

Pegylated Interferon +/- Ribavirin for Children with HCV (PEDS-C) Data Archive

The PEDS-C (Pegylated interferon +/- ribavirin for children with chronic hepatitis C virus) data archive contains the study protocol and related descriptive documentation, data collection forms and study data, and the data integrity check. Documentation files include the study protocol, manual of procedures, consent form, details of data contents, and a publications list.

The files in the archive are organized into the following directories:

1. Documentation
2. Forms
3. Data
4. Data Integrity Check

1. Documentation Directory

The Documentation directory contains five documents:

- **General Description** of study data archive, 6 pgs, includes brief study overview, description of datasets, dataset names, listing and abbreviated description of additional documentation and linkage files as provided by the Data Coordinating Center (General Description.doc)¹
- **Research Protocol**, version 25 May 2005, 74 pgs, provides background information on HCV and its treatment in children, describes the research design, specific aims, and research methods (protocol 05-2505.doc)
- **Patient Consent Form**, 17 pgs, study consent form approved by the Johns Hopkins Medical Institutions (consent_051220.doc)
- **Manual of Operations**, version 6-25-05. This file includes detailed documentation and instructions for all data collection. Individual files provided for each chapter (Chapters 1 through 20) and the appendices (Appendices A through K) have been consolidated into a single pdf.²
- **Publications**. A listing of manuscripts, publications, and presentations by the PEDS-C research team (PEDS-C PublicationsApr09rev.doc).

2. Forms Directory

The Forms directory contains 83 data collection forms (including revisions) used in the PEDS-C study. Forms are numbered and labeled by "PDC". Annotated versions of study forms include the variable names and are provided in Adobe PDF format. Users should note that, in general, annotated forms are available for the original forms only – revised forms, indicated by a final digit '1', are not annotated. For example, PDC021 is a revised version of form PDC020, the Screening Visit 1 Form, and only revisions to the original form are annotated. A complete listing of study forms and the corresponding PDF file name are provided below. Not all study forms are associated with data files; these exceptions are noted below. See, for example, PDC090, which is an administrative file and has no corresponding data file. **In addition, five "PDC" forms are copyrighted and are excluded from the repository database**, but are briefly described below.

Data Collection Forms

- **PDC010** Certification Number Report (pdc010 annotated.pdf) – Staff certification report. 2 pgs. (no associated dataset)
- **PDC020** Screening Visit 1 Form (pdc020 annotated.pdf) - Demographics, vital signs and physical measurement, acknowledgment of consent, medical history, physical exam, depression screen, ophthalmologic exam, liver biopsy. 8 pgs
- **PDC021** Screening Visit 1 Form (pdc021 annotated.pdf) – Revision 1 of Form PDC020, dated 3/22/2005. NOT ANNOTATED. 8 pgs.

¹ We note that the file linkages.doc is not included in the NIDDK archive, but can be requested by users. The license agreement for using the Childhood Depression Inventory is also not included in the archive materials.

² Appendix I has been revised to exclude copies of copyrighted forms for posting to the NIDDK repository.

