Standard Operating Procedures and Policies

Of the Spinal Cord Injury Model Systems

October 1, 2016 – September 30, 2021

October 2018

The National Spinal Cord Injury Statistical Center

University of Alabama at Birmingham

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Abbreviations and Definitions

Acute Med	Refers to acute medical unit in the hospital side of SCIMS (not rehab care) (previously known as 'Medical/Surgical')
BMS	Burn Model System
Catchment Area	Geographic area defined by the System from which participants may be enrolled as Form I
Core Data	Core data is a term used to differentiate from module data. Variables on the Form I and Form II are core data. Variables are reviewed and updated at each new cycle with a modified review at mid-cycle.
Day 1s	Form I participants who come to System the day of or the day after the injury (for example, date of injury = 5/1/2011 and enters your System the day of or the next day (System Admits on 5/1/11 or 5/2/11 is considered Day 1)
Eligible Form II	Used in the Tracking Report to indicate a Form II is required. It includes only required years (1, 5, 10 …) and excludes participants with Status of deceased, recovered, minimal deficit, withdrawn consent, and ID Unknown.
End (closed) window	When data collection ends (12 months after specified anniversary [or for Year 1, 6 mo after]).
F1	Form I
F2	Form II
FIPS	Federal Information Processing Standards; Secretary of Commerce approved standards and guidelines that are developed by the National Institute of Standards and Technology (NIST) for Federal computer systems (Geocodes - State and county)
First Position	Data entry point for variables that allow more than 1 code (i.e., participants may choose up to 5 Computer Assistive Devices; the primary device is entered into the first of five positions).
Followed Form II	Form II with interview or exam data (not Lost)
INSCISCI exam	Neurologic exam worksheet from the International Standards for Neurological Classification of SCI. Previously referred to as the ASIA exam.
Minimal Deficit	Neurologic damage so minimal the patient has no significant or incapacitating loss of function. Reflexes may still be abnormal. Patient's Motor Score should be 95 or greater, and patient should be free of other significant neurologic complications due to SCI (e.g., bowel, bladder or neuropathic pain). Minimal deficits are coded as ASIA D and have a neurologic level of injury (not X00). If the patient is coded minimal deficit on Form I, no Form IIs are required. Once a patient is coded minimal deficit on a Form II, further follow-up is allowed but not required.
Missing – Tracking Report	A Form II is not entered for a required year for an eligible participant
Missing – Unknown Report	Variable is coded as unknown or left blank when the criteria to complete the variable are met. That is, the variable is 'collectable'.
NatDat	National SCI Dataset is created from each data submission including current variables. It is released to researchers upon application approval.
National SCI Database	National SCI Database is data collected from SCIMS using the current list of variables. Centers access their data through the NSCISC Data Management System.
Neuro Recovered	Participants coded as Minimal Deficit or Recovered at Form I or Form II (Category of Care=8). Future follow-up is allowed but not required.

Abbreviations and Definitions (continued)

NIDILRR	National Institute on Disability, Independent Living, and Rehabilitation Research provides funding for the Model Systems, part of the Administration for Community Living, HHS.
Non-Day 1s	Form I participants who come to System within 2 or more days of injury (for example, date of injury = 5/1/2011 and enters your System any time on or after 5/3/11 is considered a Non-Day 1) and is not required to submit the Neurologic data for Admit to Acute Med Unit.
NSCISC	National SCI Statistical Center (Data Center)
Off Years	Post-injury years when Follow-up is not required (2, 3, 4, 6, 7…). If a participant is still in the initial hospitalization at Year 1, then a Year 2 follow-up replaces the Year 1 but this is rare.
OSQA	On-Site Quality Assurance – In-house review of data completed every 6 months
PD and PI	Project Director and Principle Investigator
PHQ	Patient Health Questionnaire
Pt	Participant
QA	Quality Assurance
QC	Quality Control
Record	Each Form entered is considered one record. If a participant has 1 Personal Data Form, 1 Record Status, 1 Form I, and 3 Form IIs, that participant has a total of 6 records.
SCIMS	Spinal Cord Injury Model Systems
Start (open) window	When Form II data collection may begin (6 mo prior to anniversary date for required years).
SWLS	Satisfaction With Life Scale
System	Each SCIMS defines which facilities are included in their SCI Model System. Typically, at least 1 Acute Medical Hospital and 1 Rehabilitation Center are included.
System Discharge	Refers to final discharge from the System Rehab after completing initial rehabilitation
TBIMS	Traumatic Brain Injury Model Systems
Window	Span of time allowed for collection of follow-up data. Required F2s may be collected from 6 months prior to the anniversary date to 12 months after the anniversary date (for Year 1, data may be collected 6 months before to 6 months after).
Year Due	Post-injury Anniversary Years based on anniversary of the spinal cord injury

To add words or abbreviations to this list, contact Tori vtallen@uab.edu

Introduction

National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) funded SCI projects

The NIDILRR sponsors the following projects to improve education and treatment of people with spinal cord injuries. NIDILRR is sponsored by the Administration of Community Living of the Department of Health and Human Services.

The Spinal Cord Injury Model Systems (SCIMS)

The SCIMS is a program that supports innovative projects and research in the delivery, demonstration, and evaluation of medical, rehabilitation, vocational and other services to meet the needs of individuals with SCI.

Each SCI Model System contributes to the National SCI Database, participates in independent and collaborative research, and provides information and resources to individuals with SCI, their family and care givers, health care professionals and the general public. SCIMS recruit and enroll new participants who have completed rehabilitation in their respective System. These participants are interviewed at 1 year and every 5 years post-injury by Model System staff.

National SCI Statistical Center (Data Center)

The NSCISC supports and directs the collection, management and analysis of the world's largest spinal cord injury database. In addition to maintaining the national SCI database, the NSCISC personnel conduct ongoing, database-oriented research. Many of the findings resulting from these investigative efforts have had significant impact on the delivery and nature of medical rehabilitation services provided to SCI patients.

Since not all Model Systems receive funding each cycle, the NSCISC initiated a contracting program to fund former Model Systems' Form II follow-up data collection. Last cycle, 4 Centers were approved to collect follow-up (Form II) only data on previously enrolled participants. NSCISC also initiated a program to collect Form II follow-up data from two Centers that are no longer funded and are not situated to collect follow-up data; these Form II follow-ups are being collected by NSCISC personnel.

Model System Knowledge Translation and Dissemination (MSKTC)

The Model Systems Knowledge Translation Center (MSKTC) summarizes research, identifies health information needs, and develops information resources to support the Model Systems programs in meeting the needs of individuals with spinal cord injuries (SCI), traumatic brain injuries (TBI), and burn injuries.

Objectives of the SCIMS program

The purpose of the SCIMS Program is to study the course of recovery and outcomes of persons with traumatic spinal cord injury. The SCIMS Program is also designed to generate new knowledge to improve outcomes in the following three categories: health and function, community living and participation, and employment. The objectives of the SCIMS program are to:

1. improve the quality and utility of disability and rehabilitation research;
2. foster an exchange of expertise, information, and training to facilitate the advancement of knowledge and understanding of the unique needs of traditionally underserved populations;
3. determine the best strategies and programs to improve rehabilitation outcomes for underserved populations;
4. identify research gaps;
5. identify mechanisms of integrating research and practice; and
6. disseminate findings.

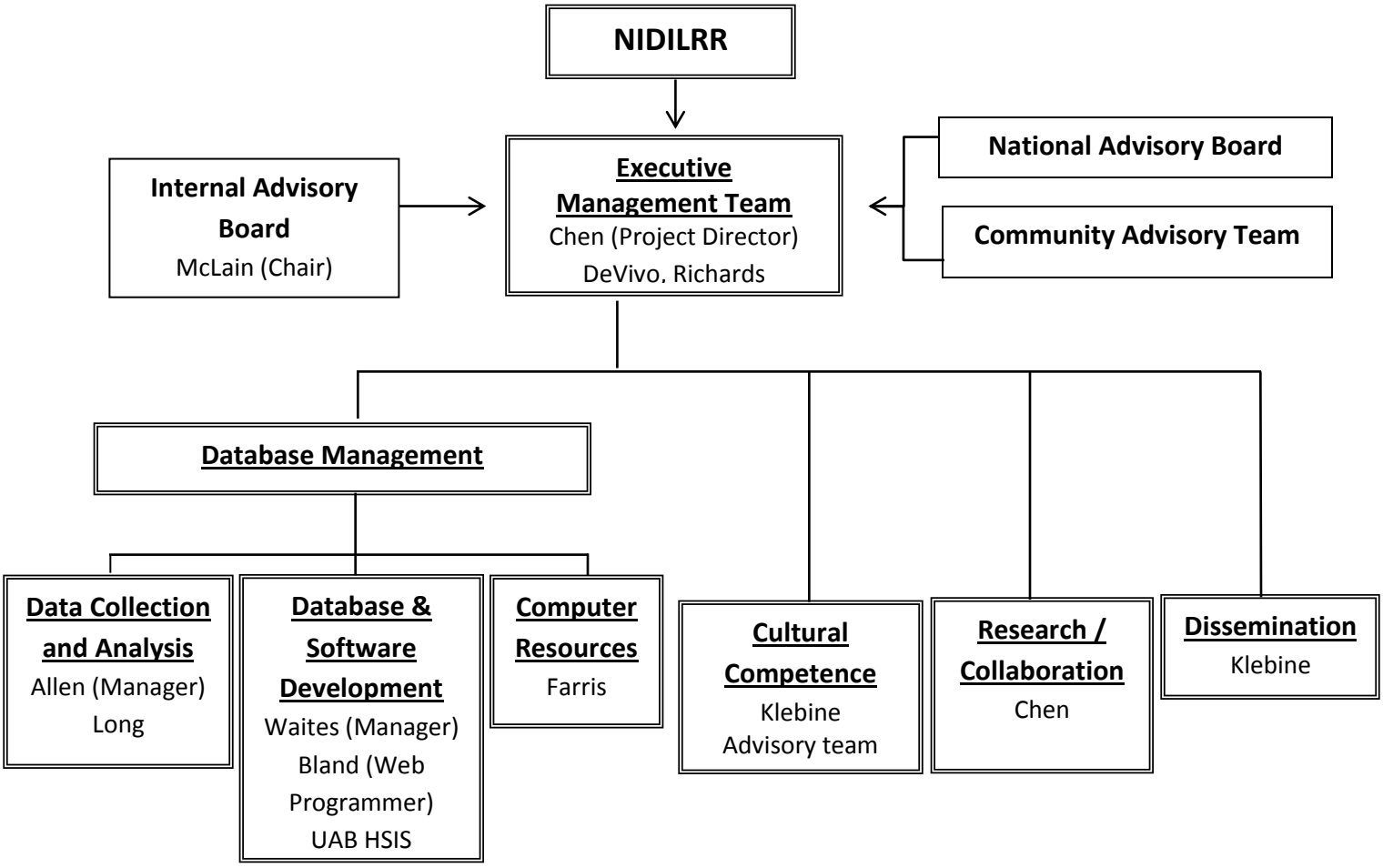
Objectives of the National SCI Database

Data from the National SCI Database is intended to:

1. identify demographics and the use of services by individual with SCI;
2. examine specific rehabilitation, health and life course outcomes of SCI;
3. establish expected rehabilitation treatment outcomes for SCI;
4. identify and evaluate trends over time associated with SCI; and
5. serve as a resource for conducting historical, prospective, and longitudinal SCI-related research.

The Database is not intended to study the effectiveness of model systems care as compared to other systems of health care delivery. It is also not by itself intended to gather and maintain population-based data on spinal cord injuries.

NSCISC Organization & Contact



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*Spain Rehabilitation Center

SCIMS Centers contact information: https://www.nscisc.uab.edu/sci-model-systems.aspx

SCIMS Contact Information by State

Birmingham, Alabama
UAB SCIMS at Spain Rehab Center Website: www.spinalcord.uab.edu
Public Contact: 205-934-3342

Los Angeles, California
Southern California SCIMS at Rancho LANRC Website: www.larei.org
Public Contact: 562-401-8111

Englewood, Colorado
Rocky Mountain Regional SCI System Website: www.craighospital.org
Public Contact: 303-789-8306

Miami, Florida
South Florida SCIMS Website: http://scimiami.med.miami.edu/
Public Contact: 305-243-243-4497

Atlanta, Georgia
Southeastern Regional SCIMS Program Website: www.shepherd.org
Public Contact: 404-352-2020

Chicago, Illinois
Midwest Regional SCI Care System (MRSCICS) Website: https://www.sralab.org/conditions/spinal-cord-injury
Public Contact: 312-238-2826

Boston, Massachusetts
Spaulding New England Regional SCI Center Website: http://www.sh-sci.org/
Public Contact Phone: 617-573-2754

West Orange, New Jersey
New Jersey SCI System (NJSCIS) Website: http://kesslerfoundation.org/researchcenter/spinalcordinjury/modelsystems.php
Public Contact: 973-324- 3576 (Dyson-Hudson); 973-243-6977

New York, New York
Icahn School of Medicine Website: http://icahn.mssm.edu/research/spinal-cord-injury/research
Public Contact: Thomas.Bryce@mountsinai.org ; Phone: 212-659-9369

Cleveland, Ohio
Northeast Ohio Regional Spinal Cord Injury System (NORSCIS) Website: http://www.metrohealth.org/rehab
Public Contact: 216-957-3500

SCIMS Contact Information by State (continued)

Columbus, Ohio
Ohio Regional SCI Model System Website:
Public Contact: 614-366-3877; Jennifer.Bogner@osumc.edu

Philadelphia, Pennsylvania
Regional SCI Center of the Delaware Valley Website: www.spinalcordcenter.org
Public Contact Phone: 215-955-6579

Pittsburgh, Pennsylvania
University of Pittsburgh Model System on SCI Website: www.upmc-sci.org
Public Contact Phone: 412-232-7949

Houston, Texas
The Texas Institute for Rehabilitation and Research
Website:http://www.memorialhermann.org/locations/TIRR/research.aspx
Public Contact Phone: 713-797-5972

Follow-up Centers (previously funded - collecting Follow-ups only)

San Jose, California
Santa Clara Valley Medical Center Website: www.tbi-sci.org
Public Contact Phone: 408-885-4177

Ann Arbor, Michigan
University of Michigan SCIMS (UM-SCIMS) Website: www.med.umich.edu/pmr/modelsci
Public Contact Phone: 734-763-0971

Seattle, Washington
Northwest Regional SCI System Website: http://sci.washington.edu
Public Contact Phone: 800-366-5643

Rusk Rehabilitation Center, Columbia Missouri, collected by UAB
Public Contact Phone: 205-934-3283

Woodrow Wilson Rehabilitation Center, Fishersville Virginia, collected by UAB
Public Contact Phone: 205-934-3283

Model System Structure

Facilities

Each Model System is designed to provide a continuum of care from acute hospitalization to rehabilitation discharge and to continue to offer care throughout the post-injury years. The Model Systems differ in their organization, but maintain a continuum of care for patients.

Personnel

In order to obtain accurate and complete data, a system must establish effective data collection mechanisms. The personnel required and the mechanisms for retrieving data will depend on the system's resources.

Minimally, a system must have a Project Director and a Primary Data Collector. Together they should assess what data are routinely being collected and documented at their system and develop mechanisms to collect and document the data for all required variables.

The **Project Director and/or Project Co-Director** conducts or assists in SCI research, assigns data collection activities to staff members and must be familiar with the data dictionary, Policies and SOPs. This person provides support for the Primary Data Coordinator/Collector and is a source of information regarding policies and variable questions.

The **Primary Data Coordinator/Collector** assumes the responsibility of assuring that data collection is completed as described in this document and the data dictionary, in addition, this person provides reporting data to the NSCISC as requested. The Data Coordinator may also be assigned site manager responsibilities of controlling database logins (access to site data, training, and center specific reports). This person needs experience in Excel and intermediate computer skills. They may need to establish and maintain channels of communication with other departmental staff to keep or enhance the proper flow of data. For example, the Primary Data Coordinator may need to identify ways to capture or recover data from residents or nurse practitioners who have access to required data, such as ASIA, neurological data, or bladder management at acute hospitalization or discharge. Often the Primary Data Coordinator assures the use of up-to-date forms, training of data collection staff, and assures that appropriate policy is followed by all data collectors. This person is designated to receive all NSCISC mail-outs to data collectors.

A **Liaison Nurse** is helpful for obtaining the initial informed consent from a potential participant as well as capturing Form I Medical care data and may conduct Form I interviews.

An **Interviewer** may also be needed since data for the majority of the follow-up variables may be obtained by phone. An interviewer who speaks languages other than English is very useful for systems that have high percentages of non-English speaking participants. This person needs basic interviewing skills.

A **Data Entry Clerk** may be needed if the data collector does not have sufficient time to collect and enter data. Often this clerical level person may do other tasks such as record filing, contacting patients to schedule visits, confirming appointments, etc. This person needs intermediate computer skills and knowledge of data entry procedures.

An **Analyst** may be needed if a system wishes to utilize statistical software (such as SAS or SPSS) to analyze Center's data and/or the national database.

National SCIMS Database

Design

The basic structure of the SCIMS Database has remained the same since 1987: Form I, Form II, and Registry datasets. As of May, 2017, the SCIMS Database contains data on 32,428 Form I participants, 13,763 Registry participants, and 118,189 Form II records among 27,027 participants. The longest follow-up is 40 years post-injury.

Form I & Registry: Initial hospitalization data

Participants are eligible for one of two categories of data, Registry or Form I. Form I includes demographic data and information on acute medical care, inpatient rehabilitation experiences and treatment outcomes on all participants who meet the inclusion criteria. The Registry data set was created in 1987 for participants who are not fully qualified for Form I and on whom no follow-up data are collected. The Registry includes only very limited demographic and clinical data, which serves to provide a complete picture of patients who receive initial hospital care at each SCIMS.

Form II: Follow-up data file

Originally, Form II follow-up was completed on a yearly basis for all Form I participants. Participants were followed until one of the following occurred: death, neurologic recovery, or withdrawal of consent. From 1996 through September 2000, Form II was collected in post-injury years 1, 2, 5, 10 and every 5 years thereafter except for a sample of 125 participants from each SCIMS who continued to have a reduced set of Form II data collected every year. To further reduce the workload, beginning in October 2000, Form II data collection was collected only in post-injury years 1, 2, 5, 10 and every 5 years thereafter, and the sampling process of 125 participants per SCIMS was terminated.

Research Module

Effective in the 2006-2011 funding cycle, in addition to contributing data to the SCIMS database, the SCIMS centers were required to lead or participate in one or more research module projects. In contrast to the longitudinal and exploratory nature of the SCIMS Database, research modules are typically time-limited and hypothesis-driven, and each involves only a few SCIMS centers. Seven module projects were funded in the 2006-2011 cycle to develop the next generation of measurement instruments of quality of life, participation, trunk muscle strength, and motor recovery and to examine the natural history of depression after SCI, vocational outcomes, and utilization of assistive technology for mobility. Ten module projects are currently underway during this 2016-2021 grant cycle. Details about these modules can be found in the Model Systems Knowledge Translation Center website (http://www.msktc.org/sci).

Collection of Form II data from discontinued model system

One of the most critical threats to the validity of the data in the SCIMS Database is bias caused by loss to follow-up. However, the problem of loss to follow-up has been compounded by SCIMS centers' exclusion in the program over time, as successive grant applications were not funded. In recognition of this problem, beginning in the 2006-2011 funding cycle, NIDILRR required NSCISC to develop and implement a plan to obtain as much lost data as possible from up to 4 SCIMS centers that are no longer funded.

Since funds were not available in the NSCISC budget to contract with every possible former model system, a review was undertaken to determine which model systems should be offered contracts to collect and submit the Form II data to the Database. Factors considered during this review include past performance and data quality, available sample size, ability to perform the required tasks (some model systems cannot identify their former participants), history of database usage for published research, and cost. Plans and contract terms were developed in full consultation with NIDILRR.

NSCISC has established two successful mechanisms to collect data from unfunded centers: 1) Subcontracts with previously funded SCIMS centers to continue data collection on their patients and 2) centralized data collection conducted by NSCISC to reach participants enrolled by former SCIMS centers.

Variables included in the Database

Variable changes in both Form I and Form II have occurred every two or three years. Variables with poor reliability or diminished utility are retired, and new items of importance and interest are added. Lists of all changes have been documented in the NSCISC statistical reports. Additionally, each variable page of the data dictionary briefly documents the historical changes a variable has gone through over the years. Whenever changes are made to a variable in the Database, the previously existing formats and coding schemes are converted to coincide with the new format and coding scheme for a particular variable. All previous versions of the Database are stored at the NSCISC.

Data Collection Forms

Variables in the National Spinal Cord Injury Database are divided into 5 data files:

1) **Personal Data – Establishes Patient ID for all participants.**
2) **Record Status – Describes status of Registry and Form I participants.**
3) **Registry – limited data for participants who are eligible for Registry but not Form I.**
4) **Form I – for all participants who are eligible for Form I.**
5) **Form II – for all Form I participants. Data collection is done in follow-up years 1, 5, 10, and every 5 years thereafter.**

Each participant has 1 Personal Data Form, 1 Record Status, either a Registry or a Form 1, and if eligible, may have multiple Form IIs.

A Personal Data form is completed for every participant entered to the SCIMS national database. Model Systems may elect to store their participants' personal data (name, date of birth …), contact information and alternate contact information on the NSCISC's encrypted, firewall protected SQL Server or to keep that data in a separate secure on-site database. Storing participants' personal data in the NSCISC database allows data collectors to list, by name, participants who are due for Form II follow-up interviews and to fully utilize the data management features through the NSCISC web. Please note that in order to assign a patient ID to a new participant who is eligible for Registry or Form I, a Personal Data form must be submitted; however, entry of the participant's personal identifiers is not required.

Record Status provides basic information concerning the status of Registry and Form I participants. This form is created by NSCISC programming when the initial Personal Data Form is saved. Record Status includes the vital status variables, death variables and NSCISC generated follow-up status variables.

Registry variables are collected for participants who are eligible for Form I inclusion except for residing in geographic catchment area (See eligibility criteria). The Registry variables include a limited number of Form I variables. Form II follow-up interviews are not collected for Registry participants.

Form I variables provide data on the participant's status at the time of SCI and document events occurring during the initial hospitalization and inpatient rehabilitation. Beginning in November 1995, a distinction was made between participants who were admitted to the Model System within one day of injury (Day-1) and those admitted more than one day post-injury (Non-Day-1). **Non Day-1** variables are collected on all Form I participants. The **Day-1** (Neuro exam at Admit to Acute Medical) variables are additional variables that are collected only on those who enter the system within 1 day of injury (admitted to System the day of or the day after injury).

