



8. Source of the participants to be studied:

9. Details of payments to participants:

10. Investigators are asked to note that research proposals involving the following **must** be submitted to an NHS Research Ethics Committee for ethical review. Please indicate which of the categories below, if any, applies to your research, and provide details of your NHS REC application. The Ethics Committee will not consider research proposals which meet any of these criteria until NHS REC approval has been obtained.

- a. patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, the NHS. It includes NHS patients treated under contract with private sector institutions.
- b. individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above.
- c. access to data, organs or other bodily material of past and present NHS patients.
- d. fetal material and IVF involving NHS patients.
- e. the recently dead in NHS premises.
- f. the use of, or potential access to, NHS premises or facilities.
- g. NHS staff – recruited as research participants by virtue of their professional role.

11. Has a risk assessment been carried out in respect of this research, either for potential participants or the researchers? If yes, please attach a summary document of the issues considered. If no, please explain why it has not been done.

12. What are the potential adverse effects, risks or hazards for (a) research participants? (b) researchers?

13. What are the potential benefits for research participants?

14. Please provide details of arrangements for the collection, retention, use and disposal of research data:

15. Has a Criminal Records Bureau (CRB) check been carried out in relation to this research? (This will be required for research activity which will bring staff and/or students into contact with children or vulnerable adults). If yes, please attach copies of the relevant documentation.

**16. For Drugs Trials**

- i. Please state Phase:
- ii. If a new drug, does it have a Clinical Trials Exemption Certificate or Product Licence Number ?
- iii. If a new drug, give details of toxic/side effects so far reported:
- iv. In addition to the recorded toxic/side effects, state any potential risks to the subjects and the precautions taken to deal with the situation:

17. **Checklist of Accompanying Documents** (Please tick the appropriate boxes)

Please ensure that, where appropriate, the following documents are submitted along with your application:

- |      |  |                          |
|------|--|--------------------------|
| i    | A summary of the project, (approximately 500 words), including its principal aims and objectives ; this should provide a clear description of who is doing what, to whom, to how many, where, when and why in non-technical, lay terms | <input type="checkbox"/> |
| ii   | The detailed protocol for the project  | <input type="checkbox"/> |
| iii  | Evidence of agreement of other collaborators   | <input type="checkbox"/> |
| iv   | Copy of the Information Sheet for participants   | <input type="checkbox"/> |
| v    | Copy of the Consent Form   | <input type="checkbox"/> |
| vi   | Copy of questionnaire/Interview Schedule   | <input type="checkbox"/> |
| vii  | Copies of standard letters related to the project  | <input type="checkbox"/> |
| viii | Copy of risk assessment  | <input type="checkbox"/> |
| ix   | Protocol Submission Proforma: Insurance  | <input type="checkbox"/> |
| x    | Confirmation that CRB (Criminal Records Bureau) checks have been carried out – this will be required if there is contact with children and vulnerable adults for significant periods of time   | <input type="checkbox"/> |
| xi   | Evidence of insurance cover/indemnity, particularly for drugs trials (Please refer to the <b>Insurance Guidelines</b> )  | <input type="checkbox"/> |
| xii  | Copy of the Clinical Trials Exemption Certificate or Product Licence Number  | <input type="checkbox"/> |
| xiii | Information concerning any other Ethical Committee to which an application for approval is being made  | <input type="checkbox"/> |
| xiv  | Letter of notification of NHS approval   | <input type="checkbox"/> |

18. Names and signatures of all Investigators:

19. Date of Application: