CHARTER
of
THE EUROPEAN CONGENITAL HEART SURGEONS ASSOCIATION
CONGENITAL DATABASE
“ECHSA CONGENITAL DATABASE”
(“ECDB”)

1. INTRODUCTION

(i) The following Charter (the “Charter”) outlines the purpose, the conditions for use and the governance of the European Congenital Heart Surgeons Association Database (“ECDB”).

(ii) This ECHSA Congenital Database Charter has been approved by the ECHSA Board and can be periodically modified by the Board in response to evolving goals and needs of the Database, in order to ensure optimal use of its resources and potential to achieve the chartered goals of the European Congenital Heart Surgeons Association.

(iii) The ECDB including its software and its intellectual property is owned exclusively by The European Congenital Heart Surgeon’s Association (“ECHSA”), an Association under the laws of Finland, with its seat at Kotimetsä 2, 002300 Espoo, Finland and registration no 1776830-7. In addition, ECHSA is the sole owner of all copyrights and all other IP address rights regarding the ECDB database.

(iv) The original data contained in the ECDB derives from the submitting cardiothoracic Surgery Centres (“CTS Centres”), who are thus responsible for the integrity of the data as they are submitted. The ECDB (and all its anonymized data kept within the ECDB) has been and will be residing exclusively on ECHSA servers (or those of its contracting parties).

(v) ECHSA and its predecessor have designed the database and its structure and have also been responsible for the collection of the data and relevant scientific reports and publications.

(vi) The software, which has been developed in order to make use of the database, processing and storing the data in the database and the administration of the ECDB possible and user friendly has been developed and is maintained by the Software Company Magnum 2 (“Magnum 2”). All the work Magnum 2 has carried out has been done on behalf of ECHSA and has been based on agreement with and assignment by ECHSA, and the software has been developed following the instructions given by ECHSA. The data included in the ECDB database currently resides on the servers owned by Magnum 2. This is based on the agreement with ECHSA, and ECHSA has total control over the data.

(vii) ECHSA retains the right at any time to alter both the said software development company as well as the location of the servers on which the database resides.

(viii) For the purpose of managing the ECDB, a committee (“Database Committee”) has been empowered by ECHSA, as specified below.

(ix) Each CTS Centre, by submitting the registration form or logging on to the ECDB, acknowledges the Charter and agrees to follow it. Payment of appropriate dues, as set forth by the ECDB, is a prerequisite for CTS Centre access to the ECDB.
2. AIMS

(i) The immediate aim of the ECDB is to collect data relating to treatment of patients with congenital heart disease, including diagnoses, risk factors, surgical and other procedures, and immediate and eventually long-term outcome.

(ii) The goal of the ECDB is to improve the quality of care as well as the quality of life of surgically treated patients (children and adults) with congenital heart disease.

(iii) The ECDB will actively seek cooperation with other scientific societies to strengthen its data collection and analysis capabilities.

(iv) The data collected will allow comparisons of outcomes, performances, and of the manner with which congenital procedures are carried out. Collected data analysis shall enable risk stratification and help define optimal surgical treatment for subsets of patients exposed to incremental mortality and morbidity risk factors.

(v) In order to realize its goals, the ECHSA Congenital Database assumes the responsibility to take an active role in analysing the collected data. In order to achieve this, ECHSA will take efforts to engage the Members of ECHSA individually or in the context of multi-institutional studies to assume an active role in utilizing and analysing the data, with the support and guidance of the Database Committee (see below, Section 9).

(vi) The ECDB does not serve to rank CTS Centres or surgeons, and does not participate in malpractice investigations or conformity checking of CTS Centres and surgeons. To this end, the data contained therein remains anonymous and does not enable identification of either CTS Centres, surgeons, or patients.

(vii) The ECHSA Congenital Database was created and developed for non-commercial purposes.

3. HISTORY

(i) The ECHSA Congenital Database has originally been created by the European Congenital Heart Surgeons Foundation (“ECHSF”, a Foundation established in the Netherlands), originally under the name of European Congenital Heart Defects Database (“ECHDD”), in 1992. This was a database of congenital heart surgical procedures and was established for academic purposes. The original seat of the ECHDD was in London. The ECHDD was moved from London to Warsaw in 1999.