Form II follow-up data are required on all participants who are eligible for follow-up at post-injury anniversary year 1, year 5 and every 5th anniversary year (i.e., years 1, 5, 10, 15, 20, etc.). For participants who are still in the initial hospitalization/rehabilitation process on their first anniversary of injury, a year 2 replaces the year 1 Form II. Form IIs are allowed but not required to be submitted for other years. Form II data submission is required of all participants who have a Form I [except for participants who die, neuro recovered, ID Unknown or withdraw consent]. Any participant having Form II data must have a Form I record.

Data Dictionary

The data dictionary (formerly known as Syllabus) was developed by the NSCISC to provide information detailing the collection and coding of all variables included in the current National Spinal Cord Injury Database (Database) as a means to standardize data collection methods amongst all SCIMS Centers. The Data Dictionary is updated, as needed, with recommendations and input from the SCIMS project directors and data collectors.

Over the last four decades, the Database has gone through a number of major revisions. Failure to recognize these evolutionary changes in the planning and conducting of research projects that analyze the Database could essentially skew the results and produce misinterpretation of findings. Therefore, the Data Dictionary also serves as an initial guide for researchers to ensure proper use and interpretation of the Database.

All variables are listed in the Data Dictionary. They are ordered the way they appear on their respective data collection forms. Each variable has a page that contains the following sections when applicable:

Variable Name	The name assigned to that variable in the database.
Description	Descriptive information on that variable including the data collection time(s)
Character	The number of characters for each coding position in the variable
Codes	A list of all valid codes for that variable As much as possible, the following "Universal codes" have been assigned: 0 or all 0's = "No" 7 or all 7s = 'Participant Declined' 8 or all 8's = "Not Applicable" "Not Tested" or "Yes, Number Unknown" 9 or all 9's = "Unknown"
Format	Numeric, Text, or Date (mm/dd/yyyy)
Comments	Other information regarding the variable
Source	Sources of information pertaining to a variable.
QC	Comments on the quality control checks performed on that variable
Software	Instructions/clarification regarding how the software processes the variable.
Revisions	Dates and historical information on changes in the variable
Conversion	Information on how data in the variable were converted whenever there were coding and/or reporting criteria revisions.
Example(s)	Hypothetical situations and the appropriate code(s)
Variable Aliases	Information for data management. Includes the following sections:
Variable ID:	Links the variable on the form to the dataset for data management purposes.
8-Character Name:	Name provided in the National Database for analysis/research purposes. 8-character names for Personal Data variables begin with 'P', Record Status with 'S', Registry with 'R', Form I with 'A', and Form II with 'B', .

The Data Dictionary includes 4 Appendices: A) Forms, B) Occupational Classification, C) Enrollment, Recruitment & Follow-up Information, D) External Cause of Injury ICD 10-CM.

Dynamic Data Dictionary

The Dynamic Data Dictionary is linked to the NSCISC website data entry screens. A pop-up box shows each variable's Description and Codes when tabbing through the variables on the data entry pages.

Data Management Variables

Data management variables (QC Status, Indate, and Update) are included in all National Datasets. Data management variables are generated by the NSCISC's software and cannot be modified by the user. Additional data management variables (Current Follow-up Status, Registry/Form I, Number of Form IIs Not Lost, Anniversary Year of Last Form II Followed, Last Form II Category of Care, and Last Form II Reason for Lost) are present in the Record Status file.

Common Data Element

To further expand the usefulness of the National SCI Database, a list of common data element names is provided to researchers upon request.

Database History

The SCIMS program began with one center in Phoenix, AZ in 1970. Over the years, it has grown to a national program with a total of 31 centers having been funded since its inception, 29 of which have contributed data to the SCIMS Database (Table 1). The funding for the SCIMS program was originally from the Rehabilitation Services Administration and is now from the National Institute on Disability and Rehabilitation Research (NIDILRR) in the Administration for Community Living (ACL), Department of Health and Human Services (HHS). During the current 2016-2021 cycle, 14 sites are funded and designated by NIDILRR as the SCIMS centers; another 5 previously funded centers are sponsored by NSCISC as Form II Centers to collect follow-up data on their previously enrolled participants.

Table 1: Spinal Cord Injury Model Systems Centers 1970-2021

Center	Years Funded
Alabama, Birmingham	1972-2021
Arizona, Phoenix	1970-1985; 2006-2011*
California, Downey	1980-2006; 2006-2011*; 2011-2021
California, Northridge†	1982
California, San Jose	1972-1985; 1990-2006; 2006-2021*
Colorado, Denver	1974-2021
District of Columbia, Washington	2006-2011
Florida, Miami	1979-1985; 2000-2006; 2011-2021
Georgia, Atlanta	1982-2021
Illinois, Chicago	1972-2000; 2006-2021
Kentucky, Louisville	2011-2016
Louisiana, New Orleans	1982-1985
Massachusetts, Boston BUMC	1975-1990; 1995-2016††
Massachusetts, Spaulding-Connecticut	2011-2021††
Michigan, Ann Arbor	1985-2016; 2016-2021*
Michigan, Detroit	1983-2000
Minnesota, Minneapolis†	1982
Missouri, Columbia	1979-1981;1995-2006; 2006-2021*
New Jersey, West Orange	1990-2021
New York, Mt Sinai	1990-2011; 2011-2016*; 2016-2021
New York, New York University	1972-1990; 2006-2011*
New York, Rochester	1982-1990
Ohio, Cleveland	1995-2000; 2006-2011; 2016-2021
Ohio, Columbus	2016-2021
Pennsylvania, Philadelphia	1979-2021
Pennsylvania, Pittsburgh	2000-2021
Texas, Houston	1972-2011; 2011-2016*; 2016-2021
Virginia, Fishersville	1972-1990; 2006-2021*
Virginia, Richmond	1995-2006; 2006-2011*
Washington, Seattle	1974-1985; 1990-2016; 2016-2021*
Wisconsin, Milwaukee	1995-2000

*Form II Center that collects follow-up data only.
†Their data are not in the current National SCI Database.
††Boston BUMC merged with Spaulding (2016 – 2021 cycle).

Collaborative data collection among SCIMS centers began in 1975. Data were obtained retrospectively back to 1973 and prospectively since 1975. The first SCIMS data center was established in 1975 in Phoenix, Arizona. In 1981, the federal funding for data center was terminated, which temporarily suspended all collaborative data collection efforts among the SCIMS centers. By 1983, the University of Alabama at Birmingham (UAB) proposed to recreate the database and provide all necessary services to the model systems for a small monthly fee. The monthly fee was to be paid by each individual SCIMS center from the grant funds they received. At that time, 16 of the 17 SCIMS centers agreed to contract with UAB for this service. In October of 1984, NIDILRR re-established separate funding for the data Center. Funding was awarded to UAB, and the National Data and Statistical Center for SCIMS became known as the National Spinal Cord Injury Statistical Center (NSCISC). A detailed description and updates of the Database history can be found in the issues of the Archives of Physical Medicine and Rehabilitation in November 1999, November 2004, March 2011 and October 2016.

Historical eligibility criteria

With some exceptions, data have been collected on all persons receiving initial inpatient rehabilitation at a SCIMS within one year of injury. The following eligibility criteria have remained unchanged throughout the course of the Database: patients must have had a clinically discernible degree of neurologic deficit, must reside in the geographic catchment area of the SCIMS, must be a U.S. citizen or permanent resident, and must have sustained a SCI due to a traumatic event. The remaining eligibility criteria for inclusion in the Database, nevertheless, have changed somewhat over the years in an attempt to obtain as much information as possible and yet restrict entry into the Database so that meaningful data could be obtained both at the initial injury and later follow-up (Table 2).

Table 2. History of major changes in the eligibility criteria for Form I.

1976	1. Admission to a model system within one year of injury. 2. Injured and residing in the catchment area of the model system. 3. Continual hospitalization from injury to model system admission, except for brief periods no longer than normally accepted as a therapeutic leave of absence; not completed rehabilitation prior to system admission. 4. Discharge from the model system as either neurologically normal, having completed rehabilitation, or deceased.
1987	Above criteria, except patients are eligible for either Form I or Registry: Form I: Admission to a model system within 60 days of injury. Registry: Patients admitted to a model system between 61 and 365 days of injury; or within 60 days but for whom no follow-up is planned.
October 2000	Increase enrollment and incorporate treatment phases, several changes were made: 1. Admission to a model system within one year of injury. 2. Reside in catchment area, but may be injured outside of catchment. Registry: Form I criteria applies except for residing inside catchment area. 3. Must receive acute care, rehabilitation, or both in the system.
January 2005	Above criteria, except: 1. Must receive rehabilitation in system unless patient is discharged as expired, minimal deficit or recovered.

Evolution of the NSCISC Data Management System

Until 1990, data obtained at the SCIMS centers were submitted on hard copy data forms and entered by NSCISC staff into the database. For 16 years prior to the 2006-2011 funding cycle, the NSCISC developed and provided a software package (Dbase/Clipper DOS-based system and then a Visual Basic/Microsoft Access Window-based system) that was installed and maintained on one or more computers at each SCIMS center. Data collectors entered, maintained, and stored the required data, using the NSCISC software package via their personal computers. The information was both identifiable and non-identifiable; identifiable information is necessary to facilitate local data management and to schedule patients for follow-up visits. Several hundreds of functions were built into the software package for quality control, data management and submission processes. On a semi-annual basis, each data collector copied his/her entire database (without personal identifiers) into an encrypted format and sent it to the NSCISC on floppy disks, cassette tape, CD, or via modem transmission and, more recently, via a File Transfer Program. NSCISC staff decrypted the data and merged it into a limited dataset for reporting and research purposes.

During the 2006-2011 cycle, NSCISC took advantage of the latest internet and centralized database technology and successfully rebuilt the distributed desktop software application into a web-based data management system. Numerous features have been built into the NSCISC Web System to increase the security and scientific integrity of the data as well as to decrease the effort and time required of SCIMS data collectors and NSCISC staff for data management and software maintenance.

For the 2011-2016 cycle, the database was converted to a normalized data table structure to better ensure data integrity of the SCIMS Database and alleviate potential performance issues in the near future. The Web-Based system has undergone an elaborate process of enhancements and modifications to reflect the underlying database changes and overall enhanced functionality.

Web-Based Data Management System

The web-based Data Management System is a compilation of services and security required to support the SCIMS. The NSCISC website is separated by a login. Prior to login, consumers have access to public reports (de-stratified Mid-Year and Annual Reports, and Facts & Figures), data collection documents, Model System links, NSCISC History and contact information. After login, access is allowed to data entry pages, quality control, stratified reports, and resources for data collectors and researchers.

The NSCISC developed and maintains extensive data entry quality control checks (QC) for all Forms including: range checks, valid code checks, checks that compare codes within the Form and across other forms. For more details about the data entry and QC process, see the Data Management Software System manual.

Security

Multiple layers of security are in place to ensure data security and confidentiality, including user authorization, data storage security, and data access security. Utilizing all of these security measures will help restrict direct access to the SQL Server Database to only identified users.

User authorization The centralized database is password-protected. Each SCIMS center only has access to its own data and not to the data submitted by other SCIMS centers. Since it is a web-based system and accessible from anywhere with internet access, it is the responsibility of the SCIMS centers to control and maintain user logins.

Data storage security All values are stored encrypted in the database.

Data access security The SQL Server Database is housed behind a series of secure access layers and firewalls within the control of UAB Health System Information Services (UAB HSIS). UAB HSIS is a disinterested third-party administrator and is an entity not affiliated with either the NSCISC or the Department of Physical Medicine and Rehabilitation. Once an SCIMS data collector is set up in the system, he/she will be able to use any local personal computer with a web browser to access the NSCISC software on the UAB web server.

Minimum PC Requirements

The NSCISC requests all users of the Data Management System have a minimum or preferred PC requirements: Since the NSCISC Data Management System is a Web Based Application, and all that is really needed is a personal computer running an up to date versions of Windows, Internet Explorer or other modern browser, Microsoft Office Suite, and a high speed internet access. However, there are some minimum processing requirements for the personal computer accessing the program, in order to utilize the NSCISC Data Management Web System 2016 to the full extent.

A high speed Internet access is a “must” for all the Model System computers. As a rule, we do recommend using and officially support Microsoft Browser (IE or Edge), but it is not prohibited to use Chrome or Mozilla Firefox. Some documents contained in the Web Site are in the Adobe PDF format and will require Adobe Acrobat Reader. The NSCISC’s Web System provides a multitude of reports and tools as well as custom dataset building functionality that primarily exports resulting data to a Microsoft Excel format.

The published twice a year National Database that is exported from the SQL Server NSCISC Database is in the Microsoft Access format for flexibility and portability purposes. In order to utilize these features Microsoft Access and Microsoft Excel should be installed and updated, both of which are included in the Microsoft Office Suite. Due to the growing size of the National Database, it is recommended that personal computers used to analyze the National Database should meet the "Preferred" requirements.

Required Item	Minimum	Preferred
Operating System	Microsoft Windows 7	Microsoft Windows 10 / Latest version of Windows
Processor	Intel DualCore or equivalent (AMD)	5th Generation IntelCore i7
RAM	4 GB	8 GB +
Hard Drive	100 GB + with a minimum of 50 GB of free disk space	500 GB + with a minimum of 100 GB of free space
Resolution	1024 x 768	1680 x 1050
Internet Access	High Speed	High Speed
Internet Explorer	IE 11	Microsoft Edge
Microsoft Office	2010	2013 or 365
Adobe Acrobat Reader	Current Version	Current Version

Minimum- The NSCISC's Web System will run, but possibly inefficiently

Preferred - The NSCISC's Web System will run efficiently and users will be able to process data and run the reports and downloads quickly.

Reports: NSCISC & Center

There are two categories of reports: those generated by NSCISC after each data submission and those initiated by each Center when needed, containing data collected by the Center.

NSCISC Reports are accessed at the NSCISC website, after login, using the Reports and Stats tab at the top of the page. Typically, the NSCISC reports include all Centers' data using the most recent national dataset and are for Model System dissemination only (requires log- in). For the NSCISC reports that use the SCIMS National Dataset (NatDat) as the base data set, only records with passed QC are included. *When a Form fails QC, all chronologically subsequent Forms are also excluded from the NatDat (see table).

Center Reports are initiated by the System User at each center using options found on Management Tools. These reports compile the Center's data using 'up-to-the-minute' data. The 'Projected Follow-up Tracking Report' and the 'Data Used for the Projected Follow-up Tracking Report' only includes records with Passed QC Status, but other Center Reports include records regardless of QC Status. For more information on how to create these reports, see the Users' Manual.

NSCISC Reports	**Data set**	**QC Status**
Enrollment & Consent Pending Final Destination	Compiled by NSCISC	N/A
Missing Data Report	Up-to-the-minute after data submission	Any QC Status
Follow-up Tracking Report	Up-to-the-minute after data submission	Passed QC*
Follow-up Tracking Trend & Summary	Up-to-the-minute after data submission	Passed QC*
NSCISC Mid-Year & Annual Report	NatDat	Passed QC*
Benchmark Report	Compiled from NSCISC Reports	N/A
Center Reports (Management Tools - left-side tab)		
Projected Follow-up Tracking Report	Up-to-the-minute	Passed QC
Data Used for the Projected Follow-up Tracking	Up-to-the-minute	Passed QC
Total Forms Entered & Dynamic Forms Entered	Up-to-the-minute	Any QC Status
Form 2s Due	Up-to-the-minute	Any QC Status
Dynamic Missing Report	Up-to-the-minute	Any QC Status
IRB Report (Sex, Age, Race/Ethnicity)	Up-to-the-minute	Any QC Status

NSCISC Reports

Enrollment

Enrollment rates and reasons for non-enrollment of potential participants are shown in the Enrollment Eligibility Report. Data from each fully funded Model System is collected on a set schedule (regardless of data submission date), October 1 to March 31 (6 months) and October 1 to September 30 (12 months). Centers submit counts of all Form I eligible participants; those not enrolled are categorized by the reason for non-enrollment. Centers also report the race/ethnicity, age group, and gender of non-enrolled patients. NIDILRR's benchmark for Form I eligible patients enrolled is 80%.

Enrollment Report Adjusted for Consent Pending Capture

Patients are usually enrolled during in-patient acute rehabilitation. Occasionally, patients are unable to enroll at that time and are categorized as 'Consent Pending' in the Enrollment Report indicating the enrollment process remains active. To show the efforts of enrollment after discharge from rehabilitation, an adjusted Enrollment Report is published on an annual basis to credit centers for their efforts.

Missing Data Report by Variable

Missing Data Reports are based on records from the National Database that have been entered since the beginning of the cycle. The report provides a tool to monitor each variable's missing or unknown rate. The benchmark is <10% of records coded missing/unknown for each variable. The report is disseminated after each data submission and is cumulative within the current cycle; including records entered for the current 5-year cycle, October 1, 2016 – September 31, 2021.

Follow-up Tracking Report Trend & Summary

This summarizes data collection follow-up rates by Center and the national averages. The research standard benchmark for follow-up rates for Year 1 is 90% of eligible participants and for all other years it is 80%. 'E**ligible**' refers to participants who were NOT previously coded Deceased, Neuro Recovered, Withdrawn, Identity Unknown or Incarcerated (these participants are not considered 'eligible' since there is no way to recover interviews). For example, if you have 100 participants Followed, 20 Lost, and 2 Missing, your Follow-up rate is calculated as (100/122) = 82%.

Follow-up Tracking Report

The Tracking Report contains a count of all Form I participants with Anniversary Dates between dates specified in the Proposed Data Submission table AND with required Anniversary years (1, 5, 10…). All of these record's windows have closed for formal data collection by the time of data submission and have passed QC. This report does not include all Form IIs that were submitted at the data submission; Form IIs are included only if their data collection window closed within the specified timeframe. A Year 2 that replaces a Year 1 (when pt was still in acute rehab at the time of the First Anniversary) is not included in the Follow-up Tracking Report.

The following Patient Status categories are prioritized in the order they appear (if a Form II was collected and then the participant dies before their window closes, that participant will count as Followed).

Followed: a required Form II was submitted, and the Category of Follow-up Care was NOT coded "Lost to System" (code 5). The Followed also includes those required Form IIs coded 8 "Not Applicable" (neurologic status as Minimal Deficit or Normal) submitted this time.

Dead: those individuals who died before the closing of data collection window.

Neuro Recovered: those individuals who were alive before the window closing and whose neurologic status was previously coded as "Minimal Deficit" or "Normal" at discharge from the initial hospital care or at last Form II entered (Category of Follow-up Care coded 8).

Withdrawn: those individuals who withdrew consent and do not wish to be contacted anymore (Reason for Lost coded 6 on the required Form II). If no Form II was submitted this time, the Withdrawn status was based on the last Form II entered.

ID Unknown: Model Systems with a break in funding may have destroyed participant identifying data. In those cases exclusively, Identity Unknown (Reason for Lost coded 7) is allowed. If no Form II was submitted this time, the Identity Unknown status was based on the last Form II entered.

ID Unknown at Data Center: Former Model Systems made arrangements for the Data Center to collect Form II interviews from their participants. In some cases, participant's identity is not known at the Data Center, but may still be available at the former Model System.

Incarcerated: individuals who were incarcerated and no follow-up data submitted during the follow-up window. Future follow-up is required at next required year due. (Reason for Lost = 2 on the required Form II). (Category added March 2014).

Lost: a required Form II was submitted with the Category of Follow-up Care coded "Lost to System" and with the Reason for Lost NOT coded 2 (Incarcerated) or 6 (Withdrawn) or 7 (ID Unknown) or 97 (ID Unknown at Data Center).

Missing: a required Form II was not submitted this time, and the Follow-up Status is not Deceased, Neuro Recovered, Withdrawn, ID Unknown or Incarcerated.

Eligible Follow-up Rate: Eligible participants have a status of Followed, Lost and Missing. The calculation is Followed / (Followed + Lost + Missing)

NOTE. For those individuals who were still hospitalized for the initial system care during their first anniversary year (Date of Discharge > Date of Injury + 365 days), a year 2 Form II may be substituted for the year 1 Form II. If the Year 1 Form II is not entered, the Missing Year 1 Form II is not counted in this report.

NOTE: If the Date of Death Modifier equals 9 (Unknown Date of Death), then Vital Status cannot be confirmed as Deceased during the reporting period, therefore, a Form II is required.

Benchmark Report

The Benchmark Report is a center-specific summary of the enrollment rate, follow-up rate, and missing/unknown rate. It is sent to NIDILRR, center PI and Project Director after each data submission. The Project Director works with their NIDILRR Project Officer to develop a Benchmark Management Plan when two consecutive benchmarks are missed. The Benchmark Management Plan includes the reason(s) for missing the benchmark(s), strategies and a timeline to meet the benchmarks, if appropriate. The final report is sent to the Data Center by the next data submission. The plan will be included in the next Benchmark Report. A sample of the Benchmark Management Plan is available from NSCISC.

NSCISC Mid-Year & Annual Report

The Mid-Year Report is disseminated in the summer and contains NSCISC activities for the current cycle, the status of the National Database and when warranted, new variable tables. The Annual Report is disseminated in winter and contains all the above, plus most variables' frequencies and percentages (or means), variable descriptions and a condensed history of that variable.

Center Reports

Projected Follow-up Tracking Report

This report is a tool to track Center's follow-up rates on the next NSCISC generated Follow-up Tracking Report (hence **Projected**). After each data submission, the Projected Follow-up Tracking Report is reset with the next set of Anniversary dates for the next data submission. See NSCISC Reports: Follow-up Tracking Report for category definitions. This report only includes records that have passed QC.

Data Used for Projected Follow-up Tracking

This report gives a list of each participant listed on the Projected Follow-up Tracking Report and their status. See NSCISC Reports: Follow-up Tracking Report for category definitions.

Total Forms Entered & Dynamic Forms Entered

Total Forms Entered gives a count of your Center's records entered as Personal Data, Registry, Form 1 and Form 2 (and any module your System may participate in) at 3 time points: since last data submission, since the beginning of the cycle and since the beginning of your Center's data collection. This table reflects current (up-to-the-minute) data regardless of QC Status.

The Dynamic Center Stats shows a count of your Center's records entered within the date range specified by the user. This table reflects current (up-to-the-minute) data regardless of QC Status.

