



ICOR

International CardioCel Outcomes Registry

**Registry Information
& Start Up**

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Welcome to ICOR!

ICOR (International CardioCel Outcomes Registry) is a secure, free web-based database developed using the REDCap application which is specifically designed for building and managing online database projects and surveys. The purpose of the ICOR database is to manage CardioCel clinical and follow-up data.

ICOR will collect and store clinical data on the perioperative outcomes of patients receiving CardioCel for repair of congenital heart disease worldwide and will enable us to report regional patient demographics, risk factors, mortality and morbidity. This in turn will contribute to the consent process and help to inform parents' decisions with regard to the available treatment options.

Ethics Approval/Governance

Australian Public Hospitals

Ethics and Governance approval or local equivalent is required for each centre. A copy of your institution's Ethics and Governance approval letters is required prior to database access details being provided.

Ethics Submission - Central Registry submission can be amended by CHQ and submitted on behalf of site.

Governance - Central Registry can assist with governance submission. Documents will be according to site specifications and may include site specific consent forms. Data Transfer Agreement (DTA) may also be required.

Australian Private Hospitals

Ethical approval for private hospitals will be according to that institution's policy. Assistance can be provided by the Central Registry team, it may be that they will ratify the original approval.

International Sites

Ethics submissions - will be supported by Central Registry team.

All copies of documents for submission are available from the **ICOR Dropbox**. Access to the **ICOR Dropbox** is via the link below.

Documents available in the **ICOR Dropbox** include:

- Master Consent Form
- Master Ethics Submission
- Data Transfer Agreement template

Registry Ethics Approval letter will also be available in the File Repository.

ICOR Dropbox link:

<https://www.dropbox.com/sh/pkymxb2v9ogy4d4/AAAh8xVZgXOXfv1WGRgTs6Ea?dl=0>

Consents

The Registry recommends that every patient be consented to allow their data to be entered in the ICOR Registry. Patient Consent Form templates are available from the Registry to assist in this process and can be accessed from the **ICOR Dropbox**.

Data

Data Transfer

The responsibility for data transfer resides solely with the participating surgical team.

Data Reports/Requests

All data report requests are to be directed to the Steering Committee by completing a **Data Request Form**.

The **Data Request Form** is available for download under the File Repository in the database and once completed should be emailed to the ICOR Administrator.

All requests will be presented at the next Steering Committee meeting for approval.

Any requests of an urgent nature can be negotiated.

Research Projects

Applications for any research projects should be directed to the Steering Committee for approval. Email application should be made to chq_qpcr_cardiacresearch@health.qld.gov.au with project aims and team members detailed in the email. Once approved by Steering Committee the Researcher will need to sign the Researcher agreement.

Steering Committee

The International CardioCel Outcomes Registry (ICOR) Steering Committee will govern and oversee the appropriate use of Registry data, ensuring we have high quality data available for research projects.

The Steering Committee will also ensure the protection of privileged personal data located in the Registry.

For further details please refer to the ICOR Terms of Reference available via the ICOR Dropbox or contact the ICOR Administrator for a copy.

Management Committee

The International CardioCel Outcomes Registry (ICOR) Management Committee will act as a sub-committee of the Steering Committee and will be responsible for the day to day management of the Registry database including auditing, reporting and processing data requests.

For further details please contact the ICOR Administrator.

ICOR Administrator: *Janelle Johnson*
QPCR Research Data Manager
Janelle.johnson@health.qld.gov.au
(07) 3069 7824

Management Group: *Nelson Alphonso*
Director Cardiac Surgery
Nelson.alphonso@health.qld.gov.au

Jessica Suna
Research Manager
Jessica.suna@health.qld.gov.au
(07) 3069 7256

Janelle Johnson
Research Data Manager
Janelle.johnson@health.qld.gov.au
(07) 3069 7824

Current Registry Participants

Queensland Children's Hospital
501 Stanley Street
South Brisbane Q 4001

Royal Children's Hospital
50 Flemington Road
Parkville VIC 2052

Perth Children's Hospital
15 Hospital Avenue
Nedlands WA 6009

Star Ship Children's Hospital
2 Park Road, Grafton
Auckland NZ

Institut Jantung Negara
145 Jalan Tun Razak
Kuala Lumpur

Queen Mary Hospital
Department Cardiothoracic Surgery
New Clinical Building Room 308
102 Pokfulam Road
Hong Kong

Registry Site Manager – Start Up Checklist

Welcome to ICOR! To better assist you with the registry set-up items, we have provided a check list to ensure you are on a pathway to registry success! As the Registry Site Manager for our hospital, it is important to review and perform each of the items listed below. If you have any questions, please feel free to contact the ICOR Administrator.

	Ethics approval & Governance – Please Email Ethics Approval letter to ICOR Administrator (<i>Janelle.johnson@health.qld.gov.au</i>)
	Request access to the ICOR database – User Name and Password will be emailed directly from REDCap. Please ensure you change the password as instructed.
	Create profiles for all participating staff including, Site Manager/Data Manager, Medical/Clinical Director using the Site User Administration form. Please complete and return via email to ICOR Administrator.
	Complete Staff Participation Form and return via email to ICOR Administrator.

Register Your Site for Access

1. Following your request for access to the ICOR Registry, you will receive a *User Name and Password* in a separate email from REDCap. You will be instructed to change your password to a site-specific password according to the instructions.
2. You will also receive an email from the ICOR Administrator containing a **Site User Administration** form, a **User Access Request** form and a **Staff Participation** form. Please complete and return by email to the ICOR Administrator.
 - a. The **Site User Administration** form includes contact details for:
 - Site Manager/Data Manager

The Registry Site Manager/Data Manager will be responsible for ensuring the accuracy and integrity of the data collection process and will be the central contact person for your site.
 - Medical/Clinical Director

The Medical/Clinical Director will be responsible for point of care data entry.
 - b. The **User Access Request** form requires details of all staff who require access to the database. Individual user rights will be set up according to the level of access required.
 - c. The **Staff Participation Form** must be completed for **ALL Cardiothoracic Surgeons** to be included in the ICOR Registry as part of the data collection process.

Site User Administration Form

Please complete the following and return to the ICOR Administrator via email as soon as possible (*Janelle.johnson@health.qld.gov.au*).

Name of Site/Centre: _____

Address: _____

Site Manager/Data Manager:

Surname/First Name: _____

Position: _____

Telephone: _____

Email address: _____

Medical/Clinical Director:

Surname/First Name: _____

Position: _____

Telephone: _____

Email address: _____

User Access Request Form

Please complete the following for any **new User/s** who requires access to the ICOR Registry database and return to the ICOR Administrator via email.

User Details

Site/Centre: _____

Surname/First Name: _____

Position: _____

Telephone: _____

Email Address: _____

User Details:

Site/Centre: _____

Surname/First Name: _____

Position: _____

Telephone: _____

Email Address: _____

User Details:

Site/Centre: _____

Surname/First Name: _____

Position: _____

Telephone: _____

Email Address: _____

Staff Participation Form

Please complete the following as soon as possible and return to the ICOR Administrator via email as soon as possible (*Janelle.johnson@health.qld.gov.au*).

Please include the name of ALL **Cardiothoracic Surgeons** to be included in the ICOR Registry. Names will be included in the database as part of the dataset.

The **Staff Participation Form** is also available in the **File Repository** of the ICOR Registry Database for including additional/new staff members to the Registry when required.

Surname	First Name	Position	Email	Telephone