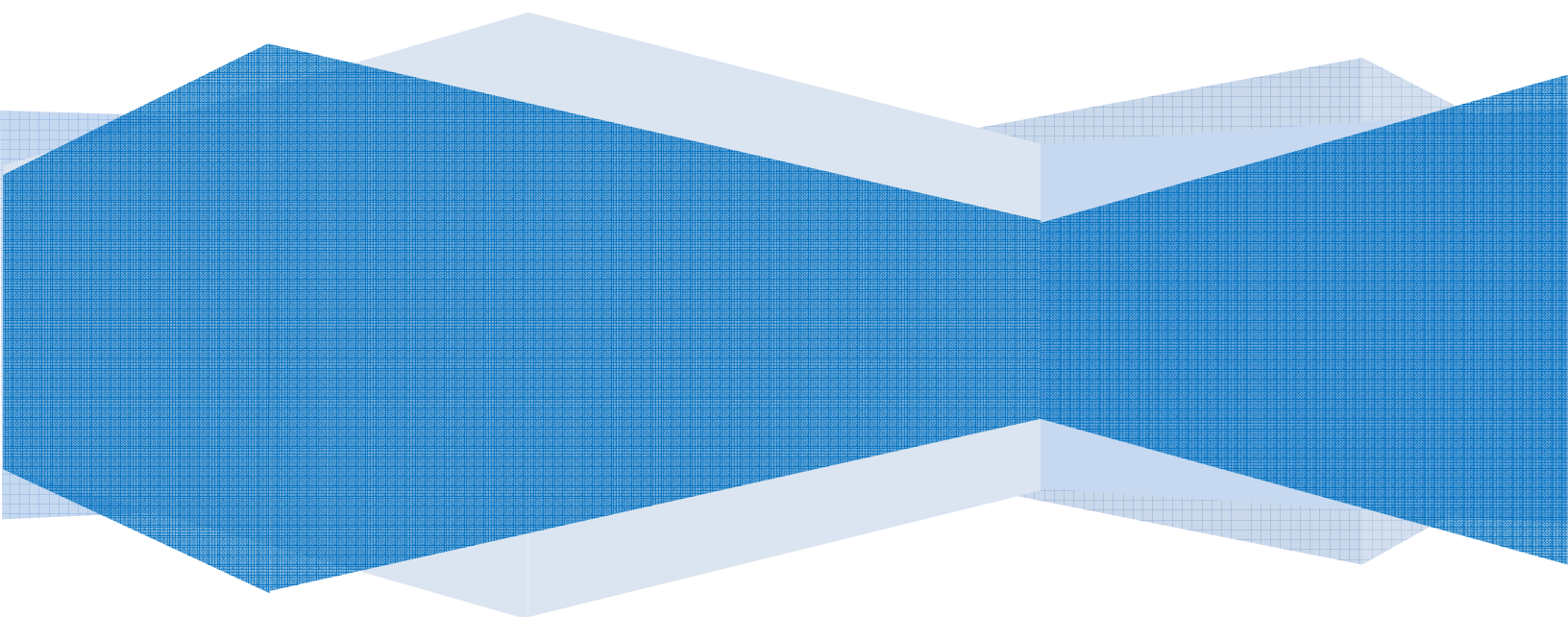


Saudi Congenital Heart Defects Registry

Multi- Institutional Committee Bylaws

Registries Core Facility



Saudi Congenital Heart Defects Registry

Multi- Institutional Committee Bylaws

INTRODUCTION

Congenital Heart Defects Registry is prospective since 1998. The registry started on a hospital level as research collaboration between King Faisal Heart Institute and Biostatistics Epidemiology and Scientific Computing department at King Faisal Specialist Hospital and Research Center, Riyadh. Being successful both on hospital and regional levels, the registry is now extending its collaborative efforts on a national level. The goal is to have key hospitals from major cities of the Kingdom on board for this collaborative program.

Bylaws of the registry are to empower and regulate the interaction between the committee members.

The Committee of the Saudi Congenital Heart Defects Registry is a group of experts in the management of cardiac diseases and management of health databases and disease registries. The committee is responsible for

- Defining scope, accountability, and delineating roles played by the nominated officers.
- Reviewing research projects proposals for a national dataset request.
- Reviewing reports and publications originating from the national dataset of the CHD registry database.

Changes in the structure of the individual CHDR committees must be in the knowledge of the Head office of the Congenital Heart Defects Registry at King Faisal Specialist Hospital and Research Center, Riyadh. This is important for timely and accurate correspondences.

