Lancaster University
Faculty of Health and Medicine
Research Ethics Committee

Constitution and Terms of Reference

**Principles**
1. The FHM Research Ethics Committee (FHMREC) reports to the University Research Ethics Committee (UREC) and will conform to the Constitution and Terms of Reference of Lancaster University Faculty Ethics Committees and ultimately work to the Constitution and Terms of Reference of the UREC.

2. More specifically, the remit of the FHM Research Ethics Committee (FHMREC) is to provide guidance to FHM postgraduate PhD research students and staff on ethical issues with respect to research projects that involve human participants or other possible ethical risk factors, and that therefore will subsequently require ethical approval/ratification by FHM REC. The committee will consider UK-based research that needs to be reviewed by the National Health Service (NHS) National Research Ethics Service (NRES) committee via the Integrated Research Application System (IRAS), a prison authority committee, or another UK committee external to the university. For research conducted overseas that has or will be considered by a research ethics committee in another country, a judgement will be made by the Chair and/or Deputy Chair, if necessary in consultation with FHMREC, as to whether a full review is necessary or recommendation for approval by Chair’s action.

3. It is the responsibility of the Faculty Heads of Division or delegated member(s) of staff to review and approve applications involving undergraduate and taught postgraduate students undertaking research projects that involve human participants or other possible ethical considerations.

4. The FHM Research Ethics Committee has final approval powers.

**Membership and Meetings**
5. The Committee will be chaired by an appointed member of the Faculty and supported by a Deputy Chair, chosen from a Division different to that of the Chair wherever possible*. The Faculty Research Ethics Officer will be responsible for screening incoming applications. The Chair and/or Deputy Chair have the responsibility for chairing meetings and will have the authority to take Chair’s action, including for approval recommendations. The workload involved will be included in that individual’s workload allocation. The Deputy Chair will chair at least two meetings per year. (*Currently the FHM ADR job description includes this role but this will be subject to review.)

6. The membership of the Committee will be drawn from the research, academic and/or clinical staff of FHM, as set out in 7 below. The Chair will serve for 3 years and can be reappointed once, ordinary members will serve for a term of two years, renewable twice by mutual agreement. Chair and members will not serve for more than 6 years except in exceptional circumstances and with prior agreement of UREC.

7. **Membership:**
   a) The Chair and Deputy Chair.
   b) Normally at least one member drawn from the staff of each of the Divisions of Biomedical and Life Sciences (BLS), Health Research (DHR), CETAD and Lancaster Medical School.
   c) a Lay Member who will be recruited and appointed via UREC to act as ‘critical friend’ and to represent study participants (see role profile).
   d) In addition to the DHR divisional representative normally:
      d.1) One-two members drawn from the staff responsible for the delivery of the Doctorate in Clinical

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Operational Procedures

8. Quoracy of the committee requires the presence of Chair and/or Deputy Chair, the FREC Secretary and members with sufficient expertise to assess the type and quantity proposals at each meeting. Nominally we would require a minimum of 2 divisional ordinary members. The attendance of the Lay member whilst important is not essential as long as the Lay Member has noted receipt of the meeting papers, has been given the opportunity to comment and considers that no issues prevail. However, if the Lay member has concerns and cannot attend, then the Lay member should submit the concerns in writing to the Research Ethics Officer copied to the Chair and Deputy Chair and these will be discussed at the meeting on the Lay member’s behalf. The result of the discussion will then be relayed to the Lay Member and if the concerns are satisfied then the proposal will be approved subject to other queries raised by the committee. If not satisfied, the proposal will be held back until it is resolved by consensus or Chair’s action. Furthermore, all documentation is made available to all committee members to comment on if they wish, should they not be present at the meeting.

9. The work of the committee will be supported by the Faculty Research Ethics Officer, who will act as secretary, and will be responsible for organising meeting dates, securing a meeting room for the meetings, circulating proposals, drafting responses based on notes from the committee meetings, maintaining records related to applications and acting as an initial focus for any enquiries. The Chair and/or Deputy Chair will check all correspondence before it is sent.

10. The committee’s procedure will be as follows:

a) Applications are initially reviewed by the Faculty Research Ethics Officer to check for completeness and suitability.

b) A lead reviewer for each application is nominated.

c) Papers are circulated to all members in advance of the meeting. Members should read the papers and if possible send any comments to the lead reviewer in advance of the meeting.

d) At the meeting, the lead reviewer comments on the application, drawing the main ethical issues to the attention of members.

e) If additional comments are then invited on the study from those present.

f) If required, the applicant is invited into the meeting to engage in a discussion regarding questions and concerns by the committee. If they are required, but unable to attend, they are expected to be available by telephone or other means of communication during the meeting time. The lead reviewer may speak to the applicant in advance of the meeting if they feel this is necessary.

g) In circumstances where there appear to be no concerns significant enough to require direct discussion the applicant will not be required to attend. The normal review process will take place, but if on further discussion significant issues become apparent the applicant may be required to attend a subsequent meeting of FHMREC.

h) The lead reviewer gives the applicant feedback on behalf of the committee, and seeks to clarify any issues raised by members.

i) The applicant, if present or available by telephone/other means, is invited to ask the committee questions.

j) Suggested changes or requests for additional information are then summarised by the lead reviewer on behalf of the Chair in a letter to the applicant.

- If requests are for minor or moderate amendments, applicants are instructed to provide amended...
materials to the Chair. These amendments are considered by the lead reviewer for that application. If requests are adequately met, the Chair and/or Deputy Chair then awards final approval for the study to go ahead.

- If the proposal requires major revision, applicants are instructed to make amendments and resubmit for subsequent FHM committee review. If requests for resubmission and amendments are subsequently met, the Chair and/or Deputy Chair then provides Chair’s recommendation for approval and awards final approval for the study to go ahead.

11. Applicants requiring amendments to a previously approved project should contact the Faculty Research Ethics Officer, who will provide the appropriate form and procedure. Amendments are considered by the Chair and/or Deputy Chair and will be dealt with by Chair’s action in the case of minor changes that do not raise significant ethical concerns, or be submitted to full review as appropriate. In the latter case the review process starts afresh and the lead reviewer may or may not be the same as in the original submission.

12. The committee’s dates are noted on the FHM website (http://www.lancs.ac.uk/shm/research/ethics). All paperwork should be submitted to the committee by the deadline indicated on the website. The Faculty Research Ethics Officer will endeavour to write to applicants within one week after the meeting. The letter will indicate whether the research is approved (staff and postgraduate research students), requires minor to moderate amendments, needs to have major amendments with full resubmission to FHMREC. The letter will indicate those changes that are required e.g. matters of ethical concern, and those that are suggestions e.g. improvements to methodology. An approval letter from FHM REC is needed before data collection can commence.

13. Applications are to be submitted on the relevant FHMREC ethical approval application forms (available from the website), along with supporting documents.

14. The Committee will have a procedure for considering appeals against a decision. (See Lancaster University research ethics appeals procedure).

Promoting Good Practice

15. The Committee will promote awareness and understanding of ethical issues in research amongst colleagues and students in the faculty. This may include training for staff and students, in department and/or at faculty level (e.g. as part of research training programmes for PhD students.)

16. The FHM Research Ethics Committee will remain abreast of current ethical issues through appropriate training available via the OED courses, University seminars, external courses, or the FHM REC itself.