

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

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 eliminaplet2.024 441.4.s23(n)-3(t)-3(rv)13(

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