SCMR Registry Data Access Policy
October 2021

Summary:
This document outlines SCMR Registry policies and guidelines for Data Access, Publications, and Sub-Studies.

The SCMR Registry contains de-identified CMR images and patient data relating CMR results to patient treatment and the practice of medicine. The main goals of the Registry are to:

- Promote evidence-based utilization of CMR through a collaborative global effort
- Provide a web mechanism for CMR centers to upload de-identified patient data, CMR indications, and images to share for purposes of research, education, and quality control
- Provide a mechanism of tracking patient outcomes (death, events)
- Support data access globally to make registry data available to the wider CMR research community
- Support the SCMR mission: To improve cardiovascular health by advancing the field of CMR

The overriding objective of the SCMR is to encourage and facilitate appropriate use of the Registry for research, education, and quality control. The policies and procedures to access Registry data for these purposes derive from the following key principles:

- The Registry is accessible to all SCMR Members for all types of health-related research that is in the public interest.
- All researchers will be subject to the same application process and approval criteria.
- Registry data remains in control of each contributing center. Each contributor has the option to allow or restrict the use of his or her data on a project specific basis.
- All users will be required to publish their findings and agree to perform data clean up in the provided user interface of the SCMR Registry (rather than a local spreadsheet or study specific database) so that the data are available for researchers to use for other health-related research aligned with the mission of the Society.

General Principles:

The SCMR Registry (the "Registry") has been established under the auspices of the Society of Cardiovascular Resonance ("SCMR") and the SCMR Registry Committee. SCMR Registry policies conform to existing SCMR policies and bylaws wherever possible.

All Registry data are contributed in accordance with HIPAA and other privacy legislation in place in the countries of contributing sites. All data are de-identified before being stored in the repository. No attempt will be made to identify individuals. All users with data access must endeavor to protect the privacy of the participants.

A "Registry Study" is defined as any research project that includes SCMR Registry data, but may also include the use of additional data outside of SCMR Registry database.

Those sites who contribute data to Registry ("Contributing Centers") should be recognized and acknowledged appropriately on the SCMR Registry website, and this website should be referenced in publications in the acknowledgement.

ICMJE recommendations regarding authorship and non-authorship will be followed to the extent possible. If journals allow, the Registry Contributors should be listed following the authors using the phrase "on behalf of the SCMR Registry contributors" (http://www.icmje.org/recommendations/).

Each institution opting to join the Registry will designate a site-specific registry manager ("Medical Director"). The Medical Director will act as the intermediary between the institution and the SCMR Registry. The roles of the Medical Director will include:

- Leading the administrative discussions between institution and the SCMR Registry (e.g., with the site institutional review board, information technology group, and legal advisors).
- Making the final determination as to whether a site will participate in any Registry Study.
- Specifying who may have access to the Registry or propose Registry studies at their own site.

Research Studies and Grant Proposals:

Any SCMR member may request access to Registry data for the purposes of research and publication, and for the development of grant proposals that will potentially lead to external funding. The member, or members, requesting access will be required to submit a proposal to the Registry Committee for approval.

- Only investigators from Contributing Centers are permitted to lead Registry Studies.
- SCMR Members who are not working at a Contributing Center are encouraged to participate in in Registry Studies as Co-Investigators, but investigators from non-contributing centers may not formally lead or submit a data access application as the sole Principal Investigator.
- Sites currently in the process of establishing a Registry connector to enable data contribution will be permitted to lead Registry Studies, provided they make reasonable progress towards connection and data contribution.

Access to Registry data for research and funding proposal development will follow a two-step process: first, a search of the Registry data will determine the number and contributor of cases meeting the specific search criteria. Second, a proposal for access to the data resulting from the search will be submitted to the Registry Committee for approval.

SCMR Members who <u>are active contributors</u> of data to the Registry are permitted to view and search the Registry database at any time through the Registry portal.

