



THE NATIONAL ARCHIVES OF THE UNITED STATES

LITTERA
SCRIPTA
MANET

★ 1934 ★

**NINCDS COLLABORATIVE
PERINATAL PROJECT
A User's Guide to the Project and Data**

**Volume II: Project Study Forms
and Documentation of Transfer
to Computerized Data Items
in Master File**

**Part A: Prenatal Record and
Medical History**

December 1983

**Prepared for
the National Institute of Neurological
and Communicative Disorders and Stroke
under Contract 2311105150**

 **Battelle**
Pacific Northwest Laboratories

LEGAL NOTICE

This report was prepared by Battelle as an account of sponsored research activities. Neither Sponsor nor Battelle nor any person acting on behalf of either:

MAKES ANY WARRANTY OR REPRESENTATION, EXPRESS OR IMPLIED, with respect to the accuracy, completeness, or usefulness of the information contained in this report, or that the use of any information, apparatus, process, or composition disclosed in this report may not infringe privately owned rights; or

Assumes any liabilities with respect to the use of, or for damages resulting from the use of, any information, apparatus, process, or composition disclosed in this report.

**NINCDS COLLABORATIVE PERINATAL PROJECT:
A USER'S GUIDE TO THE PROJECT AND DATA**

**Volume II. Project Study Forms and Documentation
of Transfer to Computerized Data Items
in Master File**

Part A. Prenatal Record and Medical History

**NR Hinds
A Brix**

**JS Littlefield
CR Watson**

December 1983

**Prepared for
National Institute of Neurological
and Communicative Disorders and Stroke
under Contract 2311105150**

**Battelle
Pacific Northwest Laboratories
Richland, Washington 99352**

INTRODUCTION

DOCUMENT OBJECTIVES AND READER ASSUMPTIONS

Volume II, Project Study Forms and Documentation of Transfer to Computerized Data Items in Master File, provides researchers with detailed documentation for how data were collected, coded and stored on the data base. Volume II will help investigators decide: if data were collected in a suitable way for addressing particular research questions; if revision of forms affected the collection of specific data items; if data were coded on master, variable or work files, or are available only on microfilm. The reader is assumed to be the principal investigator for a project in which data from the data base will be used.

DOCUMENT STRUCTURE

Because of its size, this volume is divided into ten separate parts, each containing material on a group of forms related by subject. Each part groups together similar study forms. Generally, a part covers a single time period. The parts do not correspond exactly to the hierarchical classification structure described in Volume I. The parts of Volume II include:

- A. Prenatal Record and Medical History
- B. Labor and Delivery
- C. Pathological Exams and Autopsies
- D. Family and Socioeconomic History
- E. Neonatal Exams and Observations
- F. Pediatric and Neurological Exams, Four Months - One Year
- G. Pediatric Neurological Exams, Seven Years
- H. Psychological Exams, Eight Months
- I. Psychological Exams, Four Years and Seven Years
- J. Speech, Language and Hearing Exams, Three Years and Eight Years (Final)

This part of Volume II contains Part A: Prenatal Record and Medical History and includes Forms AR-1, OB-2, OB-3, OB-4, OB-5, OB-6, OB-7, OB-8, OB-9, OB-42, OB-43, OB-10, OB-44, OB-45, OB-11, OB-46, OB-12, OB-47, and OB-15.

To allow easy access to the data as they appear on the master file, all documentation for each form or form grouping representing a card series on the master file is identified by form number appearing at the bottom of each page. Forms are arranged in what may appear to be illogical numerical order in some cases, but the arrangement presented here ties forms and their revisions together and allows an investigator to trace an item through all revision cycles. Thus, in Part A of Volume II, OB-42 follows OB-9 and OB-10 appears next to OB-44 and OB-45. (For an explanation of how the master file was organized to result in this ordering, see the next section of the Introduction.)

