “DCCT Raw Datasets” directory contains 53 datasets, in SAS version 7-8-9 format, associated with data collected in the 53 aforementioned study forms. See **Appendix 1** for a list of the datasets. In previous versions of the archive, this directory was called “DCCT SAS Data”. As part of the curation process, the repository modified randomization dates to ensure proper de-identification of the data. The day portion of the randomization date was changed to always be the first day of the randomization month, e.g., January 18th, 1989 would have been changed to January 1st, 1989; July 4, 1991 to July 1, 1991; etc. This change affected thirteen of the datasets. The affected datasets are identified by a “\_c” suffix appended to the dataset name. Also, the following changes were made to the dataset F001cmb6 for de-identification purposes and a “\_c” suffix was appended to this dataset name:

- For the variable **oaprevin** (previous initials), any non-blank entry was changed to XXX. Entries that were already blank were left blank.
- For the variable **oaprevid** (previous id number), any non-missing entry was changed to 99999.

**Epidemiology of Diabetes Interventions and Complications (EDIC)**

Information about EDIC is contained in these directories and subdirectories:

DCCT\_EDIC Documents\EDIC  
DCCT\_EDIC Documents\SAS Formats  
EDIC

*Note on EDIC study years:* The EDIC baseline visit (=EDIC Year 0) is the same as DCCT close-out visit. Study years in EDIC are counted from EDIC baseline. The current version of the archive contains data collected up to April, 2007 (the end of EDIC Year 13). EDIC data collection is ongoing and data are released in progressive increments.

**\DCCT\_EDIC Documents\EDIC** contains 5 documentation files:

- \EDIC\_Forms-to-Datasets\_Mapping\_Years01-13.xls spreadsheet listing forms,

datasets, numbers of variables and observations. In addition, the document indicates exactly which forms correspond with which datasets, for each data collection period (Years 1-8 , Years 8-13, Year 13 Part 2.). It also indicates anomalies such as which datasets are lacking corresponding forms, which forms are lacking corresponding datasets, and which forms have two (or more) associated datasets. The reasons for these anomalies are also given. Users are strongly advised to consult this spreadsheet prior to beginning any analyses using EDIC raw (forms) datasets. Analysis datasets are *not* itemized on this spreadsheet, as they represent merged and transformed versions of the raw datasets.

- \EDIC\_Manual\_and\_Protocol—Oct2013.pdf—EDIC Protocol and Manual of Operations, last revised in October, 2013.
- \EDIC\_Manual\_Chp-14\_historic--Mar2012.pdf—A historic version of Chapter 14 of the EDIC Manual. It describes the collection of Cystatin C in serum, which was discontinued August 1, 2012.
- \DataReleaseDescription\EDIC\_Data\_Release\_Nov2012.pdf—Documentation file provided by the study Data Coordinating Center, with information on individual data abnormalities, etc. Highlighted notes have been added by the NIDDK Repository.
- \EDIC Summary\_Year12.pdf – Brief summary of the primary results of DCCT/EDIC.

**\DCCT\_EDIC Documents\SAS Formats** contain five SAS format files submitted by the data coordinating center to assist with the labeling of data values in DCCT and EDIC raw/ analysis datasets. Limited description of formats may be found at the top of each program. The NIDDK Repository has not verified the utility of these programs; they are simply provided here for the possible benefit of the user:

- fmt.SAS
- fmt\_base.sas
- fmt\_dcct.sas
- fmt\_ee.sas
- fmt\_mnsi.sas

**\EDIC** directory contains five subdirectories, as described below. The order of appearance in the archive varies from presentation below but contents are identical.

- EDIC Forms- study data collection forms used anytime during EDIC Years 1-13
- EDIC\_Years\_01-08 - data collected in March 2004 to September 2001 (EDIC Years 1-8)
- EDIC\_Years\_08-13 - data collected in September 2001 to September 2006 (EDIC Years 8-13)<sup>1</sup>
- EDIC\_Years\_13\_Part2 remaining data collected to April 2007 that was not submitted previously (through the close of EDIC Year 13)<sup>2</sup>
- EDIC Analysis Datasets- datasets associated with key publications; may represent data collected throughout the EDIC period.

<sup>1</sup> More accurately, the time span encompasses mid-year 8 through mid-year 13.

<sup>2</sup> Data was in EDIC\_Years\_13\_Part2 was submitted separately from data in EDIC\_Years\_08-13. Due to coincident file names, materials were retained in separate subdirectories.

**\EDIC\EDIC Forms**

This subdirectory contains files in two subdirectories:

**\EDIC\EDIC Forms \EDIC Forms**

The “EDIC Forms” subdirectory contains 67 study forms in pdf format used during EDIC Years 1-13. See Appendix 3 for a list of the forms. Also, refer to the document:

\DCCT\_EDIC\Documents\EDIC\EDIC\_Forms-to-Datasets\_Mapping\_Years01-13.xls, an exact cross-listing of EDIC Forms to Datasets.

**\EDIC\EDIC Forms \EDIC Annotated Forms**

The “EDIC Annotated Forms” subdirectory contains 65 annotated study forms in pdf format used during EDIC Years 1-13. Annotated forms have their questions labeled with the corresponding variable names. Two EDIC Forms (52.1 and 53.1) do not have corresponding annotated forms, because they carry no associated data.

**Notes about EDIC Forms:**

- Some forms were utilized during the EDIC Years 1-8, others during EDIC Years 8-13, and some throughout the entire period. For ease of reference, all forms were combined into one “EDIC Forms” directory.

- The DCC submitted duplicate copies of several forms, as they corresponded with progressive data releases. Only one unique copy of each form is retained in the archive.

- Some individual forms have multiple corresponding datasets. All datasets are mutually exclusive. Multiple datasets occur when:

- Forms in use across the three periods (Years 1-8, Years 8-13, Year 13 Part 2) have mutually exclusive datasets representing data collected within each period.

- A database change at the study Data Coordinating Center took place in 2005-06. All data entered into the new database were retained in separate datasets. See footnotes in \DCCT\_EDIC Documents\EDIC\EDIC\_Forms\_and\_Datasets\_Years01-13.xls.

**\EDIC\EDIC\_Years\_01-08**

This subdirectory contains materials pertaining specifically to data collected in March 2004 up to September 2001 (EDIC Years 1-8). Users are advised to refer to the document:

\DCCT\_EDIC\Documents\EDIC\EDIC\_Forms-to-Datasets\_Mapping\_Years01-13.xls to see how forms match to corresponding datasets utilized during the EDIC period.

**\EDIC\EDIC\_Years\_01-08\EDIC\_Years\_01-08 Raw Datasets**

The “EDIC Raw Datasets” directory contains 44 datasets in sas7bdat format; see Appendix 4 for a list of the datasets. These datasets represent raw (forms) data collected during EDIC Years 1-8.

**\EDIC\EDIC\_Years\_01-08\EDIC\_Years\_01-08 Data Dictionaries**

This directory contains two documents:

- EDIC\_Years\_01-08contents.pdf documents the number of observations and ranges for all variables in the raw datasets (except variables in f1301.sas7bdat, which are in a separate document (called DescribeData\_ALL.pdf in previous versions of the archive).
- F1301\_contents.rtf documents the number of observations and ranges for each variable in f1301.sas7bdat. This dataset is associated with Form 130.1, “Parents and Siblings of EDIC/DCCT Patients”. Note that:

1. Form 130.1 is considered both an analysis dataset (included in the EDIC Analysis Datasets directory), and a raw data collection form that was used during the EDIC Years 1-8 period. Form 130.1 was also used during the EDIC Years 8-13 period.
2. There is a separate protocol associated with this EDIC family substudy that is **not** currently in the archive. The goal of this substudy was to obtain additional DNA samples from patients and family members not sampled in DCCT. This includes DNA and lymphocytes from all parents, all diabetic full siblings, and at least one diabetic full sibling of DCCT/EDIC participants.

