

RE: Rick Hansen Spinal Cord Injury Registry – Amendment Cover Letter

Dear members of the REB,

This letter provides clarification about the RHSCIR amendments and the changes associated with RHSCIR documents.

Protocol

For administrative purposes, sections of the protocol have been updated to reflect changes in definitions, data disclosure policies, and various operating procedures since the last protocol amendment. To assist in this review, those changes have been summarized in an attached document titled “RHSCIR Protocol –Summary of Changes”.

We have also made alterations to data elements collected in RHSCIR, which is outlined in the updated “RHSCIR Schedule I – RHSCIR Dataset” document.

As RHSCIR has grown at participating sites, it has been increasingly seen as a valuable and useful resource in supporting local and national quality improvement processes in the clinical care of participants with a traumatic spinal cord injury (tSCI). As tSCI is only a portion of the SCI population, we will now be including non-traumatic spinal cord injury (ntSCI) participants in the registry in order to capture a more complete picture of SCI incidence in Canada.

This protocol amendment includes the expansion of data collection to the ntSCI population who have been admitted to participating rehabilitation facilities. Only the standard of care minimal dataset will be collected on the ntSCI group. We are asking local research ethics boards to consider approval for a waiver of consent related to this additional group of 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. All information will be collected via retrospective chart review related to their rehabilitation inpatient visit. The ntSCI participants will be identified only by a registry assigned ID, and their data will be entered into the GRP (the same process currently followed for the tSCI RHSCIR participants). The addition of ntSCI participants will significantly impact the workload of local RHSCIR study coordinators at rehabilitation facilities. With the current resources available, using a non-consented model (waiver of consent) for the ntSCI participants provides a practical and reasonable solution. 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. The permitted purposes of RHSCIR, as detailed in the RHSCIR protocol version 3.0, have been expanded to reflect the inclusion of ntSCI; data collected under previous versions of the RHSCIR protocol will be combined with data collected under this new version.

For traumatic SCI patients, the previous 1 and 2 years community follow up (CFU) visits have been combined to a single visit at 18 months post-injury. The schedules of all other community follow up visits remain unchanged. In order to reduce the burden on local RHSCIR site staff, an automated CFU option has been implemented, where local sites can opt to send out automated reminders to participants to complete their CFU questionnaires via a link to a secure website, where participants can input their responses to CFU questionnaires online. For this purpose



only, email addresses of study participants will be stored on the Global Research Platform (GRP), which is an electronic data capture system.

Currently consented RHSCIR participants will receive a letter [attached as part of this ethics submission] that outlines the changes described in this protocol amendment.

Schedule I – RHSCIR Dataset

Following a comprehensive consultation process with all local RHSCIR site leads, new data elements were added to

- Address local RHSCIR site feedback
- Allow for ntSCI data collection at rehabilitation facilities
- Improve collection of secondary complications across the SCI continuum

Deletions were made on several data collection forms to reduce the number of time-consuming questions, and modifications were made to surgical procedures, bony diagnosis, pain, and respiratory assessment to further improve efficiencies in data collection. New data collection forms were added at rehabilitation facilities to enable minimum dataset collection for patients with ntSCI. To display the data elements collected across the spectrum of care in a clear and concise manner, Schedule I was updated to include time points for data collected in RHSCIR. In addition, this section also documents the site-specific minimum age for RHSCIR participation and site's ability to enter participant email addresses into GRP for the sole purpose of using the new automated CFU processes.

Data Collection Forms

Updates were made to data collection forms to reflect the changes in data elements, as well as the new Praxis branding. Version dates were updated to all forms impacted. As part of this RHSCIR update, sites have been provided with data collection forms for the entire RHSCIR dataset. Based on local REB approval, sites will subsequently be provided with customized data collection forms if required.

Consent Form

The consent form template has been updated to include the above-mentioned changes to the protocol and Schedule I, and has been provided to all sites. Each site will subsequently submit site-specific consent forms that capture all study changes and any additional local REB requirements.

Participant & Family Information Package

This document has been re-formatted and updated to be inclusive of all spinal cord injuries (traumatic and non-traumatic) that will be captured in the registry.

Currently, RHSCIR has 30 participating facilities across Canada. Sites will transition to the updated forms following REB approval and site-specific training. We appreciate your understanding and thank you in advance for reviewing the updated RHSCIR documents.

Finally, a note about the sponsoring organization. The Rick Hansen Institute, which operates RHSCIR, was officially renamed the Praxis Spinal Cord Institute as of July 2019. 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. Praxis is the process by which a theory, lesson, or skill is applied practically – moving



knowledge into action. All electronic communication regarding RHSCIR will now be sent and received at RHSCIR@praxisinstitute.org or through the website at www.praxisinstitute.org. Emails sent to RHSCIR@rickhanseninstitute.org or hyperlinks to www.rickhanseninstitute.org will be automatically redirected.

Kind Regards,

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