All material related to a form is organized as a single unit within each part of Volume II. The material included for each form is given below in the order it appears:

- **Descriptive Summary of Form.** Includes purpose of form, history of use, revisions and location of records stored on Master File. A table is provided for each form (except those on microfilm only) showing the number of records available for each revision.
- **Data Items Referencing Form.** A list of all data items in computer files originating from form. List ordered by data item identification with reference to item number on form.
- **Form.** Copy of last revision of form.
- **Form item numbers linked to data items.** A list organized by form item numbers of all computerized data items originating from the form.
- **Definition of codes.** Coding instructions detailing the codes assigned to each computerized data item from the form.
- **Master File Card Image.** Illustrates transfer of data on form to Master File card.
- **Instructions for Completing Form.** The instructions used by study personnel to complete the form for each case.
- **Earlier Forms or Manuals.** Copies of earlier versions of forms or manuals that were used during the study.

MASTER FILE ORGANIZATION AND REVISION OF FORMS

Some understanding of how the master file was organized should aid investigators who want to trace the entry of data into computerized study files. The numbering system used both on forms and cards provides information on how data may be retrieved from the master file.

Forms

The first forms used in the study were the OB forms; as a consequence, this group of forms underwent the most revision. At first glance, it appears that forms disappear from the file and reappear in strange or bewildering places. In actuality, revisions were made according to a specific method.

Two types of revision and subsequent recodes appear in the master file, both of which appear in the OB series. In the first type of revision, radical changes in the concept of a form created a need for new coding in the computer file. Form OB-9, for example, was replaced by forms OB-40 (an optional form retained by the institution), OB-42, and OB-43 in April 1962. Data for earlier patients were recorded on OB-9 and entered on cards 1309, 2309, 3309 and 4309 of the master file; after April 1962, data was recorded on OB-42 and OB-43 and were entered on cards 0342, 1343 and 2343 of the master file.

In the second type of revision, the Collaborative Perinatal Task Force considered revisions important enough to warrant the distinction of a new form number, but considered the data for both forms to be similar enough to allow combining of data from both the old and new forms on the same card series. An example of this type of revision is form OB-35, replaced by OB-57 in April 1962. Records for both OB-35 and OB-57 are entered on cards 0357, 1357, 2357, 3357, 4357, and 5357 in the master file.

In assigning numbers to forms and their revisions, designers of the study followed a plan: prenatal records, history, and summaries of the prenatal period received numbers 1 through 15; when revised, these forms were assigned numbers in the forties. Labor and hospital records appeared on the 30 series of forms. When these forms were revised, they were assigned numbers in the fifties. Some OB data in the master file were abstracted by NINCDS staff members from forms filled out at the hospital. Cards derived from this procedure were designated as coming from forms ADM-49, 50 and 51 (which were actually ABSTRACT SHEETS). Autopsy protocol and laboratory exams of the placenta were recorded on forms PATH-1, PATH-2 and PATH-3.

Forms for recording family health history and genetic information during pregnancy also received a fair amount of revision. Early records appear on forms FHH-1,2,3 and 4. With revisions in April 1963, form St-1 replaces part of FHH-1 and FHH-3; FHH-2, FHH-4 and parts of FHH-1 and FHH-3 were replaced by

forms GEN-5 through GEN-8 in May 1961. Form FHH-9, initiated in November 1965 for collection of socioeconomic data at time the child was seven years of age, was not replaced or revised.

The PED series of forms underwent little revision. Records for newborn babies appeared in PED-1 through PED-8; records for children up to age one and interval records were placed on PED-10 through PED-29. Seven year records were included in the series numbered PED-74 and up. Only one pediatrics form was radically revised: PED-7 was replaced by PED-8 in March 1963.

No replacements occur in the PS series, where results of psychological and speech, language and hearing tests were recorded. The PS forms are divided into distinct groups based on time of testing and subject of testing. Psychological testing occurred at 8 months, 4 years and 7 years; speech, language and hearing exams were administered at ages 3 and 8. Only the 8 month psychological examination underwent substantial revisions.

Master File Card Number and NINDB Case Number Rationale

Computer cards for each NCPP study form are numbered to reflect their origin and possible revisions. Card numbers are assigned to identify the type of data (subject), the presence of multiple cards in a series, NCPP study form and form revisions. The first five digits of each card on the master file are the card number. The study forms and card numbers are given in Figure 1.

The first fourteen columns of each master file computer card contain the master file card number and the NINDB case number. Table 1 identifies the function of each of these columns.

Column 1 identifies multiple cards in a series. It contains a zero for cards unique to a particular form (that is, no other cards are present), for example OB-3, or for cards where repetitive data are contained. Cards for OB-2 are an example of this second type; no new categories of information are included on successive cards, but previous births in excess of four must be recorded on an add-on card. For card series where data entered are unique to a card and more than one card is required to complete the series, a "1" is used to designate the first card, for example OB-5. OB-57, PATH-2 and PED-14 are exceptions to these rules.

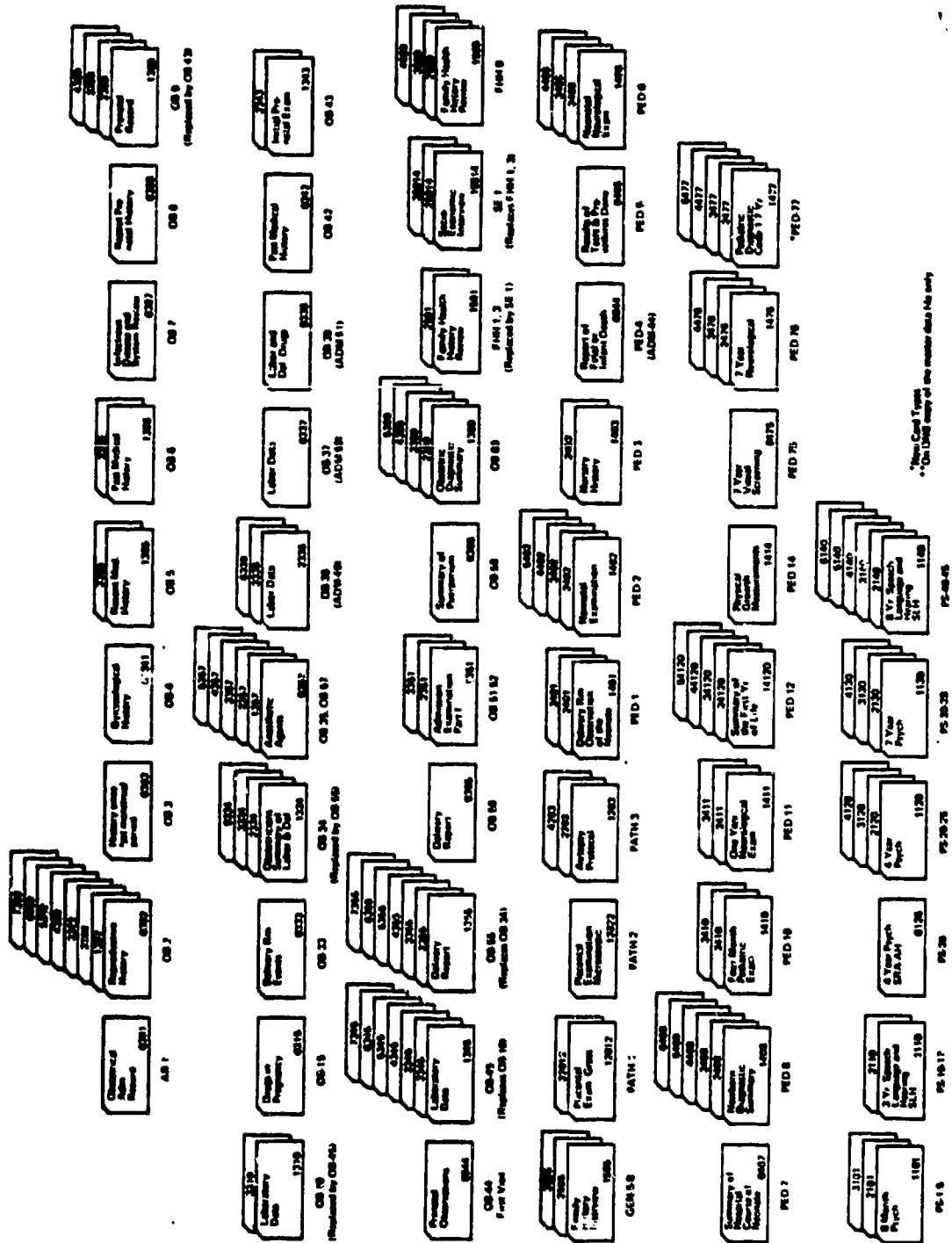


FIGURE 1. Cards on the Master Data File

TABLE 1. Derivation of Master File Card Number and NINDB Case Number.

