

**UNIVERSITY OF NOTTINGHAM
MEDICAL SCHOOL**

Medical School Research Ethics Committee

The Terms of Reference of the Medical School Research Ethics Committee shall be as follows:

- 1 The University Medical School Research Ethics Committee (hereafter referred to as "the Committee") is concerned with the review of research studies where both the following criteria apply:
 - (i) The study is being conducted by a member of the University
 - (ii) The study involves healthy human subjects

The purpose of the Committee is to ensure that such studies are satisfactory in terms of welfare of the research subject, the dignity of the research subject and the validity of the research. Specifically, the Committee shall ensure that:

- (a) Predictable risks, and at risk subjects, are excluded
- (b) Facilities exist for the management of unpredictable risks
- (c) Subjects understand what is involved
- (d) Subjects volunteer for studies and do not participate through fear or career disadvantage or through excessive financial inducement
- (e) The study can achieve its stated objectives
- (f) Documentary evidence of indemnity is provided

Approval by the Committee is a pre-requisite for the provision by the University Insurers of indemnity for acts of negligence

The Committee is not empowered to consider research studies being carried out in the private sector, even when these studies involve University students or staff

Studies involving patients should be referred to the relevant Hospital Ethics Committee

- 2 The Committee shall be responsible to the Board of the Faculty of Medicine and Health Sciences and shall keep a record of its meetings and conclusions. The Committee shall produce an annual report of its activities for the Faculty Board
- 3 The membership of the Committee shall be:
 - One academic member nominated by each of the 6 Schools
 - One General Practitioner nominated by the Head of the Division of General Practice
 - One lay member of the University Council
 - One lay member nominated by the Faculty Board
 - One undergraduate medical student representative, from the third year, nominated by the third year student representatives

Each nomination shall be accompanied by the name of a deputy. Committee members shall normally serve for a period of 3 years

- 4 The Chairman shall be nominated by the Faculty Board from amongst the medically qualified members of the Faculty

- 5 A Deputy Chairman shall be elected by the Committee from amongst its medically qualified members
- 6 The Committee shall consider each project on its individual merits and in its consideration the Committee shall be guided generally by the Code of Ethics of the World Medical Association (Declaration of Helsinki).
- 7 Two medically qualified members of the Committee may consider a project and where they consider that the matter is of a minor nature may make provisional proposals where the requirements of an investigation demand a recommendation before the next formal meeting
- 8 The Committee may co-opt specialists in the appropriate disciplines when considering specific investigations
- 9 The Committee may ask for the resubmission of a project if there is a change in the ethical considerations attaching to the project
- 10 The Committee shall be prepared to discuss a project with the initiator should the project appear unsatisfactory on ethical consideration
- 11 In line with charges being imposed by other Ethical Committees the Committee shall impose a charge of £250 on all commercially funded projects (which could be varied in consultation with the Dean and in line with inflation). An additional charge may be imposed for resubmission or for re-assessing amendments to the original proposal. 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 bodies.
- 12 These terms of reference have been drawn up to comply with the ICH Good Clinical Practice Guidelines.