

DEPARTMENT OF HEALTH AND SOCIAL SECURITY

LOCAL RESEARCH ETHICS COMMITTEE

APPLICATION FORM

Please complete this form and return to

Secretary,
Isle of Man Local Research Ethics Committee,
PO Box 281,
Douglas,
Isle of Man
British Isles

e-mail: colinbrown@iom.com

www.gov.im/dhss/health/centraladmin/ethics_committee.xml

It is the responsibility of the applicant to provide the Secretary with a total of 13 copies of the form and relevant research documentation for distribution to members of the committee. Where questions require a yes or no answer please state N/A if not applicable.

SECTION 1 - Details of applicants

1. Short title of project (including any version dates):

Full title

2. Principal researcher (who will be responsible for dealing with the committee)

Surname

Forename

Title

Present appointment of applicant

Qualifications

Address

Telephone

Fax

E-mail

3. Senior researcher at LEAD centre (if different from above)

Surname

Forename

Title

Present appointment

Qualifications

4. Who is funding the study?

Contact name

Organisation

Address

Telephone

Fax

E-mail

5. Drug Company Reference Number

6. Will researchers be paid for taking part in the study?

If so, will BMA guidelines be followed?

If not, why not?

7. Proposed start date and duration of the study

8. What other researchers are/do you intend to be involved in the project? (Details of researchers added subsequently must be notified to the Committee)

SECTION 2 - Details of project

This section must be completed fully. A copy of the protocol should be enclosed with the application form but it is not sufficient to complete questions by referring to the protocol.

9. Aims and objectives of project (no more than 250 words)

10. Scientific background of study (no more than 250 words)

11. Brief outline of project (no more than 250 words)

12. Study design (RCT, cohort, case control, epidemiological analysis)

13. Size of the study (including controls)

Will the study involve

a) Human Subjects?

- i) How many patients will be recruited?
- ii) How many controls will be recruited
- iii) What is the primary end point?
- iv) How was the size of the study determined?
- v) What is the statistical power of the study?

b) Patient records

- i) How many records will be examined?
- ii) How many control records will be examined?
- iii) What is the primary end point?
- iv) How was the size of the study determined?
- v) What is the statistical power of the study?

14. Scientific critique

Has the protocol been subject to scientific critique?

If so, please give the following information:

- If the critique formed part of the process of obtaining funding, please give the name and address of the funding organisation
- If the critique took place as part of an internal process, please give brief details
- If you are in possession of any referees' or other scientific critique reports relevant to your proposed research please forward copies with your application form.

SECTION 3 - Recruitment of subjects

15. How will the subjects in the study be:

- a) selected?
- b) recruited?
- c) what inclusion criteria will be used?
- d) what exclusion criteria will be used?

16. How will the control subjects group (if used) be:

- a) selected?
- b) recruited?
- c) what inclusion criteria will be used?
- d) what exclusion criteria will be used?

17. Will there be payment to research subjects of any sort?

If yes, how much per subject and for what?

SECTION 4 - Consent

18. Is written consent to be obtained?

If yes, please attach a copy of the consent form to be used

If no written consent is to be obtained, please justify

19. How long will the subject have to decide whether to take part in this study?

If less than 24 hours please justify

20. Please attach a copy of the written information sheet or letter to be given to the subject

If no information sheet is to be given, please justify

21. Have any special arrangements been made for subjects for whom English is not a first language?

If yes, give details

If no, please justify

22. Will any of the subjects or controls be from one of the following vulnerable groups?

Children under 18
People with learning difficulties

Unconscious or severely ill
Other vulnerable groups e.g mental illness, dementia

If yes, please specify and justify

23. What special arrangements have been made to deal with the issues of consent for the subjects above?

SECTION 5 - Details of interventions

24. Does the study involve the use of a new medicinal product or medical device, or the use of an existing product outside the terms of its product licence?

If yes, please complete Annex A of the application form

25. Will any ionising or radioactive substances or X-Rays be administered?

(NB) Please ensure information in Question 14 includes exclusion criteria with regard to ionising radiation if appropriate)

If yes, please complete Annex B of the application form

26. Please list those procedures in the study to which subjects will be exposed, indicating those which will be part of normal care and those that will be additional (e.g. taking more samples than would otherwise be necessary.) Please also indicate where treatment is withheld as a result of taking part in the project.

SECTION 6 - Risks and ethical problems

27. Are there any potential hazards?

If yes, please give details and state the likelihood and details of precautions taken to meet them, and arrangements to deal with adverse events.

28. Is this study likely to cause any discomfort or distress?

If yes, please give details and justify

29. What particular ethical problems or considerations do you consider to be important or difficult with the proposed study?

Please give details

30. Will information be given to the patient's General Practitioner?

Please note: permission should always be sought from research subjects before doing this.

If yes, please enclose an information sheet/letter for the GP

If no, please justify

31. If the study is on hospital patients, will the consent be sought of all consultants whose patients are involved in this research?