| <u>Contents</u> | <u>Columns</u> |
|-------------------------------|----------------|
| Master File Card Number | |
| card identifier | 1 |
| general subject matter | 2 |
| form number | 3-4 |
| revision code | 5 |
| NINDB Case Number | |
| collaborating institution | 6-7 |
| type of patient selection | 8 |
| gravida identification number | 9-12 |
| order of the pregnancy | 13 |
| identifies child or gravida | 14 |

The second digit on the card reveals the general subject matter covered by data on the card. All cards containing information pertaining to obstetrics, for example, are designated by a "3" in column 2; family histories are designated by a "5"; pathology with a "2"; pediatrics, with a "4"; and psychological testing with a "1".

Columns three and four reveal the form number. In the case of forms where old and new forms having different numbers are included together, the number of the latest form appears on the master file. This rule does not apply to data abstracted from several forms by NINCDS staff (ADM forms).

Column 5 of the card contains a revision code indicating which form or combination of forms was used in arriving at data on a particular card. A typical card will have one to three revision codes, with a zero indicating the first version of a form and "1", "2", and "3" indicating later revisions. As a rule, revision codes used on cards differ from card to card; investigators should check the definition of codes provided in Volume II to determine the meaning of revision codes used.

Each woman and child studied in the project received a unique case number (NINDB case number) composed of nine digits, recorded in columns 6 through 14 of all master file cards. The case number identified the institution, the mother and the child. The first two digits represented the collaborating institution (see Table 2). The third digit indicated the type of patient

selection. A "1" was used for patients selected for the central core study; a "6" indicated that a patient had been transferred from one institution to another, and a "7" indicated that the patient was part of a special study undertaken by the collaborating institution. The fourth through seventh digits were used to identify the gravida, while the eighth digit identified the order of the pregnancy of a given gravida in the project. The ninth digit was used to identify the gravida or child of the pregnancy; "9" indicated the gravida, "0" indicated the child of a single birth, "1" indicated the first child of a multiple birth, "2" indicated the second child of a multiple birth, etc.

TABLE 2. Collaborating Institutions and Their Code Number
(Columns six and seven of all master file cards.)

| | |
|---|--|
| <p>05 - <u>Boston, Massachusetts</u> Harvard Medical School Boston Lying-In Hospital Children's Hospital Medical Center</p> | <p>50 - <u>Minneapolis, Minnesota</u> University of Minnesota Hospital Health Sciences Center</p> |
| <p>10 - <u>Buffalo, New York</u> University of Buffalo Children's Hospital</p> | <p>55 - <u>New York, New York</u> New York Medical College Metropolitan Hospital</p> |
| <p>15 - <u>New Orleans, Louisiana</u> Charity Hospital Tulane University School of Medicine Medical Center Louisiana State University</p> | <p>60 - <u>Portland, Oregon</u> University of Oregon Medical School</p> |
| <p>31 - <u>New York, New York</u> Columbia University College of Physicians & Surgeons Columbia-Presbyterian Medical Center</p> | <p>66 - <u>Philadelphia, Pennsylvania</u> University of Pennsylvania Pennsylvania Hospital The Children's Hospital of Philadelphia</p> |
| <p>37 - <u>Baltimore, Maryland</u> The Johns Hopkins University School of Medicine The Johns Hopkins Hospital</p> | <p>71 - <u>Providence, Rhode Island</u> Brown University Child Study Center</p> |
| <p>45 - <u>Richmond, Virginia</u> Virginia Commonwealth University Medical College of Virginia</p> | <p>82 - <u>Memphis, Tennessee</u> University of Tennessee College of Medicine Gaylor Hospital</p> |

Data Item Identification and Naming

The NCPP data base contains over 6700 different data items and blank filler locations on computer files. We have assigned each of these a unique identification and a terse, stylized name. Because names were chosen to facilitate use of this guide, they do not duplicate names used by NINDB during the active phase of the project. Users should consult appropriate documentation before using data items from the master, variable or work files (Volumes II, III and IV).