### ***\EDIC\EDIC\_Years\_08-13***

This subdirectory contains materials pertaining specifically to data collected in September 2001 up to September 2006 (EDIC Years 8-13). More accurately, the time span encompasses EDIC mid-year 8 through mid-year 13. Again, users are encouraged to refer to the document: `\DCCT_EDIC\Documents\EDIC\EDIC_Forms_and_Datasets_Years01-13.xls` to see how forms match to datasets utilized during the EDIC period.

Note: In a previous version (version 8) of the Archive, `\EDIC\EDIC_Years_08-13` was called “2008 and 2009 Release”.

### ***\EDIC\EDIC\_Years\_08-13\EDIC\_Years\_08-13 Raw Datasets***

This directory contains 35 sas7bdat datasets; see Appendix 5 for a list of the datasets.

### ***\EDIC\EDIC\_Years\_08-13\EDIC\_Years\_08-13 Data Dictionaries***

This directory contains 35 SAS proc contents files, mostly in rtf format except for 3 files in doc format (f0025\_rev, f0026\_rev, and f0027\_rev), corresponding with the 35 raw datasets. See `\DCCT_EDIC\Documents\EDIC\EDIC_Forms_and_Datasets_Years01-13.xls` for a matching of contents files to datasets.

### ***\EDIC\EDIC\_Years\_13\_Part2***

This subdirectory contains materials pertaining to data collected from September 2006 to April 2007 (the close of EDIC Year 13). This time span encompasses the second half of EDIC Year 13. However, some data, e.g., records from the Neurology/Autonomic Neuropathy Studies (ANS) component, may have been collected before Year 13.

### ***\EDIC\EDIC\_Years\_13\_Part2\EDIC Year13 Part2 Raw Datasets***

This directory contains 28 sas7bdat datasets; see Appendix 6 for a list of the datasets.

### ***\EDIC\EDIC\_Years\_13\_Part2\EDIC Year13 Part2 Data Dictionaries***

This directory contains 28 variable summary files, in pdf format, corresponding with the 28 datasets in the “EDIC\_Year13\_Part2 Raw Datasets” subfolder.

### ***\EDIC\EDIC\_Years\_14-18***

This subdirectory contains materials pertaining specifically to data collected in May 2007 up through June 2012 (EDIC Years 14-18).

### ***\EDIC\EDIC Analysis Datasets***

This subdirectory contains files associated with key publications from EDIC. Each study-specific subdirectory listed above includes a brief “documentation” file that describes the study, including numbers of patients and observations, main outcome, covariates and data collection schedule.

Each study comes with one or more codebook files, which describes the variables in each dataset, including variable name, label, type, length, format, number, range.

Each study also comes with a “fdmean” file that provides summary statistics, including variable label, N (number of observations), answer (Y/N), %, Mean, STD, Min, Max. Lookup values and ranges for variables are contained in SAS format files (“.sas”).

Contents of the `\EDIC\EDIC Analysis Datasets` archive directories are as follows:

`\EDIC\EDIC Analysis Datasets\EDIC Baseline\`: EDIC baseline cohort

- `EDIC_Baseline_Integrity_v1.0.pdf`. Analysis by repository statisticians to ensure that the dataset distributed by the repository is a true copy of the study data.
- `Edicbase.sas7bdat`
- `edicBase_codebook.rtf`
- `edicBASE_documentation.doc` ). A description of the EDIC cohort at baseline includes definitions of albumin excretion rate, hypoglycemia, diabetic ketoacidosis, overweight, and IMT thickness.
- `edicBase_fd_mean.rtf`

`\EDIC\EDIC Analysis Datasets\EDIC_Cheiroarthropathy\`

This subdirectory contains analysis data and documentation associated with the EDIC cheiroarthropathy paper. Subdirectory contents are as follows:

- Documents - This subdirectory includes the following:
  - `CHEIRO_DOCU.docx` – Includes a bibliography entry for the paper as well as notes on the structure of the datasets
  - `CHEIRO_CONTS.htm` and `CHEIRO_SHOULDER_CONTS.htm` – Contents listings for the “cheiro” and “shoulder” datasets
  - `CHEIRO_STATS.htm` and `CHEIRO_SHOULDER_STATS.htm` – Variable statistics for the “cheiro” and “shoulder” datasets
- `SAS_DATA` – This subdirectory contains “cheiro.sas7bdat” and “shoulder.sas7bdat”.

`\EDIC\EDIC Analysis Datasets\EDIC_CMRI\`

This subdirectory contains analysis data and documentation associated with the EDIC cardiac magnetic resonance imaging (CMRI) paper. Subdirectory contents are as follows:

- Documents - This subdirectory includes the following:
  - `Circulation-2011-Turkbey-1737-46.pdf` – EDIC CMRI paper
  - `EDIC cMRI paper 2015.doc` – Document containing brief summary of the dataset and variables used in the paper
  - `NIH_CMRI1240_Contents.pdf` – Dataset contents
  - `DSInfo_CMRI1240.pdf` – Variable statistics
- `SAS_DATA` - This subdirectory includes the SAS dataset “nih\_cmri\_risk1240.sas7bdat”

`\EDIC\EDIC Analysis Datasets\EDIC_CVD\`

This subdirectory contains analysis data and documentation associated with EDIC cardiovascular (CVD) outcomes. Subdirectory contents are as follows:

- Documents – This subdirectory includes the following:
  - `CVD 30yr Update Documentation 2016.doc` and `CVD Risk Factors Documentation 2016.docx` – Includes a bibliography entry for the paper as well as documentation on the 30 year update and risk factors datasets, respectively
  - `NIH_CVD30YR_EV_366_contents.pdf`, `NIH_CVD30YR_1441_contents.pdf`, and `CVD_RISKFACTORS_REL_Contents.pdf` – Contents listing for the “nih\_cvd30yr\_1441”, “nih\_cvd30yr\_ev\_366”, and “cvd\_riskfactors\_rel” datasets

- DSInfo\_CVD30YR\_1441.pdf, DSInfo\_CVD30YR\_EV\_366.pdf, and DSInfo\_CVD\_RiskFactors\_rel.pdf – Variable statistics for the “nih\_cvd30yr\_1441”, “nih\_cvd30yr\_ev\_366”, and “cvd\_riskfactors\_rel” datasets
- CVD\_30\_yr\_DSIC.pdf – Dataset Integrity Check for the 30 year update datasets
- CVD\_Risk\_Factors\_DSIC.pdf – Dataset Integrity Check for the CVD risk factors dataset
- SAS\_DATA – This subdirectory includes the SAS datasets “nih\_cvd30yr\_1441”, “nih\_cvd30yr\_ev\_366”, and “cvd\_riskfactors\_rel.sas7bdat”

\EDIC\EDIC Analysis Datasets\EDIC\_GFR\

This subdirectory contains analysis data and documentation associated with the EDIC glomerular filtration rate (GFR) paper. Subdirectory contents are as follows:

- Documents - This subdirectory includes the following:
  - GFR\_PAPER.doc - Document containing brief summary of the dataset and variables used in the paper
    - GFR2010\_CONTS.htm – Dataset contents
    - GFR2010\_STATS.htm – Variable statistics
- SAS\_DATA – This subdirectory includes the SAS dataset “gfr2010.sas7bdat”

\EDIC\EDIC Analysis Datasets\EDIC\_Neuro\_ANS\

This subdirectory contains analysis data and documentation associated with the Neurology/ANS component of EDIC. These datasets have no associated publication. Subdirectory contents are as follows:

