International Council of Cardiovascular Prevention and Rehabilitation (ICCPR)

International Cardiac Rehabilitation Registry
Data Access Proposal Form

This application form is for requests for access to the data of the International Cardiac Rehab Registry (ICRR). Applicants must complete this entire application form before access to data will be considered. Submitted applications should be directed to iccpr.icrr@gmail.com.

Research projects will be verified by the ICRR research sub-committee for, among other aspects, the qualifications of the Applicant to carry out the proposed research; whether the research project includes a scientifically and ethically appropriate research plan; proof of local ethics review; the adequateness of the Applicants' and their Host Institutions' processes regarding privacy and confidentiality; and the availability of resources to effectively complete the study (collaborators and staff). Applicants may be contacted with requests for additional information to complete the application review process.

The names, institutions and lay summaries of the scientific abstracts of all applicants having been granted access to ICRR data will be added to the ICCPR website. Links to final outputs shall be added upon successful completion as well.

Date of Application: _____

Section I: Research Personnel

1. Principal Applicant:

A full CV of the principal applicant shall be provided.

Name:	
Qualifications:	
Institution:	
Position:	
Email:	
Phone:	

a) Are you a volunteer with ICRR? Yes □ No □
If yes, please specify: _____

b) Are you a member of an ICCPR member association (list available here: https://globalcardiacrehab.com/Members): Yes □ No □

If yes, please specify: _____

c) Are you affiliated with a CR program that has, currently does, or hopes to contribute data to ICRR?

□ Previous
□ Current
□ Potentially future (see: https://globalcardiacrehab.com/ICRR_sites)
□ None of the above

d) Corresponding Institution:

Please provide a valid institutional website and a full postal address.

Webpage:	
Address:	
Country	

e) Is this institution for-profit? Yes □ No □

2. Research Team:

Is the data being requested for a student thesis or project? Yes □ No □

Please provide the names of all investigators, collaborators, students and research staff that will have access to the data in order to work on the research project. No one who is not listed here should have access to ICRR data. Add additional rows as needed.

Name	**Institutional Affiliation**	**Position**	**Contact Details (e-mail)**

2b. ICRR Volunteer(s) on writing committee

As per the data access and dissemination policy, suggest 1-2 ICRR volunteers (see here for current volunteers https://globalcardiacrehab.com/ICRR-Governance) to contribute to the work based on their expertise and level of contribution to the registry, and to serve as guarantors of the data:

_____

The research sub-committee shall consider and make suggestions in their response.

Section II: Research Project

3. Project Title:

4a. Research Rationale:
Describe the importance and rationale of the research and the potential knowledge to be gained. Please explain in detail. Append key references.

4b. Research Question and Objectives:
Clearly state the research question, with primary and secondary (as applicable) objectives of the study.

5. Lay Summary of Project:
Please provide a short description of the project for the general public in no more than 250 words. Scientific jargon and acronyms should be avoided as much as possible. In the interests of transparency, should your request be approved, this description will be made available on the ICRR website before analyses commence, along with your name.

6. Ethics Approval:
Has this study been approved by a research ethics board or a comparable decisional committee that has been formally designated to approve and/or monitor research involving humans with the aim of protecting the rights and welfare of the research participants? Yes □ No □

If yes, please append a copy of the approval.
If no, please specify arrangements for obtaining the appropriate approvals. Please be in touch with ICRR if your institution has no research ethics committee.

**Please note that ICRR data access cannot be reserved pending ethics approval should another similar request be received, even if the ICRR Data Access Application is approved.*

The ICRR and its' Research Sub-Committee are not responsible for the ethics approval/monitoring of individual research projects and bear no responsibility for the Applicant's failure to comply with local/national ethical requirements. Applicants are required to maintain ethics approval through to the point where analyses are complete, and dissemination has begun.

7. Funding:
a) Has the project been, or will it be, submitted to a funding competition? Yes □ No □
*Note, ICRR can provide a quote for budget purposes upon request

If yes, by what organization, and which competition(s) (incl. website)?

If applicable: Budget – describe the funding requested or secured for ICRR data access and analyses (please attach a detailed budget for the project):

b) Has funding been approved? Yes □ No □ Not yet known □

If applicable, when will the funder notify you of competition results, or when will funding commence*?

**Please note that ICRR data access cannot be reserved pending funding approval should another similar request be received, even if the ICRR Data Access Application is approved.*

8. Requests for Ancillary Data / Sub-Studies / Participants & Time / Linkage:

a) Does the proposed project involve contacting ICRR participants for additional data collection?
Yes □ No □

If yes, please provide a copy of the proposed consent form, and the data collection form or instruments. Please also provide additional detail on proposed methods to collect the data and scope of participants. Approval may require consultation with participating sites, and hence the research sub-committee will be in touch to discuss the proposed research further. ICRR will assume no expense for this undertaking, and a potential fee shall be discussed.

b) Does the proposed project involve embedding sub-studies or trials within the ICRR?
Yes □ No □
If yes, please attach a copy of the proposed methods.

c) Will you use data from all countries, or specific regions for example? (Note contact ICRR for information on how many sites have contributed data, from what countries, and sample sizes if needed, particularly given data will not be released if a site can be identified)

- □ All available data, across all time points
- □ All available data, specific time point (specify: _____)
- □ Subset of data (if selected, please specify: _____)

d) Will data from other sources be utilized to complete the proposed project?
Yes □ No □

If yes, please list all data linkages required to complete the proposed project, and their sources.

