RNHRD Site-Specific Information Form for research projects **not subject to NHS Ethics approval**

Please complete this form together with an RNHRD Data Protection form and submit with all project documentation including:- Research protocol (if not reproduced at Q17); Participant information sheet (s); consent form(s); questionnaires; interview topic guide(s); other relevant documentation. For projects which may be considered borderline, please include confirmation from NRES that ethics approval is not required if advice has been sought

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Short title and version number:

Name of NHS Research Ethics Committee to which application for fast-track ethical review is being made:

Project reference number from above REC:

1. Title of the research:

Full title:

Key words:

2. Name of Chief Investigator:

Title: Forename & Initials: Surname:

3. Name of organisation acting as lead sponsor for the study:

4. Research reference numbers, if known:

Applicant's/organisation's own reference number, e.g. R&D:

Sponsor's/protocol number:

Funder's reference number:

6. Give the name of the NHS site within or through which the research will take place under the responsibility of the PI or local collaborator. *Please give the name only. Further details of locations should be given in question 8. The name of the site is normally the name of the relevant NHS organisation.*

Is this a primary care site?

Yes No (Please delete as appropriate.)

If Yes, give the name of the primary care organisation responsible for the site below:

8. Specify all locations, departments, groups or units at which or through which research procedures will be conducted at this site and describe the activity that will take place.

List all locations/departments etc where research procedures will be conducted within the NHS organisation or academic partners, describing the involvement in a few words. Where access to specific facilities required these should also be listed for each location.

Name the main location/department first. Include details of any centres at other NHS organisations where potential participants may be seen or referred for inclusion in the research at this site. Give details of any research procedures to be carried out of site, for example in participants' homes.

12. Who is the Principal Investigator or Local Collaborator for this research at this site?

Title:
Forename & Initials:
Surname:

Work Address:

Post:
Qualifications:
Organisation:

Postcode:
Telephone:
Fax:
E-mail:

Will this person interact with research participants, their organs, tissue or data in a way that has a direct bearing on the quality of care?

Yes No (Please delete as appropriate.)

Does this person hold a current substantive or honorary contract with, or accepted by, the NHS organisation?

Yes No (Please delete as appropriate.)

Please provide a copy of the c.v. for the PI.

If an honorary contract is held, a copy of the contract should be submitted, unless previously provided to the R&D office.

14. Give details of all other members of the research team at this site, including academic supervisors and all people who will interact with research participants, their organs, tissue or data in a way that has a direct bearing on the quality of care.

a) Research Member

Title:
Forename & Initials:
Surname:

Work Address:

Post:
Qualifications:
Organisation:

Postcode:
Telephone:
Fax:
E-mail:

Will this person interact with research participants, their organs, tissue or data in a way that has a direct bearing on the quality of care?

Yes No (Please delete as appropriate.)

Does this person hold a current substantive or honorary contract with, or accepted by, the NHS organisation?

Yes No (Please delete as appropriate.)

Please provide a copy of the c.v. for the research member.

If an honorary contract is held, a copy of the contract should be submitted, unless previously provided to the R&D office.

B) Research Member

Title:
Forename & Initials:
Surname:

Post:
Qualifications:
Organisation:

Work Address:

Postcode:
Telephone:
Fax:
E-mail:

Will this person interact with research participants, their organs, tissue or data in a way that has a direct bearing on the quality of care?

Yes No (Please delete as appropriate.)

Does this person hold a current substantive or honorary contract with, or accepted by, the NHS organisation?

Yes No (Please delete as appropriate.)

Please provide a copy of the c.v. for the research member.
If an honorary contract is held, a copy of the contract should be submitted, unless previously provided to the R&D office.

c) Research Member

Title:
Forename & Initials:
Surname:

Post:
Qualifications:
Organisation:

Work Address:

Postcode:
Telephone:
Fax:
E-mail:

Will this person interact with research participants, their organs, tissue or data in a way that has a direct bearing on the quality of care?

Yes No (Please delete as appropriate.)

Does this person hold a current substantive or honorary contract with, or accepted by, the NHS organisation?

Yes No (Please delete as appropriate.)

Please provide a copy of the c.v. for the research member.
If an honorary contract is held, a copy of the contract should be submitted, unless previously provided to the R&D office.

15. Does the Principal Investigator or any other member of the site research team have any direct personal involvement (e.g. financial, share-holding, personal relationship etc) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?

Yes No (Please delete as appropriate.)

