



Rick Hansen Institute
Institut Rick Hansen



PROTOCOL:

Rick Hansen Spinal Cord Injury Registry (RHSCIR)

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NATIONAL PRINCIPAL

INVESTIGATOR: Marcel Dvorak MD, FRCSC
University of British Columbia
Department of Orthopaedics; Division of Spine

Signatures

By signing this protocol, I, the Site Investigator, agree to conduct ~~the~~ RHSCIR in accordance with the protocol, generally accepted standards of good clinical practice, and all applicable federal, provincial, and local laws, rules, and regulations. Publication of the results of ~~the~~ RHSCIR will be governed by ~~the~~ conditions stipulated in the Site Agreement.

I have read and ~~understand~~ understood the information in this protocol, and will ensure that all associates, colleagues, and employees assisting in the conduct of ~~the~~ RHSCIR are informed of the obligations incurred ~~upon~~ by their participation. I will attest to the delegation of any obligation under this protocol to my associates, colleagues, and employees by signing such delegation in the Study Delegation Log.

Local RHSCIR Site Principal Investigator

Name and Signature

Date

Institution

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1 Introduction

1.1 Overview

This ~~p~~Protocol details the:

- Background and objectives of the Rick Hansen Spinal Cord Injury Registry (RHSCIR);
- Study design and participant recruitment;
- Organizational structure of national and local RHSCIR teams;
- Informed consent process and research ethics board (REB) approval;
- Data collection process including local data abstraction, data linking, and data entry;
- Data management process; ~~and~~
- Privacy, security framework, and governance for ~~the~~ RHSCIR's data handling for both local and national RHSCIR operations.

1.2 Definitions and Abbreviations

Discharge Abstract Database (DAD): The DAD is a database for information on all separations from acute care institutions, including discharges, deaths, sign-outs and transfers, within a fiscal year (April 1 to March 31). Over time, the DAD has also been used to capture data on day surgery procedures, long-term care, rehabilitation and other types of care.

Global Research Platform (GRP): GRP is a state-of-the-art, web-based, and secure data collection and research management system developed and operated by ~~RH~~the Praxis Spinal Cord Institute, formerly the Rick Hansen Institute (herein referred to as the "Institute"). GRP is highly flexible and adaptable, and can be used to run multiple concurrent registries and studies, from local institution clinical data gathering to multi-centre clinical trials. GRP is hosted in a top-tier secure data centre in Canada, and meets global privacy and security standards (documented proof may be obtained from ~~the Praxis Spinal Cord Institute~~ RH Institute).

Health data: health data refers to data about an individual that is related to the individual's health or the provision of health services to the individual.

National Rehabilitation Reporting System (NRS): The NRS collects data from participating adult inpatient rehabilitation facilities and programs across Canada. Facilities collect client data on admission and discharge from the inpatient rehabilitation program.

RHSCIR database: refers to the structured set of spinal cord injury related data stored in the GRP.

RHSCIR dataset: refers to the data elements that are requested to be collected for the RHSCIR database.

RHSCIR sites: ~~the~~ acute and rehabilitation sites involved in ~~the~~ RHSCIR-, where local investigators, clinicians, research coordinators, research assistants, as the case may be, gather health data directly from participants during the acute, rehabilitation, and post-injury phases of their care for submission to ~~Institute~~the Praxis Spinal Cord Institute~~RHI~~.

Facility vs. site: ~~the~~ term 'facility' is synonymous with an acute care, rehabilitation, or integrated acute care and rehabilitation hospital. A 'site' is a collection of one or more facilities in a geographical region, and generally consists of facilities providing the continuum of care from pre-hospital ~~to~~ acute and rehabilitation ~~for patients with Spinal Cord Injury (SCI)~~or facilities providing rehabilitation care for non-traumatic SCI patients. The four sites of the Greater Toronto Area (~~GTA~~)and the two New Brunswick sites are ~~an~~ exceptions to this definition, as each ~~GTA~~ facility provides only acute or rehabilitation care, but is still considered a site.

RHSCIR study: ~~Launched~~ in 2003, ~~the~~ RHSCIR- is an observational and investigator driven long-term, national ~~spinal cord injury (SCI)~~ registry that tracks the experiences and outcomes of people with ~~traumatic~~ SCI during their journey ~~through~~through pre-hospital, acute care, rehabilitation, and community reintegration.

For the purposes of this protocol, the RHSCIR study refers to ~~the Rick Hansen~~Praxis Spinal Cord Institute~~Institute's (RHI's)~~ and ~~the~~ local facilities' collection of health data about individuals who sustain ~~traumatic~~ spinal cord injuries across Canada, including the people, processes, and technologies involved in the conduct of its database. RHSCIR encompasses ~~the Praxis Spinal Cord Institute~~Institute~~RHI~~ and all sites in which RHSCIR staff are tasked with managing the local RHSCIR operations.

RHSCIR Phase I: ~~the~~ implementation of ~~the~~ RHSCIR on the original data collection and storage system, referred to as the RHSCIR legacy software.

RHSCIR Phase II: ~~the~~ implementation of ~~the~~ RHSCIR on ~~the RHI~~ GRP (please see below).

~~The Rick Hansen Institute~~ Global Research Platform (RHI GRP): ~~The RHI GRP is a state-of-the-art, web-based, and secure data collection and research management system developed and operated by RHI. The RHI GRP is highly flexible and adaptable, and can be used to run multiple concurrent registries and studies, from local institution clinical data gathering to multi-centre clinical trials. The RHI GRP is hosted in a top-tier secure data centre in Canada, and meets global privacy and security standards (documented proof may be obtained from RHI).~~

Spinal cord injury (SCI): includes both traumatic and non-traumatic SCI

- Traumatic SCI (tSCI): impairment of the spinal cord or cauda equina function (i.e. motor or sensory deficit) resulting from application of an external force of any nature (e.g. blunt, penetrating, etc.) and any magnitude; this includes new neurological motor or sensory deficit secondary to surgical procedures that result in the direct application of an external force to the spinal cord or cauda equina (this does not include motor or sensory deficit related to vascular injury such as ischemia or infarction of the cord).
- Non-traumatic SCI (ntSCI): impairment of the spinal cord or cauda equina function (i.e. motor or sensory deficit) that is not caused either directly or indirectly by an external force (also called spinal cord damage or spinal cord myelopathy).

Trauma Registry: provides trauma health care providers, researchers and injury prevention programs with essential information on injury or trauma. Participating trauma registries and trauma centres typically collect demographic data, preadmission information (such as on ambulance transfers and circumstances of injury) and information on hospital care and patient outcomes using specialized trauma software.

1.3 Background of ~~the~~ RHSCIR

~~The~~ RHSCIR is a long-term, national ~~spinal cord injury (SCI)~~ registry that tracks the experiences and outcomes of people with ~~traumatic forms of~~ SCI during ~~their journey through~~ pre-hospital, acute care, rehabilitation, and community reintegration. ~~The It~~ RHSCIR was initiated in June 2003 in order to develop a national prototype database that would link researchers, clinicians, SCI communities, as well as tSCI patients across Canada to move translational research to evidence-based best practices. The registry started with enrolling individuals with tSCI, and aAs of 2019, RHSCIR will begin enrolling individuals with ntSCI.

The database itself is designed to serve as a national repository of high quality health data about ~~Canadian SCI~~ patients in Canada with SCI through the pre-hospital, acute, rehabilitation, and community integration phases of their care in support of SCI translational research and best practices. It is intended to be used as a data retrieval, information management, and reporting service in support of evidence-based decision making, standardized outcome measures, integrated research, quality improvement of care, and discoveries in SCI.

~~The~~ RHSCIR ~~study~~ was previously funded by the Rick Hansen Foundation (RHF). Subsequently, a Health Canada funding grant was assigned to the ~~Rick Hansen Praxis Spinal Cord Institute~~ Institute (RHI) – a national organization that sponsors and conducts SCI translational research, promotes best practice implementation, and related activities across Canada and internationally. ~~The Praxis Spinal Cord Institute~~ Institute RHI is now responsible for implementation and delivery of ~~the~~ RHSCIR's objectives. Currently, Western Economic Diversification Canada (WD) directly funds ~~the Praxis Spinal Cord Institute~~ Institute RHI for the operation and conduct of ~~the~~ RHSCIR ~~study~~. Additional funds have also been received from various provincial organizations and governments.

~~The~~ RHSCIR encompasses the work of the national RHSCIR team at ~~the Praxis Spinal Cord Institute~~ Institute RHI, located in Vancouver, BC, and participating facilities/sites across the

country, where local RHSCIR operations are managed by local RHSCIR principal investigators and their designated staff.