- Documents- This subdirectory includes the following:
  - Neuro\_ANS Annotated Forms (9 PDF data forms from EDIC used to collect data for the Neurology/ANS component of EDIC with corresponding variable names in the raw data for those forms: EDIC050\_3\_annotated, EDIC051\_1\_annotated, EDIC052\_2\_annotated, EDIC054\_1\_annotated, EDIC055\_1\_annotated, EDIC055\_2\_annotated, EDIC055\_3\_annotated, EDIC057\_1\_annotated, EDIC058\_1\_annotated)
  - Neuro\_ANS Forms (11 PDF data forms from EDIC used to collect data for the Neurology/ANS including all 9 annotated + EDIC052\_1 and EDIC053\_1)
  - NEURO\_ANS\_DOCUMENTATION\_20121110. Data documentation submitted by the study data coordinating center.
- SAS\_DATA - This subdirectory includes the following:
  - Data\_Dictionaries (contains ANSONLY\_contents.pdf and ANSREPT\_contents.pdf, variable content lists for the analysis)
  - ansonly.sas7bdat- analysis file with variables derived from the raw datasets.
  - ansreprt.sas7dbat- analysis file with variables derived from the raw datasets.
  - ReadMe.rtf : a note from the NIDDK repository about location of raw dataset for forms used in the analyses (50-58). **note:** the raw datasets are located in the subdirectory: \EDIC\EDIC\_Years\_13\_Part2\EDIC\_Year13\_Part2Raw Datasets

\EDIC\EDIC Analysis Datasets\EDIC relatives – Form 130\

This form was used to collect data on parents and siblings of EDIC cohort patients. Note that:

1. Form 130.1 is considered as both an analysis dataset, and as a raw data collection form that was used during the EDIC Years 1-8 period.
2. It was also used during the EDIC Years 8-13 period.
3. There is no specific publication associated with this dataset.
4. There is a separate protocol associated with this EDIC family substudy that is not currently in the archive. The goal of this substudy was to obtain additional DNA samples from patients and family members not sampled in DCCT. This includes

DNA and lymphocytes from all parents, all diabetic full siblings, and at least one diabetic full sibling of DCCT/EDIC participants.

Documents in this subdirectory include:

- EDIC\_Form\_130.1.pdf –Parents and Siblings of EDIC/DCCT Patients form used in study.
- EDIC130\_1\_annotated.pdf- form annotated with variable names
- f1301.sas7bdat – analysis file
- F1301\_contents.rtf – dictionary for form data
- F1301\_fdmean\_g.rtf- summary statistics for the participants

\EDIC\EDIC Analysis Datasets\EDIC Year 1 Carotid IMT: one year carotid intima-media thickness (IMT) study. Subdirectory contents are as follows:

- DiabeticPatients. Data and associated documentation are provided for **1352** diabetic patients. This subdirectory contains 5 files: edicimt1.sas7bdat (analysis file); edicIMT1\_Codebook.rtf (dictionary for form data); edicIMT1\_Fd\_Mean.rtf (summary statistics for the diabetic participants); edIMT1\_documentation.doc (description of descriptions of the data and atherosclerosis of the carotid artery, including definitions of IMT, albumin excretion rate, hypertension, and attained age); fmt.sas
- NonDiabeticPatients. Data and associated documentation are provided for **153** non-diabetic subjects This subdirectory contains 3 files: edcimt1x.sas7bdat; edicIMT1X\_Codebook.rtf (dictionary for form data); edicIMT1X\_Fd\_Mean.rtf (summary statistics for the non-diabetic participants)
- EDIC\_CarotidArteryThickness\_Integrity\_v1.0.pdf – integrity check of the data used to produce “Effect of Intensive Diabetes Treatment on Carotid Artery Wall Thickness in the Epidemiology of Diabetes Interventions and Complications, Diabetes, February 1999; Volume 48: 383-390.” Publication included.

\EDIC\EDIC Analysis Datasets\EDIC Year 4 Adolescent Retinopathy: four year adolescent retinopathy study. Subdirectory contents are as follows:

- Hypoglycemia\_EDAD4HYP. Data for **195** patients who were adolescents when randomized at DCCT entry, one record per patient. This subdirectory contains 3 files: edad4hyp.sas7bdat; edAD4HYP\_Codebook.rtf (dictionary for form data); edAD4HYP\_FD\_Mean.rtf (summary statistics on coma and seizure)
- Retinopathy\_and\_Nephropathy\_EDICADO4. Data for **171** patients who were adolescents when randomized at DCCT entry and had retinopathy or nephropathy data at EDIC Year 4, one record per patient. This subdirectory contains 4 files: edicAD04\_Codebook.rtf (dictionary for form data); edicAD04\_FD\_Mean.rtf (summary statistics on events related to analysis); edicado4.sas7bdat; fmt\_ado4.sas
- Retinopathy\_Nephropathy\_Hypoglycemia\_EDAD4ADL. Data for **1129** adults and **171** adolescents with retinopathy or renal data at EDIC Year 4, one record per patient. This subdirectory contains 3 files: edad4adl.sas7bdat; edAD4ADL\_Codebook.rtf (dictionary for form data); edAD4ADL\_FD\_Mean.rtf (summary statistics on events related to analysis)
- EDIC\_4YrAdolescent\_Integrity\_v1.0.pdf – integrity check of the data used to produce “Beneficial effects of intensive therapy of diabetes during adolescence: Outcomes after the conclusion of the Diabetes Control and Complications Trial (DCCT)”, The Journal of Pediatrics, December 2001; Volume 139, Number 6: 804-812.
- edicADOL4\_documentation.doc (description of analysis and outcome). A description of retinopathy, glomerular filtration, and acronyms.

\EDIC\EDIC Analysis Datasets\EDIC Year 4 Retinopathy and Nephropathy: Retinopathy was evaluated annually using fundus photographs through year 4 of the EDIC study (**369** patients year

**1, 443** patients year 2, **419** patients year 3, **1208** patients year 4) and nephropathy was evaluated using 4-hour urine specimens (649 patients year 3, 653 patients year 4). Subjects included roughly equal numbers of patients from the conventional and intensive therapy groups.

Subdirectory contents are as follows:

- 4\_Year\_Nephropathy\_REN4. This subdirectory contains 3 files edicREN4.sas7bdat; edicREN4\_codebook.rtf (dictionary for form data); edicREN4\_fdmean.rtf (summary statistics on events related to analysis)
- 4\_Year\_Retinopathy\_RET4. This subdirectory contains 5 files: edicRET4.sas7bdat (analysis file); edicRET4\_codebook.rtf (dictionary for form data); edicRET4\_fdmean.rtf (summary statistics for participants); edicRET4\_documentation.doc (includes the data collection schedule, fundus photography methods, the ETDRS diabetic retinopathy scale, ETDRS codes describing severity, and both versions (interim and final) of the ETDRS scale of severity (step 1 through 6); fmt\_ret4.sas
- EDIC\_RN\_Integrity\_v1.pdf – integrity check of the data used to produce “Retinopathy And Nephropathy In Patients With Type I Diabetes Four Years After A Trial Of Intensive Therapy”, The New England Journal of Medicine, February 2000; Volume 342, Number 6: 381-389.

*\EDIC\EDIC Analysis Datasets\EDIC Year 6 Carotid IMT*: Six year carotid Intima-Media Thickness (IMT) study. Subdirectory contents are as follows:

- DiabeticPatients. Data and associated documentation are provided for DCCT/EDIC patients comprising **1229** patients that were reported in EDIC Year 1 and Year 6 carotid data. This subdirectory contains 4 files: edicIMT6.sas7bdat (analysis file); edicIMT6\_codebook.rtf (dictionary for form data); edicIMT6\_fdmean.rtf (summary statistics for the diabetic participants); edicIMT6\_documentation.doc (description of descriptions of the data and atherosclerosis of the carotid artery, including definitions of IMT thickness, albumin excretion rate, hypertension, hyperlipidemia and attained age)
- NonDiabeticPatients. Data and associated documentation are provided for non-diabetic control subjects comprising **222** control healthy non-diabetic subjects, age- and sex-matched. This subdirectory contains 3 files: edicIMT6x.sas7bdat ; edicIMT6x\_codebook.rtf (dictionary for form data); edicIMT6x\_fdmean.rtf (summary statistics for the non-diabetic participants)
- EDIC\_CarotidArteryThickness\_Integrity\_v1.0.pdf – integrity check of the data used to produce “Intensive Diabetes Therapy and Carotid Intima-Media Thickness in Type 1 Diabetes Mellitus. New England Journal of Medicine, 348(23):2294-2303. Publication included.

