**The Rick Hansen Spinal Cord Injury Registry (RHSCIR)**

**PARTICIPANT INFORMATION & CONSENT FORM**

**Principal Investigator:**

**Co-Investigators:**

**Sponsor:** The Praxis Spinal Cord Institute

**Funders:** Western Economic Diversification Canada, *[Add provinces BC or MB]*

**Local contact person:** *[insert local contact information]*

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### **INTRODUCTION**

You are being invited to participate in the Rick Hansen Spinal Cord Injury Registry (RHSCIR) because you have sustained a traumatic spinal cord injury (SCI). The information in this consent form is intended to help you understand exactly what we are asking of you so that you can decide whether or not you want to participate in RHSCIR. Please read this consent form carefully and ask as many questions as you need to understand what RHSCIR involves. Please take whatever time you need before reaching a decision, and consult with others as you wish. Your participation in RHSCIR is entirely voluntary, and a decision not to participate will not affect your clinical care.

*[Insert name of participating RHSCIR site]* is participating in RHSCIR, which is funded by Western Economic Diversification Canada (and the provinces of BC and MB). These funds are managed and distributed by the Praxis Spinal Cord Institute (the Institute), a non-profit organization that supports research and improvements in clinical care for people with a spinal cord injury (SCI). RHSCIR is currently being conducted at 30 acute and rehabilitation centres across Canada.

The national RHSCIR team at the Institute in Vancouver, BC, operates RHSCIR, which contains and stores information about individuals who have sustained SCIs in a national database. This database is supported by a network of local site teams (e.g. physicians, nurses, physical therapists, occupational therapists, hospital administrators, clinical research coordinators, and data analysts) at participating acute and rehabilitation centres across Canada. These centres are referred to as “local RHSCIR sites”, and together they form the RHSCIR Network.

### **WHO CAN PARTICIPATE?**

You are invited to participate in RHSCIR because you have sustained a traumatic spinal cord injury.

### **PURPOSE**

The primary objective of RHSCIR is to collect clinical care information (a data repository) about all Canadians who sustain a SCI (both traumatic and non-traumatic). The combined collection of clinical care information is used to

* Make clinical care and hospital administration processes across Canada better to improve health outcomes for individuals with SCI;
* Answer local and national research questions; and
* Create collaborations between health care centres across the country to help ensure that all individuals with SCI receive the best and similar types of clinical care.

Data collected about you through RHSCIR may be used for purposes that meet the goals and objectives (Permitted Purposes) of RHSCIR, specifically:

* Supports and helps manage patient care: Supports continued research;
* Quality improvement in patient care through partnerships: Evaluates data quality and assessment tools;
* Promotes business planning and future development.

### **PROCEDURES**

If you agree to participate in RHSCIR, the quality of your care will be no different than if you do not agree to participate. You may refuse to answer any of the questions that you are not comfortable with at any time.

**Hospital Data Collection**

After agreeing to participate in RHSCIR and signing the consent form, a local RHSCIR representative will perform a short interview with you to gain a complete picture of your health status. The interview will take approximately 10-15 minutes including questions about: demographics, contact information, sociodemographics, and medical history.

A local RHSCIR representative will also review your medical record for information on; demographics, medical history, admission/discharge, diagnosis, neurology, procedures, interventions and outcomes.

Prior to your discharge from the hospital, a local RHSCIR representative will perform another short interview (10 minutes) with you to collect some additional information including: additional contact information, sociodemographics, medical history, interventions, complications, and independence in daily activities.

A local RHSCIR representative will combine the information collected from you and your medical record with information that has already been collected about your injury from your local hospital Trauma Registry, Discharge Abstract Database (DAD), and National Rehabilitation Reporting System (NRS). This is done in order to obtain a complete record of your injury and to avoid re-collecting information that has already been collected.

**Follow-up Data Collection**

After you have been discharged from the hospital, local RHSCIR research representatives will contact you in the community, by telephone, mail, or email link to a secure website, or in person, asking you to complete questionnaires related to your health and quality of life. This will be done at 18 months post injury, 5 years post injury, and then every 5 years. Information collected at this time includes: contact information, sociodemographics, medical history, health care utilization, pain, independence in daily activities, quality of life, community and environment accessibility, health conditions & secondary complications.