(ii) In 1999, at the Congenital Business Meeting of the EACTS held during the Annual Meeting of the EACTS in Glasgow, Scotland, it was agreed that the ECHDD would become part of the EACTS “ECSUR” Project, and was renamed to “EACTS Congenital Database”. EACTS was to assume the responsibility to co-fund the database along with ECHSF, providing all of the necessary funds.

(iii) In 2003, the ECHSF was dissolved and its members established a new scientific Association in Finland under the name European Congenital Heart Surgeons’ Association (“ECHSA”), which assumed all of the ECHSF’s purposes, associated members, and administration. All the rights relating to the database (at the time named EACTS Congenital Database), originally vested in ECHSF, were simultaneously assigned and transferred fully, irrevocably, permanently and exclusively to ECHSA.

(iv) The scientific concepts of the European Congenital Database, which were originally developed under the umbrella of ECHSF continued to be developed under ECHSA, and software development as well as web hosting and maintenance was contracted to the software company Magnum 2 by ECHSA after the database was moved to Warsaw. Funding for the database, initially derived from both ECHSA and EACTS, would rely, over the last seven years, solely on ECHSA. For the avoidance of doubt it shall be noted that the regardless of initial co-funding of the database, all the rights and the ownership...
to the database remained solely to ECHSA, and ECHSA continued to have total control, at all times, over the data and the database. All the agreements regarding the database, such as maintenance contracts and agreements concerning the software regarding the use of the database with Magnum 2, were made by ECHSA.

(v) In 2006, a Database Policy was adopted and posted on the website, describing the position of ECHSA and EACTS as to the management of the Database. The question of ownership was not discussed in this document, nor are there any prior documents relating to ownership or transfer thereof.

(vi) For the last several years EACTS has not contributed to Database, due to differing opinions of ECHSA and EACTS regarding management of the Database, including the issue of auto-financing of the database so as to render it independent of third party support. Prolonged unsuccessful attempts by ECHSA to achieve mutual agreement between with the EACTS led to the ECHSA decision to change the database name to “ECHSA CONGENITAL DATABASE” and to continue managing and financing the database without assistance or partnership with other Societies.

4. ACCESS

Access to the ECDB is available online. Access is possible to the aggregated data organized in the form of reports; the input data submitted by the CTS Centres remain anonymous in accordance with the principles set out in Section 5. The following types of access can be distinguished:

(i) Public access

Certain aggregated data may be made publicly available to individual guest users after appropriate registration, as determined by the ECDB Committee. The scope of any publicly available data is defined by the Database Committee.

(ii) Access of CTS Centres

Any registered CTS Centre which is in a good standing with regard to dues payments, as these are determined or revised by the ECHSA Board has access to all kinds of reports generated via the ECDB using the aggregated anonymized data submitted by the CTS Centres and contained in the Database.

(iii) ECHSA Member Access

Any ECHSA Member who is in good standing with regard to payment of ECHSA membership fees.

5. ANONYMITY OF THE DATA

(i) The data regarding congenital heart surgical procedures performed by surgeons from Europe and around the world contained in the ECDB is collected, stored, analysed, and presented in an anonymous manner. The anonymized data will reside exclusively on servers belonging to ECHSA or its contractors.

(ii) The ECDB does not enable disclosure of the identity of surgeons who performed a procedure, the identity of patients, or the identity of the CTS Centre that submitted the data.

(iii) Subject to the CTS Centre's fulfilment of the obligations under this Charter, ECHSA shall make all reasonable efforts to safeguard the full anonymity of the data in the ECDB and to ensure that the data is not traceable to the name of the CTS Centre which submitted data.

(iv) Save for the circumstances described in Sections 5(v) and (vi), the name of the CTS Centre that submitted data may not be decoded by any institution, person or entity, including ECHSA.

(v) In order to ensure technical functionality of the ECDB and enable verification of the data
as referred to in Section 8, the ECDB Chair or Director, or his duly authorized representative (any of them or collectively referred to as “ECDB Staff”), have access to information as to which CTS Centre submitted the data.

