International Council of Cardiovascular Prevention and Rehabilitation (ICCPR)

ICRR DATA ACCESS & DISSEMINATION POLICY

V2

Introduction

The International Cardiac Rehabilitation Registry (ICRR) is an initiative of the International Council of Cardiovascular Prevention and Rehabilitation (ICCPR) whose goal is to enable assessment of cardiac rehabilitation (CR) quality in low-resource settings, with the aim of ultimately improving patient outcomes. However, ICRR also recognizes the need for research that adds to the body of scientific knowledge that leads to improving the quality of care and patient outcomes when disseminated within an appropriate framework. ICRR's mission is to make the most use of ICRR data to benefit the LMIC community, while remaining solvent (profit is not a motive).

Policy statement and objectives of policy

Within the ICRR governance structure, the Research Sub-committee has within its responsibilities overseeing access to data, and it's dissemination in publications, reports and presentations.

This policy takes into account the privacy policies regarding the use of registry data defined in the Contributing Site Agreement and privacy legislation in contributing site jurisdictions. The policy is necessary to ensure scientific integrity and accurate interpretation of the registry data findings. It is also intended to maintain consistency and avoid duplication among the various publications and presentations that are generated.

The objectives of the ICRR policy are:

1. To ensure and expedite the orderly and timely presentation to the scientific community of all findings derived from the ICRR.
2. To assure scientifically accurate and objective presentations, reports and papers from the ICRR.
3. To establish procedures to enable the ICRR Research Subcommittee to exercise responsibility for the timely review of publications and presentations using ICRR data.
4. To ensure that multiple publication of the same data by different authors is avoided.
5. To standardize the identification of the registry, and the acknowledgement of both the registry and potential local or global external supporters.
6. To maintain a complete and up-to-date list of proposals using ICRR data for public posting on ICRR's website

7. To maintain a complete and up-to-date list of presentations and publications using ICCR data, and to distribute such lists to the ICCR Steering Committee and the ICCPR on a regular basis.
8. Ensure that other outreach, such as press releases and interviews that include ICRR findings are accurate and objective, and do not compromise the scientific integrity of ICRR.

Data Access – Who, When and Cost

- As per the contributing site agreement, each site has access to their own data at all times (e.g., administrative reports, quality improvement, meeting presentations). No consent from ICRR is needed to use their local data for internal purposes.
- If local data will be presented externally, it is preferred the sites share this with ICRR in advance. ICRR is happy to provide some input for consideration.

- The ICRR research sub-committee has access to all site data to perform its' functions as per their terms only, including data quality monitoring and preparing an annual research report.
    - Note the annual report shall be marketed in the following ways, although others are possible as well: ICRR's website, ICCPR's social media channels, shared with contributing sites via email (lifetime), a lay version to patients who have consented and provided contact information (email or text), and through the ICCPR community (including member association newsletters; see: https://globalcardiacrehab.com/Members).

- Sites that have contributed data at any time (minimum 50 patients, and in good standing on follow-up data), current ICRR steering and sub-committee members are considered "ICRR volunteers" (the latter considered part of ICRR governance).
- Once the ICRR has been launched for 6 months and/or there are a minimum of 5 contributing sites and 350 patients, ICRR volunteers and their primary trainees shall have initial opportunity to submit data access requests for pre-program data.
- Their requests must still meet all requirements outlined in this policy. These requests will be vetted by either the ICRR Steering or Research Sub-Committee (depending on which has fewer members on the proposed research team) to avoid conflict of interest. Any parties listed on the application must recuse themselves from deliberations.
    - 1 year from launch, active ICRR volunteers shall have the same opportunity to make data access requests for pre and post-program (progress) data, as per above
    - 2 years from launch, current and former ICRR volunteers shall have the same opportunity to make data access requests for pre, post-program (progress) and anual data, as per above
    - At every 5-year increment from launch (e.g., 5 yrs, 10 yrs, 15 yrs), active ICRR volunteers shall have the same initial opportunity to make data access requests for pre, post-program (progress) and anual data, as per above
- ICRR shall be open to requests from any parties 6 months following any of the above time points.

