Interventions Research Ethics Committee: Procedures

1. The definition of interventional studies for LSHTM ethical review purposes is: interventional studies include all trials based on random allocation of interventions and also non-randomised interventions where participants or groups of participants are given treatments (of whatever nature) that they would not otherwise be receiving in the ordinary course of events and which are allocated by the investigators.

2. The Interventions Research Ethics Committee is a sub-committee of Council.

3. The Committee is responsible for safeguarding the rights, safety, and wellbeing of all human participants in School interventional research projects (both randomised and non-randomised), paying special attention to studies that may include vulnerable participants.

4. No participant may be admitted to an interventional study before the Interventions Research Ethics Committee issues its written approval of the research project.

5. No deviations from, or changes to, the protocol should be initiated without prior written approval from the Interventions 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 trial (e.g., change of monitor(s), telephone number(s)).

6. All interventional studies must comply with the principles of Good Clinical Practice, and the full ICH Guideline for Good Clinical Practice for drug trials.

Membership of the Committee

7. The membership of the Interventions Research Ethics Committee will comprise 7 staff members (Chair (appointed by the Director), 2 medical,1 statistical,1 social science,1 laboratory science) and 1 lay member (non scientific backgrounds). Staff members should be at least Senior Lecturer level and, where possible, have experience as an investigator in a phase 3 randomised controlled trial. Terms of office will be for a minimum of three years. There is no maximum service..

8. 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 liance with human tissue regulations may also attend meetings.

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

11. The principal responsibilities of the Interventions Research Ethics Committee are to:

i. review ethics applications for interventional 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) 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 interventional research projects, including (at least) annual review of reports from Investigators which will be submitted via the LEO system (continuation of LSHTM ethical approval for intervention studies is contingent on the annual submission of this report for the duration of the project);

iv. ensure compliance with Good Clinical Practice (as set out at section 3 of ICH Guideline for Good Clinical Practice).

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 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.

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 Interventions Research Ethics Committee, must be submitted to the Ethics Committee Administrator by the Investigator before approval is granted.

15. The Committee will conduct continuing review of each interventional research project at intervals appropriate to the degree of risk to human participants, but at least once per year. Continuation of LSHTM ethical approval for intervention studies is contingent on the annual submission of the Annual Progress Report to the Committee for the duration of the project.

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