SCMR Members who <u>are not active contributors</u> of data to the Registry are unable to directly view or search the Registry database. While any SCMR member may submit a search request to the SCMR Registry Committee, as outlined above, investigators who are not active contributors cannot serve as the sole principal investigator Registry Studies. The Registry Committee will review the request and work with the submitting member(s) to either a) run the search as requested; b) modify the search to be appropriate and effective given the constraints of data included within the Registry; or c) explain why the requested search cannot be effectively executed given the constraints of the Registry data.

The outcome of an effective search executed either directly by an active contributor, or with assistance from the Registry Committee, will result in a tally of the number of cases meeting the specific search criteria, a list of which sites contributed these data, and the number of cases contributed by each site. This information (number of cases and contributing sites) will be incorporated into an application for access to these data and submitted for approval by the Registry Committee. The application will incorporate key elements including the purpose of the study, a projected timeline and milestones, and expected outcomes (publications and/or funding proposals). A publication plan is required detailing hypotheses, proposed authorship, pre-existing intellectual property (if any), and timelines.

The SCMR Registry Committee will review and render a decision on each proposed study. If approved, the SCMR Registry Committee will contact the Contributors of data required for the project, present the research proposal, and request data access. In addition to scientific impact, investigators should recognize that the feasibility of the study will be an important criterion. Proposals that require the significant data collection not already present in the SCMR Registry database or additional image

analysis by individual Contributors may be barriers to approval by the Committee. This presentation and request may be made together with the requesting researcher to explain the motivation and expected outcomes of the proposed project, and the expected involvement and benefit to those contributing data. Approval from the SCMR Registry Committee does not guarantee participation from the individual Contributors. Each individual Contributor reserves the right to decide whether their data may be used in the proposed study. Those Contributors who permit their data to be used may be granted co-authorship, co-investigator status, or other acknowledgement commensurate with their contribution to the project. The exact nature of this acknowledgement and participation will vary depending on the scope of the project and the level of contribution beyond data submission. Access will be granted for a specific period determined by the project milestones and scale of the work involved, and only for the purposes of the proposed research study or grant application.

The Registry Committee may reject studies with substantial overlap (similar aims and methodology) to existing studies. To help avoid overlap, the Registry webpage will list brief descriptions of all current ongoing approved studies. Researchers will be informed if their proposal overlaps with an existing study, and may wish to modify their proposal accordingly. Multiple groups may be permitted to work on similar or overlapping topics, particularly if the methodology differs or if confirmation of results by an independent group seems warranted. In some cases this may lead to conflicting reports, but this is part of the open scientific process.

Having been granted access, researchers are expected to pursue the proposed studies and make reasonable effort to complete the project within the proposed timeline. Amendments and additions to the publications associated with a project can be requested subject to the approval of the Registry Committee. While it is understood that research projects can take longer than anticipated, or take different directions than originally planned, if reasonable progress is not demonstrated the Registry Committee reserves the right to rescind data access.

Data Access:
Once a research project is approved, and contributing sites have agreed to participate, the relevant data from the participating sites will be aggregated into an SCMR Registry folder. Only the SCMR Registry Committee has the ability to create an aggregate data folder comprised of data from multiple contributors. Access by researchers to the aggregate data is granted only for the purposes of the specific research project detailed in the approved proposal, and under the terms and conditions specified below:

1. The Data will be used solely for the purposes outlined in the study and will not be used for any other purpose. Investigators who have been previously approved for Data use must submit a new application to conduct another study (even if subject matter is related) and receive approval from the Registry Committee and the individual sites prior to using any Data for a new project.
2. Data access is not transferable to another investigator. Substantive changes made to study design, and/or replacement of the lead investigator, require review and approval by the Registry Committee.
3. Active contributors to the SCMR Registry will have the ability to view the aggregate study data in real time through the Registry portal.
4. SCMR Members who are involved in a project but are not contributing data to the Registry will not have real time access to the data; they will instead receive a periodic dump of the aggregate study data at time intervals appropriate for the particular study.
5. Researchers must comply with the Publication policy (below).
6. Researchers must acknowledge the SCMR Registry and its funding sources in any oral and written presentations, disclosures, and publications resulting from data access.