- Some applicants will pay an application fee, which will not be refunded if the application is not approved. Funded applicants shall pay a $500USD application fee (charged retroactively upon funding decision if applicable). Applicants at for-profit institutions shall pay a $1500USD application fee.
- Funded applicants and those at for-profit institutions maybe charged additionally should they wish to use a high proportion of ICRR variables, as well as international data.

- To protect the ICRR and patient privacy, the full data set cannot be released to any parties. ICRR requires that a qualified statistician or analytical group with a business contract with ICRR (please be in touch to express interest) conduct the data analyses. ICRR must charge for data analysis by the in-house statistician to cover this cost.
- Fees are outlined below, and are subject to change to meet the goal of covering statistician cost to support the ICRR but not making profit.
- The data shall be analyzed as per any approved proposal by the ICRR statistician, within one month.
    - The statistician hourly rate shall be charged to ICRR volunteers (rate to be announced upon hiring)
    - a higher rate will be charged to external parties at not-for-profit institutions to offset costs associated with maintaining the registry.
        - Researchers in LMICs (hourly rate +25%) shall pay a lower rate than those in HICs (rate +50%)
            - If ICRR is in good financial position in future, we may be able to waive the additional +25% for LMIC investigators, particularly those who have contributed data and have no funding for their project, upon request. ICRR will post a policy on this on its' website should funding permit regarding the process to make the request should this be feasible. We aim to support the needs of CR in low-resource settings.
            - For HICs, there will be a minimum analysis cost of $1,000USD
    - Additional fees apply for for-profit institutions (application fee; hourly rate +75%, with a minimum of $2500USD).

Upon direction from the ICRR steering committee, if no such requests are forthcoming, the ICRR research sub-committee may commission (i.e., no statistician charges) a paper on specific findings from the ICRR that would be important to disseminate to meet ICRR's mission. If the article is international in scope, the sub-committee may invite qualified ICRR volunteers to participate as members of a writing group for that paper. If the article is regional in scope (i.e., it uses data from sites in a specific region), the sub-committee may contact contributing CR center leads to request nominees of qualified and interested collaborators to participate as members of a writing group for that paper. The request for nominees will include a specific date for submission of nominations. A lead shall be named by ICRR Steering, who shall propose final author list and order, based on the established conventions outlined below, as well as develop a formal data access request.

Proposal, evaluation and approval process

The process starts with the submission by a qualified researcher (provide CV), of a proposal for access to the data (completed Data Access Proposal Form). The proposal shall include a list of authors for consideration. The appendix must be signed by the applicant. This should be remitted to iccpr.icrr@gmail.com with the subject line of "ICRR data access request".

The proposal will be reviewed by the ICRR research subcommittee within one month of receipt as per their terms of reference (available at https://globalcardiacrehab.com/ICRR-Governance); any members that are on the proposal shall not be involved in the discussion to avert conflict of interest. There must be a minimum of 3 ICRR members adjudicating, so if there are conflicts, an ICRR member from another committee shall be enlisted to serve. All efforts will be made to have a virtual adjudication webmeeting within the allotted time (rather than email, although one member may have to provide input and vote via email for example). The statistician will also report on the appropriateness of the proposed analyses and that due consideration of risk adjustment is made.

If more than one application is received during the same review period, priority will be given to applications received from ICRR volunteers, followed by ICRR members, but due attention shall be paid to scientific merit. A response will be provided by the secretary within 2 months maximum. If the data requested or the objectives proposed by the applicant are similar to those of a previously-approved ICRR access request or available report, the request will not be considered (applicants may wish to email ICRR to check prior to developing a request).

To appropriately recognize significant contributions and to ensure guarantors of the data are represented on all papers (considering it cannot be posted publicly at this time, as discussed below), if the applicants have not done so, please note the ICRR research sub-committee shall specify that member(s) of ICRR governance co-author the manuscript where the scope of the work is international; at least one Steering Committee member and another volunteer with expertise in the area of study shall be proposed for applicant consideration. ICRR volunteers shall only be granted authorship in accordance with established guidance named herein.

The decision on the data access proposal shall be to: (1) accept as is, (2) accept pending revision, or (3) reject. If the decision is not the latter, an estimated number of hours of the statistician's time shall be provided (and any required discussion will be facilitated), so the applicant understands the cost to move forward (note: applicants may request estimates in advance if needed).

