Constitution and Terms of Reference

1. The remit of the FHM Research Ethics Committee (FHMREC) is to provide guidance to FHM postgraduate 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 the University Research Ethics Committee (UREC). This guidance is provided following detailed review processes outlined in section 8 below. The committee does not 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, if necessary in consultation with FHMREC, as to whether a full review is necessary or recommendation for approval by Chair’s action.

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. This process is overseen by the Chair of FHMREC who may take any relevant action in the event of a concern being raised including, if necessary, consideration by FHMREC. These projects are reported by the Chair to UREC.

3. The committee’s dates are noted on the FHMREC webpage. All paperwork should be submitted to the committee by the deadline indicated on the website. The Chair of FHMREC will endeavour to write to applicants within one week after the meeting. The letter will indicate whether the research is being recommended to UREC for approval (staff and postgraduate research students), requires minor to moderate amendments, needs to have major amendments with full resubmission to FHMREC, or is being referred to UREC for full review. 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 the university is needed before data collection can commence.

4. The Committee will be chaired by the FHM ADR, (or their nominated representative) and supported by a Deputy Chair, normally from the Division of Health Research (DHR), which is the division from which the majority of applications are received. The Chair will be responsible for screening incoming applications, 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.

5. The membership of the Committee will be drawn from the research, academic and/or clinical staff of FHM, as set out in 6 below. Members will serve for a term of two years, renewable by mutual agreement.

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. By agreement, CETAD, the Centre for Training and Development, will not have a member on the committee at this time but may consider membership in the future.
   c) In addition to the DHR divisional representative normally:
      c.1) One-two members drawn from the staff responsible for the delivery of the Doctorate in Clinical Psychology (DClinPsy) programme in DHR.
c.2) One member drawn from the staff of the SPECTRUM Centre in DHR.
c.3) One member drawn from the staff responsible for the delivery of the other taught doctorates.
d) Any other member of FHM staff as recommended by the Chair and with approval of the Committee.

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. The work of the committee will be supported by the FHMREC Research Support 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 will check all correspondence before it is sent.

8. The committee’s procedure regarding staff and postgraduate research students will be as follows:
a) Applications are submitted on the pro-forma application form which can be found on the FHMREC webpage
b) Applications are initially reviewed by the Chair and secretary of the committee to check for completeness and suitability, and may be referred directly to UREC if there is a conflict of interest.
c) 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 any 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.
f) The lead reviewer gives the applicant feedback on behalf of the committee, and seeks to clarify any issues raised by members.
g) The applicant, if present or available by telephone/other means, is invited to ask the committee questions.
h) 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 then provides Chair’s recommendation for approval and papers are forwarded to the Chair of the University Ethics Committee for final approval.
   • 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 then provides Chair’s recommendation for approval and papers are forwarded to the Chair of the University Ethics Committee for final approval.
k) If deemed necessary at any stage, FHMREC or the Chair in consultation with the lead reviewer will refer the application to the UREC for further review.
l) Applicants requiring amendments to a previously approved project should contact the FHM RSO, who will provide the appropriate form and procedure. Amendments are considered by the 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.
9. Applications are to be submitted on the relevant FHMREC ethical approval application forms (available from the website), along with supporting documents.

10. The FHM Research Ethics Committee will remain abreast of current ethical issues, and liaise as appropriate with the University Research Ethics Committee (UREC).

11. The FHM Research Ethics Committee has no final approval powers. It provides ethical guidance to researchers, reviews applications for ethical approval and makes application approval recommendations to the Chair of UREC. These recommendations serve as the primary decision guides for formal approval by the Chair of UREC but allow for further review or divergent decision by the UREC Chair. Formal final approval rests with the University.