If Yes, please give further details:

16. What is the proposed local start and end date for the research at this site?

Start date (*dd/mm/yyyy*):
Duration (months):
End date (*dd/mm/yyyy*):

17. Summary of the research:

Give a full summary of the purpose, design and methodology of the planned research, including a brief explanation of the theoretical framework that informs it. It should be clear exactly what will happen to the research participant, how many times and in what order.

This section must be completed in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.

18. Give details of any intervention(s) or procedure(s) to be received by research participants over and above those which would normally be considered a part of routine clinical care or for staff, outside their role.

(These include questionnaires, focus group, individual interview etc)

Additional Intervention	Average number per participant		Average time taken (mins/hours/days)	Details of additional intervention or procedure, who will undertake it, and what training they have received.
	Routine Care	Research		

Only need 18 or 19 not both

19. Give details of any non-clinical intervention(s) or procedure(s).

(These include interviews, non-clinical observations, and the use of questionnaires..)

Additional Intervention	Average number per participant	Average time taken (mins/hours/days)	Details of additional intervention or procedure, who will undertake it, and what training they have received.

20. How many research participants/samples is it expected will be recruited/obtained from this site?

21. Give details of how potential participants will be identified locally and who will be making the first approach to them to take part in the study?

22. Who will be responsible for obtaining informed consent at this site? What expertise and training do these persons have in obtaining consent for research purposes?

23. What local arrangements will be made to seek consent from a legal representative on behalf of adults unable to consent for themselves?

24. What is the procedure and contact point for any complaints from potential or actual participants whether before, during or after the study?

25. Is there a contact point where potential participants can seek independent advice about participating in the study?

26. Please provide a copy on headed paper of the participant information sheet and consent form that will be used locally. *This must be the same generic version submitted to/approved by the main NHS sponsor organisation (if different) for the study while including relevant local information about the site, investigator and contact points for participants (see guidance notes).*

27. What arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? ***(e.g. translation, use of interpreters etc.)***

28. What arrangements, if any, will be made to inform the GP or other health care professionals responsible for the care of the participants?

29. Will any external funding be provided for the research at this site?

Yes No (Please delete as appropriate.)

If Yes, indicate the source and details of the funding:

30. Which organisation will receive and manage this funding?

31. Authorisations required prior to R&D approval

This section deals with authorisations by managers within the NHS organisation. It should be signed in accordance with the guidance provided by the NHS organisation. This may include authorisation by line managers, service managers, support department managers, pharmacy, data protection officers or finance managers, depending on the nature of the research. Managers completing this section should confirm in the text what the authorisation means, in accordance with the guidance provided by the NHS organisation. This section may also be used by university employers or research staff to provide authorisation to NHS organisations, in accordance with guidance from the university.

a) Type of authorisation: *(e.g. data protection manager, line manager, R&D manager etc)*

Signature: _____

Date:

Title:
Forename & Initials:
Surname:

Work Address:

Post:
Qualifications:
Organisation:

Postcode:
Telephone:
Fax:
E-mail:

b) Type of authorisation: *(e.g. data protection manager, line manager, R&D manager etc)*

Signature: _____

Date:

Title:
Forename & Initials:
Surname:

Work Address:

Post:
Qualifications:
Organisation:

Postcode:
Telephone:
Fax:
E-mail:

c) Type of authorisation: *(e.g. data protection manager, general manager, R&D manager etc)*

Signature: _____

Date:

Title:
Forename & Initials:
Surname:

Work Address:

Post:
Qualifications:
Organisation:

Postcode:
Telephone:
Fax:
E-mail:

Declarations

Declaration by Principal Investigator

1. The information in this form is accurate to the best of my knowledge and I take full responsibility for it.

2. I undertake to abide by the ethical principles underpinning the World Medical Association's Declaration of Helsinki and relevant good practice guidelines in the conduct of research.

3. If the research is approved, I undertake to adhere to the study protocol, the terms of the full application of which the main NHS Sponsor has given a favourable opinion and the terms of this application.

4. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to the conduct of research, including legislation on human tissue and personal data.

5. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.

6. I understand and agree that study files, records and data may be subject to inspection by the main NHS Sponsor/REC for audit purposes.

7. I understand that personal data about me as a researcher will be held by the relevant NHS R&D Department and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

8. I understand that the information contained in this application, any supporting documentation and all correspondence with NHS R&D Department or their operational managers relating to the application:

    - Will be held by the R&D system until at least 3 years after the end of the study.
    - May be disclosed to the operational managers or the appointing body for the NHS Trust in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by members of the Trust R&D committee for peer review
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - Will be subject to the provisions of the Bribery Act and may be disclosed in response to requests made under the Acts.

Signature of Chief Investigator: .....
Print Name: Date:

Signature of Principal Investigator: .....
Print Name: Date