~~The Praxis Spinal Cord Institute~~~~Institute RHI~~ ultimately endeavors to allow the majority of persons sustaining a traumatic SCI in Canada (~~initial incidence of traumatic SCI is approximately 1,700 individuals per year and discharge incidence of non-traumatic SCI is approximately 2,300 individuals per year¹~~) to participate in the RHSCIR through this network of participating Canadian RHSCIR sites.

1.4 Historical Overview of the ~~Rick Hansen~~Praxis Spinal Cord Institute

In 2003, ~~the Rick Hansen Foundation (RHF)~~, with the support of the federal government, initiated the SCI Solutions Alliance, the SCI Translational Research Network (SCI-TRN), and the RHSCIR study. In April 2008, a decision was made to combine these entities and their respective mandates into a single organization to more effectively and efficiently address priority needs for people with SCI. A year later, the organization was named, ~~called the SCI Solutions Network (SCISN)~~Rick Hansen Institute, ~~to more effectively and efficiently address priority needs for people with SCI.~~

~~SCISN, now operating under the name the Rick Hansen Institute (of the Praxis Spinal Cord Institute RHI)~~. Fast forward to 2019, the Rick Hansen Institute was renamed the Praxis Spinal Cord Institute. The change reflects the journey of the Institute over the past 10 years to improve the health of individuals living with spinal cord injuries, while at the same time, remaining committed to its vision and mission. ~~has a mission to lead collaboration, across the global SCI community, by providing resources, infrastructure, and knowledge; and to it also aims to identify, develop, validate, and accelerate the translation of evidence and the best practices to reduce the incidence and severity of paralysis after SCI, to improve health care outcomes, reduce long-term costs, and to improve quality of life for those living with SCI.~~

1.4.1 Historical Overview of ~~the~~ RHSCIR

~~The~~ RHSCIR began as a pilot registry study that was implemented at selected sites across Canada during the period of 2003-2008. During the pilot program, only the lead site in Vancouver participated fully in the data collection process. The other sites - Calgary, Edmonton, Winnipeg, and Hamilton - collected some data, but due to a variety of issues (i.e., lack of privacy infrastructure, funding, minimal training), data collection was not complete. In 2008, work began to more effectively engage the pilot sites and to bring on the remaining sites across Canada (in the provinces of Quebec, Ontario, Saskatchewan, Nova Scotia, Newfoundland, and New Brunswick) to fully implement ~~the~~ RHSCIR as a pan-Canadian network. Sites invited to participate were identified as ~~the~~ primary SCI admitting sites in Canada. Phase I of ~~the~~ RHSCIR included ~~ds~~ both the pilot and the roll-out stages.

Phase I required RHSCIR sites to install a local version of the RHSCIR legacy software, subject to a Data Sharing Agreement, that enabled health data to be collected and stored locally. Data was then de-identified by local RHSCIR staff and transmitted (on a quarterly basis) to the national

¹Noonan et al, Incidence and Prevalence of Spinal Cord Injury in Canada: A National Perspective. *Neuroepidemiology* 2012;38:219–226

RHSCIR database in Vancouver, BC. ~~The RHSCIR is currently was~~ limited to enrolling traumatic SCI cases that ~~are were~~ admitted to RHSCIR sites. Phase II was deployed in September 2011 (protocol version 2.0). ~~and f~~Following local ethics approval, RHSCIR sites began capturing and transmitting all RHSCIR data into a centrally hosted, web-based, secure data collection and research management system called ~~the RHI GRP~~. ~~The RHI GRP~~ enables real-time data collection and reporting functionalities, using state-of-the-art technologies to secure and manage the information centrally, avoiding the redundancies and inefficiencies associated with the Phase I de-centralized model. -This provides RHSCIR with the optimum privacy and security protection and improved data management processes ~~to facilitateing~~ effective use of the data.- This phase was deployed with a strict privacy and security framework that utilizes specific role-based access controls for authorized RHSCIR users. -A privacy impact assessment has been completed for Phase II operations, and is available for review by contacting the Privacy Officer at ~~the Praxis Spinal Cord InstituteInstituteRHI~~.^{2 1} During Phase II, the national RHSCIR team continued to have access to only a national de-identified dataset. ~~The Praxis Spinal Cord InstituteInstituteRHI~~ access to identifying data is restricted to a limited number of individuals required to support the technical requirements of the ~~RHI GRP~~ database. The ultimate goal of ~~the~~ RHSCIR is for ~~the Praxis Spinal Cord InstituteInstituteRHI~~ to become the primary data steward of a robust and high quality national RHSCIR dataset using ~~the RHI GRP~~, and to leverage this infrastructure and participant engagement to support its objectives (listed in Section 2.1) enabling promising translational research studies, clinical quality improvement and ultimately best practices support to be implemented across ~~the the~~ RHSCIR network of sites.

1.5 Scope

This protocol outlines the design for ~~the~~ RHSCIR. -It details the management, storage, and use of health data both locally and nationally within a defined privacy and security framework.

1.6 Study Timeline

A study participant's involvement ~~is depends on their type of SCI. For participants with tSCI, involvement is~~ from the time of injury, and per their consent is ongoing for that person's lifetime. This includes identification of the participant for eligibility for participation in ~~the~~ RHSCIR, the consent process, and data collection from ~~the onset of the participant's injurytheir initial involvement~~ to follow up questionnaires at ~~4, 2, 18 months, -5 years~~, and every 5 years thereafter ~~from the date of theirpost-~~injury; until the participant withdraws from the RHSCIR study.

For participants with ntSCI, involvement is from rehabilitation admission, and ends upon discharge from inpatient rehabilitation.

¹²Privacy@rickhanseninstitutepraxisinstitute.org

2 RHSCIR Objective

The objective of ~~the~~ RHSCIR is to track specific outcome measures for people with ~~traumatic~~ SCI by providing researchers, clinicians, and health care professionals with a research and quality improvement and administrative reporting tool that will collect and store comprehensive, national health data.

In order to support this objective, 5 primary purposes were identified for the use and disclosure of the data collected, detailed in section 2.1.

2.1 RHSCIR Permitted Purposes

In the development of the national RHSCIR dataset (see Sections 5.2 and 5.4 of this protocol for a full description of the RHSCIR dataset), the national RHSCIR team identified a set of broad permitted purposes for ~~the~~ RHSCIR. These purposes, which are provided in more detail ~~below in section 2.2~~, were used to identify the specific data elements required to support ~~the~~ RHSCIR, and include:

- Clinical support and management;
- Research support;
- Partnerships and quality improvement;
- Quality data and information; ~~and~~
- Business planning and future development.

These purposes also represent the topics that may be investigated with the dataset. ~~For~~ For example, the following geographic-related questions, which correlate to listed program objectives, may be asked of the dataset:

- i) ~~•~~ What is the incidence of ~~traumatic~~ SCI in Canada, and what changes do we see year to year?
- ii) ~~•~~ What are the general demographics of the ~~traumatic~~ SCI population (age ranges, gender, mechanism of injury, diagnosis, etc.)?
- ~~•~~ Are there differences in the type and mechanism of injury / etiology across provinces?
- ~~•~~ Are there seasonal trends in SCI in Canada?
-

~~Refer to Appendix I for a list of potential and relevant RHSCIR research questions.~~

However, ~~the Praxis Spinal Cord Institute~~ Institute RHI acknowledges that all potential and useful questions cannot be foreseen at the outset of ~~the~~ RHSCIR, given that research and quality improvement is likely to evolve over time as findings from early studies emerge. Should additional data elements be required, new REB approval will be sought.

To manage the prospective use of RHSCIR data in accordance with the above-noted purposes and to ensure the privacy of the individual participants, the Praxis Spinal Cord Institute has created a policy for disclosure of national record level data, including a governance structure that involves oversight by its Data Executive Scientific and Data Access Committees. All individuals requesting access to the national RHSCIR record level data from two or more RHSCIR sites must undergo the data access request and approval process to ensure future data uses are within the scope of the RHSCIR objectives, otherwise an ethics approved research protocol is required. The data access request and approval process, and related governance structure is discussed in more detail in section 56.3 below in the context of the Praxis Spinal Cord Institute's RHSCIR Data Use and Disclosure Policy.

2.1.1 Clinical Support and Management

To promote, encourage, and develop an efficient and effective national health data retrieval and management reporting service.

Create a standardized national database of SCI events.

