

RESEARCH GOVERNANCE COMMITTEE

TERMS OF REFERENCE AND APPLICATION PROCEDURES

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 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 proper management of data. Subsidiary aims of the HSRGC are to advance the research skills of the Department's research students, and to ensure that the reputations 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, usually 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 induce participants.

Research participants have the right to confidentiality and control over the use of their personal data. All research must be conducted in accordance with relevant legislation such as the General Data Protection Regulation (GDPR). Details about the acquisition and use of data must be clearly communicated to participants. Participants must have the opportunity to consent explicitly to the processing of their data, including how, when, and by whom data will be collected, stored, shared and destroyed. The HSRGC expects that all data will be anonymous; if data is not anonymised, this requires strong justification, and must be clearly communicated to participants, and any means of identifying participants should be removed as soon as possible. The rights of participants regarding their personal and sensitive or 'special category' data, as set out in the GDPR, must be clearly stated. Where the nature of the research necessitates divulging confidential information about participants – for example, for statutory reasons or to avoid further harms – this should be fully justified and requires participants' explicit consent.

3. Application procedures

All information pertaining to the following governance procedures, including links to related key documents, 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) If a study **does require external approval** then the study and final approval must be logged by the HSRGC. 'External approval' means approval by a committee outside the University, i.e. an NHS REC or an equivalent body, such as another UK university ethics committee. Having put the study through the relevant review process and gained approval send all study documentation (IRAS form, or equivalent, and all supporting documents, such as information sheets) together with the external committee's final approval letter, as an email attachment to sandi.newby@york.ac.uk. If it is unclear whether an external committee is equivalent to an NHS REC, consult with the Chair of the HSRGC for advice. If the study is going to an **overseas ethics committee** then the researcher must consult with the Chair of the HSRGC for advice as to whether full HSRGC review is also required.

(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 as an email attachment to sandi.newby@york.ac.uk. Please note: **student submissions will not be considered unless they have been signed by the supervisor(s).**
- (ii) If the study **does require external approval** the submission must be approved by the HSRGC *before* being sent out. 'External approval' means approval by a committee outside the University, i.e. an NHS REC or an equivalent body, such as another UK university ethics committee. Send the final version of the submission for external approval (IRAS form, or equivalent, and all supporting documents, such as information sheets) 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 studies that involve Health Sciences' staff or students as participants

If a study involves **Department of Health Sciences' staff or students as participants** you must first contact the Head of Department (HoD) with a brief one page summary of your research in order to request permission to approach Health Sciences' staff or students. When the HoD approves the request, the study will then be reviewed by the HSRGC in accordance with the application procedures set out above.

Information regarding application for external research funding

Any **application for external research funding** 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. 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.