9. Variables

Upon review of the data dictionary on the ICRR website (https://globalcardiacrehab.com/ICRR-Variables-&-Data-Dictionary), please list ALL the variables that you are requesting to report on for this project (you will not be granted access to others without a further approved request to ICRR):

10. Design & Methods

Please describe the design and methodology of the proposed project, including the primary outcome measures.

b) Describe the methods you propose that the statistician shall use to analyze the ICRR variables requested. Ensure due consideration of risk adjustment or propensity matching for example, as applicable. Provide mock table(s) with precise outcomes to be measured and analyzed, if applicable, to enable us to better estimate time required and fulfill your approved request in the least number of hours possible.

Section III: Data Security

In order to avoid any misuse or inadvertent disclosure of ICRR data to unauthorized individuals, the ICRR Research Sub-Committee requires that you follow basic IT security practices. When you save local copies of ICRR results, you must effectively minimize the risk that this information might be disclosed to individuals who have not agreed to the ICRR's privacy protection conditions.

11. My institution has a formal IT security policy.
☐ YES ☐ NO

If yes, please attach it or provide an Internet-accessible link: _____

You are required to observe the following practices. Please provide commentary on how you adhere to each requirement below or denote the section in your attached IT security policy pertaining to each requirement below:

- ICRR data should be maintained in secure servers. If data are stored on portable computers (whether laptops or other mobile devices), they must be encrypted in order to avoid any potential disclosure in case the portable system is lost or stolen.

- Appropriate access security should be implemented to ensure that only the authorized individuals mentioned above (Section I) will be allowed to access data. This requires, for example, that if ICRR data are stored on a shared computer system or a file server, that it is password or encryption-protected. Moreover, if the computer that holds ICRR data is backed up, that the backed-up media must also be encrypted and stored in a secure location.

- Anyone who will use ICRR data (Section I above) should be trained in the responsible use of participant information and be familiar with the terms and conditions of the *ICRR Data Access Agreement*. They must also be briefed on the security plans described in this section.

- If ICRR data are stored on a network-accessible computer, there should be controls in place to prevent access by computer hackers, or contamination by viruses and spyware.

- Upon completion of your Research Project, you may keep ICRR data for archival purposes in conformity with national audits or legal requirements.

a) Please describe the safeguards in place, both physical and electronic, to protect the privacy and security of ICRR data. If appropriate, please refer to the appropriate section(s) of your attached IT policy. If ICRR data will be stored on a shared computer system or network accessible computer, please describe how access will be limited to those individuals named in this access request.

*note the appendix must be signed with submission of your proposal.

Section IV: Dissemination

12. Planned academic dissemination

Please describe any meetings or journals where you propose to disseminate this work (note we understand that you may need to submit to other journals before the work is accepted; ICRR supports submission to peer-reviewed, non-"predatory" journals/conferences only):

12b. Deadlines

If applicable, provide due date for submission to proposed venue(s) to disseminated findings (e.g., professional meeting presentation, invited article, grant proposal). Please be sure to submit your request with enough time to meet your desired target date given timelines outlined in ICRR's access and dissemination policy.

Date: _____

13. Planned non-academic dissemination

Please describe any other venues where you propose to disseminate this work, including websites, media releases and social media:

14. Do you plan to prepare materials in any language other than English?

☐ YES ☐ NO

If yes, please specify language(s) and which materials:

_____

_____

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Appendix:
ICRR Data Access Agreement / Undertakings by responsible investigators

This agreement governs the terms of access to the data generated by the International Cardiac Rehabilitation Registry ("ICRR Data" as defined below). In signing this agreement, you and your institution - through its authorized representative - agree to be bound by the terms and conditions of access set out therein.

For the sake of clarity, the terms and conditions of access set out in this agreement apply to the User and to the User Institution(s) (as defined below). User Institution and User are referred to within this agreement as "You" and "Your", and shall be construed accordingly.

DEFINITIONS

ICRR Data: data associated with a unique, but not directly identifiable, individual.

Research Participants: individual patients who have contributed their data to the International Cardiac Rehab Registry (ICRR).

User/Applicant: researcher/investigator who was granted access to ICRR data by the ICRR Research Sub-Committee.

