



University of East Anglia

Research Governance Guidance for Researchers and Supervisors

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**Please note it is the individual's responsibility to check that they are using the current version of this guidance. Please visit the Research Enterprise & Engagement intranet to check for the latest version: <http://www.uea.ac.uk/rbs/Research/Research+Governance>*

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University of East Anglia

1. Research Governance Framework for Health and Social Care

All research in the University should comply with the University's guidance and policies on Good Practice in Research

https://www1.uea.ac.uk/polopoly_fs/1.34534!policy-good-research-practice-apr2006.pdf

and the University Research Ethics Policy

http://www1.uea.ac.uk/polopoly_fs/1.29004!research-ethics-policy-final-21june2006.pdf

Q. What is the Research Governance Framework for Health and Social Care ?

- A. The RGF is published by the Department Health (currently in second version, 2005) and sets standards of good practice for all research in health and social care. It is designed to ensure quality and protect participants. It designates a series of roles and responsibilities for all those involved in research. It applies to all such research whether externally funded or not and regardless of who will undertake the research – i.e. student projects as well as staff.

The Research Governance Framework is presented with diagrams, definitions, and illustrative scenarios, and is recommended reading. It can be found here

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationPolicyAndGuidance/DH_4108962

Q. Why do we have to comply with the Research Governance Framework if we participate in research involving NHS or Social Services?

- A. The Research Governance Framework states that the responsibility of organisations providing care is to:

Require that no research study with human participants for whom the organisation is responsible (or their organs, tissue or data), begins until

- a sponsor has confirmed it has taken responsibility;
- the proposed research has a favourable ethical opinion (and if the study is a trial of a medicine, until there is a clinical trial authorisation); and
- a person authorised to do so has given written permission on behalf of the organisation providing care.

In other words, if your research study does not have written permission and a favourable ethical opinion **it will not take place !**

Q. I don't work in the Faculty of Health – does it apply to me at all?

- A. Yes it may do – if your research is undertaken within health or social care or might have an impact on those services. Any researcher, no matter from what discipline needs to be aware of the roles and responsibilities under the Framework. If in doubt – ask Research, Enterprise & Engagement for advice. It includes research that uses any NHS or Social Care resources – including staff or data.

The Research Governance Framework and the Social Sciences **Section 6**

Q. I am collaborating with staff in an NHS Trust – what do I need to do?

- A. You must make yourself aware of the Framework and obligations under it and ensure that your NHS partners are too.

You should make Research, Enterprise & Engagement (REE) at UEA and also the R&D office at the Trust aware of the project so that they can discuss the administrative arrangements for the study – including indemnity arrangements etc and help you decide the designation of responsibilities.

You must have the formal approval of the Trust's Governance Committee (or equivalent) and NHS Ethics Committee so should make yourself aware of what is needed for this, and both committees will be able to help and advise you.

See the UEA *Guidance for sponsorship enquiries – NHS partners* **Section 3**

Q. Why do I have to submit to the Research Governance Committee and the NHS Research Ethics Committee?

- A. Research Governance Committee approval (sometimes known as R&D approval, NHS management approval, research management and governance (RM&G) approval or NHS permission) considers the science of the research and ensures that adequate arrangements and resources are available, while the Ethics Committee principally protects the dignity, rights, safety and wellbeing of participants.

Q. I am collaborating with staff in a Social Care organisation – what do I need to do?

- A. Councils with Social Services Responsibilities (CSSRs) should now have systems in place to comply with the Research Governance Framework, but as their Implementation Plan was not published until 2004, the development of procedures is not as advanced as in the NHS.

You must make yourself aware of the Framework and obligations under it and make sure that your Social Care partners are too.

You should make Research, Enterprise & Engagement (REE) at UEA and the Social Care organisation aware of the project so that they can discuss the administrative arrangements for the study – including indemnity arrangements etc and help you decide the designation of responsibilities.

You are likely to need the formal approval of the CSSR and must have approval from the University Ethics Committee (although the provision of Ethics Committees for Social Care is under consultation) and you should make yourself aware of the requirements for both of these.