(vi) Under exceptional circumstances, the name of the CTS Centre that submitted data may be disclosed to the governmental authorities or courts of the competent jurisdiction, and only in accordance and as enforced by applicable laws.

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.

7. PRINCIPLES OF OPERATION

7.1 REGISTRATION

(i) Any CTS Centre interested in registration must fill in the registration form available on the ECDB Internet Page, and submit it to the ECDB.

(ii) The ECDB has the right to verify the information provided in the registration form. The verification is carried out by reviewing publicly available information, in particular by looking for data about the CTS Centre in the Internet, and checking the publications record and other relevant scientific activities of the head of the department and/or the registering person.

(iii) The CTS Centre is responsible for:

- providing accurate, complete profile data and truthful information on the registration form;
- ensuring that its registration in the ECDB complies with any applicable local laws and internal procedures;
- ensuring that the person conducting the registration of the CTS Centre holds authorization to act on behalf of the CTS Centre, and, if necessary, on behalf of any larger healthcare establishment that the CTS Centre may be organizational unit of.

ECHSA has the right to refuse registration of the CTS Centre if, in its opinion, any of the requirements set out in this Section 7.1(iii) is not fulfilled.

(iv) The ECDB waives all responsibility for any damage caused by persons who registered
with the ECDB on behalf of the CTS Centre without the proper authorization for such registration.

(v) A CTS Centre that has successfully completed the registration process becomes full participant and user of the ECDB in accordance with this Charter, after payment of the appropriate fees, as they are determined or revised by ECHSA Board.

(vi) CTS Centres are obliged to inform the ECDB without undue delay of any subsequent change of any information provided in the registration form during the registration process.

(vii) A list of the registered CTS Centres is displayed on the ECDB Internet Page, however without a possibility of linking a particular CTS Centre with any data contained in the ECDB.

7.2 DATA INPUT

(i) Data may be inserted into ECHSA Congenital Database by the registered CTS Centres only.

(ii) Data is submitted using the International Paediatric and Congenital Cardiac Code (available at www.ipccc.net) in the version of the International Congenital Heart Surgery Nomenclature and Database Project of the European Association for Cardio-Thoracic Surgery and the Society of Thoracic Surgeons.

(iii) The CTS Centre is obligated to ensure that the inserted data is accurate, complete and truthful. The ECDB is not obliged to verify whether the input data fulfils these requirements. However, the ECDB has the right to either mark the data as not valid or even remove the data from the Congenital Database if it suspects, or is informed, that the data is not accurate, complete or truthful.

(iv) CTS Centres are responsible for ensuring that only properly authorized persons submit data to the ECHSA Congenital Database. The ECDB waives all responsibility for any damage caused by persons who inserted data to the ECDB on behalf of the CTS Centre without proper authorization.

(v) After registration and payment of appropriate dues, as they are determined or revised by the ECHSA Board, a CTS Centre receives, access to the software for data collection.

(vi) The data submitted by the CTS Centre is uploaded to a secure web page provided by the ECHSA Congenital Database. The data is sent as a xml file that does not contain the names of doctors or patients, or any other personal data which would allow the identification of any natural person. Before the data is ultimately transmitted to the ECDB, the CTS Centre has an opportunity to verify the file.

(vii) Once the computer program operated by the ECDB has checked the correctness of the submitted data, the data is computed by the server and inserted into the ECDB.

(viii) In the event that the CTS Centre’s involvement in the ECDB is terminated, the data inserted by such a CTS Centre will remain in the ECDB unless otherwise decided by the ECDB Committee Chair.

7.3 CTS CENTRE ID AND USER ACCOUNT

(i) Once the registration of the CTS Centre has been successfully completed, the CTS Centres will be assigned a unique identification number (“CTS Centre ID”, previously called “Hospital ID”).

(ii) In addition to the CTS Centre ID, a CTS Centre will be assigned a requested (unlimited) number of accounts, one for each person authorized to input data into the ECDB and have access to online reports (“User”), each secured with a unique password. The User is a person named by the CTS Centre as the person authorized to log in to the ECDB on behalf of the CTS Centre.

(iii) It is the CTS Centre’s responsibility to ensure that only authorized persons within CTS Centre, on a need-to-know basis, know the Centre ID, and the User’s account or password.