**If you choose not to participate…**

A minimal amount of information will be collected on all eligible patients, regardless of whether or not you choose to enroll in RHSCIR. This information will include the items listed above **except** for interviews and follow-up data collection. The minimum information collected is essential to allow accurate reporting of the frequency of SCI, and to ensure that local RHSCIR staff do not approach participants who do not choose to participate in this study twice (for example, if you are transferred to another site). The information will be obtained from your hospital record and local hospital databases, and will not require any of your time. If you object to having any of your information added to the registry please inform the RHSCIR coordinator explaining this consent form to you and your wishes will be respected.

### **RISKS**

The questionnaires may contain questions which could provoke sadness or create anxiety for some individuals. Although every effort is made to protect your health information, there is always a minimal risk that unauthorized users may attempt to access or misuse your health information. RHSCIR uses the most advanced security measures to protect your privacy. Apart from this, there are no known risks associated with completion of the questionnaires or assessments.

### **BENEFITS**

There are no direct benefits from participating in RHSCIR. However, your participation is important in assisting clinicians and researchers working on improving the quality of care and quality of life for people who have a new SCI, as well as people who are living in the community with a SCI.

### **CONFIDENTIALITY**

Your confidentiality will be respected. Protecting your privacy is of primary importance to the Praxis Spinal Cord Institute and RHSCIR. Unless required or authorized by law, no information that might directly or indirectly reveal your identity will be released or published without your specific consent. Any reports or publications resulting from RHSCIR will be de-identified and/or summarized data so will not specifically identify you.

Records (health, data collected or other source records) identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of the Institute and *[Insert name of your local REB]*for the purpose of monitoring the accuracy of the data collected. All of these people have a professional responsibility to protect your privacy.

Your data will be shared electronically with the national RHSCIR group, which receives data from all of the participating RHSCIR sites across the country. Only a limited number of authorized staff at the national RHSCIR office will have access to your identified data for the purpose of database system administration. These individuals must comply with very strict privacy and security regulations under the Institute’s privacy and security framework (if you wish, this can be explained to you).

In every other instance (when the collected data is used) you will only be identified by a unique Registry ID Number instead of your name. All your records will be identified with this unique Registry ID Number, both locally and nationally, to protect the confidentiality of your personal health information and to respect your privacy.

Locally, only the Principal Investigator and authorized RHSCIR staff working at RHSCIR sites where you are treated will have access to your identified data. This means that if you are transferred to other participating RHSCIR sites, your RHSCIR data will be shared with that site’s local RHSCIR team. This enables your research team to have the most complete record of your progress through your acute and rehabilitation care. All RHSCIR staff who may review your medical records have received training on their obligations to protect your privacy. Your local site team will collect and store identifying patient information about you in accordance with local provincial privacy laws, which provide privacy rules for how health care providers must protect your health information.

Furthermore, local participating sites adhere to their own local privacy policies and procedures to prevent unauthorized or unintentional use, disclosure, modification, retention or destruction of your information. Your rights to privacy are also protected by all applicable provincial and federal legislation at the national level. The Privacy Officer at the Institute is responsible for overseeing and protecting the data that is managed by the National RHSCIR team. Further details about the privacy program for RHSCIR are available upon request or through www.praxisinstitute.org or email privacy@praxisinstitute.org.

The data will be entered into a secure information management system. All data entered into this system will be stored in a secure facility in Canada. The privacy and security of your information is managed using a set of administrative, technical and physical safeguards. All participants have the right to access and review their own data files in order to verify and validate the information and make corrections. Requests for access to your data will be managed by [*Insert name of PI*]. This right is limited by certain legal exceptions.

All SCI information collected will be stored by the local site [*for a minimum of 5 years after the end of the study if RHSCIR data collection is ever stopped (Please use your institutional guidelines. Health Canada requires document storage for 25 years for clinical trials only. Most institutions have lower requirements for non-clinical trials, UBC’s is at least 5 years – obviously this is easier to manage than 25)]* and by the national site in electronic form for as long as necessary to fulfill the purposes of RHSCIR and will be destroyed in a confidential and secure manner in accordance with the Institute’s Data Retention and Destruction Policy. If required, the duration of storage may be reviewed periodically by the REB for the data provided by its local site teams.