- **PDC030** Screening Visit 2 Form (pdc030 annotated.pdf) - List of laboratory tests ordered at Screening Visit 2. 1 pg.
- **PDC040** Eligibility Summary Form (pdc040 annotated.pdf) - Inclusion and exclusion criteria, concomitant medication or treatment. 3 pgs.
- **PDC041** Eligibility Summary Form (pdc041 annotated.pdf) – Revision 1 of Form PDC040. NOT ANNOTATED, except for additional variables, sibenrol, exempt, and chk93640. 3 pgs.
- **PDC050** BL Ophthalmology Summary (pdc050 annotated.pdf) – Results of baseline ophthalmology exam. 1 pg.
- **PDC060*** CDI Form (depression screen) – Depression screening form for patients ages 7 to 17 or parents of patients ages 5 or 6. 3 pgs. **This form is copyrighted and not included in the repository.**
- **PDC070** Eligibility Criteria Exemption form (pdc070 annotated.pdf) – 1 pg.
- **PDC080** Protocol Deviation Form (pdc080 annotated.pdf) – Form used to report deviation from study protocol. 1 pg.
- **PDC090** (pdc090 annotated.pdf) -- De-certification report (Administrative file, no associated data)
- **PDC100** BL Assessment (pdc100 annotated.pdf) – Baseline assessment for patients screened and randomized. Vital signs, anthropometry, concurrent medications and conditions, depression screen, patient study drug therapy, laboratory tests ordered and quality of life tests administered at baseline, 5 pgs.
- **PDC101** BL Assessment (pdc101 annotated.pdf) – Revision 1 of PDC100. NOT ANNOTATED, 5 pgs.
- **PDC110** Vital Signs and Symptom Directed Physical Exam (pdc110 annotated.pdf) – Vital signs, physical measurements, physical exam, 3 pgs.
- **PDC111** Vital Signs and Symptom Directed Physical Exam (pdc111 annotated.pdf) – Revision of Form 110. NOT ANNOTATED, except Variable 3b, *vstmpsi*, temperature site, renamed and *vstmpna* deleted. 3 pgs.
- **PDC120** CRA Visit Form (pdc120 annotated.pdf). 1 pg (Administrative form, no associated data)
- **PDC130** Physical Activity Assessment Form (pdc130 annotated.pdf) – Typical daily activities in past month. 1 pg.
- **PDC160*** BRIEF Form Parent about Patient Cognitive Function – 86-item parental assessment of patient behavior in past 6 months. 4 pgs. **This form is copyrighted and not included in the repository.**
- **PDC170*** Child Health Questionnaire Parent about Patient -- Overall assessment of child's health, physical activities, everyday activities, pain, behavior, well-being, self-esteem, general health, family relations, demographics, pre-existing conditions, parent characteristics. 7 pgs. **This form is copyrighted and not included in the repository.**
- **PDC180*** Child Health Questionnaire Patient Self-Report Ages 10+ Overall assessment of health, physical activities, everyday activities, pain, relationships and behavior, well-being, self-esteem, general health, family relations, demographics, previous conditions. 8 pgs. **This form is copyrighted and not included in the repository.**
- **PDC190*** LEC Form Parent about Patient 46-item list of potential life events and their impact, if experienced, on patient. 3 pgs. **This form is copyrighted and not included in the repository.**
- **PDC200** Your Health and Well-being Parent Self-Report (pdc200 annotated.pdf) Parent's overall health assessment, daily activities, physical and emotional health, pain in past 4 weeks. 3 pgs.
- **PDC210** Treatment Period Assessment Summary (Week 1 Visit) (pdc210 annotated.pdf) -- Patient continuing in study, physical exam completed, concurrent medications and conditions, patient study drug therapy, laboratory tests ordered. 3 pgs.
- **PDC220** Treatment Period Assessment Summary (Week 3 Visit) (pdc220 annotated.pdf) -- Patient continuing in study, physical exam completed, concurrent medications and conditions, patient study drug therapy, laboratory tests ordered. 3 pgs.
- **PDC230** Treatment Period Assessment Summary (Week 5 Visit) (pdc230 annotated.pdf) -- Patient continuing in study, physical exam completed, concurrent medications and conditions, patient study drug therapy, laboratory tests ordered. 3 pgs.
- **PDC240** Treatment Period Assessment Summary (Week 8 Visit) (pdc240 annotated.pdf) -- Patient continuing in study, physical exam completed, concurrent medications and conditions, patient study drug therapy, laboratory tests ordered. 3 pgs.

