

# Rick Hansen Spinal Cord Injury Registry (RHSCIR) Protocol

## Summary of Changes

**Protocol Version:** 13Dec2019

The following table summarizes the changes made to Rick Hansen Spinal Cord Injury Registry (RHSCIR) protocol

Protocol -	<ul style="list-style-type: none"> <li>• “the RHSCIR” is replaced with “RHSCIR”</li> <li>• “RHI GRP” is replaced with “GRP”</li> <li>• “<i>RHI’s Data Use and Disclosure Policy</i>” is replaced with “<i>RHSCIR Data Use and Disclosure Policy</i>”</li> <li>• “Gender” replaced by “sex” to clarify that the data element collected refers to biological attributes, as per CIHR definition of sex and gender</li> <li>• Due to new organizational branding, “Rick Hansen Institute” and “RHI” are replaced with “the Praxis Spinal Cord Institute” or “the Institute”</li> </ul>
Definitions & Abbreviations	<ul style="list-style-type: none"> <li>• Section 1.2 <ul style="list-style-type: none"> <li>○ Spinal cord injury (SCI) defined to include both traumatic and non-traumatic SCI</li> <li>○ Definitions for traumatic SCI (tSCI) and non-traumatic SCI (ntSCI) provided</li> </ul> </li> </ul>
Background of RHSCIR	<ul style="list-style-type: none"> <li>• Section 1.3 <ul style="list-style-type: none"> <li>○ Section updated to reflect enrollment of ntSCI participants in RHSCIR</li> </ul> </li> </ul>
Study Timeline	<ul style="list-style-type: none"> <li>• Section 1.6 <ul style="list-style-type: none"> <li>○ Follow-ups conducted at 1- and 2-years post-injury were condensed to a single follow-up at 18 months post-injury</li> </ul> </li> </ul>
RHSCIR Permitted Purpose	<ul style="list-style-type: none"> <li>• Section 2.1 <ul style="list-style-type: none"> <li>○ Section updated to reflect inclusion of ntSCI in permitted purposes for RHSCIR. Data collected under RHSCIR V2.1 will be combined with those collected under RHSCIR V3.0. Currently consented RHSCIR participants will be notified of these new permitted purposes.</li> </ul> </li> </ul>
Inclusion & Exclusion Criteria	<ul style="list-style-type: none"> <li>• Section 3.1 &amp; 3.2 <ul style="list-style-type: none"> <li>○ Inclusion and exclusion criteria for tSCI participants were outlined in sections 3.1.1 and 3.1.2, respectively.</li> <li>○ Inclusion and exclusion criteria for ntSCI participants were added in sections 3.2.1 and 3.2.2, respectively.</li> </ul> </li> </ul>

Sample Size	<ul style="list-style-type: none"> <li>Section 3.3 <ul style="list-style-type: none"> <li>Section updated with national enrollment rate of approximately 400 ntSCI RHSCIR participants annually.</li> </ul> </li> </ul>
Participant Enrollment	<ul style="list-style-type: none"> <li>Section 3.4 <ul style="list-style-type: none"> <li>Section 3.4.2 was added to describe enrollment of ntSCI participants to RHSCIR. Enrollment of ntSCI participants will only be conducted at rehabilitation facilities, and only minimum dataset will be collected from these individuals via chart abstraction.</li> </ul> </li> </ul>
National RHSCIR Team	<ul style="list-style-type: none"> <li>Section 4.1 <ul style="list-style-type: none"> <li>Updated to reflect changes in Praxis Spinal Cord Institute's privacy compliance program, including the roles and responsibilities of the Privacy Officer</li> </ul> </li> </ul>
Consent & Data Collection	<ul style="list-style-type: none"> <li>Section 4.2.2 <ul style="list-style-type: none"> <li>Role of the RHSCIR Coordinator updated to include "obtaining informed consent" and "entering data into GRP"</li> <li>Role of RHSCIR Assistant has been removed</li> </ul> </li> </ul>
Informed Consent Process	<ul style="list-style-type: none"> <li>Section 5.1.1 <ul style="list-style-type: none"> <li>Subsection updated to highlight that patient names will no longer be collected from tSCI participants</li> <li>"Clinician" was removed from section 5.1.1 to highlight that only RHSCIR Coordinators will be approaching tSCI patients for consent, not clinicians</li> </ul> </li> </ul>
Informed Consent Process	<ul style="list-style-type: none"> <li>Section 5.1.2 <ul style="list-style-type: none"> <li>Added to emphasize collection of data elements as part of minimum dataset for ntSCI patients</li> </ul> </li> </ul>
Expanded RHSCIR Dataset (tSCI)	<ul style="list-style-type: none"> <li>Section 5.4 <ul style="list-style-type: none"> <li>"tSCI" added to section title to emphasize that expanded RHSCIR dataset will only be collected in tSCI patients</li> <li>Data elements "full name, provincial medical number, and address" removed from Demographics data collected</li> <li>"physician most responsible" removed from Admission/Discharge data collected</li> <li>"Bowel and bladder management" added to Outcomes collected</li> </ul> </li> </ul>
Data Collection Process	<ul style="list-style-type: none"> <li>Section 5.5 <ul style="list-style-type: none"> <li>Wording updated to reflect changes in follow-up schedule: 1- and 2-year follow-ups will be replaced by a single follow-up at 18-months post-injury</li> </ul> </li> </ul>
The Unique Registry ID Number	<ul style="list-style-type: none"> <li>Section 5.5.1 <ul style="list-style-type: none"> <li>Participant name has been removed from data collection (only RHSCIR ID entered into GRP)</li> </ul> </li> </ul>
Privacy and Security Safeguards at the Praxis Spinal Cord Institute	<ul style="list-style-type: none"> <li>Section 6.1.1 <ul style="list-style-type: none"> <li>Name of this section has been updated to reflect the organization's new name</li> <li>Section updated to include updated <i>RHSCIR Data Use and Disclosure Policy</i> as part of organizational safeguards.</li> </ul> </li> </ul>

Data Access and Stewardship	<ul style="list-style-type: none"> <li>• Section 6.3 <ul style="list-style-type: none"> <li>◦ Subsection added to clarify data access request processes from individuals or organizations from outside of Canada, or from commercial entities</li> </ul> </li> </ul>
Publication and Communication of Results	<ul style="list-style-type: none"> <li>• Section 6.3 <ul style="list-style-type: none"> <li>◦ Section updated to include Praxis' Publication Policy</li> </ul> </li> </ul>
References	<ul style="list-style-type: none"> <li>• References updated to reflect adherence of current protocol to version 2 of ICH Guidance E6</li> <li>• Link to CIHR added</li> </ul>
Appendix	<ul style="list-style-type: none"> <li>• Appendix 1 from V2.1 Protocol removed</li> <li>• Protocol- Documents Version Control was updated to reflect the current (V3.0) Protocol</li> </ul>