*\EDIC\EDIC Analysis Datasets\EDIC Year 8 Coronary Artery Calcification (CT)*: eight year coronary artery calcification (CT) study. A total of **1205** patients (observations) who completed Computed Tomography (CT) are included. Neuropathy testing and scoring are described in edicCT\_documentation.doc. The 2008 EDIC CT dataset was supplemented in June 2009 with the addition of one variable, COMINT6A. The original datasets were replaced.

Subdirectory contents are as follows:

- Documents- This subdirectory includes 4 files:
  - EDIC\_Cardio\_DSIC\_v1.0.pdf – integrity check of the data used to produce “The Effect of Intensive Glycemic Treatment on Coronary Artery Calcification in Type 1 Diabetic Participants of the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study”. Diabetes, Vol 55 [Dec 2006], pp. 3556-65.
  - edicCT\_codebook.rtf
  - edicCT\_documentation.pdf
  - edicCT\_fdMean.rtf
- SAS\_DATA subdirectory includes the analysis file:

edicct.sas7bdat

*\EDIC\EDIC Analysis Datasets\EDIC Year 8 Nephropathy*: eight year nephropathy study. There were **1349** participants: **676** intensive treatment, **673** conventional treatment. Outcomes included microalbuminuria, albuminuria, GFR, a doubling of serum creatinine, and hypertension.

Subdirectory contents are as follows:

- Documents- This subdirectory includes 4 files:
  - edicNEU8\_Integrity\_Check.pdf – integrity check of the data used to produce “Sustained Effect of Intensive Treatment of Type 1 Diabetes mellitus on Development and Progression of Diabetic Nephropathy: The Epidemiology of Diabetes Interventions and Complications (EDIC) Study”. Journal of the American Medical Association, 290(16):2159-2167.
  - edicREN8\_codebook.rtf
  - edicREN8\_documentation.doc
  - edicREN8\_Fd\_Mean.rtf
- SAS\_DATA subdirectory includes the analysis file:
  - neph\_8yr.sas7bdat

*\EDIC\EDIC Analysis Datasets\EDIC Year 8 Neuropathy*: eight year neuropathy study. There were **1398** participants who had had at least one MNSI assessment over the first 8 years of the study: **696** from the intensive therapy group, and **702** from the conventional treatment group. The MNSI questionnaire and examination were used to measure the outcome, clinical neuropathy. Subdirectory contents are as follows:

- Documents- This subdirectory includes 4 files:
  - edicNEU8\_Integrity\_Check.pdf – integrity check of the data used to produce “Sustained Effect of Intensive Treatment of Type 1 Diabetes mellitus on Development and Progression of Diabetic Nephropathy: The Epidemiology of Diabetes Interventions and Complications (EDIC) Study”. Journal of the American Medical Association, 290(16):2159-2167.
  - edicNEU8\_codebook.rtf
  - edicNEU8\_documentation.pdf – describes outcomes including microalbuminuria, albuminuria, GFR, a doubling of serum creatinine, and hypertension
  - edicNEU8\_Fd\_Mean.rtf
- SAS\_DATA subdirectory includes the analysis file:
  - neuro\_8yr.sas7bdat

*\EDIC\EDIC Analysis Datasets\EDIC Year 10 Retinopathy*: ten year retinopathy study. **1426** patients had fundus photo data collected at any time from EDIC year 0 (DCCT closeout) up to EDIC Year 10. Of the **1426**, **1211** patients completed a retinopathy evaluation at Year 10, and **1174** completed a CSME evaluation at Year 10. These two subsets of patients formed the two analysis samples for the 10-year Retinopathy paper. Subdirectory contents are as follows:

- Documents- This subdirectory includes 6 files:
  - EDIC 10-yr Reti DSIC - wPub.pdf – integrity check of the data used to produce “DCCT-EDIC Study on the Prolonged Effect of Intensive Therapy on the Risk of Retinopathy Complications in Patients with Type 1 Diabetes Mellitus, 10 years after the DCCT”. Archives of Ophthalmology, Vol 126(12), Dec 2008, pp. 1707-1715.
  - edicRET10\_documentation – description of analysis
  - EDRET10\_DICTIONARY\_20110225.pdf
  - EDRET10\_STATISTICS\_20110225.pdf
  - EDRETTAB\_DICTIONARY\_20110225.pdf
  - EDRETTAB\_STATISTICS\_20110225.pdf

- SAS\_DATA subdirectory includes 2 analysis files:
  - edret10.sas7bdat-one record per visit (longitudinal data)
  - edrettab.sas7bdat –one record per patient (baseline data)

*\EDIC\EDIC Analysis Datasets\EDIC\_Year\_12\_Carotid\_IMT*: twelve year carotid artery intima media thickness (IMT) study. Subdirectory contents are as follows:

- Documents - This subdirectory includes the following:
  - EDIC carotid year 12 paper 2015.doc – Document containing brief summary of the dataset and variables used in the paper
  - NIH\_USONE1116\_contents.pdf – Dataset contents
  - DSInfo\_US12.pdf – Variable statistics
- SAS\_DATA - This subdirectory includes the SAS dataset “nih\_usone1116.sas7bdat”

*\EDIC\EDIC Analysis Datasets\EDIC Year 12 Cognition*: twelve year cognition study. A total of **1144** DCCT/EDIC patients (observations) were examined on entry to the DCCT and at EDIC Year 12 (an average 18-year follow-up) with the same comprehensive battery of cognitive tests. The ensuing 2007 paper reports on the long-term effects of diabetes and its treatment on cognitive function. Subdirectory contents are as follows:

- Documents- This subdirectory includes 3 files:
  - EDIC 12Yr Cognition DSIC.pdf – integrity check of the data used to produce Jacobson A, Ryan CM, Cleary P et al. Long-Term Effect of Diabetes and Its Treatment on Cognitive Function. The New England Journal of Medicine, 2007, 356:1842-1852.
  - MSCOGNIT\_contents.pdf
  - MSCOGNIT\_documentation.pdf – description of analysis dataset
- SAS\_DATA subdirectory includes the analysis file:
  - mscognit.sas7bdat

*\EDIC\EDIC Analysis Datasets\EDIC\_Year\_18\_Nephropathy*: eighteen year nephropathy study. Subdirectory contents are as follows:

- Documents - This subdirectory includes the following:
  - edicREN18\_documentation.doc – Document containing brief summary of the dataset and variables used in the paper
  - EDREN18 Data Dictionary.pdf – Dataset contents
  - EDREN18 Data Summary.pdf – Variable statistics
  - EDIC\_REN18\_DSIC.pdf – integrity check of the data used to produce DCCT/EDIC Research Group. Effect of intensive diabetes treatment on albuminuria in type 1 diabetes: long-term follow-up of the Diabetes Control and Complications Trial and Epidemiology of Diabetes Interventions and Complications study. Lancet Diabetes and Endocrinology 2014.
- SAS\_DATA - This subdirectory includes the SAS dataset “edren18.sas7bdat”

*\EDIC\EDIC Analysis Datasets\EDIC\_Year\_18\_Retinopathy*: eighteen year retinopathy study. Subdirectory contents are as follows:

- Documents - This subdirectory includes the following:
  - edicRET18\_documentation.doc – Document containing brief summary of the dataset and variables used in the paper
  - EDRET18 Data Dictionary.pdf – Dataset contents
  - EDRET18 Data Summary.pdf – Variable statistics
  - EDIC\_RET18\_DSIC.pdf – integrity check of the data used to produce DCCT/EDIC Research Group (2008). Effect of Intensive Diabetes Therapy on the

Progression of Diabetic Retinopathy in Patients With Type 1 Diabetes: 18 Years of Follow-up in the DCCT/EDIC. *Diabetes* 2015;64:631–642).