If no, please justify

SECTION 7 - Compensation and confidentiality

Product liability and consumer protection legislation make the supplier and producer (manufacturer) or any person changing the nature of a substance, e.g. by dilution, strictly liable for any harm resulting from a consumer's (subject or patient) use of a licensed product.

32. Have arrangements been made to provide indemnity and/or compensation in the event of a claim by, or on behalf of, a subject for non negligent harm?

If yes, please give details of compensation arrangements with this application

33. In cases of equipment or medical devices, have appropriate arrangements been made with the manufacturer to provide indemnity?

If yes, please give details and enclose a copy of the relevant correspondence with this application.

34. Will the study include the use of any of the following?

Audio/video recording

Observation of patients

If the answer to either of these questions is yes:

- a) How are confidentiality and anonymity to be ensured?
- b) What arrangements have been made to obtain consent for these procedures?

35. Will medical records be examined by research workers outside the employment of the NHS?

If yes, will relevant guidelines be followed?

36. What steps will be taken to safeguard confidentiality of personal records?

37. What steps will be taken to safeguard the information relating to specimens and the specimens themselves?

SECTION 8 - Additional Information

Please include here any further relevant information you would like to give which has not been covered in the preceding sections.

SECTION 9 - Declaration

- The information contained in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
- I undertake to abide by the ethical principles underlying the Declaration of Helsinki and Good Practice Guidelines on the proper conduct of research.
- If the research is approved I undertake to adhere to the study protocol without agreed deviation and to comply with any conditions set out in the letter sent by the Department of Health and Social Security notifying me of such approval.
- I undertake to inform the Isle of Man Local Research Ethics Committee of any changes in the protocol and to submit annual reports setting out the progress of the research.
- I am aware of my responsibility to be up to date and to comply with the requirements of the law and appropriate guidelines relating to security and confidentiality of patient or other personal data, including the need to register, where necessary, with the appropriate Data Protection Officer.
- I understand that research records/data may be subject to inspection for audit purposes if required in future.
- I understand that personal data about me as a researcher in this application will be held by the Isle of Man Local Research Ethics Committee and that this will be managed according to the principles established in the Data Protection Act.

Signature of the Chief Investigator

Date

Please print name

ANNEXE A - Drugs and Devices

This part to be completed if the study involves the use of a new medical product or medical device, or the use of an existing product outside the terms of its licence.

a) Is a pharmaceutical or other commercial company arranging this trial?

If no, has approval of the licensing authority been obtained by means of a DDX?

b) Does the drug(s) or device have a product licence(s) for the purpose for which it is to be used?

If yes, please attach data sheet or equivalent

c) Is any drug or medical device being supplied by a company with a Clinical Trial Certificate or Clinical Trial Exemption

Please attach CTC, CTX or DDX

d) Has a CTC, CTX or DDX been applied for but not yet received?

If so, the application can be made but a valid CTX must be provided to the Isle of Man Local Research Ethics Committee before the research can proceed.

e) Details of drugs to be used (please complete the table below for each drug)

- i) Approved name(s)
- ii) Generic Name
- iii) Trade Name

- (1) Strength
- (2) Dosage and Frequency
- (3) Route
- (4) Duration of Course

- iv) When drugs not listed in the British National Formulary are being used, applicants should provide the following information:

- (1) What is the formulation, purity and source of the Drug?
- (2) What are the pharmacological actions of the Drug - including those not relevant to the proposed therapeutic indications?
- (3) Toxicology - including details of species, number of animals, doses, duration of treatment and route(s) of administration. Important findings should be summarised.

(4) Clinical pharmacology in Man including:

- (a) Extent of use in Man;
- (b) Dosage schedules used - dose, route, duration;
- (c) Side effects and their frequency;
- (d) Information on duration of action and mechanism of elimination, if known.

(5) Applicant's experience with this drug in man. Give brief information on previous studies, number and type of subjects and nature and incidence of side effects.

v) Details of Medical Device

vi) If an electrical device, has the device been through acceptance and safety testing?

Give details

ANNEXE B - Radiation

This part to be filled in if the study involves the use of additional ionising or radioactive substances or X-Rays.

1) RADIOACTIVE SUBSTANCES

- a) Details of substances to be administered (Please complete the table below)
 - i) Investigation;
 - ii) Radionuclide;
 - iii) Chemical form;
 - iv) Quantity of radio-activity to be administered (MBq);
 - v) Route;
 - vi) Frequency
- b) Estimated Effective Dose (Effective Dose Equivalent) (mSv) (please supply source of reference or attach calculation).
- c) Absorbed dose to organ or tissues concentrating radioactivity (mGy). Specify dose and organ (please supply source of reference or attach calculation)

2) X-RAYS

- a) Details of radiographic procedures
 - i) Investigation;
 - ii) Organ(s);
 - iii) Frequency.
- b) Estimated Effective Dose (Effective Dose Equivalent) (mSv) (please supply source of reference or attach calculation)