Observational Research Ethics Committee: Procedures

1. The Observational Research Ethics Committee is a sub-committee of Council. The Committee is responsible for reviewing applications for observational studies (interventional studies fall under the remit of the Interventions Research Ethics Committee).

2. The Committee is responsible for safeguarding the rights, safety, and wellbeing of all human participants in School observational research projects, paying special attention to studies that may include vulnerable participants.

3. No participant may be admitted to an observational study before the Observational Research Ethics Committee issues its written approval of the research project.

4. No deviations from, or changes to, the protocol should be initiated without prior written approval from the Observational Research Ethics Committee for an appropriate amendment, except when necessary to eliminate immediate hazards to the participants or when the change(s) involves only logistical or administrative aspects of the study (e.g., change of monitor(s), telephone number(s)).

Membership of the Committee

5. The membership of the Observational Research Ethics Committee will comprise:

- the Chair (appointed by the Director);
- four members of School staff embracing epidemiological, clinical, biomedical and social science expertise, at least two of whom shall be medically qualified;
- a member from the nursing profession, and
- One lay member who have no professional connection with the work of the School.

Terms of office will be for a minimum of three years. There is no maximum service..

6. A research degree student representative may attend meetings but may not participate in reviewing submissions. In addition, the Director, the Chair of MSc Research Ethics Committee, and member of staff responsible for overseeing the School's compliance with human tissue regulations may also attend meetings.

7. The Committee may consult non members with expertise in special areas for assistance.

8. Members shall not be entitled to review submissions to the Observational Research Ethics Committee for research projects on which they are an Investigator.

Committee responsibilities

9. The principal responsibilities of the Observational Research Ethics Committee are to:

i. review ethics applications for observational research projects, and relevant supporting documentation as submitted via the LEO system to ensure any

ethical issues are satisfactorily addressed, including existence of appropriate consent mechanisms (see LSHTM SOP on Informed Consent for Research - LSHTM/SOP/014 http://intra.lshtm.ac.uk/trials/sops/sopsinpdf/sop_014_consent.pdf - although aimed at clinical trials the principles apply to all studies) and provision of information to potential research participants, as well as the qualifications of the investigator for the proposed research;

ii. review proposed amendment(s) in ongoing research projects that have ethical approval (which will be submitted via the LEO system;
iii. undertake ongoing monitoring of observational research projects as required.

12. Ethics applications/amendments/reports will be reviewed within a reasonable timeframe. These are reviewed virtually on a monthly basis. All applications submitted by the last day of the month, will be reviewed by the 15th of the following month. The Committee's views will be documented in writing, clearly identifying the research project, the documents reviewed and the dates for the following:

- approval;
- modifications required prior to its approval;
- negative opinion; and
- termination/suspension of any prior approval.

13. Where relevant the reasons for the Committee's decisions/opinions and procedures for appeal of its decisions/opinions will be provided.

14. Where amendments to the protocol are required following ethical review these will be tracked and a final version, incorporating all changes agreed by the Observational Research Ethics Committee, must be submitted to the Ethics Committee Administrator by the Investigator before approval is granted.

15. The Committee will undertake review of observational research projects where necessary and appropriate to the degree of risk to human participants.

16. The Committee will receive prompt reports from Investigators, via the Ethics Committee Administrator, in the event of:

i. deviations from, or changes of, the protocol to eliminate immediate hazards to participants;

ii. changes increasing the risk to participants and/or affecting significantly the conduct of the study;

iii. new information that may affect adversely the safety of the participants or the conduct of the study.

Committee meetings

17. Consideration and discussion of ethics applications and reports will normally take place electronically, unless an issue requires specific consideration at a meeting. The Investigator may provide information on any aspect of the study, but may not

participate in the deliberations of the Committee or in the vote/opinion of the Committee.

18. The Ethics Committee shall meet at least three times during the academic year (once per term). Additional meetings will be held as required. A meeting shall be deemed to be quorate when 3 members and the Chair are present.

19. The Ethics Committee Administrator shall act as Secretary to the Committee and will be responsible to give at least seven days' notice of meetings and to send out an agenda at least five days before the meeting.

Committee records

20. The Ethics Committee Administrator will retain all relevant records (e.g., written procedures, membership lists, lists of occupations and qualifications of members, submitted documents, minutes of meetings, and correspondence) for a period in accordance with School and other relevant records keeping requirements (see http://intra.lshtm.ac.uk/infoman/records/).

21. Investigators must retain copies of final applications, supporting documentation and other reports as part of their own research records in line with good practice and in accordance with School and other relevant records keeping requirements (see http://intra.lshtm.ac.uk/infoman/records/).