- Registry Database: An expanded dataset (consisting of demographic data, injury mechanisms / etiology, treatment parameters, complications, morbidity and mortality data, standardized outcome assessments, and information about movement through the health care system), and a minimal dataset limited to abstracted and linked data only (no patient-reported outcome assessments). Refer to Schedule I: RHSCIR Dataset.
- Secure data warehouse, which contains health data on individuals with spine conditions and spinal cord injuries.
- Datasets that support a prospective approach to patient monitoring, evaluation and improvement of quality of care and outcomes across the care delivery continuum from point of injury / onset and acute care through rehabilitation and including community integration and future support.
- A de-identified dataset that supports policy development to ascertain cost effectiveness and service utilization for the SCI population.
- Collaboration tools that will provide access and links to health care services to facilitate dialogue between individuals with SCI, researchers, and health care providers.
- Enable the use of a standardized approach to collection, management, and dissemination of SCI clinical information.
- A reporting tool and support services at the local, regional, provincial/territorial, and national levels that ensures results are distributed to the RHSCIR stakeholders.
- Provide system support and reporting services to RHSCIR sites.

2.1.2 Research Support

A clinical and epidemiological based information service that promotes collaboration between scientists and clinicians, supports translational research, as well as provincial/territorial, national, and international data exchange and collaboration.

- Allows researchers to identify and assess impact of interventions on patient outcomes as measured by specific interventions, practice design/changes, program design/changes, impact of practices/programs on functional capacity and changes to functional capacity over time.
- Perform high quality population observational studies; documents the natural history of SCI; determines the effectiveness of current treatment strategies, best practices and novel therapeutic initiatives (surgical, pharmaceutical or rehabilitative).

2.1.3 Quality Improvement through Partnerships

1. Provides a standardized, evidence-based, data capture system to enable local and national clinical quality improvement; -In addition, provided it provides evidence-based reports for local administrative improvement.
2. Provides opportunities to work within the SCI clinical care system to achieve SCI information objectives.
3. Ensures individuals in the SCI community are active participants in the design, development, and evolution of ~~the~~ RHSCIR. For example, participation in development of community follow-up tools.
4. Enables longitudinal tracking capabilities based on strategic linkages across care delivery systems and partnerships with relevant stakeholders.
5. Records validated and standardized outcomes for specific injury levels and categories.

2.1.4 Quality Data and Information

ET ~~To~~ ensure the quality of data stored in the national RHSCIR database.

- Standardized data definitions.
- Standardized procedures for data retrieval from third party sources.
- Enables internal quality assurance mechanisms to monitor data quality: audits and monitoring of data quality, including training and education programs, system queries and validations, and on-line standard operating procedures (SOPs) and help systems.
- Fosters an environment of continuous improvement, and corrective and preventative action (CAPA).
- Established quality control monitoring tools for local RHSCIR review for data accuracy, timeliness and completeness.
- Evaluates sd RHSCIR's effectiveness and its impact on patterns of practice and outcomes using Key Performance Indicators (KPI) ~~-~~ (For example, number of participants enrolled each year, percentage of participants consented ~~-~~).

2.1.5 Business Planning and Future Development

Remaining current with changing trends and issues in health care management.

- Ongoing networking with key resource people and organizations on a regional, provincial/territorial and national basis to facilitate validation and implementation of best practices across Canada.
- Establish relationships with other SCI-related North American and International data systems.

3 RHSCIR Design and Participant Recruitment

3.1 Inclusion Criteria

3.1.1 Inclusion Criteria

1. Traumatic SCI is defined as impairment of the spinal cord or cauda equina function (i.e. motor or sensory deficit) resulting from the application of an external force of any nature (e.g. blunt, penetrating, etc.) and any magnitude; ~~and;~~
2. Includes new neurological motor or sensory deficit secondary to surgical procedures that result in the direct application of an external force to the spinal cord or cauda equina. (this does not include motor or sensory deficit related to vascular injury such as ischemia or infarction of the cord);
- ~~6.3.~~ Admitted to a participating acute or rehabilitation facility with a new SCI or developed a SCI after admission to a participating facility.
- ~~7.4.~~ Initially classified as American Spinal Injury Association Impairment Scale (AIS) A, B, C or D or Cauda Equina (including those individuals who progress to AIS E by discharge); ~~and;~~
- ~~8.5.~~ Speak English or French, or when this is not the case, when a family member, friend, or a medical translator can translate;
6. Approved Age of Consent as per local site Research Ethics Board (REB).

3.1.2 Exclusion Criteria

1. Individuals with impairment of the spinal cord or cauda equina function (i.e. motor or sensory deficit) that is not caused either directly or indirectly by an external force (e.g., intervertebral disc disease, vertebral injuries in the absence of SCI or cauda equina, 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); ~~and;~~
- ~~9.2.~~ Individuals with SCI prior to admission to a participating facility and were admitted for management of complications;

~~4.3.~~ Individuals who do not speak English or French and a translator is not available (all attempts will be made to provide a translator) will not be approached for consent and will have the minimal dataset collected~~;~~

4. Individuals who do not meet the minimum age of consent for the RHSCIR study as determined by participating site's local ~~research ethics board~~ REB.

3.2 Exclusion Criteria Non-traumatic SCI

3.1.33.2.1 Traumatic SCI Inclusion Criteria

1. Individuals with impairment of the spinal cord or cauda equina function (i.e. motor or sensory deficit) that is not caused either directly or indirectly by an external force (also called spinal cord damage or spinal cord myelopathy);
2. Admitted to a participating rehabilitation facility with a new SCI or developed a SCI after admission to a participating facility;
3. Initially classified as AIS A, B, C or D or Cauda Equina (including those individuals who progress to AIS E by discharge);~~;~~ and;
4. Speak English or French, or when this is not the case, when a family member, friend, or a medical translator can translate;
- ~~4.5.~~ Approved a ~~Age of~~ C ~~consent as per local site~~ REB. Research Ethics Board (REB).

3.2.2 Non-traumatic SCI Exclusion Criteria

1. Individuals with impairment of the spinal cord or cauda equina function (i.e. motor or sensory deficit) resulting from the application of an external force of any nature (e.g. blunt, penetrating, etc.) and any magnitude (i.e. ~~eg.~~ traumatic SCI) or other causes (e.g. vertebral injuries in the absence of SCI or cauda equina, nerve root avulsions, and injuries to nerve roots and peripheral nerves outside the spinal canal);
2. Individuals with a diagnosis of Multiple Sclerosis or Amyotrophic Lateral Sclerosis;
3. Individuals with SCI prior to admission to a participating facility ~~and were~~ admitted for management of complications;
4. Individuals who do not speak English or French and a translator is not available (all attempts will be made to provide a translator) will not be approached for consent and will have the minimal dataset collected~~;~~
- ~~4.5.~~ Individuals who do not meet the minimum age of consent for the RHSCIR study as determined by participating site's local ~~research ethics board~~ REB.

3.23.3 Sample Size Estimates

Approximately 700 participants with an acute traumatic SCI and an estimated 400 participants with a non-traumatic SCI will be ~~are~~ enrolled ~~into~~ RHSCIR each year.

3.3.4 Participant Recruitment-Enrollment

3.4.1 Traumatic SCI

Patients who meet the tSCI eligibility ~~the tSCI~~ criteria and are admitted to a participating local RHSCIR site will be recruited for participation. -Patients will be approached for recruitment consent once their health care team has identified that they are emotionally and physically ready to be approached by a local RHSCIR representative. Refer to ~~section~~ section 5.1.1 for consent process and minimum dataset collection.

3.4.2 Non-traumatic SCI

Patients who meet the ntSCI eligibility criteria and are admitted to a RHSCIR rehabilitation site/hospital will be enrolled and a minimum dataset will be collected. - Refer to ~~section~~ section 5.1.2 details of ntSCI dataset collection.

3.4.3 Case Findings

Due to the nature of recruitment/enrollment, some patients may not be identified by the local RHSCIR team as being eligible for ~~the~~ RHSCIR before they are discharged from inpatient care. In order to ensure accurate epidemiology data, local research staff may also use their local hospital database(s) (e.g. Discharge Abstract Database) to identify all patients who, identified by injury code, are eligible for ~~the~~ RHSCIR. -Eligible patients who were missed through clinical identification techniques will be enrolled as non-consented participants for which only the minimal dataset will be collected.

4 Organizational Structure

~~The~~ RHSCIR is under the strategic direction and management of the Praxis Spinal Cord Institute/Institute RHI, located in Vancouver, BC, and is supported through a network of local RHSCIR principal investigators and their teams at participating RHSCIR sites.

These local RHSCIR teams may be comprised of clinicians, coordinators, research assistants, nurses, and administrators, who are accountable for ~~the~~ local RHSCIR.

The following sections detail the current organizational structure of the national and local RHSCIR teams.