7. Researchers agree that the Data will not be used, either alone or in conjunction with any other information, in any effort to determine the individual identities of any of the participants from whom Data were obtained.
8. Researchers will retain control over the Data, and unmodified or modified derivatives thereof, in a secure environment, and not transfer Data, and unmodified or modified derivatives thereof, with or without charge, to any other entity or any individual in a manner not previously approved by the Registry Committee. When the study is completed, the Data will be deleted from the researchers' computers, unless other arrangements are agreed upon or an extension is obtained.
9. Derived results and modifications of the data, including data cleaning, must be contributed back to the SCMR Registry for the benefit of future research.
10. All results arising from use of the data, including but not limited to trained AI models and associated source code, must be published as open source for use by any person, company, or other entity without cost or limitation.
11. Any cost for distribution of Data will be borne by the researcher. No warranties express or implied, are offered as to the merchantability or fitness for any purpose of the Data in the Registry, or that the Data may be exploited without infringing the intellectual property or proprietary rights of any third parties. SCMR is not responsible for the accuracy of Data provided.
12. The SCMR Registry Committee has the right to examine the methods of data analysis (e.g., statistical analysis and post processed data files) used by the researchers, should any issue relating to data integrity arise. The intent is to conduct such analysis at a time that is mutually agreeable with the researcher.
13. Researchers must comply with any licensing arrangements or protection of existing intellectual property agreements under which data were contributed to the SCMR. Rights to any inventions or new information arising from the study, not relating to any existing agreements, will remain the property of the researcher.
14. The Data cannot be used for commercial purposes without the permission of the SCMR Registry Committee. If approved, all results arising from commercial use of the data, including but not limited to trained AI models and associated source code, must be published as open source for use by any person, company, or other entity without cost or limitation.
15. Failure to comply with these conditions could result in denial of further access to Registry data.

Publications:
Penultimate drafts of any publications (scientific manuscripts and conference abstracts) based on Registry data must be submitted to the Registry Committee for review prior to submission. The Committee will have up to 2 weeks to complete article reviews, and up to 2 days to complete abstract reviews. If no written response is received from Registry Committee within the applicable review period, manuscript or abstract submission may proceed without delay.

The Registry Committee Chair will manage the review process. If the Chair is a co-author, or has a conflict of interest, the Co-Chair will manage the review. If both are conflicted, an alternate committee member will be selected by the Chair.

If the authors perceive any conflicts of interest with specific Registry Committee members, the authors may request that these individuals be excluded from the review process.

All publications should acknowledge any funding support of the SCMR Registry.

All publications must include the following credit, which shall be incorporated within the Acknowledgements section of such publications: “This research has been conducted using the SCMR Registry Resource.”

The Registry committee may request that specific investigators or contributors to be given the opportunity to become co-authors. However, all authors must have made substantial contribution within an agreed time frame, not unreasonably impede publication timelines, and be accountable for all aspects of the work. Established guidelines for authorship of papers will be followed (www.icmje.org/recommendations/).

Where journals permit, Registry Contributors who have contributed data to the study, but are not included as co-authors, should be recognized in the author list with the group name “the SCMR Registry contributors”.

Manuscripts and abstracts will be reviewed by the Registry Committee with the following criteria for approval:

- The manuscript is consistent with the goal of the Registry *to promote evidence-based utilization of CMR through a global collaborative effort*.
- The Registry and its contributors are properly cited and acknowledged, in accordance with the Data Access Policy
- The manuscript contains no erroneous statements regarding the Registry contents, its operation, or policies.
- The manuscript contains no confidential patient data.
- The manuscript contains no serious scientific errors.

While every effort is to be made to foster high quality research outputs, the SCMR cannot guarantee the integrity of every study published.

Intellectual Property:

The SCMR seeks to promote the development of valuable discoveries and inventions beneficial to public health based upon use of the SCMR Registry data. In some cases, intellectual property agreements may be entered into as part of the contribution of data to the SCMR Registry. Any such agreements should be designed only to protect specific existing IP and to ensure Contributor rights to any IP generated in these specific areas by third party researchers. IP generated by a researcher that does not pertain to these specific areas will remain the property of the researcher.