Form 2s Due

This report generates a list of records (with selected variables) of eligible and required (years 1, 5, 10 …) Form IIs with anniversary dates between the start and end anniversary dates which are determined by the user. The list contains participants who are Followed, Lost, and Missing. See the Tracking Report for a description of status categories.

Form 2s Due may be initiated with or without Personal Data depending on whether or not the Center submits personal data. This report also includes variables useful for the next interview because some variables have 'across Form QC checks'. For example, if Marital Status is coded divorced in a previous year (Year 1, or Form I) and at the next Form II the participant is coded Single (never married), then after saving and running QC, that record would have a QC message. It is helpful to have the previously coded Marital Status, Education Level, Vet Status and Bladder Management prior to the interview to avoid such error messages. Other variables in this report indicate injury severity. The 'Contact Log' button creates a document with the variables listed above to facilitate interviewing, to record contact attempts, and document interactions.

Dynamic Missing Data Report

The Missing Data Report shows the number and percentage of each variable's missing data this cycle. A dynamic function allows users to select variable(s) for a list of records with the reported missing data. This table reflects current (up-to-the-minute) data regardless of QC Status.

IRB Report

The report allows you to choose your start and end dates to get a count, minimum and maximum age, by Race and Hispanic/Latino Origin. This table reflects current (up-to-the-minute) data regardless of QC Status. This report may be used to report progress to IRB and APR. This table reflects current (up-to-the-minute) data regardless of QC Status.

Accessing Center Data

Data Downloader

The Data Downloader link is found on the left-hand sidebar. It provides a mechanism to download raw center data by Form: Personal Data, Record Status, Registry, Form I and Form II. Records are included regardless of QC Status. For details, see the Users' Manual.

Custom Query Builder

Users may build, edit and run queries to create a custom dataset using site data from Record Status, Registry, Form I and Form II. These queries may be saved or shared with other site Users. For details, see the Users' Manual.

Data Collection

Standard Operating Procedures

for the 2016-2021 Cycle

Definition of Spinal Cord Injury

For the purposes of the Model Systems' program, a case of spinal cord injury is defined as the occurrence of an acute traumatic lesion of neural elements in the spinal canal (spinal cord and cauda equina), resulting in temporary or permanent sensory and/or motor deficit. The clinical definition of spinal cord injury excludes intervertebral disc disease, vertebral injuries in the absence of spinal cord injury, nerve root avulsions and injuries to nerve roots and peripheral nerves outside the spinal canal, cancer, spinal cord vascular disease, and other non-traumatic spinal cord diseases.

Essentially, traumatic cases would involve an external event to trigger the injury rather than disease or degeneration. The presence of concomitant nerve root avulsions, injuries to nerve roots, and vascular infarcts does not preclude the presence of spinal cord injury.

COMMENT: This definition is a slightly modified version of the CDC's case definition. The CDC includes "temporary or permanent sensory or motor deficit, bladder dysfunction, or bowel dysfunction" and also excludes birth trauma. However, for the model systems, an ASIA E (normal sensory and motor function) on admission would not be eligible even if bowel or bladder dysfunction existed.

Eligibility

The following criterion applies to participants who are admitted to the model system on or after January 1, 2005.

Inclusion Criteria for Form I and Registry:

1. Presence of an external traumatic event that results in a spinal cord injury, including surgical procedures, radiation, and medical complications.
2. Temporary or permanent loss of sensory and/or motor function as a result of the traumatic event.
3. Admission to the system within one year of injury.
4. If patient is discharged from System Acute as Minimal Deficit or Recovered, they must be hospitalized in the system for at least one week before discharge.[1]
5. Discharge from the system as:
   a. Having completed inpatient acute rehabilitation[2],
   b. Achieving a neurologic status of normal or minimal deficit[5].
   c. Deceased
6. Signed informed consent and HIPAA authorization forms[3].
   ◊ HIPAA Authorization is not required for research on deceased persons

Additional Criteria for Form I Inclusion:

1. Reside in the geographic catchment area of the system at the time of the injury. Patients may be injured outside of the catchment area.
2. A US citizen or non-US citizen who is expected to stay in the catchment area.

The above criteria do not apply to patients who 1) are discharged as deceased or 2) achieved a neurologic status of normal or minimal deficit.

Exclusion Criteria[4] for Registry and Form I:

1. Must not have previously been treated at another model system for the injury.
   ◊ Ensures that patients are enrolled into the database by only one model system.
2. Must not have completed an organized rehabilitation program prior to the admission to the system.

NOTES:

[1] This ensures their condition is significant and requires at least one week's hospital care. One week hospitalization is not required if patient dies in acute medical unit.

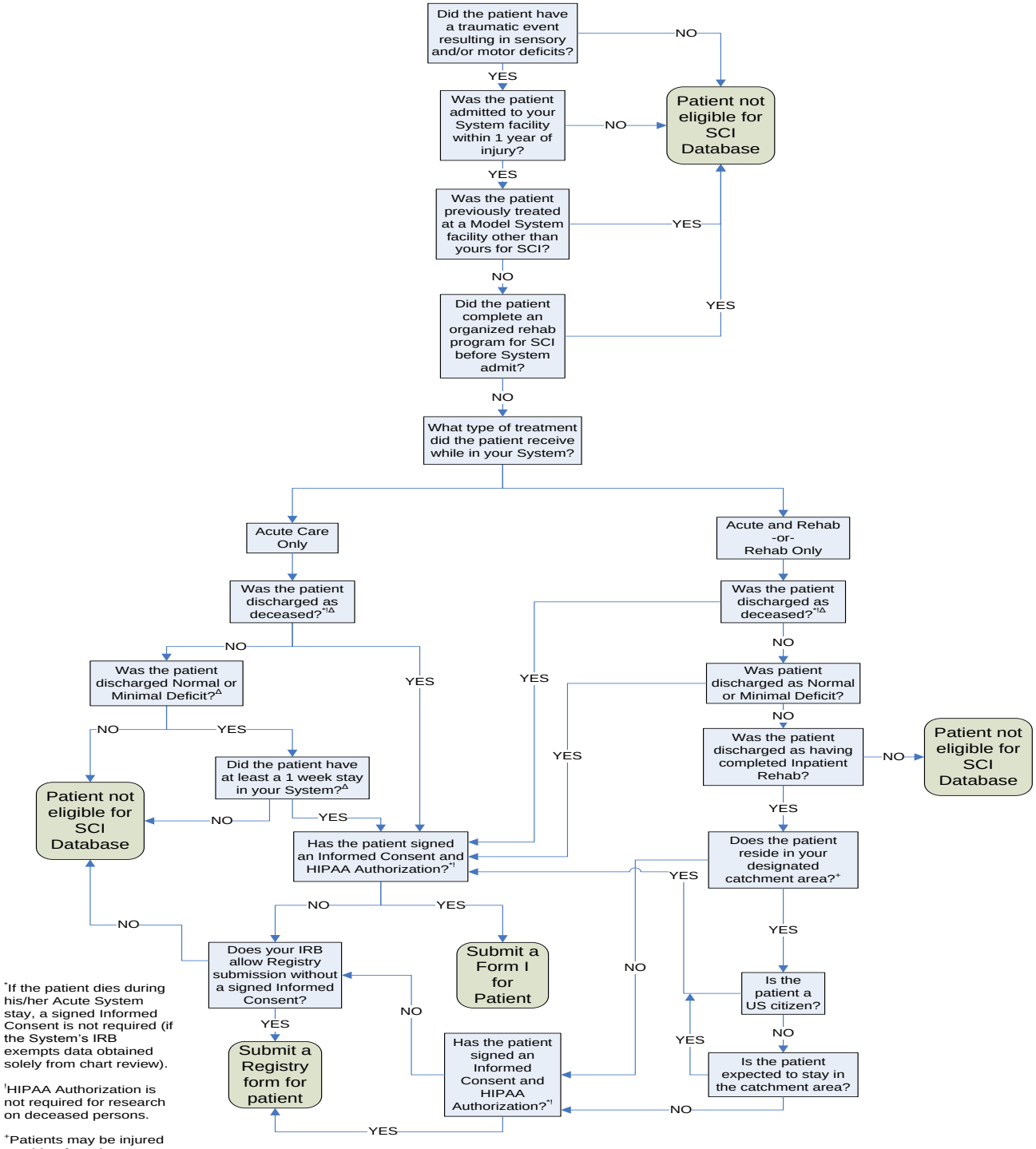
[2] Completion of rehabilitation is defined as finishing the prescribed course of inpatient rehab which may lead to a less intensive course of rehab (such as outpatient rehab), but does not include being transferred to another rehab facility for continued care. Discharges against medical advice are not considered 'completed'.

[3] Some systems' IRB may not require these forms for the Registry patients, data obtained from the deceased, or both.

[4] A prior history of spinal cord injury or other medical conditions (i.e. spinal stenosis, stroke, traumatic brain injury...etc) does not preclude individuals from being included in the database as long as an external/traumatic event could be identified as a cause of the NEW injury and further neurologic deficit.

[5] Minimal deficit is defined as neurologic damage so minimal the patient has no significant or incapacitating loss of function. Reflexes may still be abnormal. Patient's Motor Score should be 95 or greater, and patient should be free of other significant neurologic complications due to SCI (e.g., bowel, bladder or neuropathic pain). Minimal deficits are coded as ASIA D and have a neurologic level of injury (not X00). If the patient is coded minimal deficit on Form I, no Form IIs are required. Once a patient is coded minimal deficit, further follow-up is allowed but not required.

NSCISC Eligibility Criteria Flow Chart



*If the patient dies during his/her Acute System stay, a signed Informed Consent is not required (if the System's IRB exempts data obtained solely from chart review).

IHIPAA Authorization is not required for research on deceased persons.

+Patients may be injured outside of catchment area.

ΔForm II follow-up is not required for patients discharged as deceased, Normal, or Minimal Deficit.

Form I Recruitment and Retention

The following recommendations and strategies are gathered from SCI Model Systems and the NSCISC. Centers may employ these and other strategies to maintain and improve recruitment and retention as needed.

Recruitment & Retention begins before the patient is enrolled. Build a foundation for a relationship with clinic and inpatient staff:

1. Attend inpatient rehab team meetings or rounds to increase face-time with staff & patient.
2. Claim some space (at least on a part-time basis) in or near the rehab unit and/or clinic to increase face-time with inpatient/clinic staff, patients and family.

Build a relationship with the patient before recruitment:
When approaching the patient:

1. **Be casual & friendly, confident & assertive.**
2. Get introduced by the physician or medical team. If that is not possible, mention the physician's name in your introduction. Before talking about the study, ask if you can assist them in getting information and try to meet their family (this is especially helpful for certain cultures).
3. Mention a nurse or physician's name that the patient may know and if applicable, the clinician's involvement in the study.
4. Leave SCI educational material or newsletters with them.
5. Make connections by asking about family, pictures or hobbies if they are interested in talking.
6. Meet the family at scheduled meetings with staff. Take a few minutes to sit and talk with family and patient.
7. Visit patient/family in evenings as well as day hours (this may increase the chance of uninterrupted face-time).

When introducing the study: TIMING is important!

1. Be casual & friendly, confident & assertive. Convey the importance of our study and the importance of their involvement.
2. There are three types of participants 1) Those who are willing to participate, 2) Those who are hesitant to participate, 3) Those who will not participate under any circumstance.

   When approaching the patient, assume they will participate (most patients fall into this category). If they are hesitant, probe for a reason. Make an effort to connect with them or their family. Don't be too pushy – you can always come back and continue the conversation later and possibly bring material that will alleviate their concerns. 'Leave the door open'!
3. Use the word 'Study' or 'Project' instead of research. Explain why the study is important and useful: SCIMS is a well-known, highly regarded study that has been collecting data for over 40 years. It is used in legislative decisions, court cases, and it has been cited in multiple high profile newspapers like USA Today.

4. Leave a recruitment brochure, educational material, games and/or puzzles (print from free sites).
5. Consent before discharge if at all possible, but if patients are overwhelmed, suggest another time to contact them. If you need to, see them at their first clinic outpatient appointment.
6. Ask if they (or their family!) have any questions and then answer them.
7. If they are in a negative mood, then reschedule.
8. Be sure patient and family understands that this long term study should have at least 3 alternate contacts: aunts, uncles, grandparents, friends, etc… Some participants will be reluctant to offer up others' contact info. Be assertive and clear that contact will only be attempted after all means of contacting the participant have been exhausted.
9. Ask if they are on Facebook, Instagram, Twitter, or Snapchat and get that info.
10. The data collector who will be contacting the patient for the Year 1 follow-up interview may meet the patient prior to discharge.

After consenting:

1. Give patients an incentive, or certificate or logo'd items they can take home as a reminder: pen, pencil, pad, calendar or squeeze ball. This helps cement relationships after they leave with visual reminders.
2. Give them a re-location postcard with center address & phone number in case they move.
3. Call after discharge to see how they are doing or send a postcard sometime after discharge (this may be a reminder of clinic appointment or upcoming interview), or a birthday card.

Registry & Form I Data Collection

All Registry and Form I data collection periods occur during the "Initial Hospitalization Period" (i.e., from the time of spinal cord injury until definitive discharge from the System). The initial hospitalization period is an individually planned program of acute medical and/or rehabilitation services following SCI.

First System Admission: This is the first admission to the System after the traumatic SCI. The System admit must occur within 365 days of injury. Admission may be to the System's acute medical, sub-acute medical, acute rehab or sub-acute rehab unit.

During System Acute Medical Care: This is the period of time from admission to the System medical unit hospitalization following the SCI until the initial System inpatient rehabilitation admission (or the patient's death, or discharge from acute hospitalization as recovered or minimal deficit). Acute Medical Care includes all medical surgical care provided in the intensive care unit (ICU), non-ICU beds, SCI specialty unit beds and subacute medical care units.

During Inpatient Rehabilitation: This is the period of time from admission to the System's inpatient rehabilitation unit and definitive discharge from the System's inpatient (acute and/or subacute) care. Rehabilitation includes some combination of physical therapy, occupational therapy, speech therapy, recreational therapy, patient and family education, and rehabilitation psychology, medicine and nursing care.

Initial Rehab: The initial individually planned program of rehabilitation services following spinal cord injury.

Admission Date to Inpatient Rehabilitation (Admit to System Inpatient Rehab, or Rehab Admit) For all systems, the beginning of the inpatient rehabilitation stay is marked by admission to the System's inpatient rehabilitation hospital, transfer to the System's inpatient acute or subacute rehabilitation unit, or commencement of the inpatient rehabilitation program in a System's multipurpose unit.

Discharge: Discharge from initial System hospitalization to a definitive living situation.

- For those patients requiring both acute and inpatient rehabilitation care, discharge from the inpatient rehabilitation unit should be documented as the discharge.
- Discharge from the acute care unit is acceptable for patients who complete inpatient rehabilitation in the acute care unit, achieve complete neurologic recovery or minimal deficit status with no rehab admit (and at least 7 days hospitalized), or who expire during acute care.

During System: The period of time between the initial admission to and discharge from the System for the initial individually planned program of rehabilitation services (with or without acute medical unit admission) following spinal cord injury.

Second Spinal Cord Injury: Occasionally, an existing participant sustains a second spinal cord injury that significantly reduces motor and/or sensory function. When this happens, submit a Form II in an off-year (2, 3, 4, 6…) closest to the second date of injury with the neuro exam (required) and any other Form II data available. Add information about the second injury on the Notes page found on the Patient Options page. If the participant is

hospitalized in a different System than originally assigned, the original System will follow the patient and request data from the other System. Do not enter as a new Form I.

Neurologic Exam Data

When neurologic exam data is not completed or contradictory data is found in the medical chart or neurologic exam worksheets, the data collectors should consult with the examiner to ascertain the correct data. When there are two or more exam dates, record the Date of Exam that reflects the date most of the exam was completed. The Acute Medical neurologic exam is requested to be completed within 72 hours of a Day-1 admit but is acceptable at any time point within the Acute Medical stay (neurologic exams are not required for Non-Day 1 admissions). Neurologic exams at Discharge should be completed within 7 days of discharge.

Minimal deficit refers to neurologic damage so minimal the patient has no significant or incapacitating loss of function. Reflexes may still be abnormal. Patient's Motor Score should be 95 or greater, and patient should be free of other significant neurologic complications due to SCI (e.g., bowel, bladder or neuropathic pain). Minimal deficits are coded as ASIA D and have a neurologic level of injury (not X00). If the patient is coded minimal deficit on Form I, no Form IIs are required. Once a patient is coded minimal deficit on a Form II, further follow-up is allowed but not required.

FIM variables

Collect FIM variables after a final version is available (all updates have been made). For Centers submitting FIM data to UDS, the final version is categorized as 'Locked'.

Interview/Self-Report variables

Form I interviews should be conducted near the expected discharge date. Occasionally, a patient may be discharged before the interview is completed. In these cases, interviews may be conducted up to one month post discharge from initial rehabilitation. Patients may still be enrolled up to 12 months post injury, however, interview variables will be entered as unknown if the interview is not conducted within 1 month of completion of initial rehabilitation discharge.

Source Documentation

NSCISC requires all variables' source documents be available for review by institutional, sponsor and compliance entities. Documents may be in a paper file, digital file or a combination of the two. Provide a note in the file for all verbal updates or changes to variable values. Centers will comply with their IRB restrictions when deciding documentation preservation.

Form II Data Collection

Form II follow-up data are required on all participants who are eligible for follow-up at post-injury anniversary year 1, year 5 and every 5th anniversary year thereafter (i.e., years 1, 5, 10, 15, 20, etc.). An eligible participant is not categorized as: Deceased, Neurologically Recovered, Withdrawn, or Identity Unknown.

Form II data are required of all participants who have completed a Form I until one of the following occurs:

1) participant dies, or
2) participant achieves a neurologic status of Neurologic Recovered [discharged from initial medical care unit (with at least 7 days hospitalized) as minimal deficit or recovered, or Form II Category of Care = 8], or

   NOTE: A Form II for the year in which the participant's neurologic status changes should be submitted to ensure the recovery is documented during the appropriate post-injury year.
3) participant withdraws consent from the study, or
4) participant's personal identifiers are unknown (for Centers with breaks in funding only).

The first post-injury year (Year 1) begins the day after discharge from the initial rehabilitation hospitalization period and ends the day before the first anniversary of injury. For participants who are still in the initial hospitalization/rehabilitation process on their first anniversary of injury, a Year 2 replaces the Year 1 Form II. Subsequent post-injury years begin the day of the anniversary date and end the day before the next anniversary date. The date of injury is always used to calculate post-injury (anniversary) years.

Form IIs are not required for off-year collection (**off-Years** are anniversary years in which a Form II follow-up is not required (2, 3, 4, 6, 7 …)). Each Center determines its own off-year Form II collection policy.

Participant Status

Form I participants are categorized as Eligible for follow-up or Lost unless they are identified as Deceased, Neurologic Recovered, Withdrawn Consent, or ID Unknown. Form II follow-up interviews are required for Eligible and Lost status participants.

Eligible or Lost

Follow-up interviews are required for Eligible or Lost status participants. When follow-up data on a participant is entered to the National SCI Database for the most current required year, the participant's status is Eligible.

When no follow-up data have been collected at required years, a Form II is submitted by the data collector as 'Lost'. A Lost Form II is submitted with only 5 variables completed: Year Due (Anniversary Year), Category of Care, Reason Lost, Date of Last Search Modifier, and Date of Last Search. NSCISC provides a 'Lost Form II' to help guide data entry in these cases. All Lost forms must be signed by the data collector and Project (Co-) Director or Principal Investigator. A copy of the Form is not sent to NSCISC but should be stored at each center for auditing purposes such as site visits.

The *Vital Status Source* and *Vital Status Date* variables are automatically updated when a Form II is submitted. Data collectors will update both variables in Record Status when the participant is contacted in off years (post-injury years that are not required, 2, 3, 4, 6, 7 …).

Neurologic Recovered

When a participant is categorized as Neurologic Recovered (coded as 'minimal deficit', 'normal neurologic', 'norm-Min' or 'recovered'), further Form II data collection is allowed but not required. If subsequent Form IIs are submitted, Category of Care must be coded '8. Not Applicable'. Centers will continue to search for Vital Status for Neurologic Recovered participants at required years.

Minimal deficit refers to neurologic damage so minimal the patient has no significant or incapacitating loss of function. Reflexes may still be abnormal. Patient's Motor Score should be 95 or greater, and patient should be free of other significant neurologic complications due to SCI (e.g., bowel, bladder or neuropathic pain). Minimal deficits are coded as ASIA D and have a neurologic level of injury (not X00). If the patient is coded minimal deficit on Form I, no Form IIs are required. Once a patient is coded minimal deficit on a Form II, further follow-up is allowed but not required. When Category of Care is 8) Not Applicable, participant Status changes from Eligible to Neurologic Recovered and henceforth will not be included in the Forms 2 Due Report unless a subsequent Form II is entered where Category of Care is not 8.

Withdrawn Consent

In rare cases, a participant may be reluctant to complete a follow-up interview. The data collectors should first suggest setting up the interview for a later date. The data collector should not initially offer to withdraw the participant from the study because he/she may be interested in completing the interview at a later date or at the next scheduled follow-up.

When a participant asks to be withdrawn from the study and refuses all future follow-up data collection, the following should occur. A 'Lost Form II' is completed identifying the participant as Withdrawn (*Reason Lost* code '6. Patient withdrew consent'). The Lost Form requires a signature by the data collector and the Principle Investigator or Project (Co-) Director. Future Form II follow-ups are not allowed unless the participant is re-consented. However, Centers will continue to search for Date of Death (SSDI or genealogy.com) for withdrawn participants at required years if the center's local IRB allows.

If the participant is re-consented, data collectors are required to fill the gap of required Form IIs between the withdrawal and re-consent (the gap will be filled with Lost Form IIs). For example, if a participant withdraws at Year 5 (a Lost Form II is entered), and 15 years post-injury the participant contacts the center requesting to be in the study. The data collector re-consents the participant, enters a Year 10 Lost Form II (*Reason Lost* code '6. Patient withdrew consent') and completes the Year 15 interview.