See the UEA *Guidance for sponsorship enquiries – Social Care partners* **Section 7**

About the development and implementation of the Plan for the Research Governance Framework in Social Care, published in May 2004

http://www.dh.gov.uk/en/Policyandguidance/Researchanddevelopment/A-Z/DH_4002132

Report from the Planning Group on Ethics Review in Social Care Research (December 2007)

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationPolicyAndGuidance/DH_081429

Q. Why do I need a sponsor?

- A. Under the terms of the RGF all research taking place in the NHS or Social Care must conform to certain standards. These include reviews of the scientific quality, resource use and ethical issues. In order to make sure these and other requirements are satisfied each study must have a sponsor, whose responsibility it is to ensure that the RGF is implemented. (This is not to be confused with the use of the word “sponsor” to describe the funder of a research project. Many funders have declared that they are unable to stand as sponsor under the RGF.)

For further information about sponsorship see

http://www.rdforum.nhs.uk/docs/sponsorship_principles_280705.doc

and

<http://www.rdforum.nhs.uk/docs/sponsorshipfaq.doc>

Q. The Integrated Research Application System (IRAS) form asks me questions about who is sponsor of the project and about indemnity cover. How do I answer these questions?

- A. Before completing the IRAS form you should read the UEA *Guidance for sponsorship enquiries – working with NHS partners* **Section 3**

You will need to provide Research, Enterprise & Engagement (REE) at UEA with a copy of your proposal and all associated documents, a pdf copy of your draft IRAS form and a completed University Cover Sheet **Section 5**. REE will confirm if UEA are happy to act as sponsor or if it is more appropriate to ask another organisation.

Q. When do I need to do something about finding a sponsor for my study?

- A. Do this as early as possible to allow time for any issues to be investigated. UEA sponsorship and indemnity **must always** be confirmed on a project by project basis.

Some funders may require you to identify a sponsor at the time you apply for funding.

Whether your study is funded or not it is worthwhile to consider Research Governance and Ethics issues early in the development of your protocol, and to contact Research, Enterprise & Engagement (REE).

Q. Where can I find information on the NHS Ethics procedures?

- A. There are a number of sources of information:
- REE or a Trust R&D office
 - <http://www.nres.npsa.nhs.uk/>
 - Local Research Ethics Committee office (Norfolk REC, Coordinator – Mrs Jeanette Guymer janette.guymer@nnuh.nhs.uk 01603 286397) Details of other committees can be found on the NRES website.
 - Research Design Service - contact Deborah Halliday deborah.halliday@uea.ac.uk
 - any colleagues who have been through the process recently.

Q. What are the contact details for R&D offices in our local NHS partners?

- A. The Health Research in Norfolk and Waveney website provides contact details, and extensive information about health research in the local area. <http://www.norfolkhealthresearch.nhs.uk/nhr/index.html>

2. Differentiating Audit, Service Evaluation and Research

Please click here to download the NRES document on differentiating Audit, Service Evaluation and Research (pdf document)

<http://www.nres.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?alld=320>

3. Guidance for sponsorship enquiries – working with NHS partners

Use the links from **Section 1** to ensure you are familiar with the requirements of the Research Governance Framework.

Please complete the University Cover Sheet **Section 5** and email it to REE.

Send us a copy of your research proposal, any associated documents, participant information sheets and consent (electronically is preferred) a pdf copy of your draft IRAS form and your cv. We will arrange for this to be reviewed for confirmation of sponsorship and indemnity. It usually takes a couple of weeks to get the proposal reviewed by REE.

Completing the IRAS form and using NIHR CSP

ALL applicants should now be using the Integrated Research Application System (IRAS).

Guidance on completing the IRAS form is available on the website <http://www.nres.npsa.nhs.uk/> and also at <http://www.myresearchproject.org.uk>

The NIHR Coordinated System for Gaining NHS Permission (NIHR CSP) will streamline the processes by which NHS Trusts provide permission for new research.

NIHR CSP **must** be used by researchers whose research is automatically eligible for inclusion on the NIHR Clinical Research Network Portfolio, or where the researcher needs to apply for acceptance on to the Portfolio.