In the instance of the decision of revision or clarification, the applicant will have 1 month from receipt of the decision to respond to the sub-committee. The committee will then review and provide a response as per the above 3 decision ratings, within the timeline specified above. If the decision is again for revision, the process shall iterate until either the submission is approved or rejected.

The sub-committee shall document reasons for its' decisions on the ICRR Data Access Request Review Form, but is not required to share that with applicants. Decision appeals can be made to the ICRR Executive.

Authorship

As outlined herein, external parties shall specify proposed authors in their application, as well as contributions of each author. Author contributions shall be stated as per CRediT (https://casrai.org/credit/#:~:text=CRediT%20(Contributor%20Roles%20Taxonomy)%20is,contribution%20to%20the%20scholarly%20output).

An ICRR guarantor shall be named to each. Moreover, ICRR-generated publications shall include calls for interested ICRR volunteers with research experience/roles to co-author (volunteers shall be polled in advance for areas of expertise) should they meet authorship requirements.

All ICRR publications shall include "on behalf of the ICRR collaborators" at the end of the authorship line (i.e., published using group authorship such that collaborating authors are listed at the end of the paper and are credited in PubMed). The ICRR secretary shall provide the list of ICRR collaborators to list to the applicant at the time of paper initiation.

ICRR collaborators are contributing site data stewards meeting the above data contribution thresholds who specify on initial application they hold a research post, as well as those who serve in an ICRR governance role. With regard to the latter, members serving on committees or sub-committees at the time of manuscript preparation shall be listed, but if previously-serving members who completed their full terms were not yet recognized, they shall also be listed.

ICRR collaborators shall typically be listed in alphabetical order, with non-alphabetical listing reserved for select collaborators at the beginning and end of the list. This would be in recognition of their service to ICRR and/or quantity of quality data contributed to the registry; Any non-alphabetical designations are selected by the ICRR Exec or sub-committee chair.

Process for approved data access requests

Once the proposal has been approved, the principal applicant shall provide the ethics approval documentation and pay the required fee to ICRR via paypal or wire (details to be provided). If this is not received within one month, any other data access requests in the same area may be entertained (applicants will be consulted). No analyses will be conducted until all costs are paid in full.

Upon receipt, the ICRR secretary shall connect the applicant with the ICRR statistician to commence the work, and also provide the list of "ICRR collaborators" to be recognized in the byline. The date of the data pull shall be denoted and provided to the applicant to specify in any reports of the results.

Once results are provided by the statistician to the applicant's satisfaction (date to be provided by statistician to secretary, with cc to applicant), the applicant shall have 6 months to prepare the publication and/or presentation materials, as specified in the application only. If the principal applicants wishes to share the ICRR results in any additional or alternate venues than those stated in Section IV of the application, they must make a written request to the research sub-committee, and approval must be granted prior to such dissemination. If further analyses are needed, these will be charged at the hourly rate outlined above and paid in advance (any unused time shall be refunded).

Every effort should be made to accommodate the expression of differing interpretations and alternate analyses within the body of each manuscript, so that all points of view are represented to the satisfaction of every co-author. Any disagreements should be resolved by the ICRR Committee.

All publications and presentations including ICRR data must contain the words "International Cardiac Rehab Registry" in either the title and/or abstract, and in the key words (as applicable). The applicant must include in the completed work the following statement: "This study was supported by data obtained, whole or in part, from the International Cardiac Rehab Registry (ICRR; SPECIFY DATE of data pull). The opinions and conclusions reported in this [document/article/presentation] are those of the authors and are independent from the ICRR. No endorsement by ICRR is intended or should be inferred. We are grateful to ICRR committee members and contributing sites who made this registry possible (https://globalcardiacrehab.com/ICRR-Governance)." All presentations and visual materials must include the ICCPR logo and ICRR hashtag (#ICRregistry).

If a data availability statement is needed, researchers are to specify that the data are available from the International Cardiac Rehab Registry (ICRR; iccpr.icrr@gmail.com); ICRR welcomes requests to verify reports from qualified collaborators, but cannot publicly release the data for ethical and privacy reasons at this time. ICRR aims to post the data in whole or in part to a public repository at a future date.

