

Standard Operating Procedures of Information Governance Committee of North West e-Health

1. Purpose of Information 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 (hence forth 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 Terms of Reference of the Committee are outlined in the document 'Terms of Reference of Governance Committee of North West e-Health'.

1.3. 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."

2. New applications for review by Governance Committee

2.1. New applications for release of data must be submitted by the Principal Investigator (PI) on the 'Application for Consideration by Governance Committee for North West e-Health' form. This form should be accompanied by:

- A protocol, giving details of the research to be conducted
- A curriculum vitae of the PI, giving details of their qualifications and research experience relevant to the study being considered by the Committee

2.2. Applications for a repeat of a previous data releases (see 6.3) should be submitted on the 'Application for Consideration of Repeat Data Release from North West e-Health' form. This form should be accompanied by:

- A protocol, giving details of the research to be conducted that requires a repeat data release
- A copy of the previous approval letter
- A curriculum vitae of the PI, giving details of their qualifications and research experience relevant to the study being considered by the Committee

2.3. The PI must be an employee of an institution in the NWeH consortium or an employee of a qualifying affiliate institution.

2.4. The PI must be bound either by an NHS contract of employment or hold an honorary NHS contract or an NHS letter of access.

2.5. The PI should not be an undergraduate or Masters level student. Where the study is to be conducted by such a student, the PI should be their supervisor.

2.6. If they wish, the PI may contact the committee administrator for advice prior to submission of the application. The administrator may discuss the matter with the Committee chair or vice chair prior to responding, as appropriate.

2.7. An electronic copy of the application form, protocol, previous approval letter (if applicable) and curriculum vitae should be sent via email to the Committee administrator.

2.8. Upon receipt of the application, the administrator will give the PI the next available slot on the agenda of the Committee and confirm those details with the PI via email. If the PI wishes, they may request that their application is reviewed at a later Committee meeting.

2.9. In general, significant revisions of submitted applications, prior to review by the Committee, are not permitted. If significant revisions are requested, the PI will be encouraged to withdraw the application and resubmit. If necessary, and at the discretion of the Chair, the PI may make minor revisions to the application, which will be circulated to the Committee prior to review.

3. Research Studies Previously Reviewed by an NHS Ethics Committee

3.1. If a research study requiring data from NWeH has received a favourable opinion from an NHS ethics committee, it does not require a full review by the Committee. Authority has been delegated to the Chair to review such applications and to make recommendations as to whether to recommend the release of NWeH data to the PI.

3.2. The PI should complete and submit an ‘Application for Consideration by Governance Committee for North West e-Health’ form. This form should be accompanied by:

- The letter of favourable opinion from the NHS ethics committee
- The protocol that was submitted to the NHS ethics committee
- The curriculum vitae of the PI, as submitted to the NHS ethics committee

3.3. The Chair will inform the Management Board of the decision as to the release of NWeH data, as described in Section 5.

4. Meetings of Governance Committee

4.1. Approval for release of NWeH data, and hence conduct of the study, can only be given after review of an application at a Committee meeting. The Committee normally meets monthly. Additional meetings can be arranged, depending on workload requirements.

4.2. Closing dates for applications for each meeting will be available on the NWeH website.

4.3. The administrator will distribute copies of the material for the agenda (including papers to discuss, application forms, protocols and curricula vitae) to the members of the Committee within ten working days of the date of the meeting.

4.4. The agenda can include, but is not limited to, applications for consideration, topics relevant to the Terms of Reference of the Committee, continuing professional development and topics relevant to the governance of research using NHS data generally.

4.5. Under exception circumstances, papers to discuss may be circulated closer to the date of the meeting or tabled at the meeting. Applications for consideration should not be tabled.

4.6. A quorum must be present before discussion of new applications can commence. A record of attendance should be kept. A quorum is 3 members, including either the Chair or vice-chair.

4.7. Attendance of observers is at the Committee's discretion and subject to a confidentiality agreement. The PI(s) will be informed of the presence of an observer.

4.8. Members who are unable to attend may send written comments prior to the meeting, which should be circulated to the Committee or, in exception circumstances, tabled at the meeting.

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

4.10. If a member has any concerns about the application and wishes to recommend a provisional decision or a refusal, they should attend the meeting to discuss those concerns with the Committee.

4.11. Members should declare any interests they have in relation to a study, either at or before the meeting. The Committee should collectively decide which of the following options to use, depending on the closeness of the member's interest in the application.

- The member should leave the room and take no part in the discussions or decision making process.
- The member may remain in the room to provide relevant information requested by the other members, but take no part in the decision making process.
- The member may remain in the room and take full part in the review process.

4.12. The PI will be invited to the meeting to respond directly to any comments or questions raised by the Committee members. They may be accompanied by one or two

colleagues if they wish. Attendance of undergraduate or Masters level students working on the project is encouraged.

4.13. Attendance by the PI is not compulsory, however, and if an investigator is unable to attend this should not prejudice the decision of the committee.

4.14. If speakerphone facilities are available, the PI may be offered the alternative of being available by phone to answer queries of Committee members. It should be possible for all members present to both hear and speak to the PI.

4.15. If attending, the PI will be asked to leave prior to the Committee discussions and decision making about their application.

4.16. The Committee may seek the advice of a specialist referee, either to provide written advice before or after the meeting, or to attend the meeting.

4.17. The meeting is chaired either by the Chair, or if not available the vice-chair. All members must be given appropriate opportunity to express their opinion.