Identity Unknown – Break in Funding

A break in funding is defined as a model system which loses funding for at least 1 cycle and then regains funding. For Centers with a break in funding that are unable to preserve personal identifiers from the previous funding cycle, follow-up of participants enrolled in previous cycles requires extensive linkage using only a few select Form I variables (age of injury and admission/discharge dates) with medical chart records and limited data available at NSCISC (consult with NSCISC before coding since some identifiers are stored at NSCISC). If the linkage search is unsuccessful and identity is still unknown, a Lost Form II should be submitted for required years using *Reason Lost* code '7. Identity Information Lost Due to Break in Funding'. The participant must have been enrolled prior to the break in funding and personal identifiers (name, social security number, and medical record number) must be

unknown. If the participant's identifiers are recovered, data collectors are required to submit Lost Form IIs (required years only) in the gap between the Form II coded Identity Unknown and the Form II due after recovery of the identifiers (per local IRB). That is, if a Center loses funding in a participant's Year 9, the Year 10 will be automatically submitted by NSCISC as 'Lost Funding'. The Center then regains funding but does not have identifiers for the participant in Year 15 so a Form II is submitted by the Center as Identity Information Lost Due to Break in Funding. Then in Year 25, the Center discovers participant identifiers and the Center submits a Lost Form II for Year 20 (Information Lost Due to Break in Funding) and attempts to collect Year 25.

When a Center loses funding, preservation of personal identifiers (name, date of birth, medical record number or social security number) is necessary to continue to collect follow-up data at a later point in time. De-funded Centers should submit personal identifiers to a secure location. The NSCISC will make all possible arrangements to accommodate preservation of personal identifiers within the Center's IRB requirements.

Data Requirements

Form II Data Collection Time Frame (Windows)

Follow-up Form IIs should be collected as close to the required anniversary date as possible. For the year 1 (or the "substituted" year 2) Form II, data may be collected from 182 days (6 months) before the anniversary date to 182 days after the anniversary date. For all subsequent follow-up years, data may be collected from 182 days prior to the anniversary to 365 days after the anniversary date. If no data are collected within the data collection period, a Lost Form II is completed and signed by the data collector and the Center's Project (Co-) Director or Principle Investigator, and appropriate data are entered to the database.

Variable Time Frames

During past 12 months - This time frame refers to events that took place within the 12 months that preceded the *Date of Interview*. For Year 1, record events that took place since initial System discharge (except for Year 1 VA Services which are collected since injury). Centers may learn of events occurring in a variety of ways, such as during the interview or from the medical record of follow up care received at the System.

Since the last known value - Refers to the most recent Form with a value that is not missing or unknown in the variable being documented. The last known value provides a time point and value to assess the change between the current Form II and the last known value. When no previous Form IIs has a known value (that is a value that is not missing or unknown), document the change in status since the Form I. For example, if Change in Marital Status data are being collected for year 10 and Marital Status was unknown in year 5 (or if the year 5 was 'Lost'), the interviewer should ask for the changes that occurred since the Year 1 (or if Year 1 Marital Status is missing or unknown, the since the Form I). VA Services are collected since the most recent known value or since SCI onset if no Form II known values exist.

During the annual examination - Refers to variables obtained during the participant's annual physical examination if they continue to receive care at the system. For the Year 1 (or the 'substituted' Year 2), data may be collected from 182 days before the anniversary date to 182 days after the anniversary date. For all subsequent follow-up years, annual exam data may be collected from 182 days before the anniversary date up to 365 days after the anniversary date.

Preparing for the follow-up interview

Prior to the interview, annotate the following to be resolved during the interview:

- Form I missing data that may be collected at follow-up (demographics and health-related).
- Known values from the previous Form I or II, such as Marital Status, Education Level, Bladder Management, Category of Neurologic Impairment at Discharge, etc.
- Alternate Contacts for re-confirmation

Interview Variables Collected from Medical Chart Review

If no interview is done and a medical chart review contains data for interview variables (interview variables are all Form II variables except neurologic exam and weight), then use the date of the clinic visit as the interview date if it falls within the data collection window (Category of Care will be 1-Primary System Care). Also confirm the data matches SCIMS data collection procedures, for example, Pain is collected as specified: usual level of pain over the last 4 weeks on a scale of 0 - 10. If medical records from multiple visits within the window contain data for interview variables, then code Interview Date based on the date on which data for most of the variables are available or, if the data are equally available, code based on the date that was done closest to the anniversary date. For these cases, Category of Care is coded '1.Primary'.

Interview Variables Collected from Caregivers

Participants are requested to complete the Form II follow-up but sometimes the only data available are from the caregiver. A caregiver is someone involved in some type of care or contact with the participant on a routine basis and knows the participant's situation concerning the variable. Caregivers may provide data for certain variables. These variables are identified in the Data Dictionary and Forms (variables marked with '!' allow for participant's response only). The data not collected is coded as Unknown.

Recording Neurologic Data for Year 1 Follow-up

Neurologic data are required for Year 1 Form IIs. Neurologic data for all other years are allowed to be entered but are not required and may be left blank if no neurologic data are obtained. If partial neurologic data are entered to the database (off-year or otherwise), then all neurologic data must be entered. For example, if only the Category of Impairment is known, then all other neurologic data must be entered as 'unknown'. For details, see the current issue of the International Standards for Neurological Classification of Spinal Cord Injury. Data collectors are encouraged to take InSTeP training at http://www.asialearningcenter.com/.

Follow-up Rates & Benchmarks

Follow-up rates are determined using only required Form IIs (with Status of followed, lost and missing) reported in the Follow-up Tracking Report (see NSCISC Reports requires login). The benchmark for Year 1 is 90% followed and all other Years are 80% followed. Follow-up Tracking Reports are generated twice a year after each data submission. Achieving and maintaining high follow-up rate is a crucial step in providing high quality data for research. Additional resources to reach this goal include: Never Say Lost (http://www.nsabp.pitt.edu/Never_Say_Lost.pdf), and a systematic review of the effect of retention methods in population-based cohort studies (https://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-11-249).

Minimum Tracking Effort

Prior to submitting a Lost Form II, complete these activities:

1) Conduct a death search with Ancestry.com, Genealogy.com, or other appropriate internet site for a record of death. Conduct a Google search for an obituary with the patient's name and date of birth.
2) Search System (hospital and clinic) records for recent activity and updated contact information.
3) If the contact information is not valid, conduct at least 2 free internet searches and a fee-based search, if available.
4) Call viable phone numbers at least 6 times at different times of the day and week.
5) Mail Form II Survey to a viable address.

Reduced Tracking Effort

If more than two consecutive follow-ups (i.e., a Year 15 is due and years 5 and 10 are 'Lost') are submitted as 'Lost', then centers may use the Reduced Tracking Effort:

1) Conduct a death search with Ancestry.com, Genealogy.com, or other appropriate internet site for a record of death. Conduct a Google search for an obituary with the patient's name and date of birth.
2) Search System (hospital and clinic) records for recent activity and updated contact information
3) If the on-record contact information is not valid, conduct at least 2 free internet searches and a fee-based search, if available.

If no viable contact information is obtained during the search, then submit a Lost Form II and update Vital Status variables. If viable contact information is obtained, follow steps 4 and/or 5 above.

Form II Retention Strategies

The following recommendations and strategies are gathered from SCIMS and the NSCISC. Not all strategies will be feasible for all Centers.

1. Send email and/or postal mailings (newsletter, birthday cards, and/or holiday cards).
   a. Handwrite the address on the envelope and mark with 'Forwarding & Address Correction Requested'.
2. Send flyer or letter to last known address prior to interview to let participant know you will be contacting them soon.
3. Offer incentives.
4. Prior to interview, check the previous Form, for personal stories or notes written on the form but not entered to the electronic system.
5. Conduct a 'Keep in Touch' call at select Years or times (like Year 1).
6. Read 'Retaining and Tracking Cohort Study Members' article in Appendix C of the Data Dictionary.

Popular Search Strategies Used by SCIMS Centers

Documenting alternate contact information for multiple relatives is the best secondary level source for finding hard-to-find participants.

Some participants screen phone calls and decline to answer unfamiliar numbers or conversely may decline to answer calls from your Hospital System phone (using Caller ID). Consider supplementing the main phone with a phone that does not show affiliation to center/hospital or conversely, using a phone that shows center affiliation in Caller ID. Also, some phones accept only text messages.

Email the participant IRB approved messages and reminders.

Check for System hospital or clinic visits for updated contact information. Contact outpatient rehabilitation clinicians for updated status (for example, did the participant get married, move out of state, etc).

Women may change their last names after a marriage (search marriage licenses or maiden names).

Check several of these free internet sites for address and phone numbers of the participant, family members and alternate contacts:

www.whitepages.com, www.Pipl.com, www.123people.com, www.switchboard.com, www.zabasearch.com, www.peoplesearch.com, www.anywho.com, www.Google.com, or Face Book

Use Facebook as a search engine. Search for names, or phone numbers (some people link their phone number to their page). You may find where they work or town of residence. Be aware that HIPAA may restrict posting a contact request on a public space.

Fee-based searches: http://www.tlo.com, www.beenverified.com, www.Intelius.com, InstantCheckMate or www.netdetective.com .

Also check local obituaries, voter registration, and prison/jail enrollment website for your state. Another clue for follow-up may be in the previous Form, such as stories, notes or alternate contacts not entered to the system.

Death Variables in Record Status

The *Date of Death Modifier*, *Date of Death*, and *Cause of Death* variables are found in the Record Status. The NSCISC's web-based software inserts the default code for "Alive" in the Date of Death Modifier and Primary Cause of Death variables when a new Registry or Form I is created. If the participant dies, these variables must be updated with the appropriate information; however (as of November 1995) a Form II is not required to be submitted for the post-injury year in which the participant died. Vital Status variables are automatically updated by NSCISC software after Death variables are entered.

Since it may take several years to identify a participant as deceased, a Lost Form II may have been submitted between the date of death and the date the participant was identified as deceased. In these cases, enter the date of death and delete the Lost Form IIs for the Years Due after the Date of Death.

Identifying Deceased Participants It is the responsibility of the SCIMS to update the death variables in the NSCISC database when notified of a death. Notification may come from family members, care-givers, System records or internet searches. At required years, SCIMS will search a death index (Ancestry/Genealogy/SSDI) for Neurologic Recovered, Lost to System and Registry participants when identifiers are available, per local IRB guidelines. Search results are entered into Vital Status variables in Record Status.

The following activities may be employed when searching for participant's date of death:

1) Search Ancestry by name and date of birth (SSN have been removed from records with date of death within the last 10 years)
2) Search online local obituaries (by name/location) or find a grave search site such as Legacy.com
3) Conduct a fee-based search if available (i.e., Accurint or TLO)
4) Search System (hospital and clinic) records

When a record of death is found, verify at least 2 (or 3) points of data other than name to confirm that you have identified the same person: social security number, date of birth, address, or name of family member.

Each year, the NSCISC submits participants with known identifiers from its companion survival database to a TLO or Ancestry.com death search. Once this search identifies a participant as deceased, the NSCISC notifies each respective Center of their newly deceased participants. After this notification, it is the responsibility of the Center to update the death variables in the NSCISC database.

Finding Cause of Death After a participant is identified as deceased in the NSCISC database and has an unknown cause of death, NSCISC requests identifiers from Centers in order to apply for cause of death data from the National Death Index (NDI). NSCISC receives cause of death data from NDI and enters the data into a companion survival database and later the data is merged into the National SCI Database. NSCISC then notifies each respective Center of their participants whose cause of death is still unknown after the NDI search. It is the responsibility of the center to search the cause of death of these participants through other resources and update the NSCISC database. For this reason, each center maintains an agreement with their catchment state(s) to obtain death certificates.

Centers that do not provide identifiers to NSCISC will obtain and submit cause of death data to the NSCID. Sources of cause of death data include primarily death certificates but may also include System records, obituaries, and family members.

Requesting a Death Certificate An official certificate of every birth, death, marriage, and divorce should be on file in the locality where the event occurred. The Federal Government does not maintain files or indexes of these records. The records are filed permanently in a State vital statistics office or in a city, county, or other local office. To obtain a certified copy of any of the certificates, write or go to the vital statistics office in the State or area where the event occurred. To find details for each event in the State or area concerned, go to http://www.cdc.gov/nchs/w2w.htm. Each state has different requirements to request these data. See Data Dictionary - Appendix C for more details on obtaining death certificates.

In general, death certificates include a line that documents the immediate cause of death followed by two or three lines under the heading "due to or as a consequence of." There will also be a line to document "other significant conditions". As a general rule, the primary cause of death will be the cause entered alone on the lowest line of the "due to or as a consequence of" sequence unless it is unlikely that this condition gave rise to all the other conditions listed above it. An "Other significant condition" would be coded as a secondary cause of death unless it can be specifically linked to the causes listed above it, in which case it might be included in a combined primary cause of death. Any mention of spinal cord injury, paraplegia, etc. (including late effects of SCI) should be ignored. If no other information is available (no autopsy report, no death certificate, no summary information from a rehospitalization, etc.) code the cause of death unknown.

Death certificates may also contain data such as education level, military service, race and ethnicity. If the Form I values for these variables are unknown, update the values using the data from the death certificate.

Guidelines for coding Cause of Death

Code Cause of Death exactly as written in the ICD 10 (no additional leading or trailing zeros).

In general, death certificates will have a line that documents the immediate cause of death followed by two or three lines under the heading "due to or as a consequence of." There will also be a line to document "other significant conditions".

A. As a general rule, the primary cause of death will be the cause entered alone on the lowest line of the "due to or as a consequence of" sequence unless it is unlikely that this condition gave rise to all the other conditions listed above it. An "Other significant condition" would be coded as a secondary cause of death unless it can be specifically linked to the causes listed above it, in which case it might be included in a combined primary cause of death. Any mention of spinal cord injury, paraplegia, etc. (including late effects of SCI) should be ignored. After the Primary Cause, positions 2 -5 are in no specific order. If no other information is available (no autopsy report, no death certificate, no summary information from a rehospitalization, etc.) code the cause of death unknown.

For example, consider the following cases:

1. Immediate cause: Cardiac arrest I46
   Due to or as a consequence of:
   Due to or as a consequence of:

   Unless additional information can be acquired, **select cardiac arrest (I46)** because, unfortunately, it is the only option available.

2. Immediate cause: Cardiorespiratory arrest I46
   Due to or as a consequence of: Pneumonia J18.0
   Due to or as a consequence of:

   Select pneumonia (J18.0) since it led to the cardiorespiratory arrest.

3. Immediate cause: Cardiorespiratory arrest I46
   Due to or as a consequence of: Septicemia A41.9
   Due to or as a consequence of: Pneumonia J18.0

   Select pneumonia (J18.0) because it led to the other conditions. List septicemia as a secondary cause.

   If infection of unknown origin causes pneumonia then death occurs, code septicemia as primary and pneumonia as secondary.

4. Immediate cause: Cardiac arrest I46
   Due to or as a consequence of: Arteriosclerosis I70.9
   Due to or as a consequence of: Brown-Sequard syndrome

   Select arteriosclerosis (I70.9) and ignore the reference to SCI.

5. Immediate cause: Cardiorespiratory arrest I46
   Due to or as a consequence of: Septicemia A41.9
   Due to or as a consequence of: Renal failure N19

Select septicemia (A41.9) because renal failure (which would ordinarily have been chosen) cannot cause septicemia. List renal failure as a secondary cause.

6.	Immediate cause:	Arteriosclerosis	I70.9
	Due to or as a consequence of:	Pneumonia	J18.0
	Due to or as a consequence of:		

Select arteriosclerosis (I70.9) because pneumonia (which would ordinarily have been chosen) cannot cause arteriosclerosis. List pneumonia as a secondary cause.

7.	Immediate cause:	Cardiac arrest	I46
	Due to or as a consequence of:	Hemorrhage	K27.4
	Due to or as a consequence of:		
	Other significant conditions:	Peptic ulcer	

Unless there is specific evidence indicating the hemorrhage was not associated with the peptic ulcer, **select peptic ulcer with hemorrhage (K27.4)** because hemorrhage (which would ordinarily have been chosen) can be linked with peptic ulcer to identify a more specific condition. The important question is whether this death is better classified as resulting from a disease of the digestive system or a disease of veins and lymphatics. Certainly, the former seems more appropriate given the available information.

8.	Immediate cause:	Pernicious anemia	D51.0
	Due to or as a consequence of:	Cerebral hemorrhage	I61
	Due to or as a consequence of:	Arteriosclerosis	I70.9

Select pernicious anemia (D51.0). Although arteriosclerosis can cause a cerebral hemorrhage, it cannot cause pernicious anemia. Cerebral hemorrhage also cannot cause pernicious anemia. Therefore, with no apparent causal sequence leading directly to the immediate cause of death, the immediate cause is selected as the primary cause of death. The others should be listed as secondary causes.

B. In general, ill-defined conditions should not be selected as the primary cause of death unless no alternative exists.

For example:

1.	Immediate cause:	Myocardial infarction	I21.9
	Due to or as a consequence of:	Tachycardia	R00.0
	Due to or as a consequence of:		

Select myocardial infarction (I21.9) because tachycardia (which would ordinarily have been chosen) is considered a "symptom or ill-defined condition." Tachycardia can be listed as a secondary cause of death.

C. In general, trivial conditions should be ignored. If death is the result of an adverse reaction to treatment for a trivial condition (such as renal failure resulting from taking aspirin for recurrent migraines), then code the adverse reaction as the primary cause of death. If the trivial condition is not reported as the cause of a more serious complication and a more serious unrelated condition is reported, then code the more serious condition as the primary cause of death.

For example:

1.	Immediate cause:	Congenital anomaly of eye	Q15.9
	Due to or as a consequence of:	Congenital heart disease	Q24.9
	Due to or as a consequence of:		

Select congenital heart disease (Q24.9) even though it cannot cause a congenital anomaly of the eye because the latter is considered a trivial condition unlikely by itself to cause death.

D. When the normal selection process results in choosing a condition which is described only in general terms and a related cause is also reported which provides more precise information about the system or nature of the chosen condition, reselect the more informative cause as the primary cause of death.

For example:

1.	Immediate cause:	Cerebral thrombosis	I66.9
	Due to or as a consequence of:	Cerebrovascular accident	I64
	Due to or as a consequence of:		

Select cerebral thrombosis (I66.9) because it is more informative and precise than cerebrovascular accident (which would ordinarily have been chosen). Cerebrovascular accident can be listed as a secondary cause.

2.	Immediate cause:	Pyelonephritis	N12
	Due to or as a consequence of:	Kidney stone	N20.0
	Due to or as a consequence of:	Renal disease	N28.9

Select kidney stone (N20.0). Both kidney stone and pyelonephritis are more specific than renal disease, but kidney stone would have been selected if renal disease had not been listed on the certificate. Therefore, it is preferred over pyelonephritis, which can be listed as a secondary cause of death along with renal disease.

E. It is important to consider the interval between onset and death for each condition specified on the death certificate. Acute conditions that occurred a protracted time prior to death probably will not be the primary cause of death.

For example:

Immediate cause:	Congestive heart failure (3 months)	I50
Due to or as a consequence of:	Pneumonia (1 year)	J18.0
Due to or as a consequence of:		

Select congestive heart failure (I50) because the episode of pneumonia occurred a long time before the patient died as well as long before the symptomatic heart disease began.

F. The distinction between accident, suicide and homicide can be found in a separate box on the death certificate below the list of causes.

G. When the death certificate does not provide adequate information (for example when the only cause of death listed is "paraplegia"), other sources of information (such as a discharge summary if the patient was hospitalized at the time of death, or an autopsy report if one is available) should be acquired whenever possible. As a last resort, if an appropriate cause of death cannot be determined, the cause of death can be coded as unknown.

H. Obviously, there will be many instances in which the selection of primary cause of death will be a close judgment call. Unfortunately, the only way to avoid this is to make the guidelines even more burdensome than contained herein. Moreover, it is important to leave enough flexibility in the decision making process to allow the most appropriate cause to be selected in unusual circumstances and in cases where the death certificate makes no sense (a frequent occurrence).

Questions regarding the appropriate primary cause of death should be resolved by the Project Director or other system physicians.

Top 50 Causes of Death in National Database

The following list contains the top 50 Causes of Death using the 2006 version of the ICD 10. This list provides a starting point to code Cause of Death - many surrounding and more detailed codes are available at http://apps.who.int/classifications/apps/icd/icd10online2006/

SCsDth1 (ICD10)	Freq	Percent (n=8202)	ICD10_Description
A41.9	723	8.8	Septicemia, unspecified
B20	49	0.6	Human immunodeficiency virus [HIV] disease with infectious and parasitic diseases
C18.9	31	0.4	Malignant neoplasm of colon, unspecified
C34.9	168	2.1	Malignant neoplasm of bronchus or lung, unspecified
C50.9	29	0.4	Malignant neoplasm of breast, unspecified
C61	36	0.4	Malignant neoplasm of prostate
C67.9	39	0.5	Malignant neoplasm of bladder, unspecified
C80	32	0.4	Malignant neoplasm without specification of site (multiple sites)
E10.9			Insulin-dependent (Type 1) diabetes mellitus without complications (Excludes malnutrition/neonatal/pregnancy)
E11.9	94	1.2	Non-insulin-dependent (Type 2) diabetes mellitus without complications (Excludes malnutrition/neonatal/pregnancy)
E14.9			Unspecified diabetes mellitus without complications (Excludes malnutrition/neonatal/pregnancy)
G93.1	41	0.5	Anoxic brain damage, not elsewhere classified
I10	39	0.5	Essential (primary) hypertension
I11.0			Hypertensive heart disease with (congestive) heart failure
I11.9	44	0.5	Hypertensive heart disease without (congestive) heart failure
I21.0	63	0.8	Acute transmural myocardial infarction of anterior wall
I21.9	241	2.9	Acute myocardial infarction, unspecified
I25.1	196	2.4	Atherosclerotic heart diseases
I25.9	35	0.4	chronic ischaemic heart disease, unspecified
I26.9	249	3	Pulmonary embolism without mention of acute cor pulmonale
I42.9			Cardiomyopathy, unspecified
I49.9	57	0.7	Cardiac arrhythmia, unspecified
I50	90	1.1	Heart failure
I50.0			Congestive heart failure
I50.9	28	0.3	Heart failure , unspecified
I51.6	119	1.5	Cardiovascular disease, unspecified
I51.8			Other ill-defined heart diseases
I51.9			Heart disease, unspecified
I61	56	0.7	Intracerebral hemorrhage
I64	129	1.6	Stroke, not specified as hemorrhage or infarction

SCsDth1 (ICD10)	Freq	Percent (n=8202)	ICD10_Description
I67.9			Cerebrovascular disease, unspecified
I70.9	41	0.5	Generalized and unspecified atherosclerosis
J18	747	9.1	Pneumonia, organism unspecified
J18.0	127	1.6	Bronchopneumonia, unspecified
J44.9	104	1.3	COPD, unspecified
J69.0	173	2.1	Pneumonitis due to food and vomitus
J96.0	169	2.1	Acute respiratory failure
K74.6	27	0.3	Other and unspecified cirrhosis of liver
K92.2	38	0.5	Gastrointestinal hemorrhage, unspecified
L89	33	0.4	Decubitus Ulcer
N17.9	29	0.4	Acute renal failure, unspecified
N18	42	0.5	Chronic renal failure
N19	87	1.1	Unspecified renal failure
N28.9			Disorder of kidney and ureter, unspecified
N39.0	55	0.7	Urinary tract infection, site not specified
R09.2	88	1.1	Respiratory arrest
R57.8	27	0.3	Other shock
R96.1	50	0.6	Death occurring less than 24 hours from onset of symptoms, not otherwise explained. Death known not to be violent or instantaneous for which no cause can be discovered. Death without sign of disease.
R99	102	1.2	Other ill-defined and unspecified causes of mortality
T88.9	58	0.7	Complication of surgical and medical care, unspecified
V89.2	59	0.7	Person injured in unspecified motor-vehicle accident, traffic
X42	69	0.8	Accidental poisoning by and exposure to narcotics and psychodysleptics [hallucinogens], not elsewhere classified
X44	85	1	Accidental poisoning by and exposure to other and unspecified drugs, medicaments, and biological substances
X61	29	0.4	Intentional self-poisoning (suicide) by and exposure to antiepileptic, sedative-hypnotic, antiparkinsonism, and psychotropic drugs, not elsewhere classified
X72	51	0.6	Intentional self-harm (suicide) by handgun discharge
X74	56	0.7	Intentional self-harm (suicide) by other and unspecified firearm discharge
X95	33	0.4	Assault (homicide) by other and unspecified firearm discharge
Y10	26	0.3	Poisoning by and exposure to nonopioid analgesics, antipyretics, and antirheumatics, undetermined intent

Data Entry

Since the implementation of the web-based system in 2007, Model System staff enter Personal Data (if the center has IRB approval, personal identifiers are added), Registry or Form I, and Form II data by logging into the password protected web site, https://www.nscisc.uab.edu. Data are saved to a server located behind the secure UAB firewalls. All forms are required to pass through several layers of quality control before being added to the National Database.

