

Terms of Reference of Information Governance Committee of North West e-Health

1. Purpose of Governance Committee

- 1.1. The National Research Ethics Service (NRES) have granted North West e-Health (NWeH) permission to have a ‘research databank’ and to be responsible for studies performed upon the data within that data repository. As such NWeH has developed a Information Governance Committee (henceforth called ‘the Committee’) to consider applications to use these data for research and other purposes, to ensure that the proposed uses are within the limits of the generic ethical opinion that has been provided by NRES to NWeH.
- 1.2. The favourable ethical opinion from NRES allows the data to be used “for several research purposes, including
 - Healthcare delivery. Anonymised data will be used to assess the efficiency and effectiveness of different models of healthcare deployed throughout the different participating Trusts (eLabs).
 - Epidemiological research. Anonymised data will be used for a variety of population based epidemiological studies, for example, mapping the trends in obesity in children over the last 15 years.
 - Pharmaco–vigilance: As the data set will include all drug prescribing it would be possible to have real–time monitoring of drug performance and potential adverse effects such as abnormal liver function tests developing after the initiation of a new drug.
 - Genetic research: Several genetic repositories have already been established (ethical approval and patient consent has, therefore, already been obtained). If required and if permitted, we will be able to provide and link data from electronic patient records to be analysed in conjunction with the genetic data.”
- 1.3. The Standard Operating Procedures of the Committee are outlined in the document ‘Standard Operating Procedures of Governance Committee of North West e-Health’.

2. Aims

- 2.1. The Committee aims:
 - To facilitate ethical research, service evaluation and audit using the data available in the NWeH databank
 - To safeguard the rights, safety, and well-being of all study subjects, with specific regard to maintaining the integrity and confidentiality of their data.

- To make recommendations to the Management Board of NWeH as to whether data should be supplied to Principal Investigators who submit applications to the Committee
- To ensure that the research, service evaluation and audit that is proposed to be conducted on the data in the research database is in accordance with the favourable ethical opinion given by NRES, listed in 1.2 above.
- To make recommendations to the Management Board of NWeH as to whether data should be supplied to Principal Investigators who have submitted separate applications to an NHS ethics committee
- To make recommendations to the Management Board of NWeH as to whether data should be supplied for uses outside those specifically listed in 1.2 above.

3. Membership of Committee

- 3.1. The Committee will have 7 members who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed study.
- 3.2. The Committee will include:
 - At least one member who is independent of the NHS communities providing the data and is not a member of staff of the University of Manchester.
 - At least one lay member
- 3.3. A list of Committee members, their affiliations (where appropriate) and their qualifications will be maintained.
- 3.4. Three members, one of which is the chair or vice chair, will be the minimum number present for the committee to be considered to be quorate.
- 3.5. Members are expected to attend a minimum of one relevant training session per year. Training will be provided by NWeH and embedded in the meetings.

4. Potential Conflicts of Interest

- 4.1. Committee members who believe that they may have a potential conflict of interest about a particular application should outline this to the Committee at the beginning of the meeting.
- 4.2. The Committee will decide whether any action needs to be taken.
- 4.3. A register of potential conflicts of interests will be maintained and updated before every meeting.

5. Confidentiality

5.1. All Committee members will abide by confidentiality rules and regulations as set by NWeH Management Board.

6. Meeting Arrangements and Frequency

6.1. The Committee will normally meet on a monthly basis. This may be varied if the workload of the Committee makes it necessary.

6.2. The Committee should:

- Perform its functions according to written Standard Operating Procedures.
- Make its decisions at announced meetings at which at least a quorum, as stipulated in its Standard Operating Procedures, is present.
- Maintain written records of its activities and minutes of its meetings.
- Comply with the International Conference on Harmonisation Good Clinical Practice guidelines
- Give Principal Investigators the opportunity to attend the meetings at which their applications are discussed.

6.3. The Committee may invite non-members with expertise in special areas to assist them in their decision.

6.4. Members may recommend a favorable decision, and approval of data release, via email, if unable to attend the meeting.

6.5. If a member has any concerns about the application and wishes to recommend a provisional decision or a refusal, they should attend the meeting, where possible, to discuss those concerns with the Committee. Alternatively, they may send written comments outlining their concerns, but they are not included in the voting numbers.

7. Records

7.1. The Committee should retain all relevant records (e.g. written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence) in paper form (if relevant) for a period of 3 years and in electronic form (if relevant) for a period of 25 years after the end of the study and make them available upon request from the appropriate authorities.

7.2. The Committee may be asked by investigators, sponsors or regulatory authorities to provide its written procedures and membership lists.

7.3. The Committee Administrator will produce and keep a database listing Committee decisions.

8. Reporting and Accountability

8.1. The Committee shall be accountable to the Management Board of North West e-Health and to the Chief Executive Officer, Dr Burrinder Grewal.

9. Review arrangements

9.1. The Terms of Reference will be reviewed by the Committee every two years, to ensure that they continue to meet the ongoing requirements of the Committee.

Dr Mary Tully
Chair, NW e-Health Governance Committee
13 October 2009