- **PDC250** Treatment Period Assessment Summary (Week 12 Visit) (pdc250 annotated.pdf) -- Patient continuing in study, physical exam completed, concurrent medications and conditions, patient study drug therapy, laboratory tests ordered. 3 pgs.
- **PDC260** CES-D Form Patient Self-Report Ages 18+ (pdc260 annotated.pdf) – 20-item self assessment of behaviors, emotions during past week. 2 pgs.
- **PDC270** Treatment Period Assessment Summary (Week 16 Visit) (pdc270 annotated.pdf) -- Patient continuing in study, physical exam completed, concurrent medications and conditions, patient study drug therapy, laboratory tests ordered. 3 pgs.
- **PDC280** Treatment Period Assessment Summary (Week 20 Visit) (pdc280 annotated.pdf) -- Patient continuing in study, physical exam completed, concurrent medications and conditions, patient study drug therapy, laboratory tests ordered. 3 pgs.
- **PDC290** Treatment Period Assessment Summary (Week 24 Visit) (pdc290 annotated.pdf) -- Patient continuing in study, physical exam completed, anthropometry, concurrent medications and conditions, patient study drug therapy, depression screen, laboratory tests ordered, quality of life tests administered. 6 pgs.
- **PDC291** Treatment Period Assessment Summary (Week 24 Visit) (pdc291 annotated.pdf) – Revised Form PDC290 08-05-2005, NOT ANNOTATED. Urine pregnancy test results deleted, only serum pregnancy test results recorded (item 16B *w24srmpst* added and *w24urnpst* and *w24urnpstres* deleted)
- **PDC300** Treatment Period Assessment Summary (Week 28 Visit) (pdc300 annotated.pdf) -- Patient continuing in study, physical exam completed, concurrent medications and conditions, patient study drug therapy, laboratory tests ordered. 3 pgs.
- **PDC310** Treatment Failure/Reassignment Report Week 24 (pdc310 annotated.pdf) – To be completed for all patients with HCV-RNA test results at Week 24 to report responses to therapy and therapy reassignment. Initial therapy assignment, viral disappearance. 2 pgs.
- **PDC320** Unscheduled Assessment Summary (pdc320 annotated.pdf) – To be completed at all unscheduled patient visits, reason for visit, physical exam, laboratory tests, future visits. 2 pgs.
- **PDC330** Discontinued Therapy Report (pdc330 annotated.pdf) – Permanent removal from drug therapy, date and reason for removal. 1 pg. Administrative form, no associated data
- **PDC340** Study Drug Count Form (pdc340 annotated.pdf) – Record of study medication dispensed and collected, PEG-2a, Placebo/Ribavirin, open label Ribavirin, 3 pgs.
- **PDC341** Study Drug Count Form (pdc341 annotated.pdf) – Revision of PDC340 Form. NOT ANNOTATED, except for several variables added or revised regarding whether medications were returned at time of visit, number of bottles/pills returned, prescription number, bottles returned to pharmacy, new bottles dispensed by pharmacy. 3 pgs.
- **PDC351** Serious Adverse Event Form (pdc351 annotated.pdf) – Serious event or symptom, outcome, action taken with PEG-2a and/or placebo/Ribavirin, possible causes and seriousness of SAE, relevant medical conditions and risk factors, adjustments to study therapy, relevant concurrent medications. 8 pgs.
- **PDC361** Non-serious Adverse Event Form (pdc361 annotated.pdf) – Non-serious adverse event, outcome, and action taken. 2 pgs. Administrative form, no associated data.
- **PDC370** Therapy Missed Dose Form (pdc370 annotated.pdf) – Report missed PEG-2a injection, RV/Placebo missed doses, 2 pgs
- **PDC380** Therapy Stop/Restart Form (pdc380 annotated.pdf) – Data, type, and reason for therapy stop, dose and date for therapy restart. 3 pgs.
- **PDC381** Therapy Stop/Restart Form (pdc381 annotated.pdf) – Revision of PDC380 Form, 07-07-2006. NOT ANNOTATED, except added end of therapy per protocol as reason for stopping PEG-2a therapy, *stppegprotend*, and RV/Placebo therapy, *stprvprotend*, 3 pgs.
- **PDC390** Therapy Dose Adjustment Form (pdc390 annotated.pdf) – Record changes in therapy dosage following baseline assessment. 2pgs.
- **PDC400** Concurrent Medical Conditions Form (pdc400 annotated.pdf) – Report concurrent medical conditions that are not adverse events. 1 pg. No associated data.
- **PDC410** Concurrent Medications Form (pdc410 annotated.pdf) – Record non-study related medications taken after baseline assessment. 1 pg.
- **PDC411** Concurrent Medications Form (pdc411 annotated.pdf) – Revised PDC410 Form, 09-09-2005. NOT ANNOTATED. List of common concurrent medications (*med01-med10*), added indicator variable for other meds taken (*med11*). 1 pg.