- SAS\_DATA - This subdirectory includes the SAS dataset “edret18.sas7bdat”

\EDIC\EDIC Analysis Datasets\ EDIC\_Ocular: Ocular surgery study data. Subdirectory contents are as follows:

- Documents - This subdirectory includes the following:
  - OCULAR\_documentation.doc – Document containing brief summary of the dataset and variables used in the paper
  - OCULAR Data Dictionary.pdf – Dataset contents
  - OCULAR Data Summary – Variable statistics
  - EDIC\_Ocular\_DSIC.pdf – integrity check of the data used to produce DCCT/EDIC Research Group. Intensive diabetes therapy and ocular surgery in type 1 diabetes. *N Engl J Med.* 2015; 372(18):1722-1733.
- SAS\_DATA - This subdirectory includes the SAS dataset “ocular.sas7bdat”

\EDIC\EDIC Analysis Datasets\ EDIC\_Glyc\_Var: Glycemic Variation study data. Subdirectory contents are as follows:

- Documents - This subdirectory includes the following:
  - GLYC\_VAR\_LONG documentation.docx – Document containing brief summary of the dataset and variables used in the paper
  - GLYC\_VAR\_LONG data contents.pdf – Dataset contents
  - GLYC\_VAR\_LONG data summary.pdf – Variable statistics
  - EDIC\_GLYC\_VAR\_DSIC.doc – integrity check of the data used to produce "Association of glycemic variability in type 1 diabetes with progression of microvascular outcomes in the Diabetes Control and Complications Trial." *Diabetes care* 40.6 (2017): 777-783.
  - SAS\_DATA - This subdirectory includes the SAS dataset “glyc\_var\_long.sas7bdat”

\EDIC\EDIC Analysis Datasets\ EDIC\_Optimret: Ocular surgery study data. Subdirectory contents are as follows:

- Documents - This subdirectory includes the following:
  - OPTIMRET\_documentation.doc– Document containing brief summary of the dataset and variables used in the paper
  - OPTIMRET Data Dictionary.pdf – Dataset contents
  - OPTIMRET Data Summary.pdf– Variable statistics
  - EDIC\_Optimret\_DSIC.doc – integrity check of the data used to produce DCCT/EDIC Research Group. Intensive diabetes therapy and ocular surgery in type 1 diabetes. *N Engl J Med.* 2015; 372(18):1722-1733.
- SAS\_DATA - This subdirectory includes the SAS dataset “optimret.sas7bdat”

## DCCT\_EDIC Ancillary

Measurements that various DCCT-EDIC Ancillary studies have already made on DCCT-EDIC biosamples (urine, plasma, serum) are available in the archive. They are offered as provided by the investigators. The NIDDK Repository has not assessed these additional data for consistency nor completeness, and no supporting documentation is available. **Table 1** shows measurements, dataset name and responsible investigator. The “DCCT\_EDIC Ancillary” directory contains the following subdirectories that contain datasets associated with DCCT\EDIC ancillary studies:

*DCCT\_EDIC Ancillary\Brunzell DCCT\_EDIC Ancillary\Weiss*

*DCCT\_EDIC Ancillary\Lopes-Virella MUSC DCCT\_EDIC Ancillary\Hoeldtke-Hobbs GAD*

**TABLE 1**

Investigator/Measurements	Time Frame	Dataset
<b>Weiss</b>		
Urinary pentosidine	DCCT Baseline; first occurrence of macro or microalbuminuria in DCCT	DCCTData(MFWeiss-SHazen).xlsx
<b>Brunzell</b>		
Lipid protein profile Apolipoprotein B, Lp(a) ipoprotein density gradient ultracentrifugation	Measured at DCCT end on all DCCT subjects	dcct_lipoprotein.sas7bdat
<b>Hoeldtke-Hobbs (GAD Study)</b>		
GAD65Ab index	DCCT Baseline and 5 years follow-up	Results sent 7.30.03 without4.xls
<b>Lopes-Virella (MUSC Study)</b>		
Acylation Stimulating Protein; Adiponectin	EDIC PPG 1st Pass (1997-00); EDIC PPG 2nd Pass (1999-2001)	cytokines chemokines musc.sas7bdat
D-Dimer, Fibrinogen, Plasminogen Activator Inhibitor, Tissue Plasminogen Activator	EDIC PPG 1st Pass (1997-00); EDIC PPG 2nd Pass (1999-2001)	fibrinolysis musc.sas7bdat
Genetic Polymorphisms	EDIC PPG 1st Pass (1997-00)	genetic polymorphisms musc.sas7bdat
Serum Albumin, Bilirubin, Blood Urea Nitrogen, Ferritin, Iron, Iron Binding Capacity, Protein	EDIC PPG 1st Pass (1997-00)	general biochemical panel musc.sas7bdat
Fibroblast, Connective Tissue, Epidermal, Factor XII, Heparin-binding Epidermal, Hepatocyte, Platelet Derived, Transforming, Vascular Endothelial Growth Factors	EDIC PPG 1st Pass (1997-00)	growth factors musc.sas7bdat
C-Reactive Protein, Glycated LDL Antibody Level	EDIC PPG 1st Pass (1997-00)	inflammatory markers musc.sas7bdat
(not available)	(not available)	mdaldl ic dcct bl.sas7bdat nmr_lipoprotiens_v3.sas7bdat oxldl_ic_dcct_bl.sas7bdat ageldl_ic_dcct_bl.sas7bdat alaupovic_lipoprotiens.sas7bdat

## Appendix 1: DCCT raw sas7bdat Datasets<sup>3</sup>

- 1) bgpdat.sas7bdat
- 2) cb100\_c.sas7bdat
- 3) cb11\_c.sas7bdat
- 4) cb12\_c.sas7bdat
- 5) cb13\_c.sas7bdat
- 6) cb14\_c.sas7bdat
- 7) cb15\_c.sas7bdat
- 8) cb16\_c.sas7bdat
- 9) cb17\_c.sas7bdat
- 10) cb18\_c.sas7bdat
- 11) cb19\_c.sas7bdat
- 12) cb110\_c.sas7bdat
- 13) diethist.sas7bdat
- 14) f001cmb6\_c.sas7bdat
- 15) f002cmb4.sas7bdat
- 16) f003cmb2.sas7bdat
- 17) f010cmb3.sas7bdat
- 18) f013cmb3.sas7bdat
- 19) f020cmb4.sas7bdat
- 20) f021cmb6.sas7bdat
- 21) f023a\_sc.sas7bdat
- 22) f028one.sas7bdat
- 23) f0033.sas7bdat
- 24) f033new.sas7bdat
- 25) f0034.sas7bdat
- 26) f045cmb2.sas7bdat
- 27) f046cmb2.sas7bdat
- 28) f049cmb2.sas7bdat
- 29) f0051.sas7bdat
- 30) f057cmb3.sas7bdat
- 31) f0082.sas7bdat
- 32) f083cmb2.sas7bdat
- 33) f106cmb3.sas7bdat
- 34) f114cmb3.sas7bdat
- 35) f0217.sas7bdat
- 36) f0241.sas7bdat
- 37) f0271.sas7bdat
- 38) f0342.sas7bdat
- 39) f0351.sas7bdat
- 40) f0361.sas7bdat
- 41) f0372.sas7bdat
- 42) f0471.sas7bdat
- 43) f0481.sas7bdat
- 44) f0561.sas7bdat
- 45) f0882.sas7bdat
- 46) f0922.sas7bdat
- 47) f0971.sas7bdat
- 48) f1081.sas7bdat
- 49) f1221.sas7bdat
- 50) f1281.sas7bdat
- 51) hbam.sas7bdat
- 52) master\_c.sas7bdat
- 53) status\_c.sas7bdat

