

Policy and procedures for accessing information contained in the National Hepatitis C Database

for infection acquired through blood and blood products

Purpose

This document outlines the policy and procedures for accessing information contained in the National Hepatitis C Database (the database). The database is managed locally by hepatology units and nationally by the Health Protection Surveillance Centre (HPSC), and is monitored nationally by the National Hepatitis C Database Steering Committee, on behalf of the Consultative Council on Hepatitis C. The HPSC is the data controller for the purposes of the Data Protection Act 1988 (as amended in 2003).

The purpose of the document is to establish a process to ensure fair and reasonable access to the data, while preserving the integrity and confidentiality of the information contained in the database.

Information contained in the database may only be used and/or revealed for the purpose for which it was obtained. It is intended that this protocol will increase the credibility and reliability of the database by minimising subject concern over subsequent uses or misuses of the information. Preservation of data security and confidentiality is an obligation under the Data Protection Act 1988 and the Data Protection (Amendment) Act 2003. Data contained in the database are anonymised to the extent that only initials and dates of birth, but no names or addresses, are recorded.

This protocol is intended to provide guidance to those involved in the management of the database information (HPSC, hepatology units, Steering Committee) by clarifying the purposes for which the database information may be used or revealed and who can have access to the data. It will be reviewed annually by the National Hepatitis C Database Steering Committee to ensure its relevance and to review and recommend any amendments to it.

Access to the database within HPSC

Access to the database is restricted internally in HPSC to those members of staff working on the project. The data collection forms are stored in a locked storage area that is accessible only to members of staff working on the project.

A password is required to access the database. Network controls are in place to increase the security of passwords. Sensitive information being sent by email is encrypted first.

Access to the database by hepatology units

The directors/nominees of the hepatology units will have access to their own data contained in the database. They will also have access to an amalgamated dataset, once individual and unit identifiers are removed. HPSC will arrange for password set-up for the relevant unit staff member(s), as nominated by the unit director. HPSC will be notified by the director of the unit if database access is to be de-activated.

It is the responsibility of the director of the hepatology unit to ensure that data are treated with appropriate sensitivity and that existing local security policies and procedures for handling confidential information are applied.

Access to the database by others:

The appropriate use of the data will be overseen by the Steering Committee.

Requests for information from the database may take the following forms:

1. It is envisaged that most ad hoc queries related to the database will be answered by reference to data published in the annual reports and newsletters which will be produced by HPSC.
2. HPSC may be asked to do an analysis of an aspect of the data in more detail than that which is contained in the annual reports. HPSC will accommodate such requests subject to availability of staff-time and the agreement of the Steering Committee. However, where such requests involve a minor degree of additional data analysis, HPSC may provide this information without reference to the Steering Committee.
3. Researchers may wish to have access to the dataset in part or in whole (minus individual and unit identifiers), to carry out their own analysis. In general, use of the information in the database for legitimate research is to be welcomed and will be encouraged by open calls for research through the website. The procedure to be followed is outlined below.

Procedure of application for access to data

Any individual requiring information from the database is required to make a written submission to the Steering Committee outlining the information required, the reason the information is required and the manner in which the information will be used.

The committee will discuss the request at the earliest possible opportunity and will seek the advice of the Scientific and Technical Group. This Group must be satisfied that the

proposed use of the database is valid and that there is no concern about data security or misuse of the data.

The committee will make decisions regarding authorisation of requests on the basis of a consensus. If one member feels he/she cannot agree to the request, the chairperson will contact the applicant to try and resolve the issue by, for instance, requesting further information or reassurance regarding the methodology of the study or the proposed use of data.

When the committee authorises a request, the chairperson will state in writing the precise information to be made available and to whom it is being made available, and will give a copy of this statement to the database coordinator in HPSC.

The following criteria will guide the committee in assessing a request for information:

- Is ethical approval required? If yes, has it been received?
- Is the data requested appropriate to the stated purpose of the request?
- Are there any concerns regarding confidentiality or security of data?
- Do any special conditions apply?
- Within what timeframe can the information be made available by the HPSC?

Conditions of agreement

The following conditions will apply to the agreement between the applicant and the Database Steering Committee:

- 1) One copy of the data may be held centrally on the applicant's computer systems. Apart from the purpose of back-up, no other copies of the data shall be made by the applicant.
- 2) The data may be used for data analysis and presentation by the applicant for the purpose described in the application. Use of the data and/or any results obtained from use of the data for any other purposes is prohibited.
- 3) The applicant undertakes that they, or another designated employee, shall be responsible for compliance with the terms and conditions of this agreement and, in particular, for controlling access to the data.
- 4) Security arrangements on the applicant's computer facilities will be established to ensure that access to the data is limited to those persons who are permitted under this agreement to access the data.
- 5) The applicant undertakes to make all persons who are granted access to the data aware of the terms under which such access is granted.

- 6) The persons permitted to access the data under this agreement may not match or attempt to match or claim to have matched the data, or any results obtained from use of the data, with any other data at the level of individuals.
- 7) Access to the data by any other person or body apart from those authorised under the agreement is prohibited.
- 8) The applicant shall ensure that any report or published analysis based on the data shall not directly or indirectly disclose information relating to any identifiable individual.
- 9) No warranty is given by the HPSC that the data or accompanying documentation is error free.
- 10) If the applicant becomes aware of any breaches of the conditions laid down in this agreement, he/she shall notify the HPSC promptly.

Publications

Authorship of scientific papers based on the database should comply with uniform requirements for manuscripts submitted to medical journals.

All publications must acknowledge the National Hepatitis C Database and the participating hepatology units.

The committee is to be provided with advance copies of any publications that report the results of the research that uses database information at least four weeks prior to the publication date.