

Information for Researchers sept.2011 doc.

Researchers interested in using data from the CONCOR Registry or DNA material from the DNA bank may submit an application for a specific research goal. In order to apply, the following conditions and regulations should be observed. These regulations have been laid down in the Code of Conduct for the CONCOR-registry and DNA bank, version 5.1, in accordance with the Personal Data Protection Act, and as approved by the Dutch Data Protection Authority.

Conditions for the use of data and DNA material

1. Data from the CONCOR Registry and DNA material from the CONCOR DNA bank may exclusively be used for scientific research, or—when this may occur—to supplement larger European collections, and only when such activities are not contrary to the goals and purposes of the CONCOR Registry and DNA bank, and are not harmful to the interests of the patients and—secondary—of the participating centers.
2. Results that have been obtained from the CONCOR data or CONCOR DNA material can only be published under final responsibility of the Interuniversity Cardiology Institute of the Netherlands (ICIN)
3. The researcher must submit the research protocol by e-mail. The research protocol should clearly and unambiguously state exactly which data are required. In addition, it must contain a clear description of the design and methods of the study as well as a detailed time schedule. The application will be handled by the CONCOR project group which will forward it to the members of the CONCOR Scientific Advisory Committee and to the Interuniversity Cardiology Institute of the Netherlands. If the researcher wishes to use DNA material, the standard application form for requests to use DNA material (downloadable from the CONCOR web site) needs to be filled in completely and submitted by e-mail. The researcher also needs to fill in and submit the special declaration form (available on the website).
4. The maximum number of DNA requested samples may not exceed 500. Furthermore, the maximum amount of DNA per patient is 1 microgram. A larger number and/or a amount of DNA can only be obtained after submitting a document in which the background for this special request is clearly specified.
5. The application is reviewed for compatibility with the Code of Conduct by the CONCOR Scientific Advisory Committee and the Interuniversity Cardiology Institute of the Netherlands. It should be emphasized that this compatibility test does not concern content. The CONCOR Scientific Advisory Committee protects the interests of the patients and the participating centers. Within a period of two weeks after receiving the application, the Committee will notify by writing both the Interuniversity Cardiology Institute of the Netherlands and the applicant regarding its decision on the compatibility of the request with these interests. In case the application contains points that are unclear, or if unreasonable amounts of DNA material are required, the applicant will be given the opportunity to further clarify the application; when necessary, Dr. M.M.A.M. Mannens, manager of the DNA bank, and/or Prof. Dr. E.C.M. Mariman will be consulted first. After receiving the Committee's advice, the Interuniversity Cardiology Institute of the Netherlands will take the final decision on providing the requested data or DNA samples. The decision is binding for the researcher, the CONCOR Project Group and the centres.

6. Submitted research protocols must include a list of codes selected from the European Paediatric Cardiac Code (EPCC) list. The researcher must explicitly list the codes of the cardiac conditions for which data and/or DNA are being requested. Without such a list, data from the CONCOR registry or DNA material from the DNA bank cannot be provided. The EPCC coding list may be downloaded (in Microsoft Access format) from the CONCOR website (www.concor.net), or may be obtained from the CONCOR Project Group upon request (info@concor.net).

7. Researchers who use data from the CONCOR registry or DNA from the DNA bank are expected to submit yearly written reports on the progress and results of the research project for which data and/or DNA are being used.

8. Publications should contain a clear statement acknowledging use of data from the CONCOR registry or DNA material from the DNA bank under the auspices of the Interuniversity Cardiology Institute of the Netherlands/Royal Dutch Academy of Arts and Sciences.

9. Researchers are obliged, once research and possible publications have been completed, to provide the CONCOR data base with a report of the results of the DNA analyses. Positive results should be reported, but it is of special importance to also report negative results. This will prevent repetition of unfruitful research avenues and hence of unnecessary use of DNA material.

10. If the DNA test results are found that are of vital clinical importance considered for the patient and/or their relatives, researchers are obliged CONCOR to see if that patient has

Given permission to the researchers to be informed of such results. If this occurs, the results by the treating cardiologist at the patient must be informed. It must see to be taken that this is done in a careful manner and that adequate counselling about the observed finding.