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<sup>3</sup> See \DCCT\_EDIC Documents\DCCT\DCCT\_Forms\_and\_Datasets



- 1) Central Biochemistry Laboratory: Baseline (Cbl - BaselineREV.pdf)
- 2) Central Biochemistry Laboratory: Close-Out (CBL CloseoutREV.pdf)
- 3) C-Peptide Rest Results (CBLC-Peptide REV.pdf)
- 4) Monthly HbA1c Values (CBL Monthly HbA1c Values REV.pdf)
- 5) Quarterly Blood-Glucose Profiles (CBL Quarterly BGP Values Form 23.3A to 23.3G REV.pdf)
- 6) Central Biochemistry Laboratory: Year 1 (CBL Year 1 rev.pdf)
- 7) Central Biochemistry Laboratory: Year 2 (CBL Year 2 rev.pdf)
- 8) Central Biochemistry Laboratory: Year 3 (CBL Year 3 rev.pdf)
- 9) Central Biochemistry Laboratory: Year 4 (CBL Year 4 rev.pdf)
- 10) Central Biochemistry Laboratory: Year 5 (CBL Year 5 rev.pdf)
- 11) Central Biochemistry Laboratory: Year 6 (CBL Year 6 rev.pdf)
- 12) Central Biochemistry Laboratory: Year 7 (CBL Year 7 rev.pdf)
- 13) Central Biochemistry Laboratory: Year 8 (CBL Year 8 rev.pdf)
- 14) Central Biochemistry Laboratory: Year 9 (CBL Year 9 rev.pdf)
- 15) Diet History And Estimated Nutrient Intake (Diet History REV.pdf)
- 16) Form 1: Initial Clinic Visit (Form 1 rev.pdf)
- 17) Form 2: Baseline Medical History and Physical Examination (Form 2 rev.pdf)
- 18) Form 3: Annual Medical History and Physical Examination Version 3.1 and 3.2 used through September, 1990 (Form 3.1 -3.2 rev.pdf)
- 19) Form 3.3: Annual Medical History and Physical Examination Version 3.3 used September 1990 - November 1992 (Form 3.3 rev.pdf)
- 20) Form 3.4: Close-Out Medical History and Physical Examination  
Used only in the close-out period December 1992 - April 1993 (Form 3.4 rev\_2.pdf)
- 21) Form 5: Neurological History and Examination (Form 5 rev.pdf)
- 22) Form 8: Baseline Ophthalmic Examination and Ocular History (Form 8 rev.pdf)
- 23) Form 10: Neurobehavioral Assessment (Form 10 rev.pdf)
- 24) Form 13: Neurobehavioral Studies Demographic Questionnaire (Form 13 rev.pdf)
- 25) Form 20: Notification of Intercurrent Event (Form 20 rev.pdf)
- 26) Forms 21.1-21.6: Quarterly Visit Versions 21.1-21.6 used through September 1990 (Form 21.1-21.6 rev.pdf)
- 27) Forms 21.7: Quarterly Visit Version 21.7 used September 1990 - April 1993 (Form 21.7 rev.pdf)
- 28) Form 24: Resting Electrocardiogram Grading Form (Form 24 rev.pdf)
- 29) Form 27: Endpoint Visit Ophthalmic Examination (Form 27 rev.pdf)
- 30) Form 28: Autonomic Neuropathy Studies (Form 28 rev.pdf)
- 31) Form 33: Detailed Grading of Fundus Photographs (Form 33 rev.pdf)
- 32) Form 34: Detailed Grading of Fluorescein Angiograms (Form 34 rev.pdf)
- 33) Form 35: Symptom Checklist 90, Revised (SCL-90R) (Form 35 rev\_v4.pdf)
- 34) Form 36: Quality of Life Questionnaire (Form 36 rev.pdf)
- 35) Form 37: Nerve Conduction Studies (Form 37 rev.pdf)
- 36) Form 45: Volunteer Understanding Questionnaire (Version A) (Form 45 rev.pdf)
- 37) Form 46: Volunteer Understanding Questionnaire (Version B) (Form 46.pdf)
- 38) Form 47: Availability, Adherence and Expectation Interview (Form 47 rev.pdf)

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<sup>4</sup> See \DCCT\_EDIC Documents\DCCT\DCCT\_Forms\_and\_Datasets\_REV2.xls for a reference of forms to datasets.

- 39) Form 48: Family Understanding and Expectation Interview (Form 48rev.pdf)
- 40) Form 49: Request Behaviors Confidence Questionnaire (Form 49rev.pdf)
- 41) Form 56: Clinic Evaluation of Volunteer's Performance on Behavioral Tasks  
I (Clinic) (Form 56rev.pdf)
- 42) Form 57: Clinic Evaluation of Volunteer's Performance on Behavioral Tasks  
II (Home) (Form 57rev.pdf)
- 43) Form 83: Notification of Hypoglycemic Intercurrent Event (Form 83rev.pdf)
- 44) Form 88: Neurobehavioral Consensus Rating (Form 88rev.pdf)
- 45) Form 92: Further Details of Hypoglycemic Event (Form 92rev.pdf)
- 46) Form 97: GFR Worksheet (Form 97rev.pdf)
- 47) Form 106: Details of Pregnancy and Outcome (Form 106rev.pdf)
- 48) Form 108: Parents and Siblings of DCCT Patients (Family Studies) (Form 108rev.pdf)
- 49) Form 114: Body Composition Measurements (Form 114.pdf)
- 50) Form 122: Patient Experience Questionnaire (Form 122rev.pdf)
- 51) Form 128: Health Status Questionnaire (SF-36) (Form 128rev\_3.pdf)
- 52) Patient Identification (Patient Identification REV.pdf)
- 53) Patients Status (Patient Status REV.pdf)

DCCT-EDIC Roadmap- Version 19  
**Appendix 3: EDIC Forms,  
Years 1-13 (March 1994 –  
April 2007)<sup>5</sup>**

September 2019

- 1) Form 2.2 Annual Medical History and Physical Examination (22-Mar-94)  
(EDIC002\_2.pdf, EDIC002\_2\_annotated.pdf)
- 2) Form 2.3 Annual Medical History and Physical Examination (4-Oct-95)  
(EDIC002\_3.pdf, EDIC002\_3\_annotated.pdf )
- 3) Form 2.4 Annual Medical History and Physical Examination (27-Aug-96)  
(EDIC002\_4.pdf, EDIC002\_4\_annotated.pdf)
- 4) Form 2.5 Annual Medical History and Physical Examination (10-Jul-01)  
(EDIC002\_5.pdf, EDIC002\_5\_annotated.pdf)
- 5) Form 2.6 Annual Medical History and Physical Examination (21-Oct-05)  
(EDIC002\_6.pdf, EDIC002\_6\_annotated.pdf )
- 6) Form 2.7 Annual Medical History and Physical Examination (29-Jun-06)  
(EDIC002\_7.pdf, EDIC002\_7\_annotated.pdf)
  
- 7) Form 4.2 Current Medications (28-Mar-94)  
(EDIC004\_2.pdf, EDIC004\_2\_annotated.pdf)
- 8) Form 4.3 Current Medications (4-Oct-95)  
(EDIC004\_3.pdf, EDIC004\_3\_annotated.pdf)
- 9) Form 4.4 Current Medications (4-Jun-99)  
(EDIC004\_4.pdf, EDIC004\_4\_annotated.pdf)
  
- 10) Form 4.5 Current Medications (10-Jul-01)  
(EDIC004\_5.pdf, EDIC004\_5\_annotated.pdf)
- 11) Form 4.6 Current Medications (21-Oct-05)  
(EDIC004\_6.pdf, EDIC004\_6\_annotated.pdf)
  
