

RHSCIR Data Access Committee Terms of Reference

1. Committee Name

The committee shall be known as the RHSCIR Data Access Committee (DAC).

2. Constituency and Composition of the Committee

The DAC is comprised of the Facility/Site Investigators that contributed data to the requested RHSCIR data extract and are named in the RHSCIR Data Sharing Agreement with Praxis. If a DAC member is also a member of the RHSCIR Data Executive Scientific Committee (DESC) for the same request, additional approval for the request will not be sought from that member. If DESC approval was granted, DAC approval will be presumed for that member.

3. Purpose of the Committee

The purpose of the DAC is to review record-level RHSCIR data access applications previously approved by the RHSCIR Data Steward/Delegate and the DESC. Each DAC member must decide, with respect to data access requested of their facility/site, whether to:

1. Approve the access; or
2. Reject the access.

4. Summary of the RHSCIR DAC Review Process

- A. The RHSCIR Data Steward/Delegate will email an overview of the application to the relevant DAC members requesting a review within 25 business days.

Suggested headings to include in the email are below:

- Request outline
 - Purpose of data request including analyses to be conducted and permitted purpose request falls under (clinical support and management, research support, partnerships and quality improvement, quality data and information, and/or business planning and information).
 - Expected / anticipated merit (e.g., public benefit, publications).
 - High level summary of data elements requested.
- Requestor details
 - External and internal requestors details will be provided (name and organization). 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 DAC members are the requestors.
- Any relevant review comments from the DESC.

- B. The DAC member's study coordinator or designated assistant (as detailed in the delegation log) will be copied on the email. If the DAC member is unable to access and review their email (for example, due to vacation or leave), the study coordinator/designated assistant must inform Praxis of the DAC member's inability to respond and provide a reasonable alternate date of response (for example, an additional 10 business days). The DAC members may request additional information regarding the application if they wish to do a more thorough review (the application will be anonymized if forwarded to the DAC member in full). A reminder email will be sent at least 5 business days before the deadline.

- C. Upon receiving the email, each DAC member must reply to the email with their approval decision within 25 business days (or other Praxis agreed upon timeframe). If the approval decision or an explanation of absence is not received within 25 business days, the data access request for that facility/site will be considered approved.
- D. The RHSCIR Data Steward/Delegate will save each email reply on a secure designated location and the following actions will occur:
- i. Approval: The RHSCIR Data Steward/Delegate will proceed with processing the request.
 - ii. Rejection: If a DAC member denies access to their data, the rationale for denial must be stated in their email reply. The rationale for rejection will then be reviewed by the RHSCIR Data Steward/Delegate and Praxis's Director of Research and BPI who may then contact the DAC member for clarification and discussion. If the rejection stands, the facility/site's data will not be included in the data extract.
- E. If after DAC approval a requestor requests to amend the application the RHSCIR Data Steward/Delegate will review the changes requested. If there are non-material changes that have changed the information the DAC members received about the request, the RHSCIR Data Steward/Delegate will contact the DAC members with updates to the request.
- i. Upon receiving the email, each DAC 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. Confidentiality

All DAC members must maintain confidentiality with respect to all business of the committee, including but not limited to maintaining confidentiality about the content of applications.

6. Records

The RHSCIR Data Steward/Delegate will maintain accurate records of this process. Praxis will maintain these records in a secure designated location and maintain copies for a minimum of 5 years after the closure of the project.

7. DAC Member Responsibilities

DAC member is responsible for:

- Reviewing and responding to requested reviews via email.
- Understanding that non-response within 25 business days (or other Praxis agreed upon timeframe) implies approval for that specific application.
- Responding to requests for clarifications regarding rejections from the RHSCIR Data Steward/Delegate and Praxis's Director of Research and BPI.

8. Amendments

These terms of reference may be amended by Praxis. Praxis welcomes feedback from the DAC members on the processes and documentation.