

**UNIVERSITY OF NOTTINGHAM
MEDICAL SCHOOL ETHICS COMMITTEE**

Application for approval of investigations on Healthy Human Volunteers

Notes of Guidance

1. Code of Research Conduct

It is the responsibility of the investigators to ensure that they and their team follow and are aware of the University Code of Research Conduct which is available on the University Website at the following address:

<http://www.nottingham.ac.uk/research/university/research-code.htm>

2. Insurance

(a) Insurance for sponsored research involving drugs

You will need:

- The form of indemnity from the sponsoring company to the University will need to indemnify the University against claims and proceedings arising from the study. This needs to be in place before a trial will be given Ethics approval and be arranged through the Clinical Trials Manager Deborah Main for the Queen's Medical Centre or David Hetmanski for the City Hospital. Their role is to give you all the assistance you need in setting up and managing a commercially sponsored clinical trial. More information can be found on the clinical trials webpage on the University of Nottingham Research Support Office website. <http://www.nottingham.ac.uk/rso/your-research/clinical-trials/> and Deborah's email address is: deborah.main@nottingham.ac.uk
- A copy of the company's certificate of insurance.

Please find attached a form of indemnity which is acceptable to the University and which you can use as a guide when arranging indemnity with the sponsor. Companies may choose to use their own form of indemnity or the standard form of agreement, which has been drawn up in consultation with the Association of British Pharmaceutical Industry (ABPI).

Applications will not be considered without Proof Of Indemnity.

b) Insurance for research not sponsored by commercial companies and not involving novel drugs/procedures

Further information may be found on the Procurement website:

www.nottingham.ac.uk/procurement/insurance/insurancenotes.html

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2. Consent Form and Information Sheet

Please use the attached standard templates and guidelines for the University of Nottingham Medical School Ethics Committee.

3. Statistical considerations

Protocols (other than classroom procedures, pilot studies or honours projects) should not be approved unless evidence is provided concerning the statistical power of the study. **If a scientific study involves such small numbers that a definitive answer can not possibly be achieved it is unethical to proceed with the study.** A statement will be required concerning statistical power which should include a power calculation and definition of the endpoints for the study. Advice on this matter can be obtained from your Supervisor or the Chairman.

4. Pregnancy screening of female volunteers

Where screening for pregnancy is a requirement, all female volunteers should provide a urine specimen for testing of urinary HCG at least 24 hours and no more than 48 hours before the first day of the study. Where a trial is carried out in phases female volunteers must be screened before each stage when drugs or radioisotopes are administered. Urine should be tested using sensitive pregnancy kits capable of detecting 50 mIU/ml HCG in the specimen. Volunteers must be assured of complete confidentiality and when a positive result is found they should be referred for professional advice with discretion and sensitivity.

5. HIV testing of volunteers and Hepatitis B and C testing of volunteers

When HIV testing is required the reasons must be clearly stated and justified in the protocol. The information sheet must state clearly that HIV testing will be performed. It should also be stated that major insurance companies take the view that HIV testing in this context is entirely analogous to that carried out for donation of blood. Samples for HIV analysis should be sent to the laboratory identified only with a trial number unique to the subject and not with the subject's name. The results must be returned only to a registered medical practitioner who should be designated within the protocol. A protocol/procedure should be submitted as to the duty of care in the event of a volunteer testing positive. If the test is positive it will usually be necessary to tell the subject. In any event the Chairman of the Ethics Committee or his Deputy must be informed.

7. Drug company sponsorship should always be indicated on the application form.

8. Any adverse reactions arising from investigations should be reported to the Chairman.

9. Subjects must not be implicitly or explicitly pressured into participation. Clinical students must not be recruited by units to which they are attached at the time of the study. Volunteers should be approached either by an invitation placed in mailboxes that potential volunteers may or may not choose to respond to, or by general posters expressing interest in halls of residence. After the study has been explained to them the subject should be given a period of time to think about it before agreeing to take part.

10. The Three Month Rule

The three month rule exists primarily to protect volunteers from the temptation of participating in studies with such frequency that their health, academic performance or employment may suffer. A secondary consideration is the impact of the quality of research which could result from subjects participating in different studies concurrently or in close proximity. The three month rule will apply if any of the following criteria are met:

- i) A drug is taken
- ii) A disturbance allowance is paid
- iii) An invasive procedure is carried out (eg venepuncture >50ml, endoscopy) or the subject is exposed to ionising radiation.

It is the responsibility of the investigator prior to the commencement of the study to check that each potential volunteer fulfils all the following conditions:

- a) that by participating in the study the volunteer will not be exposed to a radioisotope dosage of more than 5 mSv in any 12 month period, and b), that 3 months have elapsed since the completion of the volunteer's participation in any previous study.
- b) that by participating in the study, the volunteer will not be taking part in more than 4 studies of any kind in any 12 month period.

11. Studies involving the exposure of subjects to ionising radiation as part of a research application for ethics approval.

The Ionising Radiation (Medical Exposure) Regulations (IRMER) 2000 have replaced the Ionising Radiation (Protection of Persons Undergoing Medical Examination or Treatment) Regulations 1988 (POPUMET). The 2000 regulations place obligations on individuals and organisations where any subject participating in a research procedure or trial is exposed to ionising radiation. The following notes are to assist applicants in providing the necessary information to comply with the law.

1. Ionising radiations includes all exposure to diagnostic X-ray procedures (including CT scans), procedures involving the administration of radioactive substances (radiopharmaceuticals) and radiotherapy.
2. There may be more than one type of radiation exposure included in a study protocol. Please list all procedures to be undertaken, and state whether this procedure would have been carried out if the study was not undertaken.
3. State how many times each procedure will be undertaken.
4. All exposures (X-ray and radionuclide) require a named radiological practitioner who would normally be a Radiologist or Nuclear Physician. In the case of radionuclide investigations the practitioner will be the ASAC certificate holder (It is an offence to administer radioactive substances without an appropriate ARSAC certificate).
5. The total effective dose from all procedures must be stated in mSv.

6. A procedure must be in place to identify each individual participating in the trial at the time of referral to the imaging department.
7. Radiation Protection Advisors:

Professor Alan Perkins (nuclear medicine) or Dr David Pye (X-ray)
Dept of Medical Physics
A floor
Medical School
Extn: 43597