

RHSCIR Data Executive Scientific Committee Terms of Reference

1. Committee Name

The committee shall be known as the RHSCIR Data Executive Scientific Committee (DESC).

2. Constituency and Composition of the Committee

The DESC is composed of three Spinal Cord Injury (SCI) experts; at least one of these experts will not be Praxis staff. If the request for data originates from Praxis researchers or the RHSCIR National Principal Investigator (i.e., the Lead Principal Investigator of RHSCIR: the person named in the ethics approved Protocol) then at least two non-Praxis staff will be part of the committee.

The RHSCIR Data Steward/Delegate will coordinate the review of each application by the three DESC members. The Praxis DESC member(s) will perform their review first and give feedback to the requestor via the RHSCIR Data Steward/Delegate, if necessary. The requestor can then re-submit the application before the non-Praxis DESC member(s) undertake their review.

Note that the DESC members may request the assistance of an additional expert, to provide specific knowledge or expertise (e.g. clinical or methodological), but this expert person cannot not approve, conditionally approve or reject an application.

3. Purpose of the Committee

3.1. The purpose of the DESC is to review record-level RHSCIR data access requests previously approved by the RHSCIR Data Steward/Delegate.

The following criteria are considered:

- A. If the application shows full and meaningful engagement of individuals with lived experience;
- B. If the application respects each applicable facility/site's contribution to the data;
- C. If the application, as applicable, has been peer-reviewed or otherwise demonstrates reasonable merit (e.g., scientific and/or public benefit); and
- D. If the proposed project will not duplicate other projects in progress using RHSCIR data.

Each DESC reviewer must decide whether to:

1. Approve the application;
2. Grant conditional approval; or
3. Reject the application.

The decision must be documented on the RHSCIR DESC Review Form.

3.2. As outlined in Praxis's Publication Policy, any individual may request a review of authorship by the DESC if there is a disagreement about authorship for a publication amongst a project team. A majority opinion of the DESC will determine final authorship. Note that the concept of "honorary authorship" is unacceptable.

4. Summary of the RHSCIR DESC Review Process

A. The RHSCIR Data Steward/Delegate will forward the application, his/her initial approval comments, the conflict of interest disclosure statement for external reviewers, any supporting documentation and the RHSCIR DESC Review Form to the DESC members. The Praxis DESC member(s) will perform their review first and give feedback to the requestor via the RHSCIR Data Steward/Delegate, if

necessary. The requestor can then re-submit the application before the non-Praxis DESC member(s) undertake their review.

Requestor details

- a. The DESC will be provided with the external and internal requestors' details as included in the application form. This helps provide context as to the request and allows for recognition of any duplication of research topics in the SCI research community to be highlighted. It is also important to highlight where RHSCIR Data Access Committee (DAC) members are the requestors.
- B. If any of the members of the DESC are not available to complete a review within 10 business days or a conflict of interest that must be avoided has been identified, the RHSCIR Data Steward/Delegate will designate a replacement member.
- C. The reviewers will be asked to review the application and complete the RHSCIR DESC Review Form within 10 business days. On the RHSCIR DESC Review Form, each reviewer will document their decision about the request as:
 - Approved.
 - Conditionally approved. The rationale for conditional approval must be stated on the RHSCIR DESC Review Form.
 - Rejected. The rationale for refusal must be stated on the RHSCIR DESC Review Form.
- D. The RHSCIR Data Steward/Delegate will review the responses from the reviewers and the following actions will occur:
 - Applications that are approved by a majority of reviewers will be considered approved. Approved requests will be forwarded to the DAC.
 - Applications that are conditionally approved by a majority of reviewers will be considered conditionally approved. Conditionally approved responses with the conditions for re-submission, will be returned by the RHSCIR Data Steward/Delegate to the requestor who may resubmit a revised application.
 - Applications that are rejected by a majority of reviewers will be considered rejected. Rejected applications, including the rationale for refusal, will be returned by the RHSCIR Data Steward/Delegate to the requestor.
 - If required, the RHSCIR Data Steward/Delegate will convene a DESC meeting with all the reviewers (face-to-face, conference call or video conference). DESC meetings will be minuted.
- E. If after receiving DESC approval, a requestor requests to amend the application, the RHSCIR Data Steward/Delegate will review the changes requested. If the changes are non-material from the information the DESC members received about the request, the RHSCIR Data Steward/Delegate will contact the DESC members with updates to the request.
 - Upon receiving the email, each DESC member will be given five business days in which to revoke their approval or ask questions about the non-material changes. If a response is not received within five business days, approval of the non-material changes is presumed.

5. Conflicts of Interest and Confidentiality

Each DESC member must declare in writing any conflicts of interest for each application to the RHSCIR Data Steward/Delegate.

All members of the committee must maintain confidentiality with respect to all business of the committee, including but not limited to maintaining confidentiality of applications and minutes. Reviewers must not contact applicants for additional information.

6. Records

The RHSCIR Data Steward/Delegate maintains accurate records including email correspondence, RHSCIR DESC Review Forms and minutes. Praxis will maintain these records on a secure designated location (that is only accessible to the RHSCIR Data Steward/Delegate and applicable Praxis personnel) for a minimum of 5 years after the closure of the project.

7. Reviews

Reviews of applications will be done on an as needed basis. If a large volume of applications is received, reviews may be batched.

8. RHSCIR Data Steward/Delegate Responsibilities

The RHSCIR Data Steward/Delegate is responsible for:

- a. Choosing appropriate DESC members;
- b. Coordinating the review of the application by the DESC members.
- c. Reviewing the completed RHSCIR DESC Review Forms.
- d. Ensuring that the governance model of the committee is reviewed annually for continuous improvement.

9. Amendments

These terms of reference may be amended by Praxis as required. Praxis welcomes feedback of the DESC members on the processes and documentation.