If your study is not adopted on to the NIHR Portfolio, your NHS partners will not receive support from the NIHR Clinical Research Networks and Support funding.

[CSP Info for researchers in N&S CLRN Version 1.0](#)

Non-portfolio research, which will include most student research, should continue to apply directly to the NHS Trust where the research will take place.

Important information for student projects

For student projects up to and including Masters level the student supervisor must be named as Chief Investigator. This does not prevent the student(s) from completing the application and undertaking the administration.

Sponsorship and indemnity questions

Where the Chief Investigator is a UEA member of staff or a registered student you may assume when you initially complete the IRAS form that UEA will be sponsor, and REE will confirm this once your documents have been reviewed.

For A77-1 and A77-2 (these are numbered A76-1 and A76-2 in IRAS version 2.0) we suggest The university has appropriate insurance policies in place to provide professional indemnity and public liability cover. Please refer to attached letter.

For A77-3 (this is numbered A76-3 in IRAS version 2.0) we suggest All participants will be recruited at NHS sites and NHS indemnity scheme or professional indemnity will apply.

Where this does not fit the circumstances of your study please contact REE to discuss appropriate answers.

For A78 (May not appear on all versions of the form) (A77 in IRAS version 2.0) There are no specific arrangements to provide indemnity or compensation for non-negligent harm. This is made clear to participants as part of the consent stage. [this should be included in your participant information sheet]

At A65-1 and A65-2 (A64-1 and A64-2 in IRAS version 2.0) For the Sponsor contact details you should put the name and details of the Research Contracts Manager who is handling your application, once you know who this is.

Getting confirmation of sponsorship

At this point you need to send your draft IRAS form (as pdf) the protocol or proposal, information sheet, consent form, any other study related documents and the University Cover Sheet to <mailto:researchsponsor@uea.ac.uk>

Once REE has confirmed UEA sponsorship we will email you to confirm UEA sponsorship in principle.

Submitting to Research Governance and Ethics

The IRAS system enables you to produce a form for submission to the Research Ethics Committee (REC) and an R&D form for submission to NHS CSP or the Trust.

From 1 April 2009 www.myresearchproject.org.uk **all applications for research governance approval and a favourable ethical opinion should be submitted using the IRAS form** (available at www.myresearchproject.org.uk).

Important information for student research studies

Following recent discussions by both the East Norfolk & Waveney Research Governance Committee and the East Norfolk & Waveney Research Consortium Board it has been decided that with effect from **1 April 2009** the East Norfolk & Waveney Research Governance Committee will no longer provide a scientific peer review service for **any** research undertaken for the purpose of gaining an academic award - this includes studies at doctorate level.

All students will have to demonstrate that their research application has been subject to peer review by their academic supervisor. For those applications submitted on the IRAS form the academic supervisor should sign the declaration in Part D3 of IRAS for all projects undertaken in fulfilment of educational qualifications. The declaration provides assurance of:

- The scientific and ethical quality of the research proposal and the safety and well-being of participants.
- The ability of the applicant to conduct the proposed research.
- The availability of time and resources to achieve the proposed research objectives.

- Active and effective arrangements to monitor and assess the progress of the research (in liaison with clinical supervisors and others where appropriate).
- Appropriate arrangements to disseminate the findings of the research.
- Before the student submits the application, the academic supervisor should assess the level of experience of the student, taking into account the scale of the research and the potential for harm to participants.

The NRES form will only be accepted if a student can demonstrate that a submission has already been made to an Ethics Committee using the NRES form. In these cases students will need to provide separate written confirmation from their academic supervisor that clearly demonstrates that the points above have been considered.

Research governance approval will only be given once a Favourable Ethical opinion has been obtained.

Obtaining signatures – All studies

You will need a signature from REE on part D of the R&D and Ethics forms before you can submit them. You can obtain these signatures electronically, by following the instructions on the IRAS website, or in ink on a paper copy of your forms.

We will also provide you with a letter confirming insurance and indemnity arrangements at the time that your Ethics form is signed. You should send the signed original of the indemnity letter in with your Ethics application.