4.1 National RHSCIR Team

The national RHSCIR team is led by the national RHSCIR principal investigator, and includes individuals or staff ~~includes a project team which that~~ supports ~~the~~ RHSCIR site management, training, administration, data management, and data quality control, as well as a larger Praxis Spinal Cord Institute/Institute RHI team ~~which that~~ supports privacy, research, best practice implementation, data use and disclosure, and information technology related to the study. The RHSCIR project manager is responsible for the day-to-day operations of the national RHSCIR study, which includes study management, business planning, and other related duties. -The

~~Praxis Spinal Cord Institute~~InstituteRHI has a Privacy Officer who is [responsible for overseeing key components of the Praxis Spinal Cord Institute](#)~~InstituteRHI's~~ privacy compliance program, including overall privacy compliance, privacy education and training, privacy policy and standards development, privacy impact assessments, audits, and incident management~~accountable for the national RHSCIR data holdings as well as overall privacy and security compliance by all RHI staff.~~

4.1.1 Data Access Committee

The Data Access Committee, comprised of RHSCIR site investigators, is charged with ensuring oversight for the disclosure of [record level](#) health data stored in the national RHSCIR database in compliance with ~~the Praxis Spinal Cord Institute~~InstituteRHI's [RHSCIR Data Use and Disclosure Policy](#).

4.1.2 [Data](#) Executive Scientific Committee

The [Data](#) Executive Scientific Committee considers whether applications for the release of [national record level](#) RHSCIR data respects the individual RHSCIR site contributions, if the application has been peer-reviewed or otherwise demonstrates reasonable merit (e.g., scientific and/or public benefit), and if the project would duplicate any other projects in progress, [in compliance with the Praxis Spinal Cord Institute](#)~~InstituteRHI's~~ [RHSCIR Data Use and Disclosure Policy](#).

~~—National RHSCIR Principal Investigator~~

~~4.1.3 RHSCIR Project Manager~~

~~The RHSCIR Project Manager is responsible for the day-to-day operations of the national RHSCIR study, which includes study management, business planning, and other related duties.~~

4.2 Local RHSCIR Team

The staff involved in collecting the data at a participating local RHSCIR site may include:

4.2.1 Local Principal Investigator

The [local](#) principal investigator (PI) is responsible for the scientific and ethical conduct of ~~the~~ RHSCIR₁ and for the protection of each participant.

The [local](#) PI must comply with *Tri-Council Policy Statement (TCPS): Ethical Conduct for Research Involving Humans*, *Canadian Institutes for Health Research (CIHR) Best Practices for Protecting Privacy in Health Research*, and *ICH Guidance E6: Good Clinical Practice: Consolidated Guideline* (ICH-GCP), and all other applicable local and provincial laws and regulations.

The [local](#) PI must ensure that the local RHSCIR team (all co-investigators, clinicians, and other personnel) involved in ~~the~~ RHSCIR are qualified and experienced to conduct ~~the~~ RHSCIR. The [local](#) PI must also ensure that the Local RHSCIR Team adheres to the protocol and all other RHSCIR documentation approved by the Research Ethics Board.

4.2.2 RHSCIR Coordinator

The ~~RHSCIR c~~Coordinator is responsible for confirming eligibility of patients, obtaining informed consent, coordinating local data collection, entering data into GRP, performing routine data quality checks, and day to day RHSCIR operations.

RHSCIR Assistant

~~The Assistant is responsible for obtaining informed consent, collecting prospective data from the RHSCIR participant, abstracting data from hospital records, and entering data into the RHI GRP.~~

5 Consent and Data Collection Process

The national RHSCIR dataset is comprised primarily of abstracted medical chart information and linkage to existing hospital databases collected at various time points throughout the person's SCI care. -It may also include participant reported outcomes and follow-up quality-of-life information collected directly from participants by the local RHSCIR team in the form of interviews and questionnaires.

The consent and data collection process is detailed in the following sections.

5.1 Informed Consent Process

5.1.1 Participants with (tSCI) only

The local RHSCIR ~~c~~Coordinator ~~or Clinician~~ involved in the patient's care, as resourced by the RHSCIR site, will determine whether a patient is eligible to be part of ~~the~~ RHSCIR. -The patient and/or family will be provided with the *RHSCIR Participant and Family Information Package* and the local RHSCIR ~~c~~Coordinator/~~Clinician~~ will respond to any questions they may have.

The patient and/or family will have as much time as they would like to make a decision as to whether or not they wish to participate in ~~the~~ RHSCIR. -Once the patient has agreed to participate, the local RHSCIR ~~c~~Coordinator/~~Clinician~~ will obtain informed consent from the patient or their surrogate using the document, *Guidelines for Obtaining Informed Consent for the Rick Hansen Spinal Cord Injury Registry* and their local ethics requirements.

The Informed Consent Form (ICF) outlines the consent process for ~~the~~ RHSCIR to enable collection of specified personal health information at all participating acute care and rehabilitation facilities that they are admitted to. The ability to track the movement of these participants between facilities requires access to admission notices, occupancy, and census reports to allow the local RHSCIR team staff to adequately plan for study assessments.

The ICF also contains a specific section called "Permitted Purposes" to notify participants of ~~the~~ RHSCIR's objectives and the purposes for which their consent is being sought. -These purposes were outlined in section 2.12. -In addition, the ICF also seeks consent for local data linkages, for inclusion of their data in the national RHSCIR database, and for long-term management of the

database by authorized ~~RHI~~ staff ~~at the Praxis Spinal Cord Institute~~Institute. Consent status and associated approved RHSCIR data applies to each participant throughout their continuum of care, in acute, rehabilitation, and community settings (i.e., if a patient consents to participating ~~at~~ in the RHSCIR site, their consented status will continue to hold true if the participant transfers to other participating RHSCIR sites, and they will not be asked to re-consent in order to continue to participate. -This reduces the burden on the participants, and avoids potential frustration and confusion caused by being approached for consent multiple times for ~~the~~ RHSCIR).

Local ethics requirements for translation will take precedence, but, every effort is made to have a translator present for individuals who do not speak fluent English or French to allow explanation of the content ~~of the the~~ RHSCIR Participant and Family Information Package and the ICF. -Per local ethics requirements, an individual who is not able to provide informed consent but is able to understand in a limited capacity, or if the individual is a minor, will have an opportunity to provide assent. In these cases, a legally authorized representative will be asked to provide informed consent as well. -If that person later becomes able to provide informed consent for themselves (e.g., a previous head injury resolves or a minor comes of legal age), their consent will be sought at that time.

~~Name, Date of birth (DOB), gendersex,~~ and date of injury (DOI)/date of onset -are used to check for duplicate entries of the same patient into the RHSCIR database in order to prevent double-enrolling. ~~Name and~~ full DOB/date of onset will not be released to researchers; age or year of birth may be released if required, in accordance with ~~the Praxis Spinal Cord Institute~~RHI's RHSCIR Data Use and Disclosure Policy, and only if absolutely necessary for the purposes of the study. -Only authorized staff at ~~the~~ local sites have access privileges to personal identifying data stored at ~~the~~ local RHSCIR site. -At the national RHSCIR office, only authorized ~~RHI~~ staff ~~at the Praxis Spinal Cord Institute~~Institute have access to the data held in the national RHSCIR database, in accordance with ~~the Praxis Spinal Cord Institute~~RHI's RHSCIR Data Use and Disclosure Policy.

5.1.2 Participants with ntSCI

Patients who meet the ntSCI eligibility criteria and are admitted to a participating local RHSCIR site will have their data included in RHSCIR. -Data collection for ntSCI patients will be limited to only data available collected as part of each site's standard of care and available for collection from their respective medical charts in order to reduce the burden on patients and local rehabilitation sites. -Collection of ntSCI data collection will be limited to the participating rehabilitation centres and limited to the data availability during their in-patient rehabilitation stay. This data represents the rehabilitation-rehabilitation level of care portion of the minimum dataset, as described further in section 5.24.3. -There will be no participant interviews or community follow up for ntSCI RHSCIR participants. -The ntSCI data collection involves no more than minimal risk, however, the potential benefit to the care of patients with SCI may be significant. As the addition of ntSCI participants will significantly impact the local RHSCIR study coordinator workload at the rehabilitation facilities, a non-consented model (waiver of consent) will be used for ntSCI participants. A waiver of informed consent will not adversely affect the rights and welfare of these study participants, and no study results would affect clinical decisions about the individuals' care. Given the minimal risk associated with the collection of data already collected as standard of care, ntSCI participants will not be approached for consent.