Requests for access to national RHSCIR data (which may include individuals or organizations from outside of Canada or commercial entities) are reviewed and approved in accordance with RHSCIR’s Data Use and Disclosure Policy. All data accessed will be deidentified and will not contain any direct identifiers such as name, date of birth, date of injury or postal code. 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 your RHSCIR data to other health care data sets held by the Institute or organizations such as the Canadian Institute for Health Information, Institute for Clinical Evaluative Sciences (ICES), or Population Data BC containing information about your use of the health care system including other clinical research that you may have been involved with. Any use of local site data requires the approval from *[insert principal Investigator name].* The Institute will combine your data and produce high level reports which will be publicly available (such as an annual SCI report). These reports will not contain any data that will be able to identify you. If you have any questions or concerns about data disclosure and use please contact the RHSCIR Data Steward (dataservices@praxisinstitute.org).

*For Ontario sites only: [ICES data linkage: We also require your permission to collect information on your clinical outcomes (e.g., hospitalizations, receipt of services such as dialysis, death). This will be done by linking information like your health card number and name to health care databases held at the Institute for Clinical Evaluative Sciences (ICES). The ICES databases contain information about physician, hospital, home care services and medications that are paid for by the Ontario government. The linkage of your data with ICES databases will be done in order to allow for more complete information about your injury and care to be linked in order to illustrate the complexity of the management and treatment of SCI.*

*Information like your health card number and name will be securely transferred from [list hospital, clinic, etc. where research is taking place] by or on behalf of the study investigators to the Institute for Clinical Evaluative Sciences (ICES) so the required linkages can be made to gather the information for the study. The study investigators will be permitted to access de-sensitized information only for analysis (i.e., any information that can directly identify a person like health card number or name will be removed or replaced with a code that is not known to the study investigators).]*

Prospective projects that do not meet the RHSCIR Permitted Purposes will require review by the [*Insert name of your local Research Ethics Board]*. This is to ensure that the proposals have both scientific merit and meet ethical practices. The local RHSCIR staff may then contact you to discuss your interest in future participation in approved projects.

### **VOLUNTARY PARTICIPATION**

Participation in RHSCIR is entirely voluntary. It is up to you to decide whether or not to take part in RHSCIR. If you wish to participate, you will be asked to sign this form. By signing this consent form, you are not waiving any of your legal rights.

If you decide to take part in RHSCIR, you may withdraw at any time and without giving any reasons for your decision. If you decide not to participate, you will not lose the benefit of any medical care to which you are entitled or are presently receiving. You will need to inform your local RHSCIR staff member or the Principal Investigator of RHSCIR to ensure that you are not contacted in the future. All data collected up to the point of your withdrawal will be retained in the database for analysis, but no further data will be collected or entered.

There will be no monetary compensation for participating.

### **ADDITIONAL INFORMATION**

If you have any concerns or questions about RHSCIR, you may call [*Insert name of study PI]* or the RHSCIR coordinator at [*Insert name of Participating RHSCIR Site*], [*Insert name*] at [*Insert phone number].*

If you have any concerns or complaints about your rights and/or your experiences while participating in this registry, contact [*Insert local hospital Ombudsman or local REB contact information for subjects; e.g. Research Subjects Information Line, Chair of Biomedical Research Board, Ethics review officer, etc.]*

### **NEW INFORMATION/COMMUNICATION OF RESULTS**

All new findings developed during the course of RHSCIR, which may influence your desire to continue your participation in RHSCIR, will be posted on the Institute’s website when the information becomes available. If you would like to read more about RHSCIR, please check the website at <https://praxisinstitute.org/research-care/key-initiatives/national-sci-registry/>.

### **PARTICIPANT’S CONSENT**

I have read, or have been read, and understood the information provided in this information and consent form and all of my questions have been answered to my satisfaction. I have had sufficient time to consider whether to participate in RHSCIR. I understand that my participation in RHSCIR is entirely voluntary, that I may withdraw from RHSCIR at any time, without explanation, and that my level of care will not be affected by my decision to decline or withdraw participation.