You will need to send a copy of the indemnity letter, to the Research Governance Committee, either at the time of application or when you contact them again to confirm that you have a favourable opinion from the Ethics Committee.

Submission of REC forms

Changes have been made to allow more time to collect signatures and authorisations for the REC application form prior to final submission.

When the application is booked for review, it is now possible to enter the name of the REC and REC reference number on the version of the form stored in the submission history without creating a new version with a different submission code. This means that the project owner can print the form and collect signatures prior to booking the application. It avoids the need to book the application first, then print the form with the REC details included and arrange for signature within the four days allowed for final submission.

University Confirmation that the research may take place

You **must** provide REE with a copy of the letter from the Research Governance Committee/NHS Permissions system which confirms that you have full Research Governance approval following a favourable opinion from the Research Ethics Committee, before you begin your research.

4 NIHR CSP Coordinated System for gaining NHS Permission

[Click here to download](#)

5. Research Governance Framework University Cover Sheet

Please fill in this form if you wish to confirm UEA sponsorship and indemnity cover for research that you are undertaking, and which has NHS or Social Care involvement.

[Please click here to download the Cover Sheet](#)

6. The Research Governance Framework and the social sciences

Background

The Department of Health Research Governance Framework for Health and Social Care was written with the safety, wellbeing and dignity of human research participants in mind. The greatest emphasis so far has been on improving the standards of research in health care. As a result the relevance of the Framework to other areas of research has not been fully highlighted to date.

The Department of Health Research Governance Framework for Health & Social Care was first released in 2001 with an update in 2005 to take into account a number of changes in UK law including The Health and Social Care (Community Health and Standards) Act 2003 and the Mental Capacity Act 2005.

With help from the Department of Health, Local Authorities are now turning their attention to how they can best comply with the Framework. In some instances systems development is being extended beyond ensuring compulsory compliance of just social care research to the development of corporate-wide approach to RGF compliance in research. As a result it is possible that those engaged in Education research may also find new Framework compliant local authority processes in place.

As a research-rich institution, the University already has a set of policies, codes of practice and procedures that govern how research is administered, including good research practice, research ethics and misconduct. This is a dynamic issue and these are updated in line with internal and external developments.

With particular regards to social scientists, the thread that runs through the RGF is the need to keep the rights and welfare of participants at the centre of research related decisions. The RGF draws on existing law (e.g. Health and Safety legislation and the Data Protection Act), it sets the standards by which compliance can be achieved and lists the responsibilities of all parties involved in the research process.

External drivers for investigators to comply with the Framework include expectations of host organisations such as local authorities (social care), ethics committees and funding bodies. A number of professional and funding bodies have also developed their own guidelines in support of good research practice which are very much in line with the requirements outlined within the Framework. Compliance with funding body good research practice guidelines is often a condition of grant awards.

Impact on the management of research projects

An increasing number of funders and hosts of research request evidence that investigators are putting the welfare of research participants at the centre of their research activity. As a result, evidence of compliance with the standards of the RGF will increase your chances of successful application for research funding and management approval by host care organisations (e.g. access to social care clients or even NHS patients).

Research Governance is relevant to all those involved in research including those carrying out smaller, shorter term projects or projects conducted by students. The participants in these projects also have a right to expect that their rights and wellbeing will be safeguarded.

Typically the following will be relevant for social science research:

- Research should undergo appropriate independent scientific review
- Research should be registered with employer and host organisations
- Research raising ethical issues should undergo review by a research ethics committee
- There should be appropriate arrangements for dealing with adverse events and compensation
- There should be appropriate arrangements to support participants in giving informed consent
- There should be arrangements to ensure the confidentiality of participants
- There should be appropriate monitoring arrangements and lead investigators should cooperate with audits and inspections

University authorisation

It will be standard practice for you to register your research with Research, Enterprise & Engagement and to obtain permission from host organisations you intend to work with.