Each Form created and saved to the National SCI Database is considered a **record.** Each record has an *Indate* variable which indicates the date on which the record was created. This is a computer-generated data management variable that cannot be modified by the user.

An **update** is submitted to modify an existing record. The *Update* variable is modified programmatically when a variable is changed and the data entry page on which the variable resides is saved. For Form II, each year updated is counted separately. For example, if the *Method of Bladder Management* variable is corrected on annuals 1 and 5, these forms will be counted as two Form II updates. Updates serve three purposes, 1) revise variables previously coded as unknown, (2) correct discrepancies identified by the center staff or by the NSCISC's quality control checking programs, or (3) complete a variable left blank on the original, new entry form.

NOTE: Data collectors are encouraged to update records whenever new or corrected data are obtained. However, Post-Injury Year (Year Due, BYear) is not editable after it's been saved. If Post-Injury Year is incorrect, then delete the record and create a new record. After entering a new or updated value, data collectors should 'Save & Run QC'. If QC messages are present, then investigate and fix the value in error as soon as possible after data entry.

The Personal Data Form serves several purposes, 1) identifies a unique Patient Number within the National SCI Database, 2) creates an accompanying Record Status Form, and 3) provides a location for personal identifiers. Each participant is categorized as Registry or Form I by the creation of the approriate Form depending on eligibility criteria.

A new Form I may be entered to the database as soon as possible given the time required to collect data from external sources (UDS, eRehab, physicians, etc.). A Form I update may be done at a later time to provide information that may be obtained on a delayed basis.

A new Form II should be entered to the database as soon as possible after data are collected.

Session logs are generated by the Data Management System and are available by request. Session logs include a list of forms entered or updated with the variable changes and the User name associated with the session.

Data entry best practices

Data entry should be done sitting comfortably with minimal distractions on a computer screen placed so the public does not see the data entry screen. Registry and Form I data should be entered as soon as possible given the time required to collect data. Form II data should be entered as soon as possible after the interview.

When changing data on the paper data entry form, cross out the original value and write the correct value to the side along with the initials of the person changing the value. Also, on each page of the form, include the Patient Number and Year Due.

After keying data on each web-based data entry page, review the data entered before saving each page. On the last page of the Form, save and run QC unless the record is incomplete. If there are QC messages, investigate the message to determine the correct value, change the incorrect value (or pass the QC if suspicious but valid), then save and re-run QC. All updates to the database should be updated on the paper data entry forms as well.

Quality Assurance

Standardized Interviews

Data collectors use paper interview forms with codes included for most variables during the interview process. Online data entry screens match the order of paper data forms to minimize data entry errors. Further standardization includes Data Dictionary, training, certification and a variety of quality control measures.

Data Dictionary Updates

The most recent version of the Data Dictionary may be downloaded from Training Resources. NSCISC sends Data Dictionary updates to centers on a routine basis which include examples, clarifications and changes to variable collection and procedures. Centers are required to keep electronic and paper Data Dictionaries updated. For the electronic copies, it is suggested to keep an updated copy on your computer desktop and to replace the outdated copy as soon as notified of a new Data Dictionary. An advantage to the downloaded (pdf) version is the Search function (Control + F) which quickly navigates to the selected word. For the paper copies, print the Revision Details and the revised pages of the Data Dictionary to replace the existing pages.

Data Collector Training

The following are training programs to be completed by data collectors:

1. Comply with Center IRB and HIPAA training and certification.
2. Complete the ASIA InSTeP training (with or without certification) at http://www.asialearningcenter.com/

For new data collectors, review the following: Guide to Initial Training and Resources, this document (SOP and Policies), the Data Dictionary, and the NSCISC website – Training Resources (for targeted variable review).

Data Collector Certification

NSCISC implemented a data collector certification program intended to increase standardization of data collection procedures across centers and improve data quality assurance by knowledge testing and reiterative training. See Policy on Form I and II Certification.

On-Site Quality Assurance

On-site quality assurance measures are designed to improve the quality of data used for research and provide in-house training opportunities for Form I abstraction and coding, Form II interviews, data entry and interview verification. For details, go to Policy of On-Site Quality Assurance.

Quality Control

Quality Control Checks

NSCISC has put in place several processes at the data entry level assuring data quality. Most variables have ranges in place within the page (before the data are saved) and other variables have dropdown boxes that only allow the specified values for that variable. More extensive QC occurs after the form has been saved and QC is initiated by the user.

The NSCISC website has a Quality Control page with a link to 'QC Home' which lists all records with unresolved QC checks either not initiated or not resolved. There are over 800 QC checks across Record Status, Registry, Form I and Form II. QC checks include messages for invalid blank codes, date validation, calculation validation, agreement of codes within a form and agreement across forms. QC messages do not indicate which of the listed variables are incorrect but the discrepancy should be investigated by the data collector and evaluation of the variable values in the message. A list of each site's outstanding QCs is available for export on the Data Quality page.

After each data submission, NSCISC initiates a full QC check on all database records before building the NatDat. If any record has an outstanding QC check, then that record and ALL SUBSEQUENTLY entered records for that participant are excluded from the NatDat and are not included in NSCISC reports.

Suspicious Quality Control Checks

Suspicious QC checks notify the data collector of a value that is outside of the expected range for that variable. The value may be correct, and if so, the data collector can 'Pass' the check by submitting a note of explanation or confirmation that the value is correct. The explanation (pass note) should include the reason for passing the QC or wording to verify both variables are valid. The List of Suspicious QCs Passed by the User is found in Data Quality. The list includes the Patient number, QC Check number and Description, the pass note, date passed and the User name.

Site Support Visits

In an effort to evaluate and improve data quality, the NSCISC conducts at least one site visit for each SCIMS and follow-up center during the early stages of each grant cycle. The review will be conducted on-site or virtually depending on several factors. 1) Past performance, 2) staff turnover, and 3) newly funded centers.

Prior to the visit, NSCISC sends a short questionnaire that will provide an overview of the center. Each site visit typically consists of a two day meeting with data collectors and other appropriate staff during which time recruitment and enrollment, internal data collection, file maintenance and data security procedures are reviewed, as are procedures for identifying and locating participants for Form II, and data quality reviews.

Data quality reviews provide an assessment of training needs and data quality. The NSCISC randomly selects up to 5 Form I files for re-abstraction to check accuracy of existing data, up to 10 files for checking data entry accuracy, and up to 30 files to check for proper consent and HIPPA documentation. Withdrawn and Lost Forms are reviewed for signatures, and a mock Form II interview is conducted as well. Issues concerning missing/unknown data, ways

to improve follow-up and enrollment, and center-specific problems or concerns are also discussed during the meeting.

Data Submission

Data submission is a point in time when a National SCIMS Dataset is created (called the NatDat). The NatDat is distributed to researchers upon request as well as being the basis for NSCISC reports.

Prior to data submission, data collectors are required to submit all necessary Forms, search for possible missing/unknown variables, and run and clear QC on all records.

After data submission, the NSCISC website shuts down for a short time to complete a full assessment of the National SCI Database. The NSCISC runs QC on the entire database, and those records with outstanding QC checks are NOT included in the NatDat, nor will they be counted as submitted until all QC checks are cleared. Additionally, when a Form has failed QC, all subsequent Forms are also excluded from the NatDat and NSCISC reports.

The NSCISC provides a Data Submission Worksheet as a tool to prepare for data submission.

National SCIMS Dataset

After each data submission, a limited dataset is created from a copy of the National SCI Database. The NatDat includes all variables from the current cycle from Record Status, Registry, Form I and Form II (excluding Personal Data and Geocode related variables) that have passed QC from all centers funded since inception of the SCIMS. As mentioned above, when a Form has failed QC, all subsequent Forms are also excluded. Module data supported by NSCISC are not included nor are retired variables that were collected in previous cycles but are not collected this cycle.

NSCISC encourages the use of the National SCI Dataset and depending on the requestor's affiliation to SCIMS, there are two pathways to request data. For lead investigators of SCIMS affiliated entities, use the Policy to Obtain NatDat- Affiliated (Internal). For non-affiliated requestors, use the Policy to Obtain NatDat –Not Affiliated.

The Spinal Cord Injury Model Systems'

Policies

Policy on Informed Consent & HIPAA	
Approved by: Data Committee	Effective: April 2003
Reviewed: October 2017	Revised: October 1, 2011

Description:
Form I participants who are providing data must have a signed Informed Consent which includes Certificate of Confidentiality (CoC) language as defined by the National Institute of Neurological Disorders and Stroke. The informed consent will be approved by the local model system IRB. NSCISC requires a copy of the approval letter and the approved Informed Consent and HIPAA from each center prior to submitting data to the National Database.

Purpose:
Provide NSCISC policy for local informed consent and HIPAA.

Scope:
All SCIMS and follow-up centers.

Responsibilities:
Informed consent will be completed for each Form I participant data entered to the Database (and Registry if required by center's IRB).

Procedure:
Verbal consent over the telephone may be used with permission of the local model system IRB. Once informed consent has been obtained, subsequent re-consent at the next annual evaluation is determined by the local model system IRB.

The HIPAA authorization form will be determined by the local model system IRB and may either be a separate document or may be included in the informed consent document. Each model system is required to check with its local IRB concerning the necessity of acquiring HIPAA authorization to continue to collect data (Form II) on previously enrolled participants who have never given HIPAA authorization.

The model system will inform NSCSISC in case of a lapse of IRB approval.

History: Revised October 1, 2006

Policy on Informed Consent Certificate of Confidentiality	
Approved by: Data Committee	Effective: October 2012
Reviewed: October 2017	Revised:

Description:

Certificate of Confidentiality helps researchers protect the privacy of human research participants enrolled in research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. The Certificate of Confidentiality agreement between NSCISC and the National Institutes of Health, National Institute of Neurological Disorders and Stroke (NIH/NINDS) requires NSCISC to maintain SCIMS center's IRB letters of approval and approved informed consents for review by NIH/NINDS.

On a yearly basis, NSCISC will review SCIMS informed consents' certificate of confidentiality language for the NIH/NINDS.

Purpose:

Establish and maintain Certificate of Confidentiality language in all SCIMS' Informed Consents.

Scope:

All SCIMS and follow-up centers.

Responsibilities:

Each center's Informed Consent will include the certificate of confidentiality language as defined by the NIH/NINDS and approved by both the local model system IRB. SCIMS Centers will provide a copy of their IRB approval letter and IRB approved informed consent to the NSCISC on a yearly basis.

Section of agreement with NIH:

"…multi-site projects, a coordinating center or lead institution can apply for and receive a Certificate on behalf of all member institutions. … In addition, the lead site should obtain signed assurances from each participating institution, as well as a copy of their IRB approval (http://grants.nih.gov/grants/policy/coc/appl_extramural.htm). These should be kept in the lead institutions' files, to be made available to the NIH upon request. The lead site is also responsible for ensuring that each site's IRB-approved consent forms contain appropriate language describing the Certificate of Confidentiality and should work with the appropriate NIH coordinator to review consent form language. …. After the Certificate has been issued, the lead institution should provide a copy of the Certificate of Confidentiality to each participating institution. The lead site should also develop appropriate agreements, with the participating institutions, to implement the assurances.

References: NIH CoC FAQs - http://grants.nih.gov/grants/policy/coc/faqs.htm

History: The first Certificate of Confidentiality was issued in 2001 by the National Institute on Alcohol Abuse & Alcoholism (NIAAA). The initial CoC was amended and reapproved in December 2006 and provided protection through December 2012. In 2012, NSCISC was identified as the coordinating center and application was approved by NIH/NINDS through December 31, 2017.

Policy on Enrollment Rate Benchmark	
Approved by: Data Committee	Effective: October 1, 2011
Reviewed: October 2017	Revised: October 2014

Description:

The enrollment rate is the percentage of patients discharged from rehabilitation and eligible for Form I and enrolled as Form I. The rate is found on the Enrollment Report and calculated using the number Enrolled / [Total Eligible – (Center Specific Ineligible + Consent Pending)] *100. The benchmark is 80% enrolled. For Centers with Randomized to Registry, the number of participants randomized will be excluded from Total Eligible. Currently, Randomized to Registry applies only to the Shepherd Center.

At each annual reporting period, the Consent Pending from the previous annual report is identified as enrolled or not enrolled to Form I. For those patients not enrolled as Form I, Race, Ethnicity, Age Range and Gender are identified. The previous enrollment rate will be updated to reflect the final destination of the Consent Pending.

Purpose:

Enrollment rates reflect a potential for bias. Increasing enrollment rates reduces the potential for bias.

Scope:

All SCIMS submit data to NSCISC twice a year.

Responsibilities:

Centers maintain at least 80% enrollment rate. If the enrollment rate falls below 80% for 2 consecutive reporting periods, the center will provide their NIDILRR representative and NSCISC with a plan to improve enrollment to reach the benchmark.

Procedure:

Procedures used to reach 80% enrollment rate will differ across centers. Strategies may include activities listed in Form I Retention as well as increasing data collectors' cultural knowledge and skills.

References:

Resources for cultural knowledge are found at NSCISC website > Tools and Training.

History:

October 2013 - Annual (Fall) 2013 Enrollment Report identified the number of Consent Pending from the previous annual report as enrolled or not enrolled to Form I.

October 2014 – Annual (Fall) 2014 Enrollment Report identified the number of Consent Pending from the previous annual report as enrolled or not enrolled to Form I. For those patients not enrolled as Form I, Race, Ethnicity, Age Range and Gender were identified.

Policy on Eligible Follow-up Rate Benchmark	
Approved by: Data Committee	Effective: October 1, 2011
Reviewed: October 2017	Revised:

Description:

Eligible Follow-up Rate is the percentage of eligible participants who provided successful follow-up for a required Form II during the period of time set by the Tracking Report. Eligible participants have a status of Followed, Lost or Missing. The benchmark for Eligible Follow-up is 90% followed at Year 1 and 80% followed for all other years.

Purpose:

Follow-up rates reflect a potential for bias. Increasing follow-up rates reduces the potential for bias.

Scope:

All SCIMS and follow-up centers

Responsibilities:

Centers will work towards reaching and maintaining the benchmark of 90% followed at Year 1 and 80% followed for all other years. If the follow-up rate falls below 80% (90% for year 1) for 2 consecutive reporting periods, then the center will provide their NIDILRR representative and NSCISC with a plan to improve follow-up to reach the benchmark.

Procedure:

Strategies used to reach the benchmark will differ across centers and variables. Strategies may include activities listed in Form I Retention and Form II Retention as well as increasing data collectors' cultural knowledge and skills.

Policy on Minimum & Reduced Tracking Effort	
Approved by: Data Committee	Effective: October 1, 2007
Reviewed: October 2017	Revised: October 1, 2017

Description:
A minimum effort activity list is completed prior to coding a participant as 'Lost'. If a participant has been coded 'Lost' on at least two previous consecutive follow-ups, then the Reduced Tracking Effort activity list is completed.

Purpose:
This policy standardizes the process of obtaining follow-up contact data prior to submitting a Form II as 'Lost'.

Scope:
All funded centers and follow-up centers perform the listed activities prior to submitting a 'Lost' Form II.

Responsibilities:
Data collectors complete the activities as listed.

Procedure:
Prior to submitting a Form II as Lost, complete the Data Committee's **Minimum Tracking Effort**.

1. Search SSDI (http://ssdi.rootsweb.ancestry.com/) or Genealogy for date of death
2. Search System (hospital and clinic) records for recent activity and updated contact information
3. Search at least two other internet search sites for contact information and a fee-based search if available.
4. After obtaining the most current, viable phone number, there should be at least six attempts to contact a person. These attempts should be tracked to assure attempts are made at different times during the day, evening, and weekends.
5. If unable to contact by telephone, mail the Form II survey to the participant's viable home address.

Reduced Tracking Effort applies when at least 2 previous consecutive follow-ups are coded as 'Lost'. In this case, conduct activities 1, 2, and 3 listed above. If no viable contact information is obtained during the search, then submit a Lost Form II. If viable contact information is obtained, follow steps 4 and/or 5 above depending on the type of new contact information.

History:
October 2017: Test was added to track attempts to assure they are conducted at different times during the day, evening, and weekends.

Policy on Missing/Unknown Variable Benchmark	
Approved by: Data Committee	Effective: October 1, 2011
Reviewed: October 2017	Revised:

Description:

The Missing Report shows a count of most variables' known versus missing/unknown values. It includes participants admitted to the model system during the funding cycle. The missing/unknown benchmark for all variables is 10% or less.

Purpose:

High missing/unknown rates mean that researchers may not be able to use these patient's records and thus may lead to a potential for bias. Decreasing these rates reduces the potential for bias.

Scope:

All SCIMS and follow-up centers

Responsibilities:

Centers will work to minimize missing data and work towards the benchmark of no more than 10% of records with missing values per variable. If any variable is missing more than 10% for 2 consecutive reporting periods, then the center will provide their NIDILRR Project Officer and NSCISC with an explanation and a plan to improve collection of that variable to reduce the missing data.

Procedure:

Strategies used to minimize missing data will differ across centers and variables. Strategies may include activities listed in Form I Retention and Form II Retention as well as increasing data collectors' cultural knowledge and skills.

Policy on Benchmark Management Plan	
Approved by: Data Committee	Effective: October 1, 2012
Reviewed: October 2017	Revised: October 1, 2017

Description:

The Benchmark Management Plan is a tool to help improve data quality. The Plan is required when any benchmark (Enrollment: 80%, Missing: no variable over 10% missing or unknown, or Follow-up: Year 1 – 90% and each required year – 80%) is not met for two consecutive reporting periods.

Purpose:

This provides a mechanism to identify ways to improve data quality and focus attention on improvement tasks.

Scope:

All SCIMS, follow-up centers and NSCISC.

Responsibilities:

Centers create a Benchmark Management Plan when any benchmark is not met for two consecutive reporting periods. After approval by their NIDILRR Project Officer, the center sends the plan to NSCISC prior to the next data submission and NSCISC attaches the plan to the next Benchmark Report sent to the center PI and NIDILRR.

Procedure:

The plan includes descriptions of the barriers to meeting benchmarks, action items to reduce or overcome barriers, and a timeline of completion or follow-up, as needed (a sample/template is available by request from NSCISC). The plan is submitted to and approved by the center's NIDILRR Project Officer, then the center sends the plan to the NSCISC prior to the next data submission. After a Plan is submitted for a particular benchmark, further Benchmark Plans for that particular benchmark are not required unless the barriers have changed substantially.

History:

October 2012: The first reporting period began.

October 2017: Add text to Procedure to indicate benchmarks are updated when barrier(s) to reaching the benchmarks change substantially.

Policy on Obtaining Date and Cause of Death (Death Certificates)	
Approved by: Data Committee	Effective: October 1, 2011
Reviewed: October 2017	Revised: October 1, 2017

Description:

The collection and submission of death variables (Date of Death Modifier, Date of Death and Causes of Death) are the responsibility of each center. NSCISC assists with the collection of these data by searching the National Death Index (NDI) for cause of death for participants who are deceased with an unknown cause of death. To facilitate the collection of these variables when NDI is not successful, centers maintain an agreement with the state(s) listed in their catchment area to request death certificates.

Purpose:

Maintaining a low missing rate for cause of death reduces the potential for bias.

Scope:

All SCIMS and follow-up centers

Responsibilities:

Centers collect and submit death variables and maintain an agreement with the state(s) listed as their catchment area to request death certificates.

Procedure:

Centers enter death variables to the database when notified of a participant's death or when a search of an online death index at each eligible required follow-up year (1, 5, 10…) indicates a participant's death. Death variables are also submitted on Registry, neuro recovered and withdrawn participants on required years (1, 5, 10…) when allowed by the local IRB. After a participant is identified in the national database as deceased with unknown Cause of Death, NSCISC requests personal identifiers from the center. NSCISC submits these identifiers to NDI in a batch search. NSCISC updates the database with the Causes from NDI. Cause of Death for participants who were not found in the NDI search is further searched for by the center using vital statistic agencies from the state where the death occurred. When death occurs in another systems' catchment area, an agreement may be made to request death certificates through the other systems' agreement with their state, depending on local IRBs.