5.1.25.2 RHSCIR Minimum Dataset

In the absence of a patient consenting to participate in ~~the~~ RHSCIR, and for non-traumatic SCI patients, a “minimal dataset” is collected for purposes of quality improvement in the delivery of SCI clinical care, and to provide basic information about the SCI so that complete and unbiased information about the etiology of ~~traumatic~~ SCI in Canada can be compiled. - This includes:

Medical History and Demographics - cause of SCI, date and time of injury; date of birth

Diagnosis - specific information describing the location of the spinal cord injury and any other secondary injuries or complications, including diagnosis code and location;

Admission/Discharge - admission and discharge information outlining the movement of the individual through each care centre, including facility name, date of admission, admission category, and date of discharge;

Neurology - information describing the type of SCI sustained, including ASIA Impairment Scale (AIS), motor scores, and sensory level;

Procedures - details outlining the primary operative procedure to stabilize the spinal column, including operative date, type of approach, type of implant used, neural elements decompressed, and intraoperative adverse events;

Interventions - information detailing specific elements of care provided, including ventilation and rehabilitation therapies.

In this case, the local RHSCIR ~~c~~Coordinator documents that a patient has been identified, who is appropriate for a minimal dataset collection, and stores this information securely. -The reasons for tracking ~~the~~ patients who have declined consent or are not appropriate to consent (e.g., not able to consent due to a concurrent traumatic brain injury) is to ensure they are not approached again (i.e., if they are transferred to another participating RHSCIR site), to avoid double counting cases, and to prevent bias by only collecting information from individuals who provide full consent to ~~the~~ RHSCIR.

To prevent selection bias and to generalize findings to the Canadian SCI population, significant effort is made to ensure that at least a minimal amount of congruent data is collected about consenting versus non-consenting participants. -Within the RHSCIR dataset, data for the minimum dataset will be collected from medical records and linkage with local hospital administrative database where this information is collected as part of a participant's standard of care. The information collected in the minimal dataset is limited. (Refer to Schedule I: RHSCIR Dataset for all information)

If the individual approached refuses to having any of their information added to ~~the~~ RHSCIR they can indicate this to the RHSCIR coordinator, and their wishes will be respected. -The RHSCIR ~~c~~Coordinator logs that person's wishes in the RHSCIR consent tracking form as consent not obtained for minimal dataset. For the sole purpose of capturing incidences ~~sake~~, the RHSCIR coordinator would also record level of care, ~~their local screening log only, and does not collect any RHSCIR data. The RHSCIR Ccoor~~ordinator will submit a numerical count of these

individuals to the national RHSCIR team in order to allow potential data limitations to be understood.

5.1.35.3 Ethics Approval

Each RHSCIR site must obtain ethics approval for ~~the~~ RHSCIR from an independent, local Research Ethics Board (REB).

Additional ethics approval may be required for any future access to the national RHSCIR dataset that falls outside of the scope of the permitted purposes discussed in section 2.12. For example, proposed data access request by a researcher that requires new data to be collected (i.e., data not collected as part of the RHSCIR study) and/or new data linkages must receive REB approval in addition to review by ~~the the Praxis Spinal Cord InstituteInstituteRHI~~ committees outlined in Section 4.1 (National RHSCIR Team). See section 6.3 (Data Access and Stewardship) for further details on the governance structure in place for overseeing access requests to the national RHSCIR dataset, which is subject to ~~the Praxis Spinal Cord InstituteInstituteRHI's~~ [RHSCIR Data Use and Disclosure Policy](#).

5.25.4 Expanded RHSCIR Dataset [\(tSCI\)](#)

Subject to REB approval and informed consent, the local RHSCIR ~~c~~Coordinator will collect the expanded RHSCIR dataset which includes the following [additional](#) data elements (refer to *Schedule 1: RHSCIR Dataset* for complete information):

Demographics - ~~full name, date of birth, gendersex, city, province and country of residence, forward sortation area (first three digits of residential postal code), and ;provincial medical number, address, email address;~~

Socio-demographics - information describing the societal characteristics including occupation, education, household income, relationship status, living setting, height, and weight;

Medical History -- ~~other~~ information describing prior health status and current (post-injury) health status, including alcohol use, drug use, [and](#) other medical conditions, ~~cause of SCI, date and time of injury;~~

~~**Diagnosis** -- specific information describing the location of the spinal cord injury and any other secondary injuries or complications, including diagnosis code and location;~~

~~**Admission/Discharge** -- admission and discharge information outlining the movement of the individual through each care centre, including facility name, date of admission, admission category, [and](#) date of discharge, and physician most responsible;~~

~~**Neurology** -- information describing the type of SCI sustained, including ASIA Impairment Scale, motor scores, and sensory level;~~

Procedures—details outlining the primary operative procedure to stabilize the spinal column, including operative date, type of approach, type of implant used, neural elements decompressed, and intraoperative adverse events;

Interventions—information detailing specific elements of care provided, including skeletal traction, ventilation and, rehabilitation therapies; and

Outcomes - information detailing specific measurements of physical functioning secondary to SCI, including information on respiratory function, bowel and bladder management, and pain management, including information on spasticity, pressure injuries, pain, and other secondary complications.

~~The RHSCIR participants are also asked to complete questionnaires about pain, functional independence measures, general physical and mental health, quality of life, hospital inventory and environmental factors (e.g., ability to move around the home, community and access services), health care service utilization, use of alcohol, and other health conditions.~~

These data elements are then entered into ~~the RHI~~ GRP using the unique RHSCIR ID number assigned upon enrollment, explained in more detail in section 5.53.1. ~~The RHI~~ GRP utilizes role-based access controls to manage the privacy protection and security of the information held in the national RHSCIR database (see section 5.53.3 for details outlining the data entry process).

5.35.5 Data Collection Process

For consented RHSCIR participants, data collection at participating RHSCIR sites begins from the time of enrollment and continues with follow up questionnaires at ~~1, 218 months,~~ 5 years, and every 5 years ~~after that from the date of injury or thereafter post-injury or~~ until the participant withdraws from the RHSCIR study. ~~For non-consented RHSCIR participants, data collection begins from the time of enrollment until the participant leaves their final RHSCIR participating site.~~

The data entry process is facilitated by ~~the RHI~~ GRP, which is used for data collection, transfer, management, and storage. Access will be provided to authorized users at ~~the~~ local RHSCIR sites and at the Praxis Spinal Cord Institute~~Institute RHI.~~

5.3.45.5.1 The Unique Registry ID Number

When an individual is enrolled to participate in ~~the~~ RHSCIR, the local ~~research~~ RHSCIR coordinator enters ~~the participants name,~~ DOB, gendersex, and date of injury/onset into ~~the RHI~~ GRP. ~~The RHI~~ GRP uses this information to check for any duplicate entries (i.e., if the individual has already been enrolled at another RHSCIR site), and either alerts the ~~ce~~ordinator that there is a matching entry at a designated facility, or if no duplicate entry is found, then assigns a unique RHSCIR identification (ID) number to the participant. The RHSCIR ID number is a chronologically ordered, unique number, and is used as a method to identify the participant rather than using personal identifiers.

If ~~the RHI~~ GRP has identified the participant as previously enrolled, the coordinator will be instructed to contact that site by phone in order to confirm whether or not this is the same participant. If the participant has already been enrolled, that participant's RHSCIR record can now be shared with the admitting site through ~~the RHI~~ GRP. If the participant is confirmed as

new and unique, ~~the RHI~~ GRP offers the ability to force the enrollment and assign a new RHSCIR ID number.

All data about the participant that is stored at the local RHSCIR site, such as case report forms (CRF's), will be coded with this RHSCIR ID number only instead of their name. -The documents (electronic or paper) linking the participant's name to ~~the~~ RHSCIR ID number (e.g., enrollment log, ICF, contact information forms) are only accessible to the local ~~-~~coordinator and the principal investigator and other delegated staff, and must be kept separate from the CRF's under secure, locked conditions.

5.3.25.5.2 Capturing Consent Directives

Following the assignment of the unique RHSCIR ID number, the local ~~Coordinator~~ coordinator will enter the patient's consent directives into ~~the RHI~~ GRP. -Consent options are as follows:

- **Obtained** –an eligible to participant who was approached, RHSCIR ~~introduction study~~ overview was provided, and informed consent, surrogate consent, or assent with a surrogate's consent was obtained. -The participant is then asked if they would like to be added to the ~~Praxis Spinal Cord Institute~~ Institute RHI newsletter mailing list to be kept up-to-date with what is happening within the organization -and to receive information regarding participating in other potential SCI studies.
- **Not Obtained** - when "Not Obtained" is selected, a reason must be given from those listed below:
 - Consent declined – an individual was identified as eligible to participate; they were approached and RHSCIR introduction provided, but informed consent was declined;
 - Participant not identified during visit to facility – an individual was not identified as eligible until after they had been discharged from the facility. The method of identification is then indicated as DAD, health care team, or other. -If other is chosen, the method must be specified.
 - Participant identified during the visit to facility but discharged before they were able to approached – the individual was identified as eligible during their inpatient visit, but discharged from the facility before being approached for participation in ~~the~~ RHSCIR;
 - Deceased – the individual passed away before being approached for participation in ~~the~~ RHSCIR;
 - Language barrier – the individual was not able to communicate in English or French and a suitable translator was not able to be located (individual's language spoken must be specified);
 - Unable to consent – this might apply to various situations. -An example, an individual has suffered head trauma and is unable to understand the consent form and has no surrogate available to consent on their behalf (reason for inability to consent patient must be specified);

- Other – this might apply to various situations. -For example, an individual's family has requested not to be approached, or when the individual is known to be violent (details must be specified).
- **Withdrawal** – an individual has chosen to completely withdraw his/her total participation and has changed his/her consent status; he/she declines any further follow-up.