The data item identifiers consist of 11 characters. At the far left are four unique numbers that were assigned sequentially. The next character is always a period and is followed by up to six characters. For data items on the master file, these characters describe the data collection form from which a data item was derived; for data items on the variable (VAR) or work (WXX) files, these characters indicate the appropriate file. If the right side is less than six characters, periods are inserted as shown in these examples:

| | |
|-------------|---|
| 850..OB-34 | an item from OB-34; on the master file |
| 3650.PATH-3 | an item from PATH-3; on the master file |
| 5223....VAR | an item on the variable file |
| 6340...W-10 | an item on work file 10, Rupture of Membranes |

We assigned the numbers sequentially as they appear in Volume V. For the master file, we followed the order in which the cards would be found within an NINDB case. All card columns are accounted for by one of our data item identifications. For the variable and work files, the numbers were assigned in the order that data items appear within a case.

We categorized each data item according to the person to whom the data refer, by the time of measurement and/or the time to which the item applies and by general type or subject area (Table 3). Then we assigned names to the data items using the following guidelines:

- The name and the three associated categories had to stand alone - they must describe the data item out of context.
- The first word in the data item name had to be an important or key word when all names were listed alphabetically as in Volumes VI and VII. Thus "cry, abnormal" was used rather than "abnormal cry" because a

researcher is more likely to look for this item under "C" than under "A" in an alphabetic list.

- Secondary key words were preceded with a semicolon to facilitate preparation of the permuted index. For example, "abruptio; placenta" will be found under both the "A" and "P" portion of Volume VI.
- Qualifying words are delimited by commas and will not appear as keywords in Volume VI. Thus "abruptio; placenta, degree" will not be found in the "D" section.
- If medical terminology or usage has changed since the study was conducted, modern terms may be included and will be enclosed in brackets. Thus "mongolism; [Down's syndrome]" will appear under both the "M" and "D" portions of Volume VI.
- If measurement units are associated with a data item name, they are enclosed in parentheses and placed at the end of the name as in "Birthdate (yr)."
- The categories (person, time and subject) are appended to the right of the data item name.

Definitions for each category used in naming data items are given in Table 4 at the end of this introduction. Additional information is found in Chapter 4 of Volume I.

Data item names thus assigned are terse and highly stylized; as we have already indicated, they are not the names used by NINDB during the active phase of the project. Our aim was to develop standardized names that would stand alone. These names are intended to facilitate a user's search for data items potentially useful in a research project. Before an item is used, a researcher should consult its complete description. For a data item from the master files, e.g., 850..OB-34, the data item should be traced to the appropriate study form, e.g., OB-34, located in Volume II. A variable file data item, e.g., 5223....VAR, is traced to Volume III, where it is defined and its original source given. A data item from a work file is traced to Volume IV for its description.

Some data items contained in the indexes may include the notation "DO NOT USE." These items are either inaccurate or an alternative data item is available that gives better information. Users will find more appropriate data items by consulting one of the indexes to the data items (Volumes, V, VI and VII).

Tables of Data Items: Column Headings

For each form, two sets of computer generated pages list all data items in either the master, variable or work files derived from this form. These listings enable a user to track form items to computerized data items listed in previous volumes of the User's Guide and vice versa. The computer listings provide the following information.

| <u>Column Heading</u> | <u>Description</u> |
|-----------------------|---|
| DATA ITEM ID | A unique identifier for this data item. See Data Item Identification and Naming above for details. |
| ITEM ON FORM | An identifier used on the NCPP study form to identify the question or group of questions which was used to generate this data item. |
| CARD NUM | Identifies the master file card on which this data item is located. See Master File Card Number and NINDB Case Number Rationale above for a description of card number. |
| FROM | Beginning card column for this data item. |
| TO | Ending card column for this data item. |
| DATA ITEM NAME | Terse stylized name for this data item. See Data Item Identification and Naming above for details. |

ASSOCIATED DOCUMENTS

By examining the tables provided for each, investigators will be able to determine which computer files contain data of interest. For data contained in the variable file, see Volume III of this guide; for data contained in work files, see Volume IV.

