1. Aims and objectives

The aim of the Research Governance Committee (HSRGC) is to ensure that research in the Department of Health Sciences has met stringent standards of ethical governance. It reviews the ethical content of research done by and on staff and students in Health Sciences, Centre for Health Economics and Centre for Reviews and Dissemination. HSRGC is also the Institutional Review Board registered under the University’s Federal Wide Assurance.

‘Research’ in this context means research involving human participants that is undertaken by staff and students in the Department, and research that involves the Department’s staff or students as participants. ‘Governance’ means ensuring that research is ethical – in the sense that it can be expected to cause no harm or, where some harmful effects can be anticipated, such effects are kept to a minimum and justified by the value of the research undertaken – and establishing other good research practices, such as the proper storage of data. Subsidiary aims of the HSRGC are to advance the research skills of students undertaking research in the Department, and to ensure that the reputation of the Department and University are not compromised by poorly devised research projects reaching the public domain.

2. Guiding principles

Research undertaken in the Department should be considered from the standpoint of human participants and any feature of research that might cause them foreseeable unjustified harm should be eliminated.

Research participants have the right to consent to participation. Participants are the best judges as to whether research will harm them. Prospective participants should be as fully informed about the research as is possible and reasonable. Participants should be offered an appropriate briefing about the aims, nature and outcomes of the research. Ordinarily, prospective participants should complete consent forms as part of a study. Consent forms should be administered before a study commences and include an opt-out clause explicitly allowing participants to withdraw at any point from the study at no cost to themselves. Copies of consent forms must be signed, dated, and retained by both researchers and participants. The HSRGC will scrutinise especially closely projects that would involve participants who are incapable of providing voluntary informed consent or who are members of vulnerable social groups; and projects that would deceive, or provide inducements to, participants.
Research participants have the right to confidentiality. Where the nature of the research necessitates divulging confidential information about participants, this should be done only with their explicit, advance consent. The anonymity of participants should be preserved. Where the nature of the research precludes complete anonymity the consent form should make clear that information will remain confidential to the researcher(s) and that any means of identifying participants will be removed as soon as possible. Where information has been recorded (e.g., on questionnaires or videotapes) participants should be allowed to have the record pertaining to themselves destroyed and their identity removed. All research must be conducted in accordance with relevant legislation such as the Data Protection Act.

3. Application procedures

All information pertaining to the following governance procedures is available on the HSRGC web pages at:
http://www.york.ac.uk/healthsciences/research-information/rsg/

The following are the governance procedures for the main categories of researchers:

(a) Staff-led research involving human participants

(i) If the study does not require external approval – i.e., from outside the University – you must apply for HSRGC approval by completing the Submission Form available on the HSRGC web pages. Send the completed HSRGC Submission Form and all relevant study documents as an email attachment to sandi.newby@york.ac.uk at least two weeks prior to the meeting of the HSRGC at which it will be considered.

(ii) A study that does require external approval – i.e., from outside the University – must also be independently approved by the HSRGC. If the study has to go to an NHS REC or an equivalent (such as another UK university ethics committee) then having put the study through the external review process and gained approval, send the approved study, including IRAS form, etc. – plus the external committees’ approval letter – as an email attachment to sandi.newby@york.ac.uk. Chair’s Action will then be taken on the project, reviewing it from the Department/University perspective. If necessary, the Chair will put the study to the full committee; and all Chair’s Actions are reported to the full committee. If the study is going to an overseas ethics committee it must be submitted for full HSRGC review. Send the study, plus all relevant study documents, as an email attachment to sandi.newby@york.ac.uk. If it is unclear whether an external committee is equivalent to the NHS REC, consult with the Chair of the HSRGC for advice.
(b) Student-led research involving human participants

(i) If the study does not require external approval – i.e., from outside the University – you must apply for approval by the HSRGC using the Submission Form available on the HSRGC web pages. Send the completed HSRGC submission form and all relevant study documents at least two weeks prior to the meeting of the HSRGC at which it will be considered. Send the submission in two versions: an email attachment to sandi.newby@york.ac.uk; and a hard copy signed by the supervisor(s) to Sandi Newby in Health Sciences. Please note that student submissions will not be considered unless they have been signed by the supervisor(s).

(ii) If the study does require external approval – i.e., from outside the University (e.g., it has to go to an NHS REC or any other external committee, including an overseas committee) – the submission must be approved by the HSRGC before being sent out. Send the completed submission for external approval as an email attachment to sandi.newby@york.ac.uk at least two weeks prior to the meeting of the HSRGC at which it will be considered. Do not send an application for external approval before it is cleared by the HSRGC.

Information regarding application for external research funding

Any application for external research funding for a study involving human participants has to be signed off by the Head or Deputy Head of Department of Health Sciences before being progressed. At the same time, the Head or Deputy Head of Department will undertake a risk assessment of the proposed research by considering whether it raises any major ethical or other governance issues. This does not require any additional paperwork on the part of researchers.

4. Organisational structure

The HSRGC reports to the Department’s Research Committee. The HSRGC aims to meet six times a year; details of meetings are posted on the HSRGC web pages on the staff and student intranets. Biographies of committee members are also available on the HSRGC web pages. The minimum number of members at a meeting is four, of which at least one is a member external to the Department. In the event that no one on the committee is well placed to comment on an application, expert advice will be sought. To avoid conflicts of interest, members who are supervising or undertaking a research project under consideration absent themselves from discussions. Applicants will be informed of the outcome of their application for approval by the Chair of the HSRGC by email as soon as possible after the relevant meeting. Any queries as to how to comply with the Department’s governance procedures can be addressed to the chair of the HSRGC at stephen.holland@york.ac.uk.