4.18. The Committee should reach one of the following decisions

- a favourable decision to recommend the supply of data, which may or may not be accompanied by conditions
- a provisional decision to recommend the supply of data, pending the supply of further information or agreement to specific conditions before a favourable decision can be given
- a refusal to recommend the supply of data

4.19. The Chair will take responsibility of ensuring that the conditions required under a provisional decision have been met. A letter recommending a favourable decision will then be sent.

4.20. Where possible, the Committee should reach a unanimous decision by discussion and consensus. Such a unanimous decision may include recommendations for a favourable decision made via email.

4.21. Where it is not possible to reach a unanimous decision, there should be a formal vote via a show of hands. The decision will then be made by a simple majority of committee members who are in attendance.

4.22. The minutes of the meeting should contain a record of

- the members present for the review
- the attendance of researchers or observers
- any declaration of conflict of interest
- submission of written comments by members
- a summary of the main issues considered
- the decision of the Committee on the application
- in the case of a favourable decision to recommend the supply of data, any conditions applied

- in the case of a provision decision to recommend the supply of data, any further information or conditions required to be fulfilled before a favourable decision can be given
- in the case of a refusal to recommend the supply of data, the reasons for that decision

4.23. The minutes should be ratified by the Committee at the next meeting.

4.24. The Chair will inform the Committee of any applications for the release of data for research studies that have previously received a favourable opinion from an NHS ethics committee, and the decisions that were made about these applications.

5. Communication of decision to Principal Investigator

5.1. Letters of recommendation as to whether data should be released to the PI will be sent to the Management Board of NWeH.

5.2. The final decision as to whether data will be released will be made by the Management Board. A copy of the decision letter will be forwarded to the Committee.

5.3. If the decision of the Management Board is to refuse the supply of data, where the Committee has given a favourable opinion to recommend the supply of data, the reasons for making this decision shall be communicated to the Committee, for discussion at the next meeting.

5.4. The Management Board shall not recommend the supply of data, where the Committee has given their opinion as a refusal to recommend the supply of data.

5.5. A letter will be sent from the Management Board to the PI giving the decision as to the release of the data. The letter will contain the following information:

- a summary of the main issues considered at the meeting
- the decision of the Committee on the application
- in the case of a favourable decision to recommend the supply of data, any conditions applied
- in the case of a provision decision to recommend the supply of data, any further information or conditions required to be fulfilled before a favourable decision can be given
- in the case of a refusal to recommend the supply of data, the reasons for that decision

5.6. The timescale for the decision letter to be sent to the Management Board will be 6 working days. The Committee Administrator will send out the approved letter.

5.7. Copies of favourable decision letters, application forms and CVs will be sent to either the relevant R&D Manager or the Audit Department (if necessary) of the Trust from which the data were obtained. The purpose of this is to keep the R&D or Audit departments informed of research or audit being conducted on the Trust's data.

5.8. Where there has been a refusal to recommend the supply of data, the PI may discuss this decision with the chair of the Governance Committee. Advice will be given, where possible, to enable the PI design a revised application that addresses the highlighted problems.

6. Amendments to studies given a favourable decision

6.1. Minor amendments to studies given a favourable decision (such as correction of minor errors in data requested) may be permitted, prior to data release, under exceptional circumstances.

6.2. If the PI wants additional or different data to be supplied (for example, to answer additional research questions), this should be submitted to the Committee as a new application. Such changes are not acceptable as amendments permitted under Section 6.1.

6.3. If the PI wants *exactly* the same dataset to be supplied on a further occasion, for example, to compare summarised findings with previous years or because data from additional sites have become available, this is permitted (see Section 2.2 for appropriate procedures).

7. Consideration of permissible types of research

7.1. 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).
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- 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.”

7.2. The word "including" above allows the data to be used for research purposes other than those specifically outlined.

7.3. If an application is submitted to the Committee for the data to be used for research purposes other than that outlined above, the general principle as to whether or not the NWeH data should be used for such research purposes will be discussed *prior* to the consideration of that specific application.

7.4. If it is known to a Committee member or member of the Management Board that researchers may be interested in using the data for purposes other than that outlined above, the general principle as to whether or not the data should be used for that purpose can be discussed in the absence of a specific application.

8. Responsibilities of the Committee Chair

8.1. The responsibilities of the Committee Chair are as follows:

- ensuring that all research, service evaluation and audit taking place using data from the databank is in accordance with the Terms of Reference and the Standard Operating Procedures of the Committee
- taking responsibility for the committee function, ensuring that all issues are explored and clear decisions made and recorded.
- ensuring that meetings are quorate
- asking for conflicts of interest
- checking and approve minutes (drafted by Committee Administrator)
- checking and approve letters (drafted by Committee Administrator)
- agreeing issues related to provisional decisions under delegated authority of the committee
- recruiting of new members on retirement of existing members

9. Responsibilities of the Committee Administrator

9.1. The responsibilities of the Committee Administrator are as follows:

- publishing the schedule of Committee meetings
- preparing the agenda
- distributing the agenda and papers
- inviting PIs to attend and making the necessary arrangements
- preparing the venue, including ordering of refreshments
- recording apologies for absence prior to the meeting
- raising with the Committee Chair any concerns that the meeting might not be quorate
- recording attendance of members and observers for each application reviewed
- advising the committee members present on compliance with the Standard Operating Procedures
- preparing minutes of the meeting and sending them to the Committee Chair for checking
- preparing letters to be sent to the PI
- advising the Committee Chair of responses to letters regarding provisional decisions
- write to PIs after 1 year from the date of approval, to obtain a report on the study findings and copies of disseminated work, where applicable
- assisting in recruitment of new members

Dr Mary Tully
Chair, NW e-Health Governance Committee
17 December 2009