Applicant Institution(s): the institution with whom the approved researcher/investigator is affiliated for the purpose of the research project outlined in the *ICRR Data Access Application Form.*

TERMS AND CONDITIONS

Project title: _____

In signing this *Agreement*:

1. You and Your Institution(s) agree to use the ICRR data in compliance with the ICRR *Data Access & Dissemination Policy* (https://globalcardiacrehab.com/ICRR-Governance).

2. You and Your Institution(s) agree to use ICRR data for the approved purpose and research project described in the *ICRR Data Access Application Form* and as approved by your ethics committee(s)/comparable decisional committee in the letter requested in section 6 of the *ICRR Data Access Application Form*. Use of the ICRR data for a new purpose or research project will require a new application and approval (minor changes can be emailed to ICRR for consideration by revising the application form, with tracked changes on).

3. You and Your Institution(s) agree to preserve, at all times, the confidentiality of the information and ICRR Data. In particular, you undertake not to use, or attempt to use the ICRR Data to compromise or otherwise infringe the confidentiality of information of Research Participants and their right to privacy. You and Your Institution(s) agree to follow the plans and procedures outlined in Part III of the *ICRR Data Access Application Form*.

4. You and Your Institution(s) agree that in case of involuntarily identification of a participating program, this information should be destroyed and you undertake not to record or disclose that program's identity to anyone and not to try to contact that program.

5. You and Your Institution(s) agree to protect the confidentiality of ICRR participating programs in any research papers or publications that you prepare by taking all reasonable care to limit the possibility of identification.

6. You and Your Institution(s) agree not to link or combine the ICRR data provided under this *Agreement* to other information in a way that could re-identify the ICRR participating programs, even if access to that data has been formally granted to you and your Institution(s), or is freely available without restriction.

7. You and Your Institution(s) agree not to transfer or disclose the ICRR Data, in whole or in part, or any identifiable material derived from the ICRR Data, to anyone not listed in the *ICRR Data Access Application Form*, except as necessary for data safety monitoring, audits or program management. Should you or your Institution(s) wish to share the ICRR Data with another Collaborator not listed in this application, this must be requested to the ICRR research sub-committee in writing. The request must include a separate signed *ICRR Data Access Agreement* by this party, attesting they will follow the terms herein.

8. You and Your Institution(s) accept that the ICRR:

a) bears no legal responsibility for the accuracy or comprehensiveness of the ICRR Data; and

b) accepts no liability for indirect, consequential, or incidental, damages or losses arising from use of the ICRR Data, or from the unavailability of, or break in the access to the ICRR Data for whatever reason.

9. You shall pay ICRR in advance for costs to prepare and send the ICRR results to you. You recognize that these costs will increase if further analyses are determined to be needed, as per the hourly rate for your type of institution and as per your role with ICRR (if any).

10. You and Your Institution(s) agree to recognize the contribution of ICRR, including a proper acknowledgement in all reports or publications resulting from your use of the ICRR Data, as per the "*Access and Dissemination Policy*".

11. You and Your Institution(s) agree to abide by the terms outlined in the ICRR "*Access and Dissemination Policy*".

12. You and Your Institution(s) recognize that nothing in this *Agreement* shall operate to transfer to you any intellectual property rights on ICRR's primary data. However, you have the right to develop Intellectual Property rights on subsequent innovations and downstream discoveries arising

from such data. In doing so, you and your Institution(s) agree to implement licensing policies that will not obstruct further research.

13. You and Your Institution(s) must report to the ICRR Research Sub-Committee any significant changes to your research project as outlined in section 15 of the *Data Access Policy*, and whether such change influences section 6 (Ethics Approval) of the *ICRR Data Access Application Form*.

14. You and Your Institution(s) will notify the Research Sub-Committee as soon as you become aware of a breach of the terms or conditions of this *Agreement*.

15. You and Your Institution(s) accept that it may be necessary for the ICRR or its appointed agent to alter the terms of this *Agreement* from time to time in order to address new concerns. In this event, the ICRR or its appointed agent will contact you and your Institution(s) to inform you of any changes.

16. You and Your Institution(s) agree to submit a Final Project Report (i.e., copy of academic and non-academic materials generated, summary of any issues that arose [incl. any planned dissemination that did not take place], and feedback on the ICRR data access process) on completion of the agreed purpose. You agree that ICRR may post links to these materials on their website, and disseminate the findings through their social media channels.

17. You and Your Institution(s) agree to distribute a copy of this *Agreement* and explain its content to any research member mentioned in the *ICRR Data Access Application Form*.

18. ICRR reserves the right to use legal action against you and your Institution(s) for any damages caused by the breach of this *Agreement.*

19. This *Agreement* shall be construed, interpreted and governed by the laws of Canada.

I have read and agree to abide by the terms and conditions outlined in the *ICRR Data Access Agreement.*

☐ YES ☐ NO

Applicant/Researcher:

Name: …….
Title and position: ……..
Institution: ……...
Signature: ……

ICRR Representative:
I attest that the above is in conformity with the access requirements of ICRR:

Name: …….
Approval number: …….
Signature: ……