

Research Governance within Health Education England

Introduction

Health Education England (HEE) receives many requests for access to students, trainees, staff or information for research purposes. From time to time, our local and national teams are also invited to be partners in research bids or activity.

While HEE encourages good quality research and evaluation we also have a duty of care to those whose education and training we are responsible, and to our staff. We also have statutory responsibilities (e.g. Data Protection Act, 1998) in relation to the data that we hold. We therefore carefully consider and control the impact of research and evaluation activity on our operations.

The national HEE Development team is the initial point of contact for all internal and external enquiries relating to research, evaluation and improvement activities and manages a process that ensures that all applications are reviewed by HEE's Research Governance Group. Contact details for the HEE Development team and the terms of reference for the Research Governance Group are provided within this document.

A formal application must be submitted by those seeking:

- to contact students or trainees whose education is, or was, managed or funded by HEE
- to contact HEE staff, current or past
- to access personal information about students or trainees whose education is, or was managed or funded by HEE, or current or past staff.

Who may apply?

- Higher education institution researchers
- Postgraduate students
- Researchers employed by government departments
- Professional bodies
- Regulatory bodies
- Commercial research companies
- Individual contractors or consultants
- Research fellows
- Visiting scholars
- HEE staff undertaking research for a university course or as part of sabbatical leave.

HEE staff who are undertaking work that is part of an approved HEE work programme *may not* need to apply, depending on the nature of the project, but if in doubt please contact the HEE Development team for advice.

Those seeking a research partnership with HEE please see section (e).

Subject access requests under the Data Protection Act (1998) and enquiries under the Freedom of Information Act (2000) are managed through separate processes. Please see:

<https://hee.nhs.uk/about-us/corporate-information/data-protection-act-1998>

<https://hee.nhs.uk/about-us/contact-us/freedom-information-act>

How to apply

1. Read the information provided below
2. Complete the application form
3. Submit the completed form to the HEE Development team via email at ri@hee.nhs.uk

Following application the nature of the approval process will vary depending on whether you are planning an evaluation, audit, quality improvement or research project. A key distinction is whether your project is classified as 'research'. A number of resources are available from the NHS Health Research Authority to help you make this determination:

<http://www.hra.nhs.uk/documents/2016/06/defining-research.pdf>

<http://www.hra-decisiontools.org.uk/research/>

a. Evaluation

Evaluations may range from formal evaluations of commissioned programmes to surveys of students or trainees. Requests for evaluation activity will be considered by HEE's Research Governance Group. Alongside the potential relevance and impact of the proposed evaluation on HEE's core business, the Group will also consider the implications of the proposal in relation to workload, reputation, potential conflicts of interest and interaction with existing or planned national, regional or local HEE workstreams.

Of particular concern is the need to avoid multiple surveys of trainees or students by different organisations. Normally such requests will be declined unless they are specifically aligned with HEE's operational priorities or strategic intent (see www.hee.nhs.uk).

b. Quality improvement (including audit)

HEE welcomes activities that seek to improve the education, training and development of the healthcare workforce. Small scale local quality improvement (QI) projects involving local staff, students or trainees do not require prior approval from the national team.

Requests to undertake a major programme of quality improvement (e.g. with national implications or impacting on large numbers of staff, students or trainees) will need to be submitted for consideration by HEE's Research Governance Group. Alongside the potential relevance and impact of the proposed research on HEE's core business, the Group will also consider the implications of the proposal in relation to workload, reputation, potential conflicts of interest and interaction with existing or planned national, regional or local HEE workstreams.

