

Guidance for completion of Application for consideration by Governance Committee for North West e-Health

About the application:

The application requires three documents:

- The application form
- The research protocol
- The CV of the Principal Investigator

If your access to data has been approved, the application form, protocol and CV of the Principal Investigator will be forward to the relevant NHS R&D department(s) to inform them about research to be conducted on their data. If the protocol and CV are not submitted with the application form, you will be contacted to provide them. This may mean that your application misses the deadline for the meeting.

Section 1

The title of the research study on the form should be the same as the title of the protocol

Section 2-5

The contact details provided on the form will be those used to contact the investigator before and after the committee meeting. PhD students can be named as principal investigator where the entire research study submitted is for the fulfilment of their PhD. If the PhD study is only part of the research study that is submitted, then the overall principal investigator should be the applicant.

Section 6.

All co-investigators on the research study should be listed here, including those who are members of staff of North West e-Health itself. If a PhD student is named as principal investigator, their supervisor should be a co-investigator.

Section 7

All students working on the research study should be listed here, except for a PhD student already named as principal investigator, where applicable. If the names of the students are not yet known, then list the degree and number of students that will be working on the research study, e.g. 4 undergraduate students in Computer Science, 2 MSc students in Health informatics, 1 PhD student in Public Health. If the research study submitted for is solely to be undertaken by a student or

students, in fulfilment of educational qualifications below doctoral level, an academic supervisor should take on the role of principal investigator.

Section 8

The North West e-Health governance committee is currently required to inform the relevant NHD R&D departments as to whether the principal investigators to whom we have released data have undergone ICH Good Clinical Practice Training. This training is currently only *required* by the NHS R&D for investigators undertaking clinical research. However, such training is currently recommended for investigators doing any research in the NHS. Currently, it is not expected that principal investigators will be required to undergo such training in order to obtain data from North West e-Health.

Section 9

If applicable please list the names of any other researchers or administrators who will have access to patient level data along with assurance that they are compliant with confidentiality protocols

Section 10-11

This includes, but is not limited to, relationships with any pharmaceutical companies that are providing sponsorship for this research study either directly or in the form of studentships etc for PhD students working on the study.

Section 12-13

This includes, but is not limited to, members of staff of North West e-Health acting as co-applicants for this research study or any other study currently being undertaken by the principal investigator. If members of staff of North West e-Health are listed as co-applicants in section 6, simply state this.

Section 14-15

This section applies to any applications for research studies that have previously or currently been submitted for consideration by the governance committee of North West e-Health. If the application is part of a larger study submitted elsewhere for funding, detail should be provided under section 16 and not here.

Section 16-17

This section only applies to applications for research studies that are part of a larger piece of work. Briefly describe the larger study and the place of *this* research study within it.

Section 18

Provide a summary of the research that briefly describes, in language comprehensible to a lay person, the following:

- Background to the research study
- Why it is important
- Broadly, the area (disease, therapy or service) that is being studied
- The questions the study will answer
- The potential benefits from the study (*not* the larger study described in section 16, if applicable)

Where technical terms are used they should be explained. All acronyms should be described in full.

Section 19-20

Describe succinctly the principal (and secondary, if applicable) research questions or objectives that will be addressed using the data described in section 28. Do not include here the research question or objective of the larger study described in section 15-16, unless they are addressed using the data described in section 28. That information should be provided in section 16, if applicable and pertinent.

Section 21-22

The primary and secondary outcome measures should be given as statements expressing how, in numerical terms, the objectives of the study will be met from the data requested.

Section 23

Give details of the analysis methods that will be used to achieve the primary and secondary outcomes described above including, for example, methods of summarising the data with numbers and graphs, and the main statistical tests to be used where comparisons are to be made. It is not necessary to give every detail in advance but sufficient detail should be given so that the committee knows how the research questions or objectives will be addressed.

Section 24

The results of research should be reported, whether through notification of publication in peer reviewed journals or notification of other means of dissemination. Negative as well as positive results should be published, or at least made publicly available. North West e-Health may ask for copies of such publications for its records.

Section 25

If approved, the data will become the responsibility of the principle investigator. This section will require the principle investigator to specify how long the data will likely be in their custody and the method of disposal on completion of the research. The specified dates should correspond with the outcomes in section 23. Data can be returned to North West e-Health for secure disposal on request.

Section 26

Refer to the selection of patients, whose data will form the rows of the spread sheet.

Section 27 - 23

Refers to the variables that will form the columns of the spread sheet, i.e. data that you will want about each of the patients. You would be expected to have some inclusion or exclusion criteria for the dataset you require otherwise, you are potentially asking for data about every person in the database. The latter would have to be explicitly justified in section 17. Advice should be sought from the staff at North West e-Health prior to completing this section, to ensure that it is possible to obtain the data extract that you will require.

The data items that will be used to decide which patients' data are included in or excluded from the data extracts should be provided in sufficient detail as to allow the committee to judge whether this data extract can achieve the outcomes described earlier. Examples of such data items include: specific Read codes for diagnoses or treatments (for example, patients diagnosed with diabetes mellitus or prescribed oral prednisolone) or time periods (for example, patients treated January-June 2008).

Data are potentially available from a number of primary care and acute trusts. Advice should be sought from the staff at North West e-Health about which trusts are providing data at the time of your application. Data can be requested from all available trusts or from specific named trusts.

The data items listed here are those that will be provided about each patient included in the data extract. Be as detailed as possible (for example, give specific Read codes) and give a rationale for how each data item will be used to address the research questions. For epidemiological research, you might find it helpful to separate that data that refer to exposure, outcomes (primary and secondary) and co-variates. If large amounts of data items are requested for potentially small numbers of patients, the Committee will expect assurances from the researchers that the data provided will not allow the inadvertent identification of individual patients. Such assurances can be provided in section 17.