- **PDC420** Depression Management Tracking Form (pdc420 annotated.pdf) – To be administered to all patients who score >19 on Children’s Depression Inventory (ages 5-17) or >15 on CES-D (ages 18+) 3 pgs.
- **PDC430** Death Report (pdc430 annotated.pdf) 1 pg.
- **PDC440** Withdrawal/Close Out Form (pdc440 annotated.pdf) 1 pg.
- **PDC450** Missed Forms Report (pdc450 annotated.pdf) Form number, week number, and reason for each missed form. 1 pg.
- **PDC500** BIA Report Form (bioelectrical impedance) (pdc500 annotated.pdf) Record results of the bio-electrical impedance assessment performed as part of the PEDS-C Growth and body composition battery. 1 pg
- **PDC510** Tx Assessment Summary Wk 30 (pdc510 annotated.pdf) For patients in the mono/combo therapy group who had no viral disappearance at week 24. 3 pgs.
- **PDC520** Tx Assessment Summary Wk 32 (pdc520 annotated.pdf) For patients in the mono/combo therapy group who had no viral disappearance at week 24. 3 pgs
- **PDC530** Tx Assessment Summary Wk 34 (pdc530 annotated.pdf) For patients in the mono/combo therapy group who had no viral disappearance at week 24. 3 pgs.
- **PDC540** Tx Assessment Summary Wk 36 (pdc540 annotated.pdf) For patients in the mono/combo therapy group who had no viral disappearance at week 24. 3 pgs
- **PDC550** Tx Assessment Summary Wk 40 (pdc550 annotated.pdf) For patients in the mono/combo therapy group who had no viral disappearance at week 24. 3 pgs.
- **PDC560** Tx Assessment Summary Wk 44 (pdc560 annotated.pdf) For patients in the mono/combo therapy group who had no viral disappearance at week 24. 3 pgs
- **PDC570** Tx Assessment Summary Wk 48 (pdc570 annotated.pdf) For patients in the mono/combo therapy group who had no viral disappearance at week 24. 3 pgs.
- **PDC580** Tx Assessment Summary Wk 52 (pdc580 annotated.pdf) For patients in the mono/combo therapy group who had no viral disappearance at week 24. 3 pgs
- **PDC600** Treatment Failure/Reassignment Form Week 52 (pdc600 annotated.pdf) To be completed for patients in mono/combo therapy group with HCV-RNA test results at week 52. 1 pg.
- **PDC610** Follow-Up Ophthalmology Summary (pdc610 annotated.pdf) To record results of ophthalmology exams from *Ophthalmology Worksheet*. 1 pg.
- **PDC620** Untreated Follow-up Assessment Summary, Follow-Up Week 4 (pdc620 annotated.pdf) For all therapy groups. 2 pgs
- **PDC630** Untreated Follow-up Assessment Summary, Follow-Up Week 8 (pdc630 annotated.pdf) For all therapy groups. 2 pgs
- **PDC640** Untreated Follow-up Assessment Summary, Follow-Up Week 12 (pdc640 annotated.pdf) For all therapy groups. 2 pgs
- **PDC650** Untreated Follow-up Assessment Summary, Follow-Up Week 16 (pdc650 annotated.pdf) For all therapy groups. 3 pgs
- **PDC651** Untreated Follow-up Assessment Summary, Follow-Up Week 16 (pdc651 annotated.pdf) For all therapy groups. NOT ANNOTATED. Deletes questions from PDC650 (4B,4C) on menstruation. 2 pgs
- **PDC660** Untreated Follow-up Assessment Summary, Follow-Up Week 20 (pdc660 annotated.pdf) For all therapy groups. 3 pgs
- **PDC661** Untreated Follow-up Assessment Summary, Follow-Up Week 20 (pdc661 annotated.pdf) For all therapy groups. NOT ANNOTATED. Deletes questions from PDC660 (4B,4C) on menstruation. 2 pgs
- **PDC670** Untreated Follow-up Assessment Summary, Follow-Up Week 24 (pdc670 annotated.pdf) For all therapy groups. Vital signs, physical exam results, anthropometry, concurrent medication and conditions, depression screen, laboratory tests ordered, quality of life tests administered. 6 pgs
- **PDC681** Patient re-registration Form (pdc681 annotated.pdf) To register previously ineligible residents. Only patients who had not been randomized could be re-registered. The patients’ ID and letter code remained unchanged. 1 pg. Administrative form, no associated data.
- **PDC700** Tx Period Summary, Telephone Assessment Week 28 (3) (pdc700 annotated.pdf) For patients in the original mono or original combo therapy groups with viral disappearance at week 24. 3 pgs.
- **PDC710** Tx Period Summary, Telephone Assessment Week 32 (3) (pdc710 annotated.pdf) For patients in the original mono or original combo therapy groups with viral disappearance at week 24. 3 pgs.