The RHI GRP will allow local RHSCIR coordinators to manage the consent status of the participant throughout the patient's SCI care-trajectory, tracking any changes to the consent status and their respective change dates.

5.3.35.5.3 Data Entry

After the consent process and assignment of the RHSCIR ID number is complete, the local research RHSCIR coordinator enters the appropriate data elements (using the CRFs, patient charts, questionnaires, etc.) into the RHI GRP. Additionally, within the RHI GRP, the functionality is available for the local coordinator to send an email link to a RHSCIR participant to a secure website, where the RHSCIR participant can complete the study questionnaires.

The RHI GRP has built-in access controls that ensure only authorized users from the local site(s) are able to view the participants' data. Participating RHSCIR site's facility's ability to enter personal identifying information will be determined by their ethics board approval process, and is documented in their site specific dataset, Schedule I.

The Praxis Spinal Cord Institute RHI employs strict technical, administrative, and physical safeguards to avoid any foreseeable risk of re-identification and to maintain levels of de-identification that are appropriate to the role of the user. -See section 6.3 for more information on data access and stewardship.

5.3.45.5.4 Site Monitoring Visits

It is the responsibility of the local PI to maintain adequate and accurate CRFs. All CRFs must be completed in their entirety in a neat, legible manner to ensure accurate interpretation of data. Following completion of data collection, entry into the RHI GRP should be done in a timely manner.

Monitoring visits conducted by National RHSCIR team members will occur on an as-needed basis. -The local PI, or a designated member of the PI's staff, must be available at some time during any monitoring visits to review the data and resolve any queries, and to allow direct access to the participants' records for source data verification. The CRFs should be made available in order that the accuracy of their completion may be checked.

5.45.6 Data Linkages

As applicable, -RHSCIR sites will link the information collected about the -participant with their local hospital Trauma Registry, the Discharge Abstract Database (DAD), and the National Rehabilitation Reporting System (NRS) in order to obtain a complete record of the SCI, to minimize duplication of information collected, and reduce the burden on the participant and the

personnel accessing this information. -Data linkage by participating RHSCIR sites is dependent^{ente} on level of care₁ and if their institutions contribute to the above mentioned national databases₁.

Data linkage is necessary because the more information surgeons, nurses, allied healthcare workers, administrators, ^{and} health coders/analysts have about the delivery of care to SCI patients, the better ~~can~~ they ^{can} examine clinical standards of care and improve care for the SCI population. -Furthermore, the utilization of data collected by ~~the~~ RHSCIR₁ combined with data from ~~the~~ other hospital databases₁ illustrates the complexity of the management and treatment of SCI cases₁ and ^{helps} define the local staff resources required to manage clinical care for this complicated patient group. -Presently this type of information cannot be realized from the data currently being collected in any one local or national hospital database.

The data linkages include:

- Trauma Registry
 - Information detailing medical status at the scene of the injury and on arrival to a health care centre including assessment of breathing and blood pressure, Glasgow Coma Scale (GCS) score, Numerical Injury Identifier (which includes Predot Injury Code and Abbreviated Injury Scale (AIS) Score), and Injury Severity Score (ISS).
- Hospital Administrative Database ~~{i.e., Discharge Abstract Database (DAD)}~~
 - Admission/Discharge - admission and discharge information, including length of stay in Special Care Units and transfer information;
 - Diagnose^{is} - diagnosis codes which describe the physical location of the spinal cord injury and any other secondary injuries or complications (pre-admit and post-admit comorbidities); and
 - Procedures - details outlining the primary surgical procedures utilized to stabilize the spinal column, and types of anesthesia used.
- National Rehabilitation System (NRS)
 - Admission/Discharge – admission and discharge information, including referral, length of stay, and service interruption information.
 - Diagnose^{is} – including most^{le} responsible health condition
 - Functional Independence Measure (FIM) - this questionnaire asks about the amount of assistance you require with mobility tasks such as getting in and out of bed, getting dressed and using a wheelchair or walking. It is completed by the health care team as a standard part of patient care.

6 Privacy and Security

6.1 Privacy Compliance and Governance

~~The Praxis Spinal Cord Institute~~Institute RHI adheres to a “gold standard” of data protection that ~~through-is~~compliance with Canadian legislative requirements, international data protection standards, and privacy best practices.

All research conducted or sponsored by ~~the Praxis Spinal Cord Institute~~Institute RHI adheres to the requirements established in the (1) *Tri-Council Policy Statement (TCPS): Ethical Conduct for Research Involving Humans*, (2) *Canadian Institutes for Health Research (CIHR) Best Practices for Protecting Privacy in Health Research*, and (3) *ICH Guidance E6: Good Clinical Practice: Consolidated Guideline (ICH-GCP)*.

~~The Praxis Spinal Cord Institute~~Institute RHI is subject to BC’s *Freedom of Information and Protection of Privacy Act (FIPPA)* for any RHSCIR data it receives from participating RHSCIR sites.

As a privacy best practice, ~~the Praxis Spinal Cord Institute~~Institute RHI also complies with the federal *Personal Information and Protection of Electronic Documents Act (PIPEDA)* and all provincial and territorial privacy laws for all of its information handling practices.

Participating RHSCIR sites are subject to and responsible for complying with their governing provincial/territorial privacy legislation (see applicable Act from list below), site-specific policies, procedures, and ethical/research guidelines for the collection, handling, and storage of local RHSCIR data.

- BC’s *Freedom of Information and Protection of Privacy Act (FIPPA)*;
- Alberta’s *Health Information Act (HIA)*;
- Saskatchewan’s *Health Information Protection Act (HIPA)*;
- Manitoba’s *Personal Health Information Act (PHIA)*;
- Ontario’s *Personal Health Information Protection Act, (PHIPA)*;
- Quebec’s *An Act Respecting Health and Social Services (HHS)*, the *Civil Code of Quebec* and the *Charter of Human Rights and Freedoms*;
- P.E.I.’s *Freedom of Information and Protection of Privacy Act (FOIPPA)*;
- Nova Scotia’s *FOIPPA*;
- New Brunswick’s *Protection of Personal Information Act (PPIA)*;
- Newfoundland and Labrador’s *Access to Information and Protection of Privacy Act (ATIPPA)* and *Bill 7 (the Personal Health Information Act)*;
- ~~ATIPPA~~ in Yukon, the Northwest Territories and Nunavut.
-

Participating RHSCIR sites must also follow their local and provincial regulatory policies.

~~The Praxis Spinal Cord Institute~~~~Institute~~ ~~RHI~~ has implemented a national privacy and security framework for information handling practices by national RHSCIR staff that is independent from, but complimentary to the existing local privacy infrastructure already in place at participating RHSCIR sites.

This privacy and security framework includes:

- 1) *Privacy Policy*;
- 2) *Privacy and Information Security Standard of Conduct*;
- 3) *Privacy Breach Management Protocol*;
- 4) *Data Retention and Destruction Policy*;
- 5) [RHSCIR Data Use and Disclosure Policy](#); and
- 6) *Information Security Policy*.

These policies and procedures are based on the various provincial and territorial privacy requirements applicable to RHSCIR sites to ensure a harmonized and uniform approach to privacy protection that adheres to the highest legal watermark³.

A critical component of the national privacy and security framework is ~~the Praxis Spinal Cord Institute~~~~Institute~~ ~~RHI~~'s formal privacy and security training and awareness program that all national RHSCIR staff must update annually to ensure accountability for access to and handling of the national RHSCIR dataset.

~~The Praxis Spinal Cord Institute~~~~Institute~~ ~~RHI~~ has completed a Privacy Impact Assessment (PIA) involving ~~the RHSCIR's study's~~ Phase II deployment, a copy of which is provided to each RHSCIR site upon request.- The PIA assesses the information handling practices employed at ~~the Praxis Spinal Cord Institute~~~~Institute~~ ~~RHI~~ against Canadian privacy laws and *CIHR Best Practices for Protecting Privacy in Health Research* in order to identify, assess, and mitigate ~~against~~ any significant privacy risks associated with the use of ~~the RHI~~ GRP.