References:

To obtain a certified copy of certificates, write or go to the vital statistics office in the State or area where the event occurred. To find details for each event in the State or area concerned, go to http://www.cdc.gov/nchs/w2w.htm. Each state has different requirements to request this data.

Policy on On-Site Quality Assurance (OSQA)	
Approved by: Data Committee	Effective: October 1, 2011
Reviewed: October 2017	Revised: October 2017

Description:
Twice a year, Centers perform the following quality assurance activities: 1) re-abstraction and coding a Form I; 2) dual coded Form I or II interviews; 3) data entry checks; and 4) follow-up interview verification.

Purpose:
The On-Site Quality Assurance activities are designed to improve the quality of data used for research and provide in-house training opportunities.

Scope:
All funded SCIMSs and follow-up centers perform the listed activities twice a year. Follow-up centers disregard Form I activities.

Responsibilities:
Data managers and a Project Director, Co-Director or Principal Investigator sign the OSQA Compliance Form to confirm the listed activities were completed as specified. NSCISC sends a Compliance Report to NIDILRR twice a year.

Procedure:
Centers review data collectors' activities (Re-abstraction, Interview, Data Entry Accuracy and Interview Verification) as defined by the protocol. The OSQA Compliance Form is signed by the Project (Co-) Director verifying the activities have been completed as defined by the protocol. The Compliance Form is then submitted to NSCISC by May 1 (April list) and November 1 (October list). For details, see On-site Quality Assurance (found at Data Quality).

History: Developed by NSCISC, approved by Data Committee and initiated January 2011.
December 2013: Moved release dates from January 1 to April 1 and July 1 to October 1. Length of time to complete the activities was reduced from two months to one month. Interview Verification was approved and operational for the October 2014 submission.

October 2017: Due to the longer Form I interview, Form I interviewers will be dual coded. If an interviewer conducts both Form I and II interviews, then only the Form II is dual coded.

Policy on Data Collector Certification – Form I	
Approved by: Data Committee	Effective: December 2013
Reviewed: October 2018	Revised: October 2018

Description:
The Certification Program increases across-center standardization and provides assurances that Form I medical record abstractors and interviewers are knowledgeable and prepared to provide high-quality, reliable data.

Purpose:
The Certification Program is intended to improve data quality by knowledge testing and reiterative training. It will also increase standardization of data collection procedures across centers.

Scope:
All funded SCIMS' data collectors involved with Form I medical record abstractions and interviewers will participate in the Form I Certification.

Responsibilities:
Data collection managers notify NSCISC of new Form I medical record abstractors and interviewers for certification. The data collectors complete (reach 100% accuracy) the Form I Certification using materials provided by NSCISC. NSCISC scores the case studies and provides guidance directly to the data collector to reach 100% accuracy. NSCISC reports the center's completion rate to NIDILRR.

Procedure:
Data collectors identified as being involved with Form I medical record abstractions and/or interviewers are required to code two Form I case studies using materials provided by NSCISC. The data collector completes both case studies within 5 working days using materials sent by NSCISC, tools found on the website, and other materials typically used by the data collector to code Form I data. The completed Form Is are emailed, scanned or faxed to NSCISC for scoring. NSCISC notifies the data collectors of discrepancies and all errors are corrected by the data collector until 100% accuracy is obtained. This is a reiterative training opportunity between NSCISC and the data collector. Case studies are destroyed after completion of certification (attaining 100% accuracy).

Recertifications require answering questions and reviewing new or updated policies that are pertinent to Form I data collection as well as accumulating points that are earned by attending in-person and online trainings.
Completion results are included in the Annual On-Site Quality Assurance Report (OSQA) sent to NIDILRR. Results include the number of data collectors who have passed certification and the number pending certifications.

Compliance:
Each Center reports the number of Form I data collectors who have been certified and the number pending certification on the Annual On-Site Quality Assurance. NSCISC contacts the manager to set up a certification date for the pending data collector. All data collectors are required to successfully complete certification depending on the tasks conducted by the data collector. The OSQA Compliance Report sent to NIDILRR includes the number of Form I abstractors who have completed certification and the number pending certification.

History: Certification Program began February 2014.

October 2017: Add Form I interview to certification.

Policy on Data Collector Certification – Form II Coding	
Approved by: Data Committee	Effective: December 2014
Reviewed: October 2017	Revised:

Description:
The Certification Program increases across-center standardization and provides assurances that Form II interviewers and coders are knowledgeable and prepared to provide high-quality, reliable data.

Purpose:
The Certification Program is intended to improve data quality by knowledge testing and reiterative training as well as improve standardization of data collection procedures across centers.

Scope:
All funded SCIMS' and follow-up site's data collectors involved with Form II interviews will participate in the Form II Certification.

Responsibilities:
Managers notify NSCISC of new hires and schedule certification within 6 months of hire. The data collectors complete (reach 100% accuracy) the Form II Certification using a mock interview provided by NSCISC. NSCISC scores the responses and provides guidance directly to the data collector to reach 100% accuracy. NSCISC reports the center's completion rate to NIDILRR.

Procedure:
Data collectors identified as being involved with Form II interviewing or coding are required to code a mock interview provided by NSCISC. The data collector codes the mock interview within 5 working days of receiving it using materials sent by NSCISC, tools found on the website, and other materials typically used by the data collector to code Form II data. The completed Form II is emailed, scanned or faxed to NSCISC for scoring. NSCISC notifies the data collectors of discrepancies and all errors are corrected by the data collector until 100% accuracy is obtained. This is a reiterative training opportunity between NSCISC and the data collector. The mock interview material is destroyed after completion of certification (attaining 100% accuracy).
Re-certifications require answering questions and reviewing new or updated policies that are pertinent to Form II data collection as well as accumulating points that are earned by attending in-person and online trainings.

Completion results are included in the Annual On-Site Quality Assurance Report (OSQA) sent to NIDILRR. Results include the number of data collectors who passed certification and the number pending certifications.

Compliance:
Each site reports the number of Form II data collectors who have been certified and the number pending certification on the Annual On-Site Quality Assurance. NSCISC contacts the manager to set up a certification date for the pending data collector. All data collectors are required to successfully complete certification depending on the tasks conducted by the data collector. The OSQA Compliance Report sent to NIDILRR includes the number of Form II interviewers and coders who have completed certification and the number pending certification.

References:

History: Form II Certification Program began February 2015.

Policy on Listserv Creation and Use	
Approved by: Executive Committee	Effective Date: June 2017
Reviewed: October 2017	Revised Date:

Description:

A listserv is an email manager service that allows an email to be posted to multiple email addresses using only one email address (the **listserv** forwards the email to all subscribers listed). The listserv service also provides access to a historic repository of list serve emails.

Purpose:

SCIMS list serves provide a channel for efficient communication among NIDILRR and SCIMS members for SCIMS projects and related businesses, including but not limited to the core database, collaborative projects, committees, and special interest groups. The list serves are not designed for promotion or advertisements of commercial products, political or religious comments, job postings, and personal attacks.

Scope:

Members of SCIMS and associated centers, follow-up centers, and Model System Knowledge Translation Center as well as NIDILRR project officers.

Responsibilities:

Leaders of SCIMS groups submit a request to NSCISC to create a list serve. Approval is at the discretion of NSCISC leadership. Each list serve designates a contact person, who is responsible for requesting or notifying NSCISC of changes to the subscriber list (add/delete/modify). The contact person will monitor the content of the postings for appropriate content. Subscribers agree to post appropriate content defined by the list serve contact person. NSCISC reviews continuation of all list serves at the end of each cycle.

Procedure:

To establish a list serve, the leader of the SCIMS group submits a request to the NSCISC, including a short descriptive name of the list serve and a list of subscriber names, affiliations, and email addresses. Approval is at the discretion of SCIMS leadership. NSCISC utilizes the UAB Information Technology services to create the list serve, add the subscribers, and then email the contact person with the list of subscribers from the list serve command.

At each Project Directors meeting, NSCISC provides a current list of all list serve subscribers for attendees to review and update. Subscriber maintenance will be performed by NSCISC after each Project Director meeting and on as needed basis. The most updated lists are posted on the SCIMS Group Documents page.

Policy on Handling Unexpected Events during Interview	
Approved by: Data Committee	Effective Date: December 2017
Reviewed: December 2017	Revised Date:

Description:
The SCIMS strive to ensure a continuity of process to address unexpected events with participants during Form I and Form II interviews, module interviews and communications with participants in general.

Purpose:
To have a procedure in place for data collectors to provide assistance for interview participants, as appropriate, if unexpected events arise during the Form I or Form II interview.

Scope:
SCIMS and follow-up centers collecting data for the National SCI Database.

Responsibilities:
In the process of gathering interview data and communications in general with participants, participants may describe a physical or emotional condition that may have immediate or emergent consequences, such as (but not limited to) comments reflecting a desire for harm of self or others. In such situations, each center determines the appropriate steps that should be taken to guard the health and welfare of the research participant and others, as needed.

Procedure:
Each center must establish a procedure for data collectors to employ to ensure that appropriate assistance is available to the data collector and to the research participant. The specific steps taken may be different from center to center based on the services and staff available.

Training requirements:
Each center is responsible for training data collection personnel regarding the procedure.

Compliance:
During site visits, NSCISC staff will confirm that the procedure exists and that staff have been trained regarding the procedure.

Policy on Resolving Data Collection and Coding Questions	
Approved by: Data Committee	Effective Date: December 2017
Reviewed: December 2017	Revised Date:

Description:
This policy facilitates systematic and timely resolution of data collection and coding questions and will: 1) provide a consistent data collection and coding methodology; 2) utilize a multidisciplinary approach; 3) allow for input from stakeholders; and 4) maintain the highest level of data quality in the National SCI Database (NSCID).

Purpose:
To establish procedures for assuring optimal and timely resolution of data collection and coding questions to maintain the highest level of data quality in the NSCID.

Scope:
Data collection and/or coding questions related to the NSCID proposed by SCIMS or NSCISC staff.

Responsibilities:
The SCIMS Data Collector and/or the NSCISC staff member with the coding question will submit the question to the NSCISC and the following procedural steps will be taken.

Procedure:
1. All questions about data collection or coding will be submitted to the NSCISC via email.

2. SCIMS centers will not "hold" cases with pending questions but will code their problematic variables as "Unknown" and keep track of these cases for updates once the questions are resolved.

3. Within 5 business days of receiving a data collection or coding question, the NSCISC will either answer the question or provide notification to the originator that resolution of the question will require further steps and additional time for a decision.

4. Further steps are required to obtain resolution of a question when either:
    a. NSCISC requires more information on the posed question in order to render a judgment, or
    b. The NSCISC does not have the expertise needed to answer the question, or
    c. Resolving the question involves changes that require further investigation and/or SCIMS approval.

5. In cases where the NSCISC does not have the expertise needed to answer a question:
    a. The question will be forwarded to the appropriate content expert(s) by the NSCISC and/or to the Data Committee Chair and may be added as an item on the agenda for the Data Committee Meeting. The originator of the question will be cc'd as to the status of the question.

    b. The NSCISC will forward the answer to the originator of the question within 5 business days of receiving it from the expert(s) or Data Committee.

    c. Answers requiring revisions to the Data Dictionary or Forms will be reflected at the next update with appropriate training as necessary.

Policy on Implementing Changes to the National SCI Database	
Approved by: Data Committee	Effective Date: December 2017
Reviewed: December 2017	Revised Date:

Description:
This policy describes the process for requesting and implementing core variable changes to the National SCI Database (NSCID). Changes include clarifications to existing variables, variable selection for funding cycles, enrollment criteria, and standard operating procedures.

Purpose:
This policy provides guidance to the NSCISC and SCIMS staff to make changes to variables.

Scope:
All variables in the core dataset are reviewed for relevance and collection feasibility each funding cycle. Formal reviews are conducted by Project Directors (PDs) and their associates once a cycle and selected variables are reviewed at mid-cycle as well. SCIMS staff (data collectors, data managers/coordinators, project directors, etc.) are asked to provide feedback and questions about variables and processes on an on-going basis.

Level I – Procedure for clarifying or adding an example to existing variables:
Clarifications to variable codes and collection procedures are often determined by the NSCISC staff based on historical and longitudinal precedents. If needed, experts both inside and outside of the SCIMS are contacted for feedback. Clarifications are added and distributed as needed.

Level II – Procedure for adding/deleting codes for existing variables:
Changes to variable codes are determined by the NSCISC in conjunction with the SCIMS researcher(s) identified as the expert(s), or brought to the Data Committee for discussion and vote if necessary.

Level III – Procedure for variable selection:
Preparation for the selection of cycle variables is a time intense effort and requires at least 3 PDs meetings for discussion and voting. At the first meeting, workgroups, timelines and rules are established. Workgroups are typically based on variable categories: assistive technology; sociodemographic, injury etiology, function and health services; psychosocial; and medical-neurological. A content expert from the Data Committee volunteers as a workgroup leader and recruits team members to review and investigate the feasibility of collecting the new variable(s), piloting in the SCI population, and utility of the existing and proposed variables in their chosen category.

- SIG Chairs/Module Principle Investigators are encouraged to meet with their groups to propose variable changes to the appropriate workgroup.
- Individual PDs and their staff are encouraged to propose variable changes to the appropriate workgroup.

Workgroup leaders use the 'Proposed Changes to NSCID' template to list existing variables (or set of variables) with recommendations to Keep/Retire/Modify as well as propose new variables along with information necessary to consider the recommendation (see template). The list of variables is sent to NSCISC by each workgroup.

- Changes for procedural criteria other than variable selection, such as enrollment or Standard Operating Procedures, may be submitted in a form that best suits the content.

For variable selection:

- NSCISC compiles all recommendations submitted by the Workgroup leaders and distributes the proposals. PDs, SIGs, committees and other groups review the proposed changes and provide feedback and comments (pros, cons and questions) in writing to the NSCISC 30 days prior to the PD meeting.
- At the PD meeting, each group presents the initial proposal recommendations and may schedule a group meeting to resolve duplicative or conflicting suggestions.
- The committees and workgroups have 3 months to refine the proposal: continue gathering evidence, respond to critiques from PDs and pilot data as appropriate. The refined proposal, with responses to critiques, is sent to NSCISC 3 months prior to the next PD meeting.
- NSCISC compiles the refined proposals from the workgroups and distributes via PD list serve for review. NSCISC also creates a web page to house materials needed for review/decisions. A straw poll is conducted electronically with each center indicating support, opposition, or uncertainty on each proposed variable change. Straw poll responses are due to NSCISC within 3 weeks.
- The results and comments from the poll are compiled by NSCISC and distributed to PD list serve at least 1 month prior to PD meeting so that proponents have an opportunity to prepare responses to concerns raised during the PD meeting.
- At the PD meeting, before the first round of votes are taken, all groups and proponents have an opportunity to restate their rationale and respond to concerns about each variable or set of variables. Approval of each variable (or set of variables) requires a super majority (at least 10 votes out of 14).
    - Variables with no decision will be discussed and voted at the next PD meeting.
- For variables with no decision, workgroups will have 3 months to finalize evidence, respond to critiques from PDs, and complete analysis of the pilot data. The final proposal of the outstanding variables, with responses to critiques and results of final evidence review, is sent to NSCISC 3 months prior to the next PD meeting.
- NSCISC compiles the final responses from the workgroups and distributes via PD list serve for review.
- At the PD meeting, before the votes are taken, workgroups and proponents have an opportunity to restate their rationale and respond to concerns about each variable or set of variables. After voting, NSCISC recaps the votes for all variables.

Template to Propose Changes to Variables for a New Cycle

Last update: December 2017

When preparing a proposal to change core variables, consider variables that are needed to examine trends over time, or that relate to key outcomes and meet the goals of the SCIMS database. If the variable does not meet the criteria, consider including the variable as part of a module.

In proposing new variables or time points for existing variables:

- Pay attention to data collection burden. While we agree that there is no need for variables to be deleted for each one proposed to be included, the core database must be kept manageable.
- Look for areas of conceptual overlap (consider whether it is necessary to retain an old Quality of Life-related measure if a new one is being added, for example)
- Prioritize variables to be included in the database to keep the database at a manageable size.

Lastly, pay attention to opportunities to enhance data collection by change in other aspects of the database – e.g. inclusion-exclusion criteria, policies for accessing data, order of the questions to be asked, etc. The forms may not easily accommodate those proposed changes so please communicate those changes in a separate document.

Additional comments from the Project Directors and SCIMS researchers will be added as the variables are discussed (pros and cons as well as a rebuttal from the workgroup).

Proposed Changes to NSCID: Fill out the following table for each new variable or measure proposed:

Variable Name(s) & Interview Question(s)	
Action Taken: Modify/Delete/Add	
Rationale/ Proposed Hypothesis	
Burden of Data Collection (time, etc.)	
Data Issues, Source, Used in other datasets?	
Analysis of Pilot Data: Use, reliability, validity, etc.	

Guidelines for the Project Director's Meeting

Approved by: Executive Committee	Effective: December 2011
Reviewed: October 2017	Revised: April 2017

Project Director Meetings are convened every 6 months to provide a platform for Model System leaders to discuss proposed, on-going and completed projects concerning the model systems. These guidelines are designed to facilitate sharing of information.

1. NSCISC maintains all SCIMS SOPs.
2. The center assigned to taking the minutes will bring an LCD projector and laptop.
3. Each center may bring up to 3 representatives to the SCIMS PD meeting. PDs should check with the NIDILRR-SCIMS Program Officer, Theresa SanAgustin, if they wish to bring more than 3 attendees.
4. The first draft of minutes is due to the Co-chairs (Allen Heinemann and Mike Boninger) and NIDILRR Program Officer (Theresa SanAgustin) within one month after the PD meeting.
5. The Chair will email minutes to SCIMS Listserv for review, corrections/revisions
6. PDs will provide corrections within 4 weeks after Co-chairs' review.
7. Minutes will be finalized by the 3rd month after PD meetings.
8. NIDILRR and Co-Chairs will begin agenda planning 3 months before each PD meeting.
9. Meeting Manager, Yuying Chen, will email hotel information for room reservation 3 months before PD meetings.
10. The SCIMS Chair and NIDILRR Program officer will email a draft of the SCIMS PD agenda to SCIMS list serves to solicit agenda items.
11. The SCIM PD agenda will be finalized one month before SCIMS PD meetings.
12. Committee and SIG Minutes: Presenters and Committee and SIG chairs will provide a summary of the presentation or topics discussed to the minute taker.
13. Presenters who wish to post PowerPoint presentations to the NSCISC website (in SCIMS Group Documents), will send the file to NSCISC with a request to post the documents.

NIDILRR and SCIMS members may recommend guest speakers to present at the PD meetings. Guest presentations serve the purposes of increasing collaboration with organizations external to the SCIMS, promoting the synergy with other disability research initiatives, and keeping up with national priorities. SCIMS requests the content of the presentations to be scientific and informational, but not for promotion of commercial products. The invitation does not necessarily imply NIDILRR's or SCIMS' endorsement of the presented work or projects. Guest speakers are invited for the presentations, but not invited to attend the meeting. Approval of the speakers and topics will be granted by the Executive Committee. Scheduling of the presentation will be organized cooperatively by the recommender and the Executive Committee Chair.

Guidelines for the Executive Committee	
Approved by: Executive Committee	Effective: February 2017
Reviewed: October 2017	Revised:

1. Purpose: The Executive committee serves several purposes:

    a. Develops agendas for SCIMS project directors' meetings
    b. Solicits nominations for visitors to present information related to SCI rehabilitation
    c. Coordinates feedback to NIDILRR from SCIMS project directors
    d. Plans 5-year cycle products such as special issues of journals, state-of-the-science meetings, or preconference courses with SCI organization such as ASIA and ISCOS.

2. Membership: The Executive Committee is composed of the lead SCIMS NIDILRR project officer, chair of the Data Committee, chair of the Knowledge Translation Committee, a representative from the MSKTC, and a chair and co-chair selected from among the SCIMS project directors.

3. Meetings: The Executive Committee will meet in-person during the meetings of the SCIMS Project Directors. Between meetings, communication among committee members will be facilitated through conference calls and e-mails.

4. Minutes: Minutes from in-person and telephone meetings before will be taken by an assigned member and reviewed by the Executive Committee Chair and SCIMS NIDILRR project officer before distribution. Committee minutes will be presented and distributed via the SCIMS EC list serve.

Guidelines for the Knowledge Translation Committee	
Approved by: Knowledge Translation Committee	Effective: December 2011
Reviewed: October 2017	Revised:

1. Membership: The SCIMS KT Committee encourages representation of all SCIMS grantees. Members will serve as active conduits between their individual programs and the KT Committee.

2. Meetings: The SCIMS KT Committee meets in person during PD meetings. Between meetings, members communicate through conference calls and e-mails.

3. Minutes: Records of in person meetings will be taken by the KT Committee Chair. Committee minutes will be shared during PD meetings, entered into the PD meeting minutes, and distributed to the KT Committee list serve.

4. Purpose: The KT Committee serves as a conduit for educational ideas and products among SCIMS grantees and between NIDILRR and grantees. The KT Committee will facilitate projects, manage them to completion, and notify NIDILRR and SCIMS PD when they are complete.

5. Interface with MSKTC: The KT Committee serves as the primary interface between the SCIMS PDs and the MSKTC. The Chair of the KT Committee will sit on the advisory board of the MSKTC. Through the KT Committee members, the work of the MSKTC will be supported by the SCIMS group in its entirety.

Guidelines for the Data Committee	
Approved by: Data Committee	Effective Date: December 2011
Reviewed: October 2017	Revised Date: October 2018

1. Purpose: The data committee serves several purposes:
    a. To assist with decision making on issues arising with the national database. Issues will be raised by the Data Center and brought to the data committee for discussion/recommendation and possible vote by the Project Directors.
    b. To provide recommendations for change or modification in variables for the national database (mid and end cycle changes).
    c. To provide oversight and discussion related to goal setting for enrollment and follow up including benchmarks and methods for maintaining high quality data collection.
    d. To review and provide feedback on existing policies and standard operating procedures. A working group reviews new policies and standard operating procedures.

2. Membership: Each SCIMS center will have at least one representative as a member of the Data Committee. If a data committee member is not able to attend a Data Committee meeting, they will identify a substitute from their site to attend the meeting.

3. Meetings: The Data Committee will meet in-person during the meetings of the SCIMS Project Directors. Committee members will communicate between meetings through conference calls and e-mails.

