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.

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 FHMREC.

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 for Chair’s action.

Staff members with approvals made by another institution are required to submit a copy to FHMREC and a judgement will be made by the Chair and/or Deputy Chair, if necessary in consultation with FHMREC, it complies to LU standards and if not advice is given to the applicant about any shortcomings.

For research requiring Health Research Authority approval, the IRAS application should be submitted to FHMREC for review by the Committee, which once approved, will be sent forward for university sponsorship. This should take place before submitting the application to the Health Research Authority.

2. 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.

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

Membership and Meetings
4. 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.

5. 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 REC will aspire to have a membership that is reflective of the diversity of Faculty, ideally with representation from departments, programmes, institutes, and centres where possible. Each year, a review of the membership will be undertaken, focusing upon the expertise and experience of members, as well as wider equality, diversity, and inclusivity agendas such as gender and race. The appointment of appointed and co-opted members shall be ratified by the Chair of UREC.

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6. 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), 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) Any other members within the faculty with required expertise.
In addition, we will recruit from the faculty expertise in Clinical Psychology programme and any taught programmes requiring ethical approval as a core activity.

The workload involved in reviewing application documentation, attending meetings and dealing with amendments following the meeting will also be included in each individual’s workload allocation.

7. 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.

Operational Procedures
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.

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.
   b) 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.
   c) At the meeting, the lead reviewer comments on the application, drawing the main ethical issues to the attention of members.
   d) Additional comments are then invited on the study from those present.
   e) 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.
f) 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.

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

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

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).