6.1.1 Privacy and Security Safeguards at ~~the Praxis Spinal Cord Institute~~ ~~RHI~~

~~The Praxis Spinal Cord Institute~~~~Institute~~ ~~RHI~~ employs a variety of administrative, physical and technical safeguards to protect all of its data holdings against loss, theft, unauthorized access, disclosure, copying, use, modification, transmittal, disposal and anticipated threats.

~~The Praxis Spinal Cord Institute~~~~Institute~~ ~~RHI~~ maintains two separate and distinct information technology environments, one for the ~~RHI Global Research Platform (GRP)~~, which includes the secure collection and storage of sensitive research data, and one for ~~the Praxis Spinal Cord Institute~~~~Institute~~ ~~RHI~~'s business operations.

GRP Environment

^{3,2} Contact ~~Praxis Spinal Cord Institute~~ ~~RHI~~'s Privacy Officer for a full list of all ~~RHI~~~~Praxis Spinal Cord Institute's~~ privacy and security policies and procedures (privacy@~~rickhanseninstitute~~~~praxisinstitute~~.org).

Physical safeguards include:

- Offsite hosting at a top-tier, high security hosting facility;
- 2-factor authentication for physical entry to the facility;
- 24-hr monitored video surveillance;
- Computer servers are hosted in locked racks with restricted key access.

Organizational safeguards include:

- A signed contract with the top-tier, secure, internet hosting company covering:
- A high degree of confidentiality between ~~the Praxis Spinal Cord Institute~~ RHII and the hosting company;
- Internal procedures that meet strong security and privacy requirements;
- Data is hosted in Canada, including backup tapes storage;
- The hosting company manages the infrastructure: server hardware, server operating system software, anti-virus, firewalls, power, physical security, internet connectivity, etc.;
- ~~The Praxis Spinal Cord Institute~~ RHII manages the content of the servers: GRP, database software, encrypted data, data de-identification software, data management;
- All data is stored in encrypted format. Staff at the hosting company have no access to the data;
- ~~The Praxis Spinal Cord Institute~~ RHII's ability to audit the hosting company for all of the above.

Technical Safeguards include:

- Standard high-security practices at the hosting company, plus:
- GRP utilizes:
- Unique identification numbers⁴³ and de-identification technology;
- Strong password protection for access to systems (meeting at a minimum: 10 characters, including all of the following: uppercase, lowercase, numeric, special characters);
- Access controls such as two factor authentication, time limited user registration,, automatic time-out and reporting of user access and privilege levels;
- Built-in data validation checks to ensure data accuracy;
- Detailed audit trail tracking, including all access attempts, modifications made to RHSCIR data, all screen views, and timing information;
- Disaster Recovery Plan;
- Encrypted storage of all collected research data;
- Data encryption during transmission via secure socket layer (SSL) and virtual private network (VPN) technology for authorized remote access;
- Strict access restrictions and monitoring of all computer equipment and software;
- Backups performed multiple times per day;
- Backup tapes are stored in a secure offsite storage facility.

~~The Praxis Spinal Cord Institute~~ RHII Environment:

⁴³ As noted in section ~~5.1-51.13.3~~ 5.5.1, data collected about research participants is coded with a unique registry ID number.

All information about participants stored at the local site is coded with this auto-generated number instead of their name. Any use and disclosure of the ~~central~~ national RHSCIR dataset will rely on this unique RHSCIR ID for identification of record level data. Only local site personnel have access to patient identifiers, used for contacting participants for conduct of community follow-up interviews as outlined in the study protocol.

Physical safeguards include:

- ~~The Locked RHI~~ office space, ~~which is locked and access~~ can only be ~~gained~~ accessed through electronic card entry;
- Locked filing cabinets and offices;
- Staff identification ID, visitor badges, and guest sign in log (guests can only be given access to the ~~Praxis Spinal Cord Institute~~ Institute RHI office from ~~the Praxis Spinal Cord Institute~~ Institute RHI staff members);
- ~~No Lack of raw GRP data is stored at RHI. Only~~ Raw GRP data and data that have been reviewed, approved, de-identified, and extracted are stored in strictly permissioned, designated areas on ~~the Praxis Spinal Cord Institute~~ Institute RHI's network;-
- Access to RHSCIR datasets on ~~the Praxis Spinal Cord Institute~~ Institute RHI's network is restricted and monitored.
- ~~The Praxis Spinal Cord Institute~~ Institute RHI servers are backed-up to disk and tape. Backup tapes are stored in a secure offsite storage facility;
- All servers are located in a secure, locked server room with limited access.

Organizational safeguards include:

- Mandatory privacy and security training for all ~~RHI~~ staff at the Praxis Spinal Cord Institute ~~Institute~~, which requires ~~RHI staff~~ them to read and sign ~~the Praxis Spinal Cord Institute~~ Institute RHI's Privacy and Information Security Standard of Conduct and Confidentiality- Agreement;
- Legally binding confidentiality agreements ~~or~~ data sharing agreements or research agreements with all external parties with access to personal information or SCI data held within the national RHSCIR database;
- Data sharing agreements (DSA's) between ~~the Praxis Spinal Cord Institute~~ Institute RHI and each RHSCIR site;
- Privacy Impact Assessments on all data holdings, as required;
- A Data Access Committee to govern uses and disclosures of SCI data in compliance with the Praxis Spinal Cord Institute ~~Institute RHI's~~ RHSCIR Data Use and Disclosure Policy;
- End user license agreements for the web-based application; ~~and~~
- A Privacy Breach Management Protocol to manage and report privacy incidents.

Technical Safeguards include:

- Strong password protection for access to ~~the Praxis Spinal Cord Institute~~ Institute RHI network and all systems therein: (meeting at a minimum: 10 characters, including all of the following: uppercase, lowercase, numeric, special characters)
- ~~Automatic time-out of user workstations~~
-
- Disaster Recovery Plan and procedures
- A secure SharePoint site with strictly controlled permissions for study collaboration and communication. -Secure socket layer (SSL) and virtual private network (VPN) technology for authorized remote access.

6.1.2 Privacy and Security Safeguards at Local RHSCIR Sites

Administrative Safeguards:

All RHSCIR sites must comply with their local governing privacy and security policies and related procedures, which are complemented by ~~the Praxis Spinal Cord Institute~~InstituteRHI's national privacy and security framework for the handling of all local RHSCIR data.

Local RHSCIR staff will also receive training on how to use ~~the RHI~~ GRP and RHSCIR data.

Physical Safeguards:

- All identified paper records (e.g., enrollment log) are to be stored in a locked filing cabinet, separate from participant case report forms (CRF's) in a secured room with limited, authorized access;
- All non-identified paper records (e.g., CRF's) are to be stored in a secured room with limited, authorized access.

Technical Safeguards:

- Separate storage of personal identifiers;
- Local network security is governed by the security protocols of the RHSCIR site;
- All computers that access ~~the RHI~~ GRP are to be password protected. Each local computer will utilize a unique username and password for all local RHSCIR staff, including two-factor authentication, time limited user registration, automatic time-out and role-based access controls and user profiles;
- Records linking participant identifiers and RHSCIR ID number are stored in separate encrypted, password protected files, only available to PI and their delegated personnel at RHSCIR sites.

6.2 Data Retention and Destruction

Once ~~the~~ RHSCIR data is entered into ~~the RHI~~ GRP, it will continue to be stored in the national RHSCIR database for a period of 5 years after ~~the~~ RHSCIR closure before being destroyed in a confidential and secure manner in accordance with site-specific policies, timelines and procedures.

~~All RHI staff~~The national RHSCIR team ~~are-is~~ subject to the Praxis Spinal Cord Institute~~InstituteRHI~~'s Data Retention and Destruction Policy, which requires a record of the individual whose information was destroyed to be kept, including the date, method of destruction and the person responsible for supervising the destruction.

If required, the duration of storage may be periodically reviewed and updated by the local institution for the data maintained at the by its local hospital(s).

If a participant withdraws consent, no new information will be collected or entered into ~~the RHI~~ GRP. -All information collected up to that point will remain in the national RHSCIR database and local documentation will be retained as per local site procedures. -Any data that has already been disclosed will not be recalled, as it may have already been analyzed or published.

6.3 Data Access and Stewardship

Requests for access to local RHSCIR data will be managed by the ~~the site~~local RHSCIR PI and the local RHSCIR coordinator per their institutional policy. -All participants have the right to access

and review their own files in order to verify and validate the information and make corrections. This right is limited by legal exceptions in accordance with applicable privacy laws.