4. Minutes: Minutes of in-person and telephone meetings will be taken by an assigned member and reviewed by the Data Committee Chair and PI of the Data Center before distribution. Committee minutes will be distributed via the SCIMS PD and Data Committee list serve.

Special Interest Group Mission Statement: Aging	
Approved by: Aging Special Interest Group	Effective: December 2011
Reviewed: October 2017	Revised: November 2016

1) Purpose: The Aging SIG facilitates an increase in knowledge regarding the effects of aging and long-term disability on the health and participation of individuals with SCI by:
   a) summarizing current knowledge and its dissemination via publications and presentations at conferences;
   b) advocating for increased research investments in this area;
   c) conducting rigorous research aimed at advancing knowledge of aging with SCI and strengthening the evidence base to improve rehabilitation practice and inform policy.

2) Membership: Each SCIMS center may have representatives on the Aging SIG.

3) Meetings: The Aging SIG will meet in-person during the meetings of the SCIMS Project Directors. SIG members will communicate between meetings through conference calls and e-mails.

4) Minutes: Minutes of in-person and telephone meetings will be taken by an assigned member and reviewed by the SIG Chair before distribution. SIG Committee minutes will be distributed via the SCIMS PD and SIG list serve.

Special Interest Group Mission Statement: Function Enhancement	
Approved by: Function Enhancement Special Interest Group	Effective: October 2017
Reviewed: December 2017	

1. Mission Statement: The mission of the Functional Enhancement SIG is to provide a forum for SCIMS members to collaborate and share information on knowledge related to enhancing function of persons with spinal cord injury. This will be accomplished by:
    a. summarizing current knowledge and disseminating via publications and presentations;
    b. reviewing and proposing modifications to the national database to foster new knowledge in this area;
    c. discussing current research and opportunities for collaboration on research to improve function in persons with SCI.

2. Membership: Membership is open to representatives of currently funded SCI Model System Centers.

3. Meetings: In-person meetings will be held in conjunction with regularly scheduled meetings of the Project Directors. As the need arises, ad hoc meetings will be held via conference call or video conferencing.

4. Minutes: Minutes of in-person and ad hoc meetings will be taken by an assigned member and reviewed by the SIG Chair before distribution. SIG Committee minutes will be distributed via the SCIMS SIG list serve, SCIMS_SIG_FUNCTION@LISTSERV.UAB.EDU

Special Interest Group Mission Statement: Pain	
Approved by: Pain Special Interest Group	Effective Date: October 2017
Reviewed: December 2017	Revised Date:

1. Purpose: The Pain SIG gathers those within the SCI Model Systems who have an interest in furthering research, clinical, and educational efforts regarding pain in individuals with SCI. Collaboration among members of the Pain SIG is intended to foster activities and products such as
    a. publications (e.g., review articles, guidelines);
    b. presentation/workshops at local, national, or international meetings;
    c. multi-site grant submissions; and
    d. other activities as proposed by its membership.

2. Membership: Interested persons at any of the SCIMS centers may join the Pain SIG.

3. Meetings: The Pain SIG will meet in-person during the SCIMS Project Directors' meeting, and via email or phone conference in between meetings as necessary.

4. Minutes: Minutes of in-person and telephone meetings will be taken by an assigned member and reviewed by the SIG Chair before distribution. SIG Committee minutes will be distributed via the SCIMS PD and SIG list serve.

Special Interest Group Mission Statement: Women's Health	
Approved by: Women's Health Special Interest Group	Effective: October 2017
Reviewed: December 2017	Revised Date:

1. Purpose: The mission of the Women's Health SIG is to raise awareness of the physical and psychological health of women with SCI, facilitate collaborative research, and apply knowledge to improve health and quality of life for women with SCI.

   The Women's Health SIG seeks to:

   A. Fully engage the SCIMS in expanding the knowledge base on women with SCI by making the examination of gender differences a system-wide priority.

   B. Promote research to understand the physical and psychological health of women following spinal cord injury.

   C. Initiate collaborations with other groups in these efforts, including the ACRM SCI-ISIG on Women's Health and the BI SIG on Women and Girls with ABI.

2. Membership: Each SCIMS center may have representatives on the Women's Health SIG.

3. Meetings: The Women's Health SIG will meet in-person during the meetings of the SCIMS Project Directors. SIG members will communicate between meetings through conference calls and e-mails

4. Minutes: Minutes of in-person and telephone meetings will be taken by an assigned member and reviewed by the SIG Chair before distribution. SIG Committee minutes will be distributed via the SCIMS PD and SIG list serve.

Guidelines on AdHoc Committee for Peer Review of SCIMS Collaborative Module Projects	
Approved by: Project Directors	Effective: December 2011
Reviewed: October 2017	Revised:

Description:

Module projects developed post-award do not receive external peer review, and therefore the proposers do not have the benefit of a critique by an outsider who has no vested interest in the project. The following peer review procedures establish an "AdHoc" Committee to fill that gap by providing an expert peer review from within the SCIMS, supplemented as needed by outside experts. This committee will meet before the next Project Directors' meeting (February 6-7, 2012), for the purpose of providing a peer review of the module projects that were selected for implementation. Committee meetings will take place via teleconference.

Purpose:

To describe the process for peer review of new module research projects for the 2011-2016 SCIMS funding cycle.

1. A proposal for a multi-center collaborative module project emerges from collaborators in at least 3 centers.
2. The idea for the project is sent in draft form via email, with the expectation that every effort will be made to incorporate the input and ideas of all centers expressing an interest in collaboration. The NIDILRR Project Officer for each of the participating sites must approve the site's participation in the module.
3. The proposal is written using the Module Project Template for Peer Review (attached) and submitted to the Chair of AdHoc Committee.
4. The Chair of the AdHoc Committee assigns a member of the AdHoc Committee to form a Peer Review Panel for each proposed module. Each panel consists of three reviewers with expertise in the proposal's topic areas and/or research methodology/statistics. These reviewers should not have contributed to the proposal. The reviewers should be members of the AdHoc Committee. If insufficient expertise is available within the SCIMS, outside experts may be obtained. The assigned AdHoc Committee member will serve as Panel Chair, but need not be one of the reviewers.
5. Coordinated by the Panel Chair, panel members independently review the proposal and complete the Review Form (attached). As per the Review Form, they rate each section on a 4-point scale, and give the overall proposal a global rating of 1 to 4, weighing the components as they see fit.

6. Panel Reviews must be returned to the Panel Chair within 15 business days (3 weeks) of receipt. A 30 minute teleconference is pre-scheduled for the Review Panel for the week following this deadline.

7. The Panel Chair distributes the reviews to all panel members prior to the teleconference. The teleconference is used to (a) resolve any major discrepancies between reviewers, (b) highlight the most important needs for revisions, if any, and (c) assign a final global score representing the consensus of the panel.

8. The Panel Chair forwards the reviews, with scores and suggested revisions to the AdHoc Chair, the NIDILRR SCIMS Program Manager and the NIDILRR Project Officers of the proposing Centers.

9. The Panel Chair meets by telephone with the PI/Lead Center to answer questions on the review, and supply additional detail. Other Review Panel members may join this discussion.

10. The entire process from submission of a proposal to the AdHoc Chair to receipt of a written review by proposer(s) should take no longer than 2 months.

11. A global score of 3 or 4 indicates that the project may move forward. The proposal, the reviews with any recommendations for change, and the scores will be forwarded to the members who collaborated on the proposal, the NIDILRR SCIMS Project Manager, and the NIDILRR Project Officers of the Lead Centers, with an indication that the project may proceed. A notification of the approved project will also be sent to the PD list server, so that all centers may be informed of the new module projects.

12. A score of 1 or 2 reflects a judgment by the panel that the project as proposed should not go forward. The originators of the proposal may revise and resubmit the proposal to the review panel once. If the score does not exceed 2 on the second try, the review process ends for that project. However, an appeal may be made to the AdHoc Committee by the Lead Center, if the decision is perceived as inaccurate or unfair. The AdHoc Committee will convene via teleconference call as needed and consider appeals on a case by case basis.

13. Once a project has been recommended and officially approved by NIDILRR, the Project Officer of the module will be the project officer of the Lead Center.

SCIMS Module Proposal Instructions (2011)

Module leaders create a document for the proposed module project with each of the categories below. The length of the completed form should be 3-5 pages (single spaced). It is not necessary to include formatted references. Please note that this is a minimum length. If you have a longer proposal written for another purpose, e.g. IRB submission, information from it may be included without editing.

Title of project:

PI and lead center:

Collaborators and their centers:

Period during which proposed project will collect data:

Start date:

End date:

Date this form is submitted to lead reviewer:

Background and Significance (knowledge gaps the research is intended to fill; innovative aspects of the research plan):

Research Plan (overview of research design, independent and dependent variables, specific aims, hypotheses, research questions, etc):

Methods (participants: inclusion/ exclusion and anticipated number [power calculations]; procedure and instruments to be used in data collection [attach data collection forms if available]):

Data Analysis Plan (statistical or other analytical methods to be used):

Anticipated Outcome(s):

SCIMS Peer Review Form

Peer reviewers create a document that details the proposal that is to be submitted. Then submit document to the Panel Chair.

Title of project:

PI to whom feedback will be given:

Panel chair:

Reviewer:

Date of review:
Please rate on a scale from 1(poor) - 4(excellent), and provide comments on each of the following sections. Finally submit a global score with the same scale with 1-2 indicating that the proposal should not move forward, and 3-4 indicating approval of the proposal.

Background and Significance (knowledge gaps the research is intended to fill; innovative aspects of the research plan):

Research Plan **(overview of experimental design, independent and dependent variables, specific aims, hypotheses):**

Methods (participants: inclusion/ exclusion and anticipated number [power calculations]; procedure and instruments to be used in data collection [attach data collection forms if available]):

Data Analysis Plan (statistical methods to be used):

Anticipated Outcome(s):

Background & Significance	1 2 3 4
Research Plan	1 2 3 4
Methods	1 2 3 4
Data Analysis Plan	1 2 3 4
Anticipated Outcomes	1 2 3 4
Global Rating	1 2 3 4

SCIMS Peer Reviewer's Form

Comments for investigators:

Circle: **Approved**

Approved with revisions

_____

_____

_____

Disapproved

References: **SCIMS Module Project Peer Review Procedures**, adapted from TBIMS Standard Operating Procedure (700g) – downloaded from TBI NDSC website.

Policy on Branding and Authorship of manuscripts Using Data from the National SCI Database and Module Study	
Approved by: Executive Committee	Effective: June 2018
Reviewed: June 2018	Revised:

Description:

This policy provides guidance for the branding and authorship of public-use manuscripts that partially or wholly use data from the National SCI Database or SCIMS module studies. SCIMS module studies include collaborative studies as well as archived and ongoing module studies. Public-use manuscripts include scientific abstracts, articles, presentations and other similar products.

Purpose:

The purpose of this policy is to provide branding standards for manuscripts and assigning authorship on manuscripts that use data from the National SCI Database and SCIMS module data.

Scope:

This policy pertains to manuscripts from SCIMS-affiliated entities which include staff, students and other related personnel involved in the NIDILRR-funded SCIMS and follow-up centers that use data to create manuscripts from the National SCI Database.

For non-SCIMS-affiliated entities, publications must acknowledge the NIDILRR and include a disclaimer (see 1.c below) and also follow the International Committee of Medical Journal Editors (ICMJE) guidelines for authorship.

Responsibilities:

All persons identified in the 'Scope' statement will abide by this policy.

Procedure:

1. SCIMS Branding:
    a. Branding of a study with the SCIMS name is required if the data used are from the National SCI Database or from a SCIMS module.
    b. Method of branding: The words "Spinal Cord Injury Model Systems (SCIMS)" should appear somewhere in the title or abstract to make it easier for literature searches to identify SCIMS work.
    c. The following acknowledgement should be included:
    "The contents of this (insert type of publication; e.g., book, report, film) were developed under a grant from the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR grant number 90XXXXXX). NIDILRR is a Center within the Administration for Community Living (ACL), Department of Health and Human Services (HHS). The contents of this (insert type of publication; e.g., book, report, film) do not necessarily represent the policy of NIDILRR, ACL, HHS, and you should not assume endorsement by the Federal Government.
    d. Use of branding may be waived if the journal to which the manuscript is being submitted does not allow it.
    e. Authors of a study using only local data that was funded by their local SCIMS grant may use the SCIMS branding if desired, but are not required to do so.

2. Authorship for the manuscripts using data from the National SCI Database or SCIMS module studies should follow the ICMJE authorship guidelines.

References*: International Committee of Medical Journal Editors* (http://www.icmje.org/)

Policy to Obtain National Database – Current Affiliation to SCIMS	
Approved by: NSCISC	Effective: July 1996
Reviewed: October 2017	Revised: April 14, 2003

Description:

This policy is followed when a lead investigator of affiliated entities requests a limited dataset (without personal identifiers) from NSCISC, the request follows the guidelines set below. Note: This policy is subject to change. See Appendix for form agreement.

Purpose:

The purpose of this policy is to secure an agreement for a limited dataset from the SCIMS National Dataset for research and management purposes.

Scope:

This policy pertains to currently funded and follow-up centers that participate in data collection.

Responsibilities:

A Data Use Agreement must be signed by lead investigator prior to data transfer. See Appendix A.

Procedure:

1. Requests must be submitted to the NSCISC in writing using the Data Access Request form and signed by the SCIMS Project Director. The NSCISC notifies the SCIMS group of the request and invite comments and collaboration.
2. The Model Systems' Data Dictionary is provided with the data files to assure the correct version of the Data Dictionary is used with that copy of the database as needed.
3. During their July 1996 meeting the Project Directors approved a policy that prohibits analyses that compare any or all systems (other than one's own system data against the aggregate). Also, any results that compare a system against the aggregate for marketing purposes are prohibited.
4. Beginning on April 14, 2003, the requestor must sign a data use agreement with the NSCISC prior to receiving the data as required under HIPAA guidelines for the release of limited data sets for research purposes.
5. Although the NSCISC staff will provide some assistance with analyses upon request, the system must also have the services of a statistician or data analyst to utilize the database.
6. Systems are requested to inform the NSCISC of their research topic and share the results of database analyses with the Model Systems' group. All publications must acknowledge NIDILRR funding.
7. The NSCISC's fee for this service is contingent on the complexity of the request. An estimate will be provided, upon request, based on the provision of all details from the requestor.

Policy to Obtain National Database – No Affiliation to SCIMS	
Approved by: NSCISC	Effective Date:
	Revised Date:

Description:

This policy is followed when a lead investigator of non-affiliated entities requests a limited dataset (without personal and SCIMS center identifiers) from NSCISC; the request follows the guidelines set below. Note: This policy is subject to change. See Appendix for form agreement.

Purpose:

The purpose of this policy is to secure an agreement for a limited dataset from the SCIMS National Dataset for research.

Scope:

This policy pertains to non-affiliated entities.

Responsibilities:

A Data Use Agreement must be signed by lead investigator prior to data transfer. See Appendix A.

Procedure:

1. Requestor should provide a proposal that includes:
   a. Study purpose and brief methodology
   b. Data required
   c. Commercial use and relationship if any
   d. Confidentiality precautions
   e. Responsible party
   f. IRB clearance (before the release of data)
2. Requestor must purchase a copy of the data dictionary (containing descriptions of all variables) or download this document from the NSCISC web site prior to formulating the proposal and sending the request for data.
3. Graduate students must have their proposal approved by either their department Chair or the Chair of their dissertation or thesis committee.
4. The proposal will be first reviewed by NSCISC and Executive Committee. Requestor must appropriately address the concerns raised by the initial review.
5. The final proposal will be then forwarded by the NSCISC to the Project Directors and NIDILRR Project Officer for review and approval.
6. The decision on data release will be based on a vote of the majority of Project Directors.
7. The Model Systems may at their discretion appoint a mentor to advise the research team as needed.

8. The requestor must return a signed Data Use Agreement to the NSCISC (limiting the requestor to the terms of the original proposal) and to comply with HIPAA guidelines for the release of limited data sets.
9. Personal data (name, social security number, date of birth, address, geocodes, etc) and SCIMS centers' identities will not be released.
10. Data up to 5 years prior to the request date will be available. However, this requirement may be waived on a case by case basis by a majority vote of the Project Directors.
11. A copy of the requestor's manuscript must be sent to the NSCISC for review prior to submission for possible publication, and a copy of any actual publication must be sent to the NSCISC.
12. All publications must acknowledge the NIDILRR and include the disclaimer that the opinions expressed are those of the authors and not necessarily those of the NSCISC, Model Systems, or NIDILRR.
13. The NSCISC's fee for this service is contingent on the complexity of the request. An estimate will be provided, upon request, based on the provision of all details from the requestor.

Data Release Pathways

Internal Pathway

Project Director submits Proposal to NSCISC

↓

Data is released to Director who signs the Data Use Agreement and maintains responsibility for confidentiality

External Pathway

All requests are forwarded to NSCISC

↓

Requestors should purchase or download Data Dictionary

↓

Requests should reflect:

1. Purpose
2. Commercial use & relationship if any
3. Confidentiality precautions
4. Responsible party
5. Data required
6. Scientific proposals should include IRB status

↓

NSCISC/Executive Committee reviews proposal and helps requestors refine proposal

↓

Proposals are then circulated to project directors and NIDILRR project officer with ballot by email, or else are held to general biannual meeting.

The decision will be based on a vote of the majority by project directors

↓

Data up to 5 years prior to requesting data (may be waived by a majority vote)

↓

IRB clearance and signed Data Use Agreement are required before data release

↓

Manuscripts reviewed by NSCISC and Executive Committee prior to submission for publication

Policy to Obtain National Database with Geocode Identifiers – Current Affiliation with SCIMS	
Approved by: NSCISC	Effective Date: October 2017
Reviewed: December 2017	Revised Date:

Description:

This policy is followed when an investigator of affiliated entities requests a limited data set containing geographic information from NSCISC. The request follows the guidelines set below. Note: This policy is subject to change.

A limited dataset is defined by the National Institute of Health as "health information that excludes certain, listed direct identifiers (see below) but that may include city; state; ZIP Code; elements of date; and other numbers, characteristics, or codes not listed as direct identifiers. The direct identifiers listed in the Privacy Rule's limited data set provisions apply both to information about the individual and to information about the individual's relatives, employers, or household members. The following identifiers must be removed from health information if the data are to qualify as a limited data set: Names; Postal address information, other than town or city, state, and ZIP Code; telephone and fax numbers; email addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; web universal resource locators (URLs); internet protocol (IP) address numbers; biometric identifiers, including fingerprints and voiceprints; full-face photographic images and any comparable images.

The geographic identifiers for the limited data set include the state and county Federal Information Processing (FIPS) codes and zip codes (USPS) for participants enrolled and/or interviewed after October 2011. The geographic identifiers reference the residential address provided by the participant at discharge from inpatient rehabilitation (Form I) and the residential address provided at the follow-up interview (Form II).

Purpose:

The purpose of this policy is to secure an agreement for use of the geographic identifiers collected for the SCIMS database for research activities between the NSCISC and affiliated entities. The main objectives of this policy are to ensure the data security of sensitive information and quality control of related research activities.

Scope:

This policy pertains to currently affiliated and previously funded SCIMS centers currently active in data collection.

Responsibilities:

The responsibilities of the lead investigator requesting these data include providing an application consisting of a research plan, description of the study team accessing the data, a sensitive data protection plan including a description of the secure computing environment, Human Subjects approval, and project timeline including the project termination data after which time all sensitive data will be deleted. Following preliminary approval by the NSCIC, Geographic Data Use Panel (GDUP) and Project Directors, the lead investigator must sign a data use and confidentiality agreement. This agreement will be reviewed for renewal on an annual basis by the GDUP along with the current IRB approval from the lead investigator's institution.

Procedure:

1. Requests must be submitted to the NSCISC in writing and signed by the SCIMS Project Director at the requesting site. Requests must include the following materials:
    a. A brief (1-3 pages) research plan that includes the project title, synopsis, research goals, activities, and analytic plan involving use of the geographic identifiers. The plan should include what level of geographic information (e.g., specific variables) will be required to attain the project goals and what other sources of information (e.g., Census, GIS data) will be linked with SCIMS data for the project.
    b. A description of the study team, defined as anyone who will have access to the geographic identifiers. These details must include Name, Role on Project, Contact Information (Complete business street address, Email, Telephone). In addition, describe lead investigator's affiliation with SCIMS, experience with the use of geocoded data, and research funding (if other than SCIMS).
    c. A data security plan describing the on-site procedures for management, analysis, and storage of the geographic identifiers. The plan must include information such as the computing environment (i.e., network security such as firewalls, encryption, anti-virus, and password protection), and how access to these restricted data will be managed and limited. The geographic identifiers may not be stored on a personal laptop or external hard drive at any time.
    d. Human Subjects approval from the affiliated entity's local institutional review board (IRB).
    e. The lead investigator will submit a project timeline that includes a projected end date after which time the sensitive data will be deleted following HIPAA guidelines.
2. The NSCISC will review the requested materials internally and notify the
3. The Geographic Data Use Panel will review the application for compliance with the application requirements listed above and make recommendations to the researcher if necessary. The panel guidelines include:
    a. The panel will consist of 3-5 members, ideally with large database analytic experience.
    b. Panel members may either be nominated by the Project Directors or may be volunteers from among the investigative teams at the affiliated SCIMS centers.
    c. Panel members will serve for the duration of the SCIMS grant cycle
4. Following the review by the NSCISC Geographic Data Use Panel, the NSCISC will notify the SCIMS group of the request and invite comments and collaboration.
5. Following preliminary approval by the NSCISC, GDUP and Project Directors, a Data Use and Confidentiality Agreement must be signed by the lead investigator and the originating SCIMS Project Director prior to data transfer. See Appendix A.
6. The NSCISC will log all forms and IRB communication.

Procedure (continued):

7. The NSCISC will notify the lead researcher of final approval. The sensitive data will be transmitted to the lead researcher using a secure FTP site.
8. Post application, the lead researcher is responsible for merging the geographic identifiers and the SCIMS data. The lead researcher and his/her associates are responsible for the acquisition of geographic data and all analyses using the geographic identifiers.
9. Post application, the NSCIS will review the project progress and compliance.
10. Post application, the lead researcher will notify the NSCISC of the need to renew or terminate the Data Use Agreement as appropriate.
11. During their July 1996 meeting the Project Directors approved a policy that prohibits analyses that compare any or all systems (other than one's own system data against the aggregate). Also, any results that compare a system against the aggregate for marketing purposes are prohibited.
12. Systems are requested to inform the NSCISC of their research topic and share the results of database analyses with the Model Systems' group. All publications must acknowledge the SCIMS Model Systems federal funding agency (NIDILRR).
13. The NSCISC's fee for this service is contingent on the complexity of the request. An estimate will be provided, upon request, based on the provision of all details from the requestor.