(iv) The CTS Centre is obligated to immediately inform the ECDB of any changes regarding persons authorized as Users in order to enable the ECDB to change the password of that User or
otherwise disable the account. The ECDB management shall without undue delay respond to the CTS Centre’s request to change the password or otherwise disable the User’s account.

(v) The CTS Centre shall impose an obligation on its employees and contractors who are authorized as Users to keep the CTS Centre ID and the User’s account and its password strictly confidential. The confidentiality obligation should also ensure the secrecy of such information after the termination of the employment or any other relevant relationship between the CTS Centre and the User.

(vi) ECHSA and THE ECHSA Congenital Database shall act with due diligence to ensure strict confidentiality of the CTS Centre ID or the User’s account. ECHSA and the ECDB shall not be liable for unauthorized disclosure of such information by persons who are not under ECHSA’s direct control or supervision.

8. DATA VERIFICATION

(i) ECHSA and the ECDB consider the verification of the accuracy of submitted data as a vital element of the operation of ECDB.

(ii) Verification is currently provided free of charge by the ECDB, and the CTS Centre covers only the travel and accommodation expenses incurred by the ECDB Staff conducting the verification. The ECDB reserves the right to charge a verification fee in the future.

(iii) Verification is aimed at assessing whether the data contained in the ECDB is accurate. Verification of the data at source is one of the instruments necessary to ensure the quality and reliability of the ECDB.

(iv) Verification is currently performed voluntarily at the request of the CTS Centre or on the basis of the decision the ECDB Director. However, ECHSA reserves the right, in the future, to possibly require regular on-site data verification as a necessary condition for CTS Centre enrolment.

(v) The verification process is based on an interview conducted by ECDB Staff with an appointed representative of the CTS Centre. During the verification process, the CTS Centre ensures the availability of an appointed representative of the CTS Centre at the CTS Centre’s premises for the purpose of an interview.

(vi) In the verification process, a “back-to-back” method is used: the ECDB Staff asks for certain anonymous information, while the appointed CTS Centre’s representative provides such anonymous information by accessing medical documentation and source data available at the CTS Centre (whether anonymous or non-anonymous). At any time, the ECDB Staff does not have access to non-anonymous data of patients or any other non-anonymous information resources available at the CTS Centre. In particular, the verification does not enable the ECDB Staff to identify a patient who has undergone surgery or the surgeon who performed the surgery. Only an authorized representative of the CTS Centre may have access to non-anonymous information.

(vii) The CTS Centre is responsible for ensuring that the use of medical documentation or other source data available at the CTS Centre in the verification process is made within the local statutory limits and in accordance with any internal procedures of the CTS Centre.

(viii) The ECDB Staff performing the verification process act on behalf of the ECDB and they cannot be regarded as contractors of the CTS Centre, even if the verification is conducted on request of the CTS Centre.

(ix) Once the verification process is successfully completed, the ECDB provides the CTS Centre with a certificate and report containing an assessment of accuracy of the data submitted in the ECDB by the CTS Centre.

(x) The ECDB Director publishes on the ECDB Internet Page a list of the verified CTS Centres, confirming in this way that the ECDB performed the verification process. The list does not contain any information as to the assessment of accuracy of the data submitted by the CTS Centre.

(xi) Since the ECDB Staff does not have direct access to the medical documentation or other source data of the CTS Centre, the ultimate responsibility for the accuracy, completeness and truthfulness of the data remains with the CTS Centre and the reservations contained in Section 13(iii) remain unaffected.
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.

9.2 Composition of the ECHSA DATABASE COMMITTEE and duties of its members.

The ECDB committee consists of a minimum of five full voting members including:

1. the **Chair**,
2. the **Co-Chair (ex-officio)** is the Chair of the Research Committee,
3. the **Director** of the Database,
4. one other ECHSA member,
5. the ECHSA **Treasurer (ex officio)**.

If one or more of these officers holds more than one of these positions, the Board will appoint additional ECHSA members so that at least five different persons constitute the minimum number of five voting members.