These (e.g., drafted article, or abstract and slides/poster) should be submitted to the ICRR Research Sub-Committee for review and potentially comment prior to submission to journals or meetings, or any other dissemination venues. The ICRR research sub-committee shall check that inclusion of authors (vs acknowledgment as collaborators) and order are in accordance with the principles of COPE (Committee on Publication Ethics), ICMJE (International Committee of Medical Journals Editors), any journal-specific criteria, as well as the approved application; Authors not listed on the data access application may not be added after results provision without justification and approval.

From the date of provision of results, applicants/researchers shall have 6 months to submit the drafted work(s) to the ICRR research sub-committee for review prior to submission to the journal/conference as per response(s) to item 12 on the application form, unless otherwise agreed by both parties in writing. If the report will be delayed, the ICRR shall be informed by the principal applicant, prior to the 6-month deadline. A Data Renewal Application may be requested to access / use data beyond that time (not including resubmission to other journals, and revisions), except for non-academic dissemination (item 13 from application form). If there are concerns about data becoming "stale", this shall be discussed between the applicant and sub-committee, and revised timeline mutually-agreed or other action taken by the sub-committee. Decision appeals will not be considered.

The sub-committee cannot consider the materials unless all statistical analyses fees are paid to date. Again, within 1 month the sub-committee will consider the materials, and a reply will be made to the applicant within 2 months. If the materials are not in English, Google Translate shall be used to get a rough sense of the materials. The sub-committee reserves the right to deny submission of any work which is not scientifically rigorous or is methodologically flawed; a reason

shall be provided in this instance. An iteration process as outlined above may be needed should some revision be requested, and thus the applicants should plan time for this potential outcome. Again, decision appeals can be made to the ICRR Executive.

Authors are encouraged to publish the materials open access, however ICCPR nor ICRR can provide no financial support for this; the ICRR community shall be informed if this changes. FYI ICRR funds are used to support maintenance costs, and potentially further development to support contributing CR programs, to enable as many sites as are interested to participate in the registry and assess their program quality.

The applicant shall inform the ICRR research sub-committee when the results appear in any journal, or other public venue, and are presented at any meetings. PDFs should be provided where possible/applicable. Links shall be posted on ICRR's website. In the event that there is no publicly-available report of findings to link to the application within 12 months, the applicant will be requested to provide a summary to post to ICRR's website to link with the proposal posted there.

The applicants are invited to work with ICRR to disseminate their work via social media platforms or formal media outlets. Applicants will be asked for drafted tweets to be posted to ICCPR's twitter, Instagram, TikTok and facebook accounts. Again, postings or videos should be submitted to ICRR prior to release. Videos may be shared on ICCPR's youtube account.

INVITATIONS TO INVESTIGATORS/COLLABORATORS FOR PRESENTATION OF ICRR DATA

The ICRR welcomes opportunities to disseminate the registry findings. When an invitation is received by a principal applicant who has been approved to utilize ICRR data or one of the stated members of the research team in the data access application, this policy of publications and presentations must be followed.

All presentations must be based on approved reports. Presentation of unapproved ICRR results must be reviewed and approved by the Research Sub-Committee prior to the date of presentation, as is established by this policy.

When a personal invitation is received by a principal applicant for presentations or discussions at global, regional or local meetings, the ICRR Research Sub-Committee must be notified in order to record what dissemination has occurred.

In many instances, conference abstract calls are not open in sufficient time for a data access request to be reviewed, permission granted and data provided prior to deadline. Thus, researchers are encouraged to plan ahead regarding target meetings in terms of usual annual deadlines.

USE OF ICRR DATA FOR GRADUATE/HEALTH STUDENT THESES OR DISSERTATIONS

All requests for use of ICRR data by students will be reviewed by the ICRR Research Sub-Committee as is established by this policy. The student requesting ICRR data must be "sponsored" by an investigator at a recognized University or similar institution. The sponsor investigator will support the data access request (including provision of CV), and will ensure the research project includes a scientifically and ethically-appropriate research plan.

When the thesis or presentation has been completed, the student and his/her sponsor will prepare the manuscript for publication, with authorship in accordance with guidelines above.