July 23d, 2024

RULES FOR THE CONDUCT OF ECHSA DATABASE STUDIES, PRESENTATIONS, AND PUBLICATIONS

- The ECHSA Congenital Cardiac Database is a basic pillar of the scientific endeavors of our Association, the integral product of invaluable contributions of its founders, our Members and Participating Centers.
- It is one of the largest Congenital Cardiac Databases in the world and represents a major scientific achievement of our Association, for the benefit of all pediatric and congenital cardiac patients in the world.
- As such, it has been extremely important for ECHSA to continue to develop it, while at the same time safeguarding at the highest standard its scientific quality, which is intimately related to the brand reputation and status of ECHSA, that we must maintain as a preeminent scientific organization in our field.
- To this end, ECHSA official policy regarding Database research, which has been formally incorporated in the ECHSA Database Charter many years ago, as well as in the more recent ECHSA – AEPC Agreement regarding Database collaboration, **both encourages Member engagement in Database Research and stipulates the process which safeguards the scientific quality of such research efforts.**
- As one can see in the relevant sections of the official documents referred to above, **which are reproduced for convenience in the below Appendix,** this official policy and process for conducting ECHSA Database Research can be summarized and codified as follows:

WHO CAN REQUEST DATA FROM ECHSA Congenital Cardiac Database for STUDY & PUBLICATION PURPOSES?

1. All ECHSA Members are strongly encouraged to engage in scientific Clinical Research involving analysis of information contained in the ECHSA Congenital Cardiac Database.
2. ECHSA Members (PI) with status of “full membership”. Junior members will need the endorsement of a senior ECHSA member.
3. Database Participating Centers - if the Center is represented by a non - ECHSA Member, a ECHSA member need to be included and the designation “by invitation” will be applied to that non ECHSA non-member.
4. Congenital Heart Surgeons or Cardiologists who are neither ECHSA Members nor representing a Database Participating Center may submit a research proposal requesting data only in partnership and under the overall responsibility of a *sponsoring ECHSA Member.* Then, the designation “by invitation” will be applied to that non ECHSA non-member.
5. For an ECHSA Member to request data for any research / publication purposes, the Member’s Center should be active at providing data to the Database - in fulfillment of the responsibilities of Full Membership, as specified in the ECHSA Association Rules:

"To submit the data of operations from the Member's institution to the ECHSA Congenital Database, at least as pertaining to the Member's own operations. Exception from this rule can be granted by the Board for special circumstances after application from the Member.".

REQUIREMENTS to PROPOSE an ECHSA Congenital Cardiac Database STUDY & PUBLICATION PROJECT.

1. Database research must begin by submitting a specific Research Proposal to the Database Committee Chair. The Research proposal should clearly indicate:

    a. Principal Investigator (PI) and any co-investigators.
    b. Proposal should include:
        i. Relevant Background
        ii. Specific Objectives of the study
        iii. Inclusion and Exclusion Criteria
        iv. Proposed analytical methods

2. Any proposed research will guarantee <u>full anonymity</u> of the data.
3. In particular, ECHSA <u>shall not</u> use the data to rank the CTS Centres in any way.
4. <u>All</u> Research Proposals will be reviewed by the Database Director - Database Committee Chair, and a recommendation for approval, revision, or non-approval will be made by the Chair to the Database Committee.
5. <u>Formal approval</u> by the Database Committee signed by the Chair (which can be obtained via documented electronic communication such as email or other chat platform messages, or on special platform planned for the Database website) <u>is required before data will be released for analysis.</u>
6. Following analysis of the data by the PI, results and any proposed presentations or paper submissions must be communicated by the PI to the Database Committee Chair and Members <u>well ahead</u> of any submission deadlines to allow for proper discussion, exchange of ideas, and any recommended improvements.
7. Any formal submission for, either presentation (abstract) or for full paper publication, will require the prior review and approval of the Database Committee, appropriate permission being granted in writing by the Chair**.** Only then the Study can be designated an **"ECHSA - endorsed congenital database study".**
8. Regarding authorship of any reports for ECHSA Database research, in respect and external indication of both the scientific work performed and the primary responsibility for the scientific quality of such research reports, the PI shall preferably be listed as first or last author. Other co-authors shall be included in sequence reflecting their actual contributions, that shall be described in detail by the end of the abstract.
9. Alternatively, if desired by the PI, a co-investigator designated by him (typically, a less senior associate) may be listed as first author, reflecting his/her performing the bulk of the relevant scientific work. Then, the PI can then be listed as last author and will <u>always assume major responsibility for assuring the scientific merit of the work as recorded in any proposed presentation or full pa*l by the Chair is a required pre-requisite to any Database research report or publicat*</u>