TABLE 3. Abbreviations for Person, Time and Subject Categories

| <u>Person</u> | <u>Time</u> | <u>Subject</u> |
|---------------|---------------|--------------------|
| Mother | General | Administrative |
| Father | Preconception | Anesthesia |
| Placenta | Registration | Clin. Impression |
| Fetus | Prenatal | Clinical Lab |
| Child | Admission | Current Pregnancy |
| M Surrogate | Intrapartum | Environ. Exposure |
| Family | Delivery | Events |
| Sibship | Post Partum | Hearing |
| | Neonatal | Hospitalizations |
| | Four month | Language |
| | Eight month | Linkage |
| | One year | Malformations |
| | Three year | Diag. & Cond. |
| | Four year | Med. History |
| | Seven year | Medications |
| | Eight year | Neurological Exam |
| | | Observations |
| | | Pathology |
| | | Physical Exam |
| | | Procedure |
| | | Psych. Exam |
| | | Reproductive Hist. |
| | | Serology |
| | | Socioecon. Info |
| | | Speech |
| | | Vision |
| | | Work History |
| | | X-ray |
| | | Summary |
| | | Gyn. History |
| | | Special Studies |
| | | Fam/Genetic Hist. |
| | | SLH Exam |

TABLE 4. Definition of Person, Time and Subject Categories

| PERSON | DEFINITION |
|--------------------|--|
| Mother | Study registrant bearing the "study pregnancy"; biologic mother of the "study child"; gravida. |
| Father | Biologic father of the study child or study pregnancy; in the case of socioeconomic data, this category may indicate either the "father of baby" (not necessarily husband of the mother) or the "husband" (not necessarily related biologically to the study child). |
| Placenta | The organ of metabolic and gaseous interchange between the fetus and mother; also included in this category are gross and microscopic pathologic data from examination of the umbilical cord. |
| Fetus | Conceptus; the product of conception including the embryonic stage, i.e., from conception to the moment of birth. |
| Child | Product of the study pregnancy from the moment of birth onward; study child. |
| M Surrogate | Person or persons substituting for the mother of a study child, e.g., adoptive parents, foster parents or guardian. |
| Family | Person or persons biologically related to the mother or father of the study child. |
| Sibship | Child or children having one or both of the same biologic parents as the study child; siblings; half siblings; full siblings. |

TABLE 4. Definition of Person, Time and Subject Categories (Cont.)

| <u>TIME</u> | <u>DEFINITION</u> |
|---------------|--|
| General | Data with no pertinent time period or data pertaining to more than one time period. |
| Preconception | Data pertaining to the period prior to conception of the study pregnancy. |
| Registration | Data collected at the time of study mother's registration in the study. |
| Prenatal | Data pertaining to the period from conception of the study pregnancy to delivery of the study child. |
| Admission | Data collected at the time of study mother's admission to the hospital for delivery of the study child. |
| Intrapartum | Data pertaining to the period from admission for delivery or onset of labor to delivery of the study child. |
| Delivery | Data pertaining to the time period during which delivery of the study child occurred. |
| Post Partum | Data (pertaining to the study mother) collected during the period immediately following birth of the study child. |
| Neonatal | Data pertaining to the study child during the period from birth to one month of age; the majority of these data were collected prior to or at the time a study child was discharged from the hospital. |
| Four Month | Data collected at the time of the four month examination of the study child. |
| Eight Month | Data collected at the time of the eight month examination of the study child. |
| One Year | Data collected at the time of the one year examination of the study child. |
| Three Year | Data collected at the time of the three year examination of the study child. |
| Four Year | Data collected at the time of the four year examination of the study child. |
| Seven Year | Data collected at the time of the seven year examination of the study child. |
| Eight Year | Data collected at the time of the eight year examination of the study child. |

TABLE 4. Definition of Person, Time and Subject Categories (Cont.)