- 12) Form 30.2 Ophthalmic and Visual Acuity Examination (23-Mar-94)  
(EDIC030\_2.pdf, EDIC030\_2\_annotated.pdf)
- 13) Form 30.3 Ophthalmic and Visual Acuity Examination (4-Oct-95)  
(EDIC030\_3.pdf, EDIC030\_3\_annotated.pdf)
  
- 14) Form 33.1 National Eye Institute Visual Functioning Questionnaire–25 (VFQ-25), Version 2000 (4-Jan-06)  
(EDIC033\_1.pdf, EDIC033\_1\_annotated.pdf)
  
- 15) Form 42.2 Notification and Further Details of Severe Hypoglycemia (23-Mar-94)  
(EDIC042\_2.pdf, EDIC042\_2\_annotated.pdf)
- 16) Form 42.3 Notification and Further Details of Severe Hypoglycemia (4-Jun-99)  
(EDIC042\_3.pdf, EDIC042\_3\_annotated.pdf)
  
- 17) Form 50.2 Michigan Neuropathy Screening Instrument and 10 gm Filament Exam (29-Mar-94)  
(EDIC050\_2.pdf, EDIC050\_2\_annotated.pdf)
- 18) Form 50.3 Michigan Neuropathy Screening Instrument and 10 gm Filament Exam (4-Jun-99)  
(EDIC050\_3.pdf, EDIC050\_3\_annotated.pdf)
  
- 19) Form 51.1 Neurological History and Exam (14-Sept-05)  
(EDIC051\_1.pdf, EDIC051\_1\_annotated.pdf)

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<sup>5</sup> See \DCCT\_EDIC Documents\EDIC\EDIC\_Forms-to-Datasets\_Mapping\_Years\_01-13.xls for a reference of forms to datasets.

- 20) Form 52.1 Nerve Conduction Study (17-Nov-05)  
(EDIC052\_1.pdf)
- 21) Form 52.2 Nerve Conduction Study (8-Mar-06)  
(EDIC052\_2.pdf,  
EDIC052\_2\_annotated.pdf)
- 22) Form 53.1 Report of local laboratory standards for nerve conduction values (24-Jan-05)  
(EDIC053\_1.pdf)
- 23) Form 54.1 Vibration Perception Threshold (31-Jan-05)  
(EDIC054\_1.pdf,  
EDIC054\_1\_annotated.pdf)
- 24) Form 55.1 ANS Testing Eligibility (17-Nov-05)  
(EDIC055\_1.pdf,  
EDIC055\_1\_annotated.pdf)
- 25) Form 55.2 ANS Testing Eligibility (31-Mar-06)  
(EDIC055\_2.pdf,  
EDIC055\_2\_annotated.pdf)
- 26) Form 55.3 ANS Testing Eligibility (8-Dec-06)  
(EDIC055\_3.pdf,  
EDIC055\_3\_annotated.pdf)
- 27) Form 57.1 Autonomic Symptom Profile (1-Nov-05)  
(EDIC057\_1.pdf,  
EDIC057\_1\_annotated.pdf)
- 28) Form 58.1 Neuropathy Specific Quality of Life Questionnaire (21-Jul-05)  
(EDIC058\_1.pdf,  
EDIC058\_1\_annotated.pdf)
- 29) Form 60.2 Quality of Life Questionnaire (24-Mar-94)  
(EDIC060\_2.pdf,  
EDIC060\_2\_annotated.pdf)
- 30) Form 61.2 Health Status Questionnaire 2.0 (24-Mar-94)  
(EDIC061\_2.pdf,  
EDIC061\_2\_annotated.pdf)
- 31) Form 62.1 Quality of Well-Being Scale Self Administered QWB-SA V1.04 (Years 13-14 only) (2-Dec-05)  
(EDIC062\_1.pdf,  
EDIC062\_1\_annotated.pdf)
- 32) Form 70.2 Health Care Delivery Questionnaire (13-Apr-94)  
(EDIC070\_2.pdf,  
EDIC070\_2\_annotated.pdf, )
- 33) Form 70.3 Health Care Delivery Questionnaire (5-May-94)  
(EDIC070\_3.pdf,  
EDIC070\_3\_annotated.pdf)
- 34) Form 70.4 Health Care Delivery Questionnaire (23-May-97)  
(EDIC070\_4.pdf,  
EDIC070\_4\_annotated.pdf)
- 35) Form 70.5 Health Care Delivery Questionnaire (25-Jul-97)  
(EDIC070\_5.pdf,  
EDIC070\_5\_annotated.pdf)
- 36) Form 90.2 Verification of Cardiovascular Disease (24-Mar-94)  
(EDIC090\_2\_REV.pdf,  
EDIC090\_2\_annotated.pdf)
- 37) Form 90.3 Verification of Cardiovascular Disease (4-Oct-95)  
(EDIC090\_3.pdf,  
EDIC090\_3\_annotated.pdf)
- 38) Form 90.4 Verification of Cardiovascular Disease (27-May-99)  
(EDIC090\_4.pdf,  
EDIC090\_4\_annotated.pdf)
- 39) Form 90.5 Verification of Cardiovascular Disease (20-Dec-05)  
(EDIC090\_5.pdf,  
EDIC090\_5\_annotated.pdf)
- 40) Form 90.6 Verification of Cardiovascular Disease (2-May-06)  
(EDIC090\_6.pdf,  
EDIC090\_6\_annotated.pdf)
- 41) Form 91.2 Verification of Cerebrovascular Disease (24-Mar-94)  
(EDIC091\_2.pdf,  
EDIC091\_2\_annotated.pdf)
- 42) Form 91.3 Verification of Cerebrovascular Disease (4-Oct-95)

(EDIC091\_3.pdf,

EDIC091\_3\_annotated.pdf)

- 43) Form 91.4 Verification of Cerebrovascular Disease (27-May-99)

(EDIC091\_4.pdf,

EDIC091\_4\_annotated.pdf)

- 44) Form 91.5 Verification of Cerebrovascular Disease (25-May-11)

(EDIC091\_5.pdf,

EDIC091\_5\_annotated.pdf)

- 45) Form 92.2 Verification of Peripheral Vascular Disease or Lower Extremity Ulcer (24-Mar-94)

(EDIC092\_2.pdf,

EDIC092\_2\_annotated.pdf)

- 46) Form 92.3 Verification of Peripheral Vascular Disease or Lower Extremity Ulcer (4-Oct-95)

(EDIC092\_3.pdf,

EDIC092\_3\_annotated.pdf)

- 47) Form 92.4 Verification of Peripheral Vascular Disease or Lower Extremity Ulcer (27-May-99)

(EDIC092\_4.pdf,

EDIC092\_4\_annotated.pdf)

- 48) Form 93.2 Verification of DKA (24-Mar-94)

(EDIC093\_2.pdf,

EDIC093\_2\_annotated.pdf)

- 49) Form 93.3 Verification of DKA (4-Oct-95)

(EDIC093\_3.pdf,

EDIC093\_3\_annotated.pdf)

- 50) Form 93.4 Verification of DKA (4-Jun-99)

(EDIC093\_4.pdf,

EDIC093\_4\_annotated.pdf)

- 51) Form 94.2 Verification of Psychiatric Disease Requiring Treatment (28-Mar-94)

(EDIC094\_2.pdf,

EDIC094\_2\_annotated.pdf)

- 52) Form 94.3 Verification of Psychiatric Disease Requiring Treatment (4-Oct-95)

(EDIC094\_3.pdf,

EDIC094\_3\_annotated.pdf)

- 53) Form 94.4 Verification of Psychiatric Disease Requiring Treatment (4-Jun-99)

(EDIC094\_4.pdf,

EDIC094\_4\_annotated.pdf)