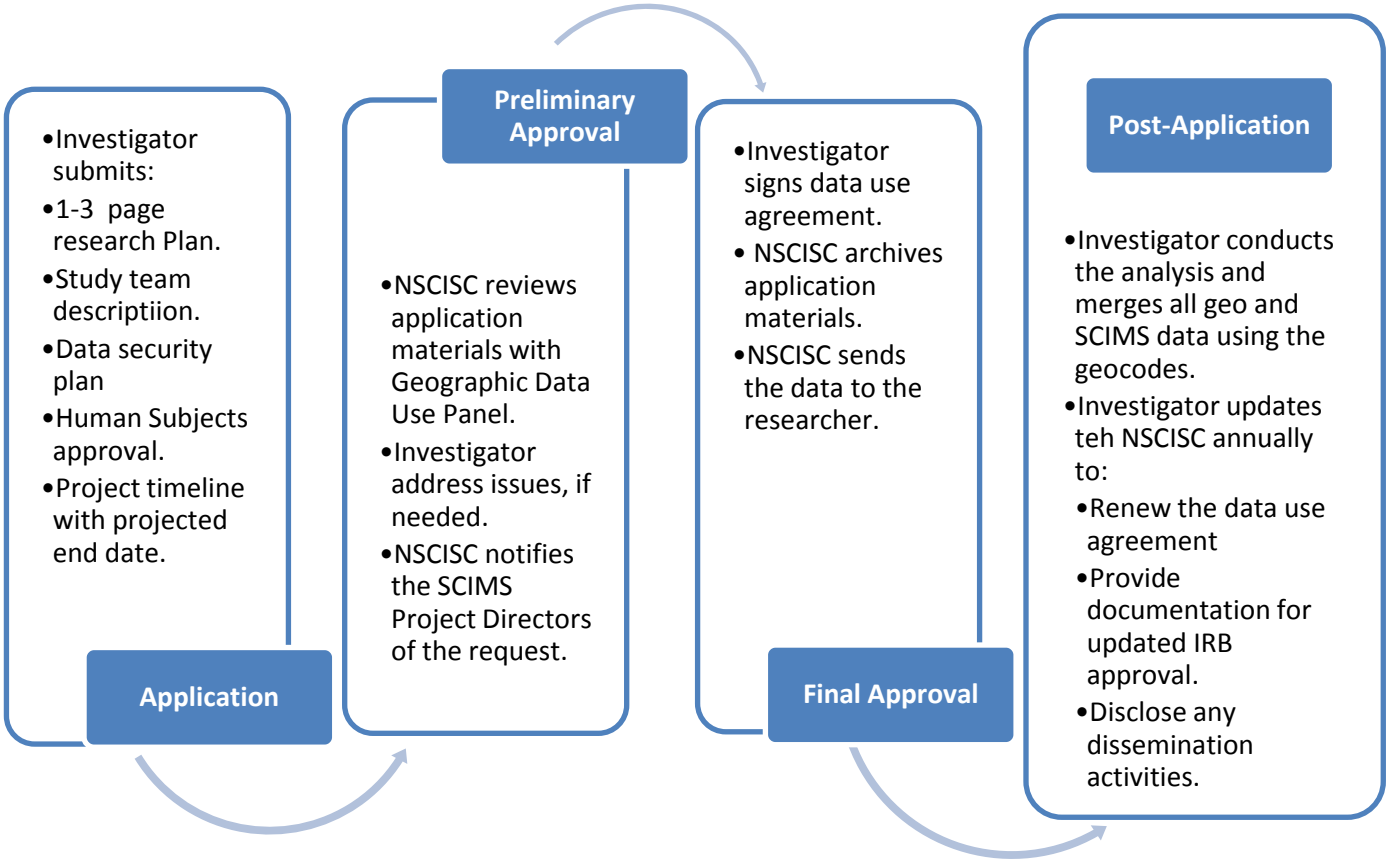
Training Requirements:

Compliance:

References: National Institute of Health (HIPAA Privacy Rule, http://privacyruleandresearch.nih.gov/pr_08.asp#8d)

History:

Figure 1. Flowchart of responsibilities for geocode identifiers for use with the SCIMS database



CONFIDENTIALITY AGREEMENT – Affiliated

This agreement, dated the day of (month, year), is between The Board of Trustees of the University of Alabama, on behalf of the National Spinal Cord Injury Statistical Center (NSCISC) at the University of Alabama at Birmingham (UAB), 515 Spain Rehabilitation Center, Birmingham, Alabama, 35294, and (name and affiliation), who is referred to hereafter as the investigator.

The NSCISC Database contains longitudinal information on patients treated since 1973 at federally-designated model spinal cord injury systems of care throughout the United States. All existing information in the database has been sent to the NSCISC in accordance with the guidelines established by both the Institutional Review Board (IRB) of the model system sending the information and the UAB IRB. This agreement outlines the procedures and circumstances under which the NSCISC may release raw data from the NSCISC Database to investigators for the purpose of conducting approved research projects.

1. **Approval Process.** Investigators who are affiliated with a model system that is currently funded by the National Institute on Disability and Rehabilitation Research (NIDRR) or subcontracted by the NSCISC may request release of raw data from the NSCISC Database to conduct a specific research project at any time.

2. **Transfer of Data.** Upon or after the execution of this agreement and subject to the terms and conditions hereof, the NSCISC shall provide or cause to be provided to the investigator, in such format as the parties shall agree, certain raw data from the NSCISC Database. Prior to release of any raw data, the NSCISC will take all steps necessary to ensure that the released raw data qualify as either "de-identified data" or a "limited data set" in accordance with current Health Insurance Portability and Accountability Act (HIPAA) guidelines. For purposes of release of a "Limited Data Set," this Confidentiality Agreement constitutes a Data Use Agreement as required by the HIPAA regulations.

3. **Use of Data from the NSCISC Database; Limitations.** The investigator understands, acknowledges, and agrees that raw data from the NSCISC Database is being provided by the NSCISC for the sole and exclusive purpose of facilitating the approved research project and that neither the investigator nor any of his/her collaborators, assistants, or other persons under his/her supervision (collectively, the "agents") shall be entitled to use the raw data from the NSCISC Database other than for the purpose of performing the statistical and other analyses relevant to the research. The investigator further agrees that all raw data from the NSCISC Database provided hereunder shall be stored in a way that provides access only to authorized personnel. This would include either storage on a single computer that is not connected to any computer network and is designated by the investigator for use in connection with the research, or storage on a file server located behind a firewall that limits access to the raw data from the NSCISC Database to authorized personnel. The investigator also agrees that the raw data from the NSCISC Database shall be stored in a password-protected

directory; that only the investigator and his/her authorized agents shall have access to the raw data; and that each agent authorized to have access to the raw data shall be bound by this agreement.

Except as specifically set forth in the preceding paragraph, neither the investigator nor any of his/her agents shall, at any time, without prior written consent of the NSCISC, (a) market, use (other than in connection with the research) or otherwise profit from any raw data derived from the NSCISC Database, (b) reproduce or otherwise copy any of the raw data from the NSCISC Database other than as required in connection with the performance of the research or for computer backup purposes, (c) license or offer to license any corporation, government body, individual, partnership, association, or other entity to use any raw data from NSCISC Database, except to the extent expressly provided herein, or (d) authorize any agent or other person to do anything described in subsections (a) through (c) above.

The raw data from the NSCISC Database and all computer floppy diskettes, tapes, records, documents, and other tangible items furnished to the investigators by the NSCISC relating thereto shall remain the exclusive property of the NSCISC and the model system project directors, and shall be returned to the NSCISC immediately upon the earliest of (a) demand by the NSCISC upon 30 days' notice, (b) termination of this agreement or (c) completion of the research. In any such event, the investigator shall destroy or erase all backup copies containing information from the NSCISC Database that are not returned to the NSCISC.

4. **Confidentiality.** The investigator acknowledges that the NSCISC Database contains certain sensitive and confidential patient and hospital information the unauthorized disclosure of which could substantially harm the NSCISC, model system program, individual model system hospitals, or patients who have been enrolled in the NSCISC Database. Therefore, neither the investigator nor his/her agents shall at any time, without the prior written consent of the NSCISC, sell, offer to sell, transfer, disclose, or otherwise make available any data from the NSCISC Database to any person, except (a) to such agents as may be reasonably necessary for the performance of the research and (b) in connection with the publication or dissemination of the results thereof (which shall be done in accordance with the provisions of this agreement). Furthermore, the investigator agrees that all appropriate safeguards shall be used to prevent use or disclosure of the data other than as provided for by this agreement. The investigator also agrees to take all other precautions to safeguard the confidential nature of the data that the NSCISC may, in its sole discretion, reasonably request.

   The investigator agrees that neither he/she nor his/her agents will re-identify the data or contact any individuals whose data are included in the NSCISC Database.

   Any unauthorized use or disclosure of the data not provided for by this agreement shall be promptly reported to the NSCISC.

5. **Work Product.** Each invention, discovery or other work product of the investigator which (a) incorporates any data from the NSCISC Database, or any summary thereof, or any specific mathematical transformation of any such data, or (b) otherwise constitutes a derivative work with respect to the NSCISC Database pursuant to applicable U.S. law, and each document, computer disk or other electronic media, model or other tangible item relating to such work product, shall be promptly disclosed to the NSCISC. Ownership of the work product will be determined in accordance with applicable state of Alabama laws. If by law the investigator owns the work product, then the investigator hereby grants to the NSCISC, the model system project directors, and NIDRRNIDRR worldwide, perpetual, royalty-free access and license to use such work product for no consideration other than that which is given in connection with this agreement.

   The investigator shall acknowledge the contribution of the NSCISC, the model systems, the U.S. Department of Education (DOE), Office of Special Education and Rehabilitative Services (OSERS), and NIDRRNIDRR to the creation of the work product.

   The parties agree to cooperate and to execute and file any documents or instruments that may be necessary or appropriate to properly reflect, record and protect each party's rights in and to any work product.

6. **Termination of Project.** The Director of the NSCISC shall be kept informed on a regular basis as to the progress of the research. This agreement shall remain in force for 5 years or until the research has been completed, whichever occurs first, and may be extended only upon written consent of the NSCISC. The covenants contained in sections 3, 4 and 5 of this agreement shall survive the termination of the research and the termination of this agreement.

7. **Warranty.** The data are being provided by the NSCISC as is without any warranties, expressed or implied, including any warranty of fitness for a particular purpose. The NSCISC does not represent or warrant that the use of the data will not infringe any patent or other proprietary right.

8. **Publication; Cooperation.** The NSCISC acknowledges that the basic objective of the research activities is the generation of new knowledge and its expeditious dissemination. The investigator shall retain discretion to publish or present at scientific conferences any results of the research, provided that he/she submits to the NSCISC before publication any manuscripts that rely at least in part on any portion of the data from the NSCISC Database, and that he/she does not reveal the identity of individual patients in the NSCISC Database. The NSCISC shall have 30 days from the date of any such submission to notify the investigator of any comments it may have with regard to any proposed publication. The investigator also agrees that data or research results that can be linked to individual model system facilities shall not be disclosed without prior consent of the project directors of those model systems.

9. The investigator agrees to acknowledge in any publication the participation and support of the NSCISC, the model systems, DOE, OSERS, and NIDRRNIDRR, and as the parties may agree is appropriate, to cooperate in the preparation of joint publications relating to the research.

10. **Supervision.** The investigator shall assume primary responsibility for overseeing the compliance of himself/herself and his/her agents with the terms and covenants contained in this agreement.

11. **Fees.** The NSCISC will charge a fee of $100 per hour payable in advance for production of data sets to be released and to cover its reasonable expenses associated with completion of its obligations pursuant to this agreement. The NSCISC, in its sole discretion under special circumstances, retains the right to waive or alter any fees regarding this agreement.

12. **Equitable Remedies.** The investigator (a) acknowledges that his/her failure to comply with the covenants contained in this agreement will cause the NSCISC, model system project directors, and NIDRR irrevocable harm and that a remedy at law for such failure would be an inadequate remedy and (b) consents to the NSCISC's obtaining from a court of competent jurisdiction specific performance, an injunction or any other equitable relief in order to enforce such compliance. The NSCISC's right to obtain such equitable relief shall be in addition to any other remedy which the NSCISC, the model system project directors, or NIDRR may have under applicable law.

13. **Miscellaneous.** This agreement shall be binding upon and inure to the benefit of the NSCISC and the investigator and each of their respective successors and assignees, except that the investigator may not assign any of his/her rights or obligations pursuant to this agreement between the parties hereto with respect to the use by the investigator of data from the NSCISC Database, and supersedes all oral or written proposals, representations, understandings or agreements with respect to such subject matter. This document constitutes the entire agreement between the parties with respect to the provision of data to the investigators, and may be amended only by written agreement of all parties. This agreement shall be governed by and construed and interpreted in accordance with the law of Alabama, without regard to principles of conflict of laws.

As conclusive evidence of their acceptance of the terms and conditions of this agreement, the parties hereto have executed this agreement on the date first above written.

_____	_____	_____	_____
Yuying Chen, M.D., Ph.D.,	Date	(Name)	(Date)
Director, National Spinal Cord Injury Statistical Center	(Affiliation)		

CONFIDENTIALITY AGREEMENT – Not Affiliated

This agreement, dated the day of (month, year), is between The Board of Trustees of the University of Alabama, on behalf of the National Spinal Cord Injury Statistical Center (NSCISC) at the University of Alabama at Birmingham (UAB), 515 Spain Rehabilitation Center, Birmingham, Alabama, 35294, and (name and affiliation), who is referred to hereafter as the investigator. The approved research project covered by this agreement is titled " ".

The NSCISC Database contains longitudinal information on patients treated since 1973 at federally-designated model spinal cord injury systems of care throughout the United States. All existing information in the database has been sent to the NSCISC in accordance with the guidelines established by both the Institutional Review Board (IRB) of the model system sending the information and the UAB IRB. This agreement outlines the procedures and circumstances under which the NSCISC may release raw data from the NSCISC Database to investigators for the purpose of conducting approved research projects.

1. **Approval Process.** Investigators who are not affiliated with a model system that is currently funded by the National Institute on Disability and Rehabilitation Research (NIDRR) or subcontracted by the NSCISC may request release of raw data from the NSCISC Database to conduct a specific research project at any time. A formal proposal will be written according to pre-specified guidelines. The project directors of each of the model systems will review the proposal and notify the NSCISC of their decision concerning release of data, and the NSCISC will notify the investigators accordingly.

2. **Transfer of Data.** Upon or after the execution of this agreement and subject to the terms and conditions hereof, the NSCISC shall provide or cause to be provided to the investigator, in such format as the parties shall agree, certain raw data from the NSCISC Database as approved by the project directors. Prior to release of any raw data, the NSCISC will take all steps necessary to ensure that the released raw data qualify as either "de-identified data" or a "limited data set" in accordance with current Health Insurance Portability and Accountability Act (HIPAA) guidelines. For purposes of release of a "Limited Data Set," this Confidentiality Agreement constitutes a Data Use Agreement as required by the HIPAA regulations.

3. **Use of Data from the NSCISC Database; Limitations.** The investigator understands, acknowledges, and agrees that raw data from the NSCISC Database is being provided by the NSCISC for the sole and exclusive purpose of facilitating the approved research project and that neither the investigator nor any of his/her collaborators, assistants, or other persons under his/her supervision (collectively, the "agents") shall be entitled to use the raw data from the NSCISC Database other than for the purpose of performing the statistical and other analyses relevant to the research. The investigator further agrees that all raw data from the NSCISC Database provided hereunder shall be stored in a way that provides access only to authorized personnel. This would include either storage on a single computer that is not connected to any computer network and is designated by the investigator for use in connection with the research, or storage on a file server located behind a firewall that limits access to the raw data from the NSCISC Database to authorized personnel. The investigator also agrees that the raw data from the NSCISC Database shall be stored in a

password-protected directory; that only the investigator and his/her authorized agents shall have access to the raw data; and that each agent authorized to have access to the raw data shall be bound by this agreement.

Except as specifically set forth in the preceding paragraph, neither the investigator nor any of his/her agents shall, at any time, without prior written consent of the NSCISC, (a) market, use (other than in connection with the research) or otherwise profit from any raw data derived from the NSCISC Database, (b) reproduce or otherwise copy any of the raw data from the NSCISC Database other than as required in connection with the performance of the research or for computer backup purposes, (c) license or offer to license any corporation, government body, individual, partnership, association, or other entity to use any raw data from NSCISC Database, except to the extent expressly provided herein, or (d) authorize any agent or other person to do anything described in subsections (a) through (c) above.

The raw data from the NSCISC Database and all computer floppy diskettes, tapes, records, documents, and other tangible items furnished to the investigators by the NSCISC relating thereto shall remain the exclusive property of the NSCISC and the model system project directors, and shall be returned to the NSCISC immediately upon the earliest of (a) demand by the NSCISC upon 30 days' notice, (b) termination of this agreement or (c) completion of the research. In any such event, the investigator shall destroy or erase all backup copies containing information from the NSCISC Database that are not returned to the NSCISC.

4. **Confidentiality.** The investigator acknowledges that the NSCISC Database contains certain sensitive and confidential patient and hospital information the unauthorized disclosure of which could substantially harm the NSCISC, model system program, individual model system hospitals, or patients who have been enrolled in the NSCISC Database. Therefore, neither the investigator nor his/her agents shall at any time, without the prior written consent of the NSCISC, sell, offer to sell, transfer, disclose, or otherwise make available any data from the NSCISC Database to any person, except (a) to such agents as may be reasonably necessary for the performance of the research and (b) in connection with the publication or dissemination of the results thereof (which shall be done in accordance with the provisions of this agreement). Furthermore, the investigator agrees that all appropriate safeguards shall be used to prevent use or disclosure of the data other than as provided for by this agreement. The investigator also agrees to take all other precautions to safeguard the confidential nature of the data that the NSCISC may, in its sole discretion, reasonably request.

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5. **Work Product.** Each invention, discovery or other work product of the investigator which (a) incorporates any data from the NSCISC Database, or any summary thereof, or any specific mathematical transformation of any such data, or (b) otherwise constitutes a derivative work with respect to the NSCISC Database

pursuant to applicable U.S. law, and each document, computer disk or other electronic media, model or other tangible item relating to such work product, shall be promptly disclosed to the NSCISC. Ownership of the work product will be determined in accordance with applicable state of Alabama laws. If by law the investigator owns the work product, then the investigator hereby grants to the NSCISC, the model system project directors, and NIDRR worldwide, perpetual, royalty-free access and license to use such work product for no consideration other than that which is given in connection with this agreement.

The investigator shall acknowledge the contribution of the NSCISC, the model systems, the U.S. Department of Education (DOE), Office of Special Education and Rehabilitative Services (OSERS), and NIDRR to the creation of the work product.

The parties agree to cooperate and to execute and file any documents or instruments that may be necessary or appropriate to properly reflect, record and protect each party's rights in and to any work product.

6. **Termination of Project.** The Director of the NSCISC shall be kept informed on a regular basis as to the progress of the research. This agreement shall remain in force for 5 years or until the research has been completed, whichever occurs first, and may be extended only upon written consent of the NSCISC. The covenants contained in sections 3, 4 and 5 of this agreement shall survive the termination of the research and the termination of this agreement.

7. **Warranty.** The data are being provided by the NSCISC as is without any warranties, expressed or implied, including any warranty of fitness for a particular purpose. The NSCISC does not represent or warrant that the use of the data will not infringe any patent or other proprietary right.

8. **Publication; Cooperation.** The NSCISC acknowledges that the basic objective of the research activities is the generation of new knowledge and its expeditious dissemination. The investigator shall retain discretion to publish or present at scientific conferences any results of the research, provided that he/she submits to the NSCISC before publication any manuscripts that rely at least in part on any portion of the data from the NSCISC Database, and that he/she does not reveal the identity of individual patients in the NSCISC Database. The NSCISC shall have 30 days from the date of any such submission to notify the investigator of any comments it may have with regard to any proposed publication. The investigator also agrees that data or research results that can be linked to individual model system facilities shall not be disclosed without prior consent of the project directors of those model systems.

   The investigator agrees to acknowledge in any publication the participation and support of the NSCISC, the model systems, DOE, OSERS, and NIDRR, and as the parties may agree is appropriate, to cooperate in the preparation of joint publications relating to the research.

9. **Supervision.** The investigator shall assume primary responsibility for overseeing the compliance of himself/herself and his/her agents with the terms and covenants contained in this agreement.

10. **Fees.** The NSCISC will charge a fee of $100 per hour payable in advance for production of data sets to be released and to cover its reasonable expenses associated with completion of its obligations pursuant to this

agreement. The NSCISC, in its sole discretion under special circumstances, retains the right to waive or alter any fees regarding this agreement.

11. **Equitable Remedies.** The investigator (a) acknowledges that his/her failure to comply with the covenants contained in this agreement will cause the NSCISC, model system project directors, and NIDRR irrevocable harm and that a remedy at law for such failure would be an inadequate remedy and (b) consents to the NSCISC's obtaining from a court of competent jurisdiction specific performance, an injunction or any other equitable relief in order to enforce such compliance. The NSCISC's right to obtain such equitable relief shall be in addition to any other remedy which the NSCISC, the model system project directors, or NIDRR may have under applicable law.

12. **Miscellaneous.** This agreement shall be binding upon and inure to the benefit of the NSCISC and the investigator and each of their respective successors and assignees, except that the investigator may not assign any of his/her rights or obligations pursuant to this agreement between the parties hereto with respect to the use by the investigator of data from the NSCISC Database, and supersedes all oral or written proposals, representations, understandings or agreements with respect to such subject matter. This document constitutes the entire agreement between the parties with respect to the provision of data to the investigators, and may be amended only by written agreement of all parties. This agreement shall be governed by and construed and interpreted in accordance with the law of Alabama, without regard to principles of conflict of laws.

As conclusive evidence of their acceptance of the terms and conditions of this agreement, the parties hereto have executed this agreement on the date first above written.

_____	_____	_____	_____
Yuying Chen, M.D., Ph.D.	Date	(Name)	(Date)
Director, National Spinal Cord Injury Statistical Center		(Affiliation)	