I voluntarily consent to participate in RHSCIR. I agree to allow clinical personnel and researchers to access my health records to collect information relevant to my SCI and to ask questions regarding my medical history and sociodemographic status, which will be used and disclosed for the purposes of RHSCIR, as described to me in this consent form. This will also include follow up questions that are conducted by RHSCIR staff or online at 18 months, 5 years, and then every 5 years to complete questionnaires related to my health status. I agree to have this information shared between all RHSCIR sites that I receive treatment from during my acute and rehabilitation care.

In agreeing to the above data collection, I also agree to allow local RHSCIR representatives to link this data, and understand that my data will be used and disclosed only for the permitted purposes of RHSCIR, as described to me in this consent form.

I confirm that I have discussed with my next of kin and that he/she has agreed to allow local RHSCIR staff to collect information about my next of kin (contact details and relationship to the participant) and be contacted for the purposes of releasing my contact information so I can continue participating in follow up reviews.

I understand that I am not waiving any of my legal rights as a result of signing this consent form.

* I agree to have my name and email address shared with the Praxis Spinal Cord Institute to be added to its mailing list so that the Institute may keep me up to date on what is happening within the organization and to receive information regarding other potential SCI research opportunities.

Any additional contact will be handled through local RHSCIR staff at *[Insert name of participating RHSCIR site]*, who may contact me about new studies or future initiatives.

I will receive a signed copy of this consent form for my own records.

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| Signature or Mark of the Participant | Date | Printed Name of the Participant |

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| **❒ *The participant is unable to give written consent and has given verbal consent to participate in RHSCIR. Witness signature to participant’s verbal consent:*** | | |
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| Signature of Witness | Date | Printed Name of Witness |
| **❒ *The participant is unable to give written OR verbal consent OR assent to participate in RHSCIR. Participant’s Legal Representative has consented on their behalf:*** | | |
| I voluntarily consent that \_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name of participant) participate in RHSCIR | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Legal Representative | \_\_\_\_\_\_\_\_\_\_\_\_\_  Date | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Printed Name of Legal Representative |
| Relationship of Legal Representative to participant:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Reason why participant is unable to provide informed consent:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **❒ *The participant is unable to understand the information and the consent form in English or French and has had the form translated for them:*** | | |
|  |  |  |
| Signature of Translator | Date | Printed Name of Translator |
| Language Translated: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

**Individual Obtaining Consent**

I have explained all the relevant aspects of the research to the Participant and/or the Participant’s legal representative and answered their questions. I have pointed out that participation in RHSCIR is voluntary and that they may stop their participation at any time.

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| Signature of Individual  Who Obtained Consent | Date | Printed Name of Individual  Who Obtained Consent |

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| **PARTICIPANT’S ASSENT TO PARTICIPATE IN RHSCIR** ***This section to be used when the participant is a legal minor or is unable to give fully informed consent (e.g., has sustained a traumatic brain injury and is able to only partially understand RHSCIR)***  I have had the opportunity to read this consent form, to ask questions about my participation in RHSCIR, and to discuss my participation with my parent(s)/guardian(s)/substitute decision-maker. All my questions have been answered. I understand that I may withdraw from RHSCIR at any time, and that this will not interfere with other health care available to me. I understand that my consent will be sought once I am able to consent for myself. I have received a copy of this consent form. I assent to participate in RHSCIR.   |  |  |  | | --- | --- | --- | |  |  |  | | Signature or Mark of Participant | Date | Printed Name of Participant | | **Legal Representative**  As the parent/guardian/substitute decision-maker (legally authorized representative) I am satisfied that the information contained in this consent form was explained to the child/participant to the extent that he/she is able to understand it, that all questions have been answered, and that the child/participant assents to participating in RHSCIR.  I voluntarily consent that \_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name of participant) can participate in RHSCIR. | | | |  |  |  | | Signature of Legal Representative | Date | Printed Name of Legal Representative | | Relationship of Legal Representative to the participant:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | Reason why the participant is unable to provide informed consent:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |

**Individual Obtaining Participant Assent and Consent of Legal Representative**

I have explained all the relevant aspects of the research to the participant and/or to the participant’s parent(s)/guardian(s) and answered their questions. I have pointed out that participation in RHSCIR is voluntary and that they may stop their participation at any time.

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| Signature of Individual Who Obtained Assent/Consent | Date | Printed Name of Individual Who Obtained Assent/Consent |