- **PDC720** Tx Period Summary, Telephone Assessment Week 36 (3) (pdc720 annotated.pdf) For patients in the original mono or original combo therapy groups with viral disappearance at week 24. 3 pgs.
- **PDC730** Tx Period Summary, Telephone Assessment Week 40 (3) (pdc730 annotated.pdf) For patients in the original mono or original combo therapy groups with viral disappearance at week 24. 3 pgs.
- **PDC740** Tx Period Summary, Telephone Assessment Week 44 (3) (pdc740 annotated.pdf) For patients in the original mono or original combo therapy groups with viral disappearance at week 24. 3 pgs.
- **PDC750** Tx Period Summary, Telephone Assessment Week 48 (3) (pdc750 annotated.pdf) For patients in the original mono or original combo therapy groups with viral disappearance at week 24. 3 pgs.
- **PDC760** Long-Term Follow-Up Assessment Annual Visit (pdc760 annotated.pdf) For all patients in all therapy groups at annual visits 1 and 2. 5 pgs.
- **PDC770** Expected Non-Serious Adverse Event Form (pdc770 annotated.pdf) To report conditions (Grade 1) related to treatment with Peg2a or RV/Placebo and conditions common during childhood. 2 pgs. Revised to PDC771, no associated data.
- **PDC771** Expected Non-Serious Adverse Event Form (pdc771 annotated.pdf) NOT ANNOTATED. Amended to record severity of conditions noted in PDC770. 2 pgs.
- **PDC780** Unexpected Non-Serious Adverse Events (pdc780 annotated.pdf) Record up to 3 unexpected non-serious adverse events. 1 pg.
- **PDC800** Tx Period Assessment Summary Week 56 (3B) (pdc800 annotated.pdf) For patients in the original mono or original combo therapy groups with no viral disappearance at week 24 and viral disappearance at week 52. 3 pgs.
- **PDC810** Tx Period Assessment Week 60 (3B) (pdc810 annotated.pdf) For patients in the original mono or original combo therapy groups with no viral disappearance at week 24 and viral disappearance at week 52. 3 pgs.
- **PDC820** Tx Period Assessment Week 64 (3B) (pdc820 annotated.pdf) For patients in the original mono or original combo therapy groups with no viral disappearance at week 24 and viral disappearance at week 52. 3 pgs.
- **PDC830** Tx Period Assessment Week 68 (3B) (pdc830 annotated.pdf) For patients in the original mono or original combo therapy groups with no viral disappearance at week 24 and viral disappearance at week 52. 3 pgs.
- **PDC840** Tx Period Summary, Telephone Assessment Week 72 (3B) (pdc840 annotated.pdf) For patients in the original mono or original combo therapy groups with no viral disappearance at week 24 and viral disappearance at week 52. 3 pgs.
- **PDC850** Tx Period Assessment Summary Week 76 Visit (3B) (pdc850 annotated.pdf) For patients in the original mono or original combo therapy groups with no viral disappearance at week 24 and viral disappearance at week 52. 6 pgs.
- **PDC860** Patient Transfer Form (pdc860 annotated.pdf) To be completed when patient transfers from one clinical center to another. 1 pg.

