The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

# Application form

## UNIVERSITY OF NOTTINGHAM
## MEDICAL SCHOOL ETHICS COMMITTEE

In completing this form please refer to the attached Notes of Guidance

Application for approval of all studies involving **Healthy Human Volunteers only conducted by Staff and Students of the University of Nottingham**

**Please complete in typewritten form one application form, consent form (template attached) and subject's information sheet (template attached), one detailed study proposal and supply 1 one signed hard copy and e-mail 1 copy of as attachments.**

**1 Title of Project**:

**2 Names, Position, Department, institution and Qualifications of Investigators:**

**3 Type of Project**: (Please tick appropriate box)

| | | | |
|---|---|---|---|
| a) Classroom procedures: | [ ] | b) Student project | [ ] |
| c) Development of technique: | [ ] | d) Assessment of new drug or formulation:* | [ ] |
| e) Pilot Study: | [ ] | f) Questionnaire-based study or community survey | [ ] |
| g) Commercially funded* | [ ] | h) Other | [ ] |

***In line with charges being imposed by other Ethics Committees a charge of £250 will be imposed on all commercially funded projects. An additional charge of £100 may be imposed for resubmission or for re-assessing amendments to the original proposal where full committee approval is required and £50 where only chairman's approval is necessary. There shall be no charge for research funded by the NHS, by other government funding sources such as the Research Councils, by charities and by educational grant giving bodies.*

**4a** **<u>Summary of Experimental Protocol</u> - Please give details below (no longer than this side of A4 ) under the following headings: - 1. Background. 2. Aims (to include hypothesis to be tested), 3. Experimental protocol and methods, 4. Measurable end points/statistical power of the study. 5. Key references. This section must be completed. This is in addition to a more detailed project proposal/protocol which should be attached to this application. Please use 10pt typeface.**

**Do not go over the page**

**4b Lay Summary of project** (in lay words):(maximum 200 words) ***Summaries which include language which is too technical for lay members of the Committee will be rejected.***

**5 Duration of Study**:

**6 Location of study**:

Proposed starting date: Proposed finishing date:

**7 Description and number of volunteers to be studied**:

**8 Will written consent be obtained from all volunteers? Yes/No**

**Please give the name, status and relevant qualifications of the person who will give a verbal explanation and obtain consent.**

**9 Will a disturbance allowance be offered? Yes/No**

If Yes, give rate (*delete as appropriate)

*Per day: *Per Study:

*Per procedure: *Give the maximum allowance payable to a volunteer:

**10 Will a medical supervisor be present: Yes/No**

If Yes, give name and qualifications:

**11a Does the study involve the exposure of the patient to radioactive materials? Yes/No**

If your project involves the administration of radioisotopes your attention is drawn to note 10 a) in the attached notes of guidance.

Radiological Practitioner/ARSAC certificate holder

Name Signature* What is the total effective dose

*The Radiological Practitioner/ARSAC certificate holder must sign to accept responsibility for the radiological procedure listed above.

It is the responsibility of the investigator to ensure that the total exposure of a volunteer to ionising radiation will not exceed 5 mSv over any 12 month period.

The Radiation Protection Adviser (RPA) must sign below to confirm that the dose estimate is satisfactory and that the appropriate arrangements are in place for undertaking the procedure.

RPA Name Signature Date

**11b Does the study involve the exposure of the patient to X-rays ? Yes/No**

Type of procedure:

**All research involving radiology must be submitted and approved by the Clinical Director for Radiology.**

RPA Name Signature* What is the total effective dose

Clinical Director Name Signature Date

**12 Will participant's General Practitioners be told about the study?** This would be regarded as essential if the study includes consumption of drugs or novel chemical entities or if you are recommending that the volunteer should see their GP as a result of the study.

**Yes/No**

If no please justify

**13a 1. If the procedure involves any intervention or treatment (blood sampling, biopsy , i.v injections, manipulation etc) does the practitioner performing this intervention or treatment have personal profession negligence insurance Yes/No**

**2. If the procedure involves new drug, formulation or device, will full insurance cover be provided by the sponsoring drug firm?**

**Yes/No**

If Yes, **See Guidelines Note 1: Insurance**

**Proof of indemnity and a copy of the company's certificate of insurance should be forwarded for consideration at the same time as the application and protocol.**

## 13b FUNDING

Will there be any material benefits from the study for the Department or individual investigator? (E.g. equipment, research salaries, consumables etc)

**Yes/No**

If yes please specify in general terms what the benefits will be:

## 13c Trust R&D

**Does the study involve any staff who hold a contract with the hospital trust?(This does not include investigators with an honorary contract with the NHS but does include staff whose salary is provided by the NHS eg Nurse, radiographer, physiotherapist)**

**Yes/No**

**Will the study use any space/facilities/ resources belonging to the hospital trust? (eg Xray, pathology, blood tests other than those used to screen volunteers).**

**Yes/No**

If you answer yes to both of the above questions please complete and submit the online QMC Trust R&D form available at the following links: http://intranet/sQMCInfo/Divisions/Others/R&D/index.htm or http://www.qmc.nhs.uk/research/index.htm.