ARTICLE 1. Committee members

Section 1: Members of the Multi-Institutional Committee

Chairmen and/or their designee from the individual collaborating hospitals constitute the multi-institutional committee members. The total number is determined by the collaborating hospitals

Section 2: Committee structure of the participating hospitals

- The committee structure of the participating hospitals is an internal arrangement according to the individual hospitals rules and regulations.

Saudi Congenital Heart Defects Registry

Multi- Institutional Committee Bylaws

- Choice of members for the committee is as per the internal arrangement of the collaborating hospitals.
- At least one registrar has to be on site for the registry. A registrar is required to communicate directly with his/her respective individual committee Chairman. An Individual registrar acts as a coordinator for the registry related matters.

ARTICLE 2. Officers

Section 1: Officers

1. A Committee Chairman
2. A Deputy Chairman
3. Two members from each collaborating hospital at large (Non-proxy)
4. One Scientific advisor to the registry (Non-Proxy, Ex-officio member)
5. A committee coordinator (Multi-Institutional Registrar)
6. A treasurer
7. A technical member (from BESC Department, with a non-voting status ex-officio member only)

Section 2: Eligibility

An individual, who has been a representative of a hospital/organization contributing data to the national registry program for at least three years, shall be eligible to hold the offices of the Chairman, Deputy Chairman and Coordinator (Multi institutional Registrar).

Section 3: Term of Office

Term of offices for Chairman and other members shall be two years while for Deputy Chairman and Coordinator the same shall be for three years conditional to their renewal of membership to the Registry Committee.

Section 4: Duties of the Officers

- A. Chairman is responsible for:
 - a. Signatory authority for the approval of
 - i. Publishing the Registry Annual/Cumulative Report.
 - b. Presiding over the Saudi Congenital Heart Defects Registry Multi-Institutional Committee meetings

Saudi Congenital Heart Defects Registry

Multi- Institutional Committee Bylaws

- c. Representing the Saudi CHDs Registry to outside organizations
- d. Approval of the registry budget and spearheading fund raising efforts
- B. Deputy Chairman is responsible for:
 - a. All responsibilities of the Chairman in his/her absence
- C. Coordinator (Multi institutional Registrar) of the Registry Committee is responsible for:
 - a. Formulating the agenda for meetings
 - b. Calling and coordinating the meetings
 - c. Keeping the minutes of the meeting
 - d. Facilitating the release of data for different kind of research (Article 3, Section 1)
 - e. Training the active work force (registry staff) of the individual hospitals.
 - f. Calling for orientation meetings once every year or as needed
 - g. Liaise with the Registries Core Facility of the Biostatistics Epidemiology Scientific Computing Department as a representative of the Saudi Congenital Heart Defects Registry
 - h. Serve as the initial contact for communication with the committee members (local and multi-institutional)
 - i. Responsibility of reporting the descriptive statistics based on the yearly collection of data in the form of a “Comprehensive Annual Report” rests upon the multi-institutional registrar of the Saudi Congenital Heart Defects Registry. However, each institute registrar is to compose their respective institutional reports on annual basis for their respective administration.
- D. A scientific advisor is responsible for providing an expert opinion on data analysis.
- E. Treasurer is responsible for looking after the financial interests of the registry. As well as reporting on the monetary status of the registry annually or when required
- F. Technical Member who is necessarily a member of the Registries Core Facility of Biostatistics Epidemiology and Scientific Computing Department, is responsible for ensuring the safety and security of the registry data along with ensuring that all technicalities involved in the successful functionality of the registry are in place

Saudi Congenital Heart Defects Registry

Multi- Institutional Committee Bylaws

ARTICLE 3. Data Release and Confidentiality policies

Section 1: Privileges and Data Policies

- Upon request, researchers and interested physicians will be able to browse registry data on both individual and multi-institutional level with a total masking of hospital information (hospital name, hospital code, and medical record number) along with patients' identifiable data (patients' name in Arabic and in English, and the identification numbers)
- The downloaded data for any research purposes, presentations, publications, etc will be totally masked for any identifiable data pertaining to the patients and the institute from where the data is downloaded
- Each collaborating institute has full access and authority on their respective institutional data for presentations and publication. Data can be downloaded for the respective institute by the institutional registrar with an understanding that the ethical committee of the respective institution has approved the research proposal or data presentation request prior to the download and making it available to the requesting researcher.
- Data release requests should be submitted to the registrar of the respective institutes who is responsible for documenting the request and informing the multi-institutional registrar and multi-institutional committee about the release of data from the registry.
- Interested physicians and researchers have to write a proposal listing clearly the variables that they would like to request from the centralized congenital heart defects registry database.
- Researchers need to contact their respective registrar for
 1. Filing the data request form
 2. Signing the oath of confidentiality prior to data release
 3. Browse only access to the registry software that requires a "Data Access" form to be completed and filed by the registrar. (Appendix III)

On the level of individual hospitals

- A written proposal should be submitted to the researcher's official research channels for approval, as per the researcher's hospital policy and regulations

Saudi Congenital Heart Defects Registry

Multi- Institutional Committee Bylaws

- In the proposal, the researcher needs to specify that the set of the data he/she is requesting will be on the individual level of his/her hospital.