Of particular concern is the need to avoid multiple surveys of trainees or students by different

organisations. Normally such requests will be declined unless they are specifically aligned with HEE's operational priorities or strategic intent (see www.hee.nhs.uk).

c. Research

In order to maintain consistency with other NHS organisations, HEE uses the Integrated Research Application System (IRAS) form - see <https://www.myresearchproject.org.uk/> Anyone wishing to conduct education or workforce-related research involving HEE staff, directly-managed students or trainees is required to complete an IRAS form. Once this has been done, a PDF of the completed IRAS form (draft or submitted) should be sent to ri@hee.nhs.uk along with the following documents:

- the research protocol
- the CV of the Chief Investigator
- written confirmation that the study has received ethical approval (if deemed necessary) from the university or other organisation sponsoring the research
- copies of any participant invitation letters, information sheets and consent forms
- copies of any research instruments (questionnaires, interview schedules, etc)

Once submitted, the IRAS application form is sent out for review by members of HEE Research Governance Group. Applications are reviewed to consider feasibility, alignment with other work within HEE, the potential impact of the research on staff, students and trainees, ethical assurance, and where HEE is acting as sponsor, that sponsorship responsibilities have been met including whether the proposed research is worthwhile and rigorous. The group will also ensure that data access and usage issues have been appropriately addressed and that HEE will benefit from the knowledge created through feedback and dissemination of findings. In some instances (see below) the group may also provide ethical review and where necessary, formal Health Research Authority (HRA) application may be advised. The terms of reference of the HEE Research Governance Group are provided within this document.

If HEE staff, students or trainees are being approached in their capacity as NHS service-providers, or patients are involved in the research in any way, then HRA approval will also need to be sought and the IRAS form will also need to be submitted to the HRA in the normal way. [HRA Approval](#) is the new process for the NHS in England that brings together the assessment of governance and legal compliance with independent ethical opinion provided through the UK Health Departments' Research Ethics Service.

For example; if as part of a project a researcher intends to ask surgical trainees about their views on a new curriculum, then HEE governance approval will be required but a formal application to the HRA will not. However, if the research will involve interviews with patients about their interaction with surgical trainees, or workplace observations of those interactions, then both forms of approval will be required.

Research ethics

If the research to be conducted is purely educational or workforce-related, does not involve patients, tissue samples etc. and is otherwise low-risk and non-contentious, there is no longer a requirement for a formal NHS research ethics committee approval. The responsibility for ethical

assurance lies with the sponsoring organisation and so for research being conducted as part of an academic qualification, the relevant university ethics processes would be expected to be followed. This would normally include a panel or committee ethical review. Where HEE is the sponsor, the HEE Governance Group will take a risk-based approach and either form a view on whether all relevant ethical issues have been appropriately addressed, or seek the opinion of a formal ethics committee.

Research Sponsorship

For research being conducted as part of an academic qualification, the employer of the student's academic supervisor should normally assume the role of research 'sponsor' - details of which will need to be included on the IRAS form.

For research being conducted under the aegis of HEE then the 'sponsorship' of an appropriate senior member of staff (e.g. postgraduate dean or director of education quality) to act as 'sponsor' must be secured. Once the IRAS form has been reviewed by the Research Governance Group a recommendation will be made to the appropriate senior member of staff to accept (or not) their sponsorship of the study.

Guidance on the expectations of a research sponsor can be found [here](#). These encompass a range of responsibilities including overseeing the quality and rigour of the research, ensuring appropriate supervision and confirming that appropriate indemnity is in place.

d. Request for research partnership

Requests for HEE to be named as a partner in a research bid will be considered by HEE's Research Governance Group. Alongside the potential relevance and impact of the proposed research on HEE's core business, the Research Governance Group will also consider the implications of the proposal in relation to workload, reputation, potential conflicts of interest and interaction with existing or planned national, regional or local HEE workstreams. The HEE Development team will ensure that all relevant teams within HEE are consulted.

What happens next?

Applications are normally reviewed within 20 working days of submission by HEE's Research Governance Group. The application may be approved, approved with modification or rejected. Applicants will then be notified of the decision by email.