Data analysts at ~~the Praxis Spinal Cord Institute~~Institute RHI have permission to access the national RHSCIR dataset or use RHSCIR data previously collected in a secured network environment for quality control and data management purposes (e.g., to create analytical datasets).

Otherwise, personnel affiliated with ~~the Praxis Spinal Cord Institute~~Institute RHI, as well as other external personnel, will need to obtain approval through ~~the Praxis Spinal Cord Institute~~Institute RHI's data access request and approval process to gain access to data held within the national RHSCIR database. Requests for such access will be made using ~~the Praxis Spinal Cord Institute~~Institute RHI's Application for Disclosure of Health-National RHSCIR Data (Data Access Request) in accordance with ~~the Praxis Spinal Cord Institute~~Institute RHI's RHSCIR Data Use and Disclosure Policy.

Those requesting data could include individuals or organizations from outside of Canada or commercial entities. If requestors are accessing data from outside of Canada, the data is subject to the laws of the country in which it is accessed and held, and may be subject to disclosure to the governments, courts or law enforcement or regulatory agencies of such other country, pursuant to the laws of such country. Some data requests may include linking participant level RHSCIR data to other health care data-sets held by the Praxis Spinal Cord Institute~~Institute RHI~~ or organizations such as the Canadian Institute for Health Information, ICES (formally known as the Institute for Clinical Evaluative Sciences), or Population Data BC containing information about use of the health care system including other clinical research that RHSCIR participants may have been involved with. Additional ethical approval will be sought where necessary.

The RHSCIR Data Use and Disclosure Policy is available upon request from ~~the Praxis Spinal Cord Institute~~Institute RHI and outlines in detail the data access request and approval process employed at ~~the Praxis Spinal Cord Institute~~Institute RHI before access is granted to the national RHSCIR dataset.

7 Publication and Communication of Results

All publications resulting from ~~the~~ RHSCIR will be listed on the ~~the Praxis Spinal Cord Institute~~Institute RHI website (www.praxisinstitute.rickhaseninstitute.org) as the results become available, and in accordance with the Praxis Spinal Cord Institute's RHI's Publication Policy.

8 ~~78~~ References

- ~~11.1.~~ 11.1. Khaled El Emam and Anita Fineberg (August 14, 2009), *An Overview of Techniques for De-Identifying Personal Health Information*, a joint paper funded by the Access to Information and Privacy Division of Health Canada. Available at SSRN: <http://ssrn.com/abstract=1456490>.
- ~~12.~~ 12. Tri-Council Policy Statement (TCPS 2): *Ethical Conduct for Research Involving Humans*, December 2010.
- ~~13.~~ 13. *International Conference on Harmonization (ICH) Guidance E6: Good Clinical Practice: Consolidated Guideline*, available at: <https://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html#6>. ~~<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php>~~.
- ~~14.~~ 14. Food and Drug Regulations – Drugs for Clinical Trials Involving Human Subjects.
- ~~15.~~ 15. Canadian Institutes for Health Research (CIHR) Best Practices for Protecting Privacy in Health Research, available at: <http://www.cihr-irsc.gc.ca/e/29072.html>.
- ~~16.~~ 16. ISO 27799:2008 Health Informatics -- Security management in health using ISO/IEC 27002.
- ~~17.~~ 17. Federal privacy legislation, Personal Information Protection and Electronics Document Act (PIEDA)

Provincial privacy laws, including:

- B.C.'s *Freedom of Information and Protection of Privacy Act* (FIPPA);
- Alberta's *Health Information Act* (HIA);
- Saskatchewan's *Health Information Protection Act* (HIPA);
- Manitoba's *Personal Health Information Act* (PHIA);
- Ontario's *Personal Health Information Protection Act, 2004* (PHIPA);
- Quebec's *An Act Respecting Health and Social Services* (HHS), the *Civil Code of Quebec* and the *Charter of Human Rights and Freedoms*;
- P.E.I.'s FOIPPA;
- Nova Scotia's FOIPPA;
- New Brunswick's *Protection of Personal Information Act* (PPIA);
- Newfoundland and Labrador's *Access to Information and Protection of Privacy Act* (ATIPPA) and Bill 7 (the *Personal Health Information Act*);
- ATIPPA in Yukon, the Northwest Territories and Nunavut.

APPENDIX 1: RHSCIR QUESTIONS

Clinical support and management—to promote, encourage and develop an efficient and effective national health data retrieval and management reporting service

1. Does delay to admission to an acute centre influence complication rate, length of stay or overall patient satisfaction?
2. Does time to injury to initial ASIA assessment influence the potential for neurological improvement?
3. Does remoteness of injury influence time to admission and overall length of stay?
4. Are there differences in the type and mechanism of injury across the provinces?
5. What types of services are received by patients in rehab centres across Canada?

Research support—to create a clinical and epidemiological based information service to promote collaboration between scientists and clinicians, and support true translational research and provincial/territorial, national and international data exchange and collaboration

1. Do the alternative level of care (ALC) days waiting for rehab vary across Canada and is this correlated to neurological level, severity or neurological change score?
2. What is the influence of early surgery on the stay in intensive care unit and how does this vary across Canada?
3. How many patients with SCI are sent out of province due to bed shortages and does this vary by province?
4. What is the effect of early neuroprotective treatment on neurological outcomes?
5. What proportion of SCI patients are eligible for clinical trials?

Partnerships and quality improvement—to demonstrate flexibility in helping partners achieve their SCI information goals

1. What is the prevalence of SCI related conditions in persons with SCI at 1, 2, and 5 years post injury and how do these relate to severity of injury?
2. What is the incidence of SCI and demographics of the SCI population across Canada?
3. What are the costs associated with treating SCI related conditions?
4. What are the environmental barriers experienced by persons with SCI in Canada, do they vary in urban versus rural settings?
5. What proportion of SCI patients receive peer monitoring and does this improve quality of life?

Quality data and information—to ensure the quality of data stored in the national RHSCIR database

1. How does consent rate for RHSCIR compare among provinces?
2. Is there a correlation between ICD10 classifications and severity of neurological injury?
3. What proportion of SCI admissions are captured by RHSCIR compared to CIHI data?
4. What is the variability of ASIA assessments among different clinicians?

Business planning and future development—to remain current with changing trends and issues in health care management

5. What proportion of RHSCIR patients complete 1, 2 and 5 year follow up interviews and how do rates vary across Canada?

1. What proportion of persons with SCI require health services in the community?

2. What is frequency of re-admissions to acute care from rehab, most common causes for re-admission and affect on length of stay?

3. What is the influence on outcome of delay in admission to a specialized SCI Centre?

4. Does adherence to SCI practice guidelines improve neurological outcomes and is this improvement related to severity of injury?

5. Which injury and personal factors predict life satisfaction scores?

Appendix 21: -Protocol – Documents Version Control

Version	Date	Author(s)	Change Description
V1.0	March 3, 2004	Vanessa Noonan	
V1.2	2007	Kris Walden Maaret Brandon	
V1.3	August 2008	Kris Walden Maaret Brandon Vanessa Noonan Cathy McGuinness	Updates -- SCI-TRN, -Organizational Structure(s), Privacy & Security Appendices – A - F
V1.4	October 2008	Kris Walden Maaret Brandon	Amendments as per changes required for Quebec legal feedback
V1.5	January 2009	Cathy McGuinness Sylvia Kingsmill	Updates to reflect current status of the National RHSCIR Program as per the National RHSCIR Privacy Report
V1.6	12 February 2009	Cathy McGuinness Sylvia Kingsmill	Updates to include unique Registry ID procedures, No-consent Data s -Set, Data Linkages, the Patient Tracking System and the Praxis Spinal Cord InstituteRHI _org chart Add Schedule I: -RHSCIR Data s -Set
V1.7	20 February 2010	Cathy McGuinness Sylvia Kingsmill	Updates to clarify additional privacy and operational concerns raised by the Toronto Rehab Institute REB.
V2.0	23 Aug 2011	Jennifer Zander	Updates to account for Phase II operations, i.e. use of web platform (RHI GRP) for RHSCIR

		Kris Walden	data collection and management. Removal of Appendices A – F.
V2.1	08Nov2013	RHSCIR National RHSCIR Project Team	Standardization of Protocol across sites Update to RHSCIR Dataset
<u>V3.0</u>	<u>07May2019</u>	<u>National RHSCIR Team</u>	<u>Update to RHSCIR Dataset</u> <u>Inclusion of ntSCI to RHSCIR Dataset</u> <u>Removal of V2.1 Appendix 1</u> <u>Organizational name change</u>