There is a **Technical Director** whose function is to run the database on a technical level and who has the status of non-voting member on the Database Committee. There can be also other non-voting members, to be determined at the discretion of the Board. The Board can alter the number and composition of the Database Committee Members to accommodate evolving needs of the database in terms of fulfilment of its goals.

1. **The ECHSA Congenital Database Committee Chair** is appointed and dismissed by and reports to the ECHSA Board. His tenure is 4 years.

   i. The first Chair is Tjark Ebels.

   a. The **ECHSA Congenital Database Committee Chair** is responsible for all aspects of the Database and can instruct the Director. The Chair organizes and chairs the meetings of the Database Committee, and he:

   b. Is responsible for monitoring the financial operations of the database including:

   i. submission of the annual budget proposals and six-monthly expense reports to the
ECHSA Board.

ii. Industry proposals requesting access to Database information in exchange for ECHSA Sponsorship, and makes relevant recommendations to the Database Committee and the ECHSA Board.

c. Gives consent to the publication of information and reports contained in the ECDB, as provided for in Section 6(ii) and 6(iv).

d. Gives consent to invalidating of data from the ECD;

e. Monitors the CTS Centre’s actions to ensure compliance with the Charter, in accordance with Section 12.

f. Oversees ECDB Data analyses and Scientific Projects by Database Committee members, as provided for in section 9.1.

g. The ECDB Committee Chair has no access to the CTS Centre Database referred to in Section 10(ii).

2. The Co-Chair replaces the Chair in his absence for whatever reason. As Chair of the Research Committee he serves as liaison with the work of the Research Committee and the conduct of multi-institutional studies, encouraging the use of ECDB Data in the context of ECHSA multi-institutional studies, according to the rules specified in section 9.1.

3. The ECHSA Congenital Database Director is appointed and dismissed by the ECHSA Board, and reports to the Database Committee Chair. The Director should possess appropriate skills and experience to ensure proper operation of the ECDB. His tenure is 4 years.

   i. The first Director is Bohdan Maruszewski.

   a. The ECDB Director is responsible for running the database and instructs the Technical Director in accordance with the Committee Chair. In particular, he is responsible for:
   b. data collection, data optimization and data protection;
   c. assisting CTS Centres and providing support to the CTS Centres. For this purpose, the Director keeps the CTS Centres Database referred to in Section 10(ii).
   d. technical organization of the process of verification of data according to the rules set out in Section 9.
   e. overseeing data analysis, and implementation of database development plans, as well as implementation of proposals for database derived scientific reports, which have been approved as specified in section 9.1.
   f. working on all above aspects with the Chairs of both the Database and the Research Committee.
   g. proposing database development to the Database Committee.

4. One other ECHSA member. Assisting in all aspects of the work of the database committee.

5. The ECHSA Treasurer (ex-officio). He oversees the execution of the ECDB budget and assists the ECDB Committee Chair in all financial matters of the ECDB, and all aspects of the work of the database committee.

6. The Technical Director is a Physician and/or IT Specialist responsible for actual software development, database web function and assisting CTS Centres and providing technical support to the CTS Centres. He supervises data verification procedures of Centres or carries these out personally. He can represent the software company running the database. He is appointed and dismissed by the ECHSA Board. The duration of this post is at the discretion of the Board. The Board of ECHSA retains the right to replace the Technical Director at any time, with due cause and after due notice is given.

   i. The first Technical Director is Zdzislaw Tobota.
7. **Representatives of other Database and / or Scientific Societies (non-voting members)**, upon approval of the ECHSA Board and the respective Societies and/or Databases, such as:
   1. The EACTS
   2. The STS National Database
   3. The CHSSS
   4. The WSPCHS
   5. The AEPC

10. **PERSONAL DATA**
   
   (i) The ECDB does not contain any personal data.
   
   (ii) For the purpose of registration and communication with CTS Centres, and verification of the data provided, a registry of CTS Centres is established (herein called the “Centre Database”).
   
   (iii) The CTS Centre Database contains data provided by a CTS Centre in the registration form and contains some personal data. It is maintained in printed form as well as in a computer system.
   
   (iv) The CTS Centre Database is kept by the ECDB Director on behalf of the ECDB. No other person has access to the CTS Centre Database.
   