| SUBJECT | DEFINITION |
|-------------------|--|
| Administrative | Data pertaining to the administrative aspects of the study. |
| Anesthesia | Data on medications and procedures used to obtain anesthesia. |
| Clin. Impression | Impression of abnormality or dysfunction gained by an examiner following evaluation of clinical signs and symptoms and including a subjective component. |
| Clinical Lab | Data obtained from laboratory examination of clinical specimens. |
| Current Pregnancy | Personal data and medically relevant information pertaining to the study pregnancy for which the mother is enrolled. |
| Environ. Exposure | Data on exposure to occupational or other environmental entities or hazards. |
| Events | Data related to a specific event, occurrence or incidence. |
| Hearing | Data obtained from examination and testing of hearing function. |
| Hospitalizations | Data on specific hospital admissions or the number of hospitalizations. |
| Language | Data obtained from examination and testing of language function. |
| Linkage | Data on the genetic relationships of family members to the study mother, father or child. |
| Malformations | Data on the conditions in which failure of normal development has resulted in abnormal physical traits existing at the time of birth. |
| Diag. & Cond. | Data on specific diagnoses or conditions obtained from past medical history or examination during the study. |
| Med. History | Data obtained from the study participant or medical records relevant to past or current medical diagnoses or conditions. |
| Medications | Data on drugs or medications used. |
| Neurological Exam | Data obtained from observation and physical examination of the central nervous system. |
| Observations | Data obtained from observations not categorized elsewhere. |
| Pathology | Data obtained from clinical and anatomical pathological examination. |
| Physical Exam | Data obtained from physical examination of the study participant. |
| Procedure | Data relating to specific procedures performed on the study participant prior to or during the period of enrollment in the study. |
| Psych. Exam | Data obtained from the psychological examinations and observations. |

TABLE 4. Definition of Person, Time and Subject Categories. (Cont.)

| SUBJECT | DEFINITION |
|--------------------|---|
| Reproductive Hist. | Data pertaining to the outcome of pregnancies prior to and or during the period of enrollment in the study. |
| Serology | Data obtained from the laboratory examination of serum by specific immunologic methods. |
| Socioecon. Info | Data related to the social and economic characteristics and environment of the study participant. |
| Speech | Data obtained from examination and observation of speech function. |
| Vision | Data obtained from examination of the eyes. |
| Work History | Data pertaining to occupation and employment prior to and during the period of enrollment in the study. |
| X-Ray | Data on diagnostic x rays and diagnostic or therapeutic radiological procedures. |
| Summary | Data presented as a summary of data collected and recorded elsewhere. |
| Gyn. History | Medical history specifically related to the female genital tract, reproductive physiology and endocrinology. |
| Special Studies | Data pertaining to participation in other special organized studies conducted during the period of enrollment in the study. |
| Fam/Genetic Hist. | Data on the medical histories of family members genetically related to the study child. |
| SLH Exam | Data obtained from the speech, language and hearing examinations not specifically or exclusively related to one of these areas. |

PAGE II.A.xviii IS MISSING

CONTENTS

| | | |
|-----------|---|----------|
| AR-1/OB-1 | Obstetrical Administrative Records | II.A.1 |
| OB-2 | Reproductive History | II.A.21 |
| OB-3 | History Since Last Menstrual Period | II.A.37 |
| OB-4 | Gynecological History | II.A.55 |
| OB-5 | Recent Medical History | II.A.69 |
| OB-6 | Past Medical History | II.A.91 |
| OB-7 | Infectious Disease and System Review | II.A.113 |
| OB-8 | Repeat Prenatal History | II.A.131 |
| OB-9 | Prenatal Record | II.A.147 |
| OB-42 | Past Medical History | II.A.195 |
| OB-43 | Initial Prenatal Exam | II.A.209 |
| OB-10 | Return Visit and Laboratory Record | II.A.237 |
| OB-44 | Prenatal Observations | II.A.259 |
| OB-45 | Laboratory Record | II.A.275 |
| OB-11 | Record of Current Pregnancy | II.A.319 |
| OB-46 | Physician's Clinic Record | II.A.327 |
| OB-12 | Summary of Hospitalization for Any Antepartum Condition | II.A.333 |
| OB-47 | Summary of Antepartum Hospitalization | II.A.341 |
| OB-15 | Drugs in Pregnancy | II.A.347 |