

Application for consideration by Governance Committee for North West e-Health

Before completing this application form, please read the Guidance document.

This form is to be accompanied by a research protocol and short CV (2 pages) of principal investigator. Failure to submit these may result in delays to the consideration of your application.

1	Title of research study:
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About the researcher(s):

2	Title & Name of Principal Investigator	
3	Address for correspondence	
4	E Mail	
5	Telephone	
6	Names & Work Addresses of co-investigators in study:	
7	Names & Work Addresses of students (undergraduate, MSc or PhD) in study:	
8	Has the Principal Investigator completed ICH Good Clinical Practice Training in the past 2 years?	Yes/No:
9	If applicable please list the names of any other researchers who will have access to patient level data along with assurance that they are compliant with confidentiality protocols	

	Names -	
10	Does the Principal Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?	Yes/No:
11	If yes, please give details:	
12	Does the Principal Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) with North West e-Health or its staff that may give rise to a possible conflict of interest?	Yes/No:
13	If yes, please give details:	

About the research study:

14	Is the research study described in this application linked to a previously or currently submitted application to NWeH?	Yes/No:
15	If yes, please give details:	
16	Is the research study described in this application part of a larger research study?	Yes/No:
17	If yes, please give details:	

18	Brief rationale and description of the research study, in language comprehensible to a lay person. Citations are not required.
19	What is the principal research question/objective to be addressed in this research study, with the data requested from NWeH?
12	What are the secondary research questions/objectives to be addressed with the data requested (if applicable)?
21	What are the primary outcome measures for the study using the data requested?
22	What are the secondary outcome measures for the study using the data requested (if applicable)?
23	Description of the statistical or other analyses to be performed using the data requested:
24	How do you intend to report and disseminate the results of the study using the data requested?

25	<p>If approved, how long do you intend to keep the data?</p> <p>Please also specify how the data will be disposed of once the research study is complete (please note that a backup copy of all data requested via North West e-Health is stored permanently in a locked fireproof safe).</p>
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About the data required:**STUDY POPULATION****Selection of patients whose data are requested:**

26	List the data items that will be used to decide which patients are included in the data extracts. Put each item on a separate line, and add extra lines as necessary:	
	Data Item	Read code
		Rationale for using this data item
27	List the data items that will be used to decide which patients are excluded from the data extracts, if applicable. Put each item on a separate line, and add extra lines as necessary:	
	Data Item	Read code
		Rationale for using this data item
28	Please specify which trusts the data is required from (if not known, please list the population)	
29	If no, please give details of the trusts from which data are required:	

Data requested about above patients:

30	Please list all the data items required using North West e-Health. Put each item on a separate line, and add extra lines as necessary:	
	Data Item	Read code
		Rationale for requesting this data item