HEE Research Governance Group

Terms of Reference

Objectives/ scope of the group

The aim of the Research Governance Group (RGG) is to provide strategic oversight of all health professions education research, evaluation and quality improvement activity across Health Education England (HEE). The group will:

- Promote research and other forms of inquiry within HEE including making recommendations from time to time on research priorities to the Department of Health R&D Committee
- Determine the appropriateness of research and related activities; assist their establishment and progress; and review their performance
- Review applications' impact on participants and their training/service delivery; and an assessment of possible risks/benefits to the organisation
- Ensure that all institutional research activity complies with research governance criteria as specified by the Department of Health and ensure HEE is accountable for its research activity
- Assess invitations from external organisations for HEE to act as a research partner in applications for research funding and projects
- Encourage and support the dissemination of research findings via appropriate media, including writing for publication and presentation at conferences
- Receive update reports from any ad hoc working groups established to oversee specific research, evaluation and quality improvement initiatives
- Make recommendations to HEE's senior leadership team on research and related activity, in line with priorities set annually
- Oversee the institutional mechanisms for the support of research, evaluation and quality improvement
- Provide ad hoc advice to HEE staff on all related matters
- Respond to all applications within 20 working days.

Membership

- Research and innovation representatives from the four HEE LETB regions
- Postgraduate Dean or nominated deputy
- NHS Leadership Academy representative
- HEE Development team research lead
- HEE information governance and access team representatives.

Members will be appointed by HEE's Director of Performance and Development on the basis of their expertise and experience.

Quorum

50% of group members are required for decisions.

Reporting arrangements

The RGG is accountable to, and will report to the HEE Board as required through the Executive Director of Performance and Development. A report of activity and issues will be produced six-monthly and will include records of enquiries received, decisions made and rationale. Minutes of group meetings will be available on request.

Frequency of meetings

The RGG will meet monthly but also convened on an *ad hoc* basis to consider proposals, and ensure that they comply with governance procedures. Business may be conducted electronically. Other working groups may be established on an *ad hoc* basis to deal with specific projects.

Terms of reference review dates

July 2018 and annually thereafter.

Application form

Name of applicant:	
Address:	
E-mail	
Telephone	
Nature of project	<ul style="list-style-type: none"> • Research • Evaluation • Quality improvement (including audit) • Request for research partnership
Title of project	
Description of project <i>Briefly explain your research question(s), why this is important, the method(s) you intend to use to answer your question, how data will be analysed and how your research will contribute to advancing the relevant field (500 words maximum)</i>	
Value of the research or inquiry <i>Please explain the value of the research in relation to the HEE's purpose and strategic objectives</i>	
HEE involvement <i>Provide details of the assistance or involvement you are seeking from HEE, such as access to</i> <ul style="list-style-type: none"> • information held by HEE • staff • students or trainees 	
Impact on staff <i>Please estimate the time required from HEE staff (if applicable)</i>	
Dissemination <i>Explain how you intend to disseminate your work and who it will be of interest to. It is expected that the final report or thesis is presented to HEE in a way that enables the sharing of key findings as widely as</i>	

<i>possible.</i>	
Other impact <i>If you think there are other important aspects of the proposal not covered elsewhere, please state them here</i>	
Ethical approval (if appropriate) <i>Please send a copy of any approval letter and a copy of the ethics application</i>	<ul style="list-style-type: none"> • Attached • Not yet received • Not required
Institution/organisation <i>Department</i> <i>Faculty</i> <i>Address</i>	
Supervisor <i>Name</i> <i>Position</i> <i>Email</i> <i>Phone</i>	
Funding <i>Is the research or related activity funded?</i> <i>If so, who by?</i>	
Project timescale <i>Start</i> <i>End</i>	
Other comments	
Supporting documents <i>Please list any supporting documents</i>	

- When you have completed all parts of the form in detail, please email it to ri@hee.nhs.uk.
- Allow 20 working days for the approval process to take place.
- Please contact the HEE Development team (ri@hee.nhs.uk) if you have any questions.