A brief summary of forms used in data collection, their corresponding SAS dataset (sas7bdat), and the number of observations in each file are summarized in Table 1 which is extracted and revised from *General Description.doc*.

Table 1. Datasets and study forms used in data collection

#	Dataset Name	Form Number	Description	No. of Observations
1	na	PDC010	Certification Number Report	
2	PDC020.sas7bdat	PDC020	Screening Visit 1 Form	30
3	PDC021.sas7bdat	PDC021	Screening Visit 1 Form (revised)	98
4	PDC030.sas7bdat	PDC030	Screening Visit 2 Form	6
5	PDC040.sas7bdat	PDC040	Eligibility Summary Form	4
6	PDC041.sas7bdat	PDC041	Eligibility Summary Form (revised)	124
7	PDC050.sas7bdat	PDC050	BL Ophthalmology Summary	123

#	Dataset Name	Form Number	Description	No. of Observations
8	PDC060.sas7bdat	PDC060	CDI Form (depression screen)*	827
9	PDC070.sas7bdat	PDC070	Eligibility Criteria Exemption Form	45
10	PDC080.sas7bdat	PDC080	Protocol Deviation Report	220
11	na	PDC090	De-certification Report	
12	PDC100.sas7bdat	PDC100	BL Assessment	25
13	PDC101.sas7bdat	PDC101	BL Assessment (revised)	89
14	PDC110.sas7bdat	PDC110	Vital Signs and Symptom Directed Physical	190
15	PDC111.sas7bdat	PDC111	Vital Signs and Symptom Directed Physical (revised)	1521
16	Na	PDC120	CRA Visit Form	
17	PDC130.sas7bdat	PDC130	Physical Activity Assessment	584
18	PDC160.sas7bdat	PDC160	BRIEF Form Patient (cognitive function)*	587
19	PDC170.sas7bdat	PDC170	Child Health Questionnaire – Parent*	584
20	PDC180.sas7bdat	PDC180	Child Health Questionnaire – Patient*	410
21	PDC190.sas7bdat	PDC190	LEC Form - Parent about patient (stress)*	585
22	PDC200.sas7bdat	PDC200	Your Health and Well-Being (parent QOL)	9
23	PDC210.sas7bdat	PDC210	Tx Assessment Summary Wk 1	114
24	PDC220.sas7bdat	PDC220	Tx Assessment Summary Wk 3	114
25	PDC230.sas7bdat	PDC230	Tx Assessment Summary Wk 5	114
26	PDC240.sas7bdat	PDC240	Tx Assessment Summary Wk 8	114
27	PDC250.sas7bdat	PDC250	Tx Assessment Summary Wk 12	112
28	PDC260.sas7bdat	PDC260	CES-D Form Patient (depression)	27
29	PDC270.sas7bdat	PDC270	Tx Assessment Summary Wk 16	112
30	PDC280.sas7bdat	PDC280	Tx Assessment Summary Wk 20	110
31	PDC290.sas7bdat	PDC290	Tx Assessment Summary Wk 24	34
32	PDC291.sas7bdat	PDC291	Tx Assessment Summary Wk 24	76
33	PDC300.sas7bdat	PDC300	Tx Assessment Summary Wk 28	30
34	PDC310.sas7bdat	PDC310	Tx Failure/Reassignment Form Wk 24	108
35	PDC320.sas7bdat	PDC320	Unscheduled Assessment Summary	8
36	Na	PDC330	Discontinued Therapy Report	
37	PDC340.sas7bdat	PDC340	Study Drug Count Form	578
38	PDC341.sas7bdat	PDC341	Study Drug Count Form (revised)	321
39	PDC351.sas7bdat	PDC351	SAE Report	4
40	Na	PDC361	Non-serious Adverse Event Form	
41	PDC370.sas7bdat	PDC370	Therapy Missed Dose Form	607