- 54) Form 95.2 Verification of Major Accident (29-Mar-94)

(EDIC095\_2.pdf,

EDIC095\_2\_annotated.pdf)

- 55) Form 95.3 Verification of Major Accident (4-Oct-95)

(EDIC095\_3.pdf,

EDIC095\_3\_annotated.pdf)

- 56) Form 95.4 Verification of Major Accident (4-Jun-99)

(EDIC095\_4.pdf,

EDIC095\_4\_annotated.pdf)

- 57) Form 96.1 Verification of Renal Failure Event (Dialysis/Renal Transplant) (17-Jul-08)

(EDIC096\_1.pdf,

EDIC096\_1\_annotated.pdf)

- 58) Form 130.1 Parents and Siblings of EDIC/DCCT Patient

(EDIC130\_1.pdf,

EDIC130\_1\_annotated.pdf)

- 59) Form 140.2 Notification of Death (24-Mar-94)

(EDIC140\_2.pdf, EDIC140\_2\_annotated

REV 02-2012.pdf)

- 60) Form 141.2 Notification of Missed Clinic Visit or Modification of Follow-up Schedule (29-Mar-94)

(EDIC141\_2.pdf,

EDIC141\_2\_annotated.pdf)

- 61) Form 141.3 Notification of Missed Clinic Visit or Modification of Follow-up Schedule (4-Oct-95)

(EDIC141\_3.pdf,

EDIC141\_3\_annotated.pdf)

- 62) Form 141.4 Notification of Missed Clinic Visit or Modification of Follow-up Schedule (20-Dec-05)

(EDIC141\_4.pdf,

EDIC141\_4\_annotated.pdf)

63) Form 142.2 Notification of Patient  
Transfer or Move (24-Mar-94)

(EDIC142\_2.pdf,  
EDIC142\_2\_annotated.pdf)

64) Form 142.3 Notification of Patient  
Transfer or Move (5-Sept-06)

(EDIC142\_3.pdf,  
EDIC142\_3\_annotated.pdf)

65) Form 144.2 Notification of Transfer  
to Inactive Status (24-Mar-94)

(EDIC144\_2.pdf,  
EDIC144\_2\_annotated.pdf)

66) Form 144.3 Notification of Transfer  
to Inactive Status (4-Oct-95)

(EDIC144\_3.pdf,  
EDIC144\_3\_annotated.pdf)

67) Form 145.2 Checklist for Tracking  
Inactive or Recalcitrant Patient (24-  
Mar-94)

(EDIC145\_2.pdf,  
EDIC145\_2\_annotated.pdf)

DCCT-EDIC Roadmap- Version 19  
**Appendix 4: EDIC raw  
sas7bdat Datasets, Years 1-8  
(March 1994 – Sept. 2001)<sup>6</sup>**

- 1) cblldata.sas7bdat
- 2) f0022.sas7bdat
- 3) f0023.sas7bdat
- 4) f0024.sas7bdat
- 5) f0042.sas7bdat
- 6) f0043.sas7bdat
- 7) f0044.sas7bdat
- 8) f0302.sas7bdat
- 9) f0303.sas7bdat
- 10) f0422.sas7bdat
- 11) f0423.sas7bdat
- 12) f0502.sas7bdat
- 13) f0503.sas7bdat
- 14) f0602.sas7bdat
- 15) f0612.sas7bdat
- 16) f0702.sas7bdat
- 17) f0703.sas7bdat
- 18) f0704.sas7bdat
- 19) f0705.sas7bdat
- 20) f0902.sas7bdat
- 21) f0903.sas7bdat
- 22) f0904.sas7bdat
- 23) f0913.sas7bdat
- 24) f0914.sas7bdat
- 25) f0922.sas7bdat
- 26) f0923.sas7bdat
- 27) f0924.sas7bdat
- 28) f0932.sas7bdat
- 29) f0933.sas7bdat
- 30) f0934.sas7bdat
- 31) f0942.sas7bdat
- 32) f0943.sas7bdat
- 33) f0944.sas7bdat
- 34) f0952.sas7bdat
- 35) f0953.sas7bdat
- 36) f0954.sas7bdat
- 37) f1301.sas7bdat
- 38) f1402.sas7bdat
- 39) f1412.sas7bdat
- 40) f1413.sas7bdat
- 41) f1422.sas7bdat
- 42) f1442.sas7bdat
- 43) f1443.sas7bdat
- 44) f1452.sas7bdat

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<sup>6</sup> See \DCCT\_EDIC Documents\EDIC\  
EDIC\_Forms-to-Datasets\_Mapping\_Years\_01-  
13.xls for a reference of forms to datasets.

September 2019  
**Appendix 5. EDIC raw sas7bdat  
Datasets, Years 8- 13 (Sept.  
2001 – Sept. 2006)<sup>7</sup>**

- 1) newcbl2.sas7bdat
- 2) f0025\_rev.sas7bdat
- 3) f0026\_rev.sas7bdat
- 4) f0027\_rev.sas7bdat
- 5) f0044.sas7bdat
- 6) f0045.sas7bdat
- 7) f0046.sas7bdat
- 8) f0303.sas7bdat
- 9) f03032.sas7bdat
- 10) f0423.sas7bdat
- 11) f0423\_2.sas7bdat
- 12) f0503.sas7bdat
- 13) f0602.sas7bdat
- 14) f0612.sas7bdat
- 15) f0705.sas7bdat
- 16) f0705\_2.sas7bdat
- 17) f0904.sas7bdat
- 18) f0905.sas7bdat
- 19) f0914.sas7bdat
- 20) f0914\_2.sas7bdat
- 21) f0924.sas7bdat
- 22) f0924\_2.sas7bdat
- 23) f0933.sas7bdat
- 24) f0934.sas7bdat
- 25) f0934\_2.sas7bdat
- 26) f0944.sas7bdat
- 27) f0944\_2.sas7bdat
- 28) f0954.sas7bdat
- 29) f0954\_2.sas7bdat
- 30) f1413.sas7bdat
- 31) f1414.sas7bdat
- 32) f1422.sas7bdat
- 33) f1443.sas7bdat
- 34) f1452.sas7bdat
- 35) f1452\_2.sas7bdat

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<sup>7</sup> See \DCCT\_EDIC Documents\EDIC\  
EDIC\_Forms-to-Datasets\_Mapping\_Years\_01-  
13.xls for a reference of forms to datasets .

## Appendix 6. EDIC raw sas7bdat Datasets, Year 13 Part 2 (through April 2007)<sup>8</sup>

- 1) newcbl3.sas7bdat
- 2) f0027.sas7bdat
- 3) f0046.sas7bdat
- 4) f0303\_2.sas7bdat
- 5) f0331.sas7bdat
- 6) f0423\_2.sas7bdat
- 7) f0503\_2.sas7bdat
- 8) f0511.sas7bdat
- 9) f0522\_2.sas7bdat
- 10) f0541.sas7bdat
- 11) f0551.sas7bdat
- 12) f0552.sas7bdat
- 13) f0553.sas7bdat
- 14) f0571.sas7bdat
- 15) f0581.sas7bdat
- 16) f0602\_2.sas7bdat
- 17) f0621.sas7bdat
- 18) f0705\_2.sas7bdat
- 19) f0905.sas7bdat
- 20) f0914\_2.sas7bdat
- 21) f0915.sas7bdat
- 22) f0924\_2.sas7bdat
- 23) f0934\_2.sas7bdat
- 24) f0944\_2.sas7bdat
- 25) f0954\_2.sas7bdat
- 26) f0961.sas7bdat
- 27) f1414.sas7bdat
- 28) f1423.sas7bdat

<sup>8</sup> See \DCCT\_EDIC Documents\EDIC\  
EDIC\_Forms-to-Datasets\_Mapping\_Years\_01-  
13.xls for a reference of forms to datasets