   (iv) Personal data contained in the CTS Centre Database is protected in accordance with the laws applicable to the data controller and data processor.

11. **FINANCING**

   - All funding for the Database is handled through ECHSA and the ECHSA Treasurer. The sources of funding for the database are as follows:

   1. **User fees (“auto-financing”)**. Centres participating in the database will be charged an annual user’s fee, as determined and modified by the ECHSA Board. In return, participating Centres will have access to all features of the database.
   
   2. **Voluntary Contributions to the Database** (E.g., from Centres, Benefactors, Charitable Organizations).
   
   3. **Industry Sponsorship of the Database**
      
      a. Upon approval by the ECHSA Board, funds must be directed to ECHSA via its Treasurer. Direct donations to the Database are not possible.
      
      b. Industry requests for information from the Database in exchange for Sponsorship must be in the form of written specific proposals to the Database Committee. All such proposals will be reviewed by the Committee and, upon approval, must also be approved by the ECHSA Board.
   
   4. **The ECDB cannot receive directly any financial resources or other forms of sponsorship than those mentioned. In particular, direct financing of the ECDB (i.e., financing not handled through ECHSA and the ECHSA Treasurer) by CTS Centres, other healthcare establishments, industry or media is prohibited.**
   
   5. **Funding from ECHSA budget to cover any remaining annual balance not covered by above sources.**
   
   6. By the end of each financial year, the ECDB Committee Chair presents to the ECHSA Board an annual detailed expense report and the proposed budget for next year. The budget proposal is negotiated until adopted by the ECHSA Board. Twice a year, the ECDB Committee Chair reports on the realization of the budget to the ECHSA Board.
12. SANCTIONS FOR BREACH OF THE CHARTER

(i) The ECDB Committee Chair monitors the use of the ECDB and reports to the ECHSA Board to ensure compliance with the Charter.

(ii) In the event of non-compliance with the Charter, the European Congenital Database Committee Chair or the ECHSA Board may request to cure the breach, setting the deadline for such a cure.

(iii) In the event of a serious breach of the Charter, the ECDB Committee Chair may request the ECHSA Board to suspend or terminate participation of a CTS Centre in the ECDB.

(iv) The party breaching the terms of the Charter shall be liable for damages in case the breach causes financial damage to ECDB or to ECHSA.

(v) The following shall in particular be considered a serious breach:
   • breach of the obligations to provide accurate and truthful information and data, as set out in Sections 7.1 and 7.2;
   • breach of the confidentiality obligations, as set out in Section 7.3;
   • breach of the publication principles, as set out in Section 6.

13. MISCELLANEOUS

(i) The Charter is subject to the laws of the country in which ECHSA has a legal seat (currently Finland).

(ii) Any disputes arising from, or in connection with, this Charter shall be settled by the court having jurisdiction over the seat of ECHSA (currently the district court of Espoo, Finland).

(iii) The ECDB and ECHSA shall not be liable for any damage, loss, or claim that may arise from an act, omission, or misconduct of any person who remains beyond control or supervision of ECHSA.

(iv) ECHSA shall make reasonable efforts to ensure the accuracy of the ECDB or the ECDB Internet Page, but accuracy cannot be guaranteed and ECHSA makes no warranties or representations in this respect. The ECDB or the ECDB Internet Page's content is provided "as is" and without warranties of any kind, either express or implied. To the fullest extent permissible pursuant to Finnish law, ECHSA disclaim all warranties, express or implied, and waives any liability for the accuracy of the data and reports produced on the basis of this data.

(v) ECHSA has in place reasonable technical and organizational security measures to ensure the proper operation of the ECDB or the ECDB Internet Page, and to ensure an uninterrupted use of this Web Site. However, absolute security cannot be guaranteed on the Internet, and the ECDB or the ECDB Internet Page might be vulnerable to attack by programs that contain viruses, "Trojan horses", or worms, or other attacks designed to interrupt, destroy or limit their functionality, the integrity of the information contained therein, or the security of transmission, or to deny access. ECHSA is not responsible for interruptions or improper operation of the ECHSA Congenital Database or the ECDB Internet Page caused by circumstances beyond their control.

Version approved on DATE (20 July 2015)