#	Dataset Name	Form Number	Description	No. of Observations
42	PDC380.sas7bdat	PDC380	Therapy Stop/Restart Form	63
43	PDC381.sas7bdat	PDC381	Therapy Stop/Restart Form (revised)	99
44	PDC390.sas7bdat	PDC390	Therapy Dose Adjustment Form	246
45	Na	PDC400	Concurrent Medical Conditions	
46	PDC410.sas7bdat	PDC410	Concurrent Medications	181
47	PDC411.sas7bdat	PDC411	Concurrent Medications (revised)	1203
48	PDC420.sas7bdat	PDC420	Depression Management Tracking Form	8
49	PDC430.sas7bdat	PDC430	Death Report	0
50	PDC440.sas7bdat	PDC440	Withdrawal/Close Out Form	115
51	PDC450.sas7bdat	PDC450	Missed Forms Report	150
51	PDC500.sas7bdat	PDC500	BIA Report Form (bioelectrical impedance)	581
53	PDC510.sas7bdat	PDC510	Tx Assessment Summary Wk 30	28
54	PDC520.sas7bdat	PDC520	Tx Period Assess. Summary Week 32	30
55	PDC530.sas7bdat	PDC530	Tx Period Assess. Summary Wk 34	27
56	PDC540.sas7bdat	PDC540	Tx Period Assess. Summary Wk 36	28
57	PDC550.sas7bdat	PDC550	Tx Period Assess. Summary Wk 40	28
58	PDC560.sas7bdat	PDC560	Tx Period Assess. Summary Wk 44	26
59	PDC570.sas7bdat	PDC570	Tx Period Assess. Summary Wk 48	28
60	PDC580.sas7bdat	PDC580	Tx Period Assess. Summary Wk 52	28
61	PDC600.sas7bdat	PDC600	Tx Failure/Reassignment Form Wk 52	28
62	PDC610.sas7bdat	PDC610	Follow-Up Ophthalmology Summary	213
63	PDC620.sas7bdat	PDC620	Untx FUp Assess Sum - FUp Wk 4	101
64	PDC630.sas7bdat	PDC630	Untx FUp Assess Sum - FUp Wk 8	93
65	PDC640.sas7bdat	PDC640	Untx FUp Assess Sum - FUp Wk 12	101
66	PDC650.sas7bdat	PDC650	Untx FUp Assess Sum - FUp Wk 16	37
67	PDC651.sas7bdat	PDC651	Untx FUp Assess Sum - FUp Wk 16	58
68	PDC660.sas7bdat	PDC660	Untx FUp Assess Sum - FUp Wk 20	30
69	PDC661.sas7bdat	PDC661	Untx FUp Assess Sum - FUp Wk 20	65
70	PDC670.sas7bdat	PDC670	Untx FUp Assess Sum - FUp Wk 24	99
71	Na	PDC681	Patient Re-registration Form	
72	PDC700.sas7bdat	PDC700	Tx Period Telephone Assess. Summary Wk 28 (3)	75
73	PDC710.sas7bdat	PDC710	Tx Period Assess. Summary Wk 32 (3)	63
74	PDC720.sas7bdat	PDC720	Tx Period Telephone Assess. Summary Wk 36 (3)	62
75	PDC730.sas7bdat	PDC730	Tx Period Assess. Summary Wk 40 (3)	61