On the multi-institutional level

- A written proposal should be submitted to the researcher's official research channels for approval, as per the researcher's hospital policy and regulations.
- The researcher has to state clearly that the needed data will be abstracted from the congenital heart defects registry database on the multi-institutional level.
- Upon approval from the researcher's hospital official research channels, the proposal will be distributed among the committee members of the Saudi Congenital Heart Defects Registry for update and documentation.
- Copy of the proposal will be submitted to the Office of Research Affairs at King Faisal Specialist Hospital Research Center, Riyadh for documentation.
- The Head office of the Congenital Heart Defects registry at King Faisal Specialist Hospital Research Center, Riyadh is responsible for downloading and providing the required multi-institutional data

Section 2: Related points for the Project Proposal

- The proposal is the researcher's call and responsibility.
- Principal investigator(s), Co-Principal investigator(s) included; are as per the call of the researcher.
- If the required data will be abstracted from the patients' medical records, researchers from the other collaborating hospitals as co-investigators on the paper will facilitate the abstraction process, especially in regard of the national expansion of the registry.

ARTICLE 4. Meetings of the Committee

Section 1: Meetings

- A. Annual business meeting of the Saudi CHDs registry committee shall be held in conjunction with the Annual Saudi Heart Association Conference

Saudi Congenital Heart Defects Registry

Multi- Institutional Committee Bylaws

- B. Quarterly meetings shall be held alternatively at BESC Department, KFSH&RC, and collaborating hospital.
- C. The Multi institutional committee Chairman can call for any ad hoc meetings.

Section 2: Notification

An official call and notice of meeting shall be sent by Fax or e-mail at least seven (7) days prior to the scheduled meeting by the Coordinator of the Multi-institutional committee. This call for meeting shall include agenda and a description of each matter requiring special consideration and attention except for ad hoc meetings mentioned in Article 4, Section 1, Clause (C) above.

Section 3: Quorum

A quorum for any meeting shall be a simple majority of the members registered at the meeting. In the absence of a quorum, the members at a called meeting will take no action.

Section 4: Action

- A. Action shall require the affirmative vote from a majority of the members; entitled to vote; during their physical presence at the meeting during which a quorum has been established.
- B. No action can be taken by the members at a meeting except for the matters described in the notice of the meeting.
- C. In case, there is a tie for votes among the members present, Multi institutional committee Chairman's vote will be the casting vote.

Section 5: Minutes and Notification of Action Taken

All actions taken by the committee shall be recorded in the minutes of the meeting. Minutes of the meetings shall be available to the members upon request.

Saudi Congenital Heart Defects Registry

Multi- Institutional Committee Bylaws

ARTICLE 5. Amendments of Bylaws

Section 1

The members of the committee may propose amendments to these Bylaws. Any voting member may propose amendments provided such amendments are accompanied by written endorsement of at least one third of the additional voting members.

Section 2

Proposed amendments to these bylaws shall be submitted to the Chairman of the Multi-institutional committee at least sixty days (60) prior to the committee meeting.

Section 3

A two-thirds (2/3) vote of the voting member present at the meeting at which a quorum has been established shall be required to adopt any amendment.

Section 4

Amendment in the committee bylaws can only be done once a year.

Section 5

A copy of the proposed amendments shall be sent to the voting members at least thirty days (30) prior to the committee meeting.

ARTICLE 6. Congenital Heart Defects Registry Executive Office

Executive Office of the Saudi CHDs Registry is located at:

Biostatistics, Epidemiology and Scientific Computing Department

MBC 03, Research Centre, King Faisal Specialist Hospital and Research Centre, Riyadh,
Saudi Arabia.

Official Phone: +966 1 4647272

Saudi Congenital Heart Defects Registry

Multi- Institutional Committee Bylaws

Secretary extension:	27853
Multi-institutional Registrar extension:	39209
Fax:	+966 1 4424542

ARTICLE 7. Financial Affairs

Since this registry is a non-profit research project geared towards maximizing healthcare delivery to our patients in the Kingdom of Saudi Arabia, this project should be looked at as a destiny of philanthropic orientation. At this level the committee will use all its resources to solicit the funding to this project. An account of such donations will be opened under the name of the “Saudi Congenital Heart Defects Registry” and will be maintained by a certified accountant under the direct supervision of the Treasurer.