Appendix

A. Excerpts from the ECHSA Database Charter:

Article 6. PUBLICATIONS AND OTHER USE OF DATA

(i) The CTS Centres have a right to publish for scientific purposes the publicly available data reports, referred to in Section 4(i).
(ii) Any further information obtained from the ECDB, in particular the reports available only to the registered CTS Centres in accordance with Section 4(ii), may be used by CTS Centres solely for internal purposes. Any publishing of such reports in whatever form, either in electronic form or printed form, in whole or in part, requires prior written consent of the ECDB Committee Chair, **which may be granted only after the ECDB Committee deliberates on and approves the relevant scientific merit** (see below section 9.1)
(iii) Any publication of the reports or other information as set out in Section 6(i) and (ii) requires reference to the ECDB as the source of publication.
(iv) **ECHSA encourages members to use the database for benchmarking, for quality improvement programs in their Centres, and also to analyse data for clinical scientific research. In order to ensure the scientific merit of analyses utilizing ECDB data, members who wish to use the information and reports available via the ECDB for scientific purposes, must submit the specific research proposal to the ECDB Committee Chair and must obtain prior written approval of the proposed research by the Chair, as specified in section 9.1. Any such research will guarantee full anonymity of the data. In particular, ECHSA shall not use the data to rank the CTS Centres in any way.**
(v) In the event of any publication made pursuant to Section 6 (iv) the publishing party shall acknowledge ECHSA.

Article 9. ADMINISTRATION OF THE ECDB.

9.1.1 The ECHSA Board appoints the ECHSA CONGENITAL DATABASE COMMITTEE.

a. The purpose of the Database Committee is to govern the database and to advise the Board either upon request or on its own initiative.
b. All important decisions regarding the functions and future of the database must be approved by majority vote of the Committee, as well as the ECHSA Board. Which decisions are or can be qualified as important is at the discretion of the Board.
c. The annual detailed budget and actual expenses on a 6-month basis must be approved by the Committee and reported to and approved by the ECHSA Board.
d. All database development plans/projects, must be presented to the Database Committee and formally approved by the Committee.
e. ECHSA members are encouraged to utilize the ECDB data for scientific research. Any ECHSA member may submit a research proposal involving use of Database non-public data to the Database Committee. Non - ECHSA member proposals will be considered only in cooperation with a sponsoring ECHSA

Member. Such co-operative proposals, especially if the non-ECHSA Member is a Scientific Society, are also encouraged. All Research Proposals will be reviewed by the database Director as well as the Database Committee Chair and the Co-Chair, and a recommendation for approval or not will be made to the Database Committee. Formal approval by the committee signed by the Chair (can be obtained via written electronic communication) **is required** before data will be released for further analysis. Analysis of the data and formal publication submission will also require the prior review and approval of the Database Committee, appropriate permission being granted in writing by the Chair

B. Excerpts from the Formal ECHSA-AEPC Database Agreement

Appendix Section IV. Governance:

1. ECHSA has established an **ECHSA Database Committee** that reports to the ECHSA Board of Directors. The ECHSA Database Committee has the following responsibilities:

a. Manage the ECHSA Congenital Database (ECHSA-CD)

b. Report to the ECHSA Board of Directors

c. Review and approve all Quality and Research Projects generated from ECHSA-CD

d. Review and approve all presentations generated from ECHSA-CD

e. Review and approve all abstracts generated from ECHSA-CD

f. Review and approve all manuscripts generated from ECHSA-CD

2. An **AEPC Representative** selected by the AEPC Council will be appointed by ECHSA as a Member of the ECHSA Database Committee, as a liaison with the AEPC Interventional Working Group, with the following objectives: …

3. The AEPC council will establish a **Steering Committee of the AEPC interventional cardiology Part of the ECHSA-CD** which will report to the AEPC Council and the AEPC Interventional Working Group. The AEPC Steering committee has the following responsibilities:

a. Manage the AEPC Interventional Cardiology Database Part of the ECHSA-CD

b. Report to the AEPC Council and AEPC interventional Working Group

c. Review and approve all Quality and Research Projects generated from AEPC Interventional Cardiology Database Part of the ECHSA-CD

d. Review and approve all presentations generated from AEPC Interventional Cardiology Database Part of the ECHSA-CD

e. Review and approve all abstracts generated from AEPC Interventional Cardiology Database Part of the ECHSA-CD

f. Review and approve all manuscripts generated from AEPC Interventional Cardiology Database Part of the ECHSA-CD

g. For projects consisting of both interventional and surgical data, these projects will be discussed with both ECHSA and AEPC database committees.

h. Keep the ECHSA database committee informed on the ongoing projects generated from the AEPC Interventional Cardiology Database Part of the ECHSA-DB and provide the approved manuscripts for information