#	Dataset Name	Form Number	Description	No. of Observations
76	PDC740.sas7bdat	PDC740	Tx Period Telephone Assess. Summary Wk 44	62
77	PDC750.sas7bdat	PDC750	Tx Period Assess. Summary Wk 48 (3)	62
78	PDC760.sas7bdat	PDC760	Long-Term Follow-Up Annual Assessment	163
79	Na	PDC770	Expected Non-Serious Adverse Event	
80	PDC771.sas7bdat	PDC771	Expected Non-Serious Adverse Event Report (revised)	1213
81	PDC780.sas7bdat	PDC780	Unexpected Non-Serious Adverse Event Report	553
82	PDC800.sas7bdat	PDC800	Tx Period Telephone Assess. Summary Wk 56 (3B)	13
83	PDC810.sas7bdat	PDC810	Tx Period Assess. Summary Wk 60 (3B)	12
84	PDC820.sas7bdat	PDC820	Tx Period Telephone Assess. Summary Wk 64 (3B)	12
85	PDC830.sas7bdat	PDC830	Tx Period Assess. Summary Wk 68 (3B)	12
86	PDC840.sas7bdat	PDC840	Tx Period Telephone Assess. Summary Wk 72 (3B)	12
87	PDC850.sas7bdat	PDC850	Tx Period Assess. Summary Wk 76 (3B)	12
88	PDC860.sas7bdat	PDC860	Patient Transfer Form	3

Na= DC010, PDC090, PDC120, PDC330, PDC361, PDC400, PDC681, and PDC770 are not associated with SAS data sets as they were used for administrative purposes or replaced by another version.

***Copyrighted form not included in the NIDDK repository.**

3. Data Directory

The Data directory contains 80 SAS datasets (.sas7bdat) that correspond to each of the study forms (PDCxxx) described above in **Table 1**. The file, *DataContents.doc*, in the Data directory provides an alphabetical listing by file name of the number of observations, number of variables, and file size for each SAS dataset. In addition, the document provides a listing of variable names, generated using SAS Proc Contents, for each PEDS-C SAS dataset.

The directory also includes 10 additional SAS datasets provided to the repository (**Table 2**). These data were collected using forms not provided to the repository (Child Behavior Checklist is copyrighted and not included). Information on the variables of the additional datasets, including variable value labels, is documented in the file *Additional Datasets Documentation.pdf*.

Table 2. Additional PEDS-C Datasets

#	Dataset Name	Source	Description	No. Obs.	No. variables
1	PDCATRSDATA.sas7bdat	MMRI (DCC)	Patient registration and randomization	128	39
2	CBCL_RAW.sas7bdat	J. Rodrigue	Child Behavior Checklist (raw scores) ³	548	123
3	CBCL_SCR.sas7bdat	J. Rodrigue	Child Behavior Checklist (summary scores)	548	47
4	COVANCE_LAB.sas7bdat	Covance	Lab test data from central laboratory	113,783	29
5	DXA_HOLOGIC.sas7bdat	UCSF radiol.	DXA scan data	352	95

³ The Child Behavior Checklist is copyrighted and has been excluded from Appendix I of the Manual of Operations.

6	DXA_PRODIGY.sas7bdat	UCSF radiol.	DXA scan data	216	80
7	ESHA.sas7bdat	Clinical site nutritionists	Total calories, grams of fat, grams of protein, grams of carbohydrates from PC scoring print-outs.	1162	8
8	HISTOLOGY.sas7bdat	Z. Goodman	Pathology data from liver biopsy	121	13
9	AUTOANTIBODY.sas7bdat	Johns Hopkins	Auto-antibody test results	285	11
10	VK_JHU.sas7bdat	Johns Hopkins	Viral kinetics data	948	6

4. Integrity Check Directory

The PEDS-C Dataset Integrity Check directory contains a report based on an examination of the data in the repository by statisticians and quality control specialists at the repository. Datasets were checked for completeness, consistency, and usability based on a comparison of the published data from the PEDS-C study (Schwarz et al (2011, in *Gastroenterology*) to values recalculated from the PEDS-C data in the NIDDK repository.