

SCMR Registry

Data Access Review Process

SCMR Registry Committee
02-June-2021

I. Registry Data Access Request

A. Following a successful search, investigator(s) submit a request to access the Registry Data to execute a potential research project.

- 1. Data access application is submitted to the Registry Committee using the standard on-line form.**
- 2. SCMR HQ triages the form to ensure that it contains the necessary information.**
 - a) Four submission deadlines each year: January 1, April 1, July 1, October 1.**
 - b) Committee will review and return decisions by the 15th of the following month (February 15, May 15, August 15, November 15).**
 - c) SCMR HQ requests missing information if needed.**
 - d) SCMR HQ forwards request on to the Committee Chair.**
- 3. Review Phase I – Committee review of proposal**
 - a) Committee Chair designates three committee members to serve as 1^o, 2^o, and 3^o reviewers.**

(1) 1^o will serve as SCMR liaison for the project as it moves through the approval process.
 - b) The 3 reviewers read and submit independent, written reviews of the application to the Committee Chair within 10 business days.**

- c) Reviews based on alignment with SCMR mission, impact, feasibility, investigators.
- d) Four scoring categories, scored 1 – 9 (1 is best)
- (1) Alignment with SCMR Mission: *To improve cardiovascular health by advancing the field of CMR. OR alignment with a specific RFA.*
 - (2) Potential impact on the field and utilization of CMR.
 - (3) Feasibility of the project based on Registry data available, work required by contributing centers, and resources available to complete the project.
 - (4) Investigators: *the team possesses the skills, expertise, and resources to accomplish the project.*
 - (5) Overall score: *not necessarily the average, but should align with categorical scores.*
- e) The overall scores will be averaged across the three reviewers to arrive at a composite score.
- (1) Composite score ≤ 3 will move on to Phase II.
 - (2) $3 < \text{Composite score} \leq 6$ will be discussed by the three reviewers and a consensus decision made whether or not to move on to Phase II.
 - (3) Composite Score > 6 will be discussed by the three reviewers and a consensus decision made whether or not to recommend revise and resubmit.
- f) If a proposal is rejected at Phase I, the 1^o reviewer, Committee Chair and/or Vice-Chair will contact the investigator(s) via TCON to explain the grounds for rejection, and if not rejected outright, suggest how the proposal could be modified for resubmission.

4. Review Phase II – getting sites on board.

- a) The 1° reviewer will work with the investigator(s) to secure the data access from the individual site contributors.**

(1) It is the primary responsibility of the investigator to get the contributing centers on board.

(2) The 1° reviewer will support the investigator by communicating to the contributing centers that the proposal has been vetted by independent reviewers and is thought to be of value to the field and worth pursuing.

- b) A TCON will be held (if needed) between the investigator(s) and the data contributors to give the investigator(s) the opportunity to pitch the project. The 1° reviewer will participate in the TCON.**

(1) Principle Investigator must clearly describe the work involved, the publication plan, and proposed coauthorship.

(2) Site investigators will indicate whether or not they agree to contribute data, and to do the work necessary to complete the project.

(3) Following the call, 1° reviewer and PI will discuss potential for project success based on response of contributing centers.

- c) Once contributing centers are lined up, the investigator will update the original proposal to reflect the actual data available, and the expected outcomes based on the work the contributing sites have agreed to perform.**

5. Review Phase III – Committee Approval

- a) Written proposal (updated project description) and reviews are distributed to the entire committee.**
- b) The three reviewers present the project and their critiques on the next monthly TCON.**
- c) Committee members on the TCON vote to approve or reject**
 - (1) Quorum = simple majority of members.*
 - (2) A simple majority is required for approval.*
- d) If a proposal is rejected at Phase III, the 1^o reviewer, Committee Chair and/or Vice-Chair will contact the investigator(s) via TCON to explain the grounds for rejection and suggest how the proposal should be modified for success.**

II. Project oversight

A. 1^o reviewer provides SCMR oversight for the project.

- 1. Secure bi-annual milestone reports from the investigators.**
- 2. Work with the investigators and data contributors to overcome obstacles to progress.**
- 3. Help to ensure that the project progresses to completion.**
- 4. Enlist the support of SCMR HQ as needed.**
- 5. Bring to the attention of the committee any projects that are stalled out.**