## 14a Drugs or other substances to be administered (including placebo and comparators)

Drug name:
Generic Name:
Proprietary Name:
Formulation:
Dose:
Frequency:
Route:
Possible complications (append details if necessary)

Please tick where appropriate

CSM status ☐ Product Licence (PL) ☐
Clinical Trials Authorisation (CTA) ☐

- For drugs with a product licence please append a copy of the relevant data sheet.
- For drugs with a CTA, please append a statement detailing present knowledge of the drug action, adverse effects, long and short-term safety.
- The number of the PL, CTA MUST be included.

If a new drug formulation is being studied an explicit statement as to the UK licensing status of the product is required. For unlicensed products then information should be given as to its licensing status in other countries and appropriate safety data should be submitted.

Arrangements for the supply, storage and dispensing of trial drugs must be discussed with the Senior Pharmacist at the relevant hospital who must sign below.

**14b Will any drug used be stored in the Pharmacy and dispensed to a prescription written in red?**

**Yes/No**

If No, please explain why:

Signature of Pharmacist ……..

Printed Name ……
NB THIS MUST BE OBTAINED

**15 Does the project involve painful/dangerous or invasive procedures on volunteers ?**

**Yes/No**

Please outline risks and degree of discomfort

**16 Will blood samples or other specimens be required?** **Yes/No**

If so, will written informed consent be obtained?

What volume will be required and over what duration?*

*Studies involving venepuncture only, where the information generated is of no prognostic significance, will be approved by Chairman's action provided no more than a total of 500mls of blood is taken over a 6 month period and no more than 200mls is taken on a single occasion. Applicants need to submit 1 copy of this form and other documentation with a covering letter to the Chairman.

**17 How will the subjects be chosen?** Please specify what criteria will be used and which groups you wish to target.

**Please include a copy of your proposed poster or advert**

**18 Describe how possible participants will be approached?** Please refer to note 9 in the Guidelines. Please specify whether posters will be used and where they will be placed.

**** If your study is community-based or epidemiological study please answer the following questions (19-21)

**19 What sources of information will be included? (tick any that apply)**

| | |
|---|---|
| Personal interview | [ ] |
| Postal questionnaire** | [ ] |
| Hospital records | [ ] |
| GP records | [ ] |
| Occupational records | [ ] |
| Other, describe | _____ |

**** Please submit a copy of your proposed questionnaire if you are a student please make sure your supervisor has reviewed and approved it.**

**20 Whose permission will be sought to access this information (eg GP, consultant)?**

**21 For interview surveys only:**

Please indicate who will do interviews (eg Students, research nurses etc)
Please submit an interview schedule including an outline of questions or topics to be discussed.

**22 What ethical problems do you foresee in this project?**

Any other relevant information?

**DECLARATION:** I will inform the Medical School Ethics Committee as soon as I hear the outcome of any application for funding for the proposed project and/or if there are any significant changes to this proposal. I have read the notes to the investigators and clearly understand my obligations as to the rights, welfare and dignity of the subjects to be studied, particularly with regard to the giving of information and the obtaining of consent.

**Signature of Lead Investigator:** **Date:**

****Nb If you are student your supervisor must sign this form otherwise it will be rejected**

**Name and address for correspondence with applicant:**

## Submission of protocols for consideration

## CHECK LIST

**1 PAPER COPY WITH ALL RELEVANT ORIGINAL SIGNATURES OF**

- **Completed form signed by the lead investigator or supervisor of project.**
- **Short study protocol/project proposal**
- **Indemnity where applicable**
- **Information Sheet**
- **Consent Form**
- **Poster or advert to be used.**
- **Letters of permission from outside institutions where applicable**
- **Copy of proposed questionnaire where applicable**
- **Outline of interviews or focus group discussions where applicable**
- **Drug data sheets where applicable**

**must be submitted to:**

**Mrs Louise Sabir**
**Ethics Committee Secretary**
**Division of Therapeutics and Molecular Medicine**
**D Floor, South Block**
**Queen's Medical Centre**
**Nottingham**
**NG7 2UH**

**1 ELECTRONIC COPY E-MAILED AS ATTACHMENTS TO: louise.sabir@nottingham.ac.uk**

**at least two weeks before the meeting.** This is necessary to ensure that all members of the Committee can adequately review the application. Applications received after this time will be held over until the following meeting. Approval cannot be given to protocols by Chairman's action.