The method by which permission from host organisations is granted varies widely. One of the new responsibilities of Councils with Social Services Responsibilities (CSSRs) is to record the basic details of the research activity involving their organisation. It is possible that in some parts of the country CSSRs will combine forces (possibly also with Primary Care Trusts and NHS Trusts) to form Research Governance Alliances to support this process.

The Framework introduces terminology such as research sponsorship. In this context the sponsor is the organisation responsible for ensuring that all other agents (research employer, care organisations, research funder and research provider) in the research process are aware of, and willing to discharge, their respective responsibilities under the Framework.

The Research Governance Framework for Health and Social Care http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962 is relevant to your research as it is the means by which quality of research can be assured and the rights of those involved can be protected.

You should also see

About the development and implementation of the Plan for the Research Governance Framework in Social Care, published in May 2004

http://www.dh.gov.uk/en/Policyandguidance/Researchanddevelopment/A-Z/DH_4002132

Report from the Planning Group on Ethics Review in Social Care Research (December 2007)

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_081429

Useful references:

1. The British Psychological Society: Good Practice Guidelines for the Conduct of Psychological research within the NHS
2. The ESRC [research ethics framework](#) for social science research
3. [Social care information governance](#)

7. Guidance for sponsorship enquiries – working with Social Care partners

Use the links from **(Section 1)** to ensure you are familiar with the requirements of the Research Governance Framework.

Please complete the University Cover Sheet **(Section 5)** and email it to [Research, Enterprise & Engagement](#).

Send us a copy of your research proposal, any associated documents, participant information sheets and consent (electronically is preferred) and your cv. We will arrange for this to be reviewed for confirmation of sponsorship and indemnity.

It usually takes a couple of weeks to get the proposal reviewed. You may wish to submit your study for approval by the Social Care organisation that you are working with while this is happening. Please let us have contact details and UEA will notify the relevant review body that UEA have agreed in principle to be Sponsor.

We will also provide you with a letter confirming UEA insurance and indemnity arrangements.

Additionally you will need to have your project reviewed by one of the University Ethics Committees. Please see the Research Ethics pages of the Research, Enterprise & Engagement intranet site.

The provision of Ethics Committees for Social Care is under consultation and you should refer to these documents for more information:

About the development and implementation of the Plan for the Research Governance Framework in Social Care, published in May 2004

http://www.dh.gov.uk/en/Policyandguidance/Researchanddevelopment/A-Z/DH_4002132

Report from the Planning Group on Ethics Review in Social Care Research (December 2007)

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_081429

Social Care and NHS research partners

It is possible that your research will involve NHS and Social Care partners. In that case you will need to apply for permission and approval to the NHS Trust, the NHS Research Ethics Committee, and the Social Care organisation.

The University Ethics Committee recognises review by NHS RECs so you will not require additional ethics review at present. However, if Social Care Research Ethics Committees are created, this may change.

8. Useful Links

Internal Links

University's guidance and policies on Good Practice in Research

https://www1.uea.ac.uk/polopoly_fs/1.34534!policy-good-research-practice-apr2006.pdf

University Research Ethics Policy

http://www1.uea.ac.uk/polopoly_fs/1.29004!research-ethics-policy-final-21june2006.pdf

Human Body Tissues [Local rules for work]

http://www.uea.ac.uk/bio/ueanetwk/safety/2004_updates/LOCAL%20RULES%20FOR%20WORK%20WITH%20HUMAN%20BODY%20TISSUES.pdf

Human Tissues [Registration form for person working with...]

http://www.uea.ac.uk/bio/ueanetwk/safety/2004_updates/HT%20REG1Human%20tissue%20registration.pdf

Human Tissues and Body Fluids [Scheme of work for handling]

http://www.uea.ac.uk/bio/ueanetwk/safety/2004_updates/SCHEME%20Approved%20scheme%20of%20work_human%20tissues_.pdf

External Links

DH Research Governance documents – Index

<http://www.dh.gov.uk/en/Policyandguidance/Researchanddevelopment/A-Z/Researchgovernance/index.htm>

The Research Governance Framework

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962

Plan for the Research Governance Framework in Social Care, published in May 2004

http://www.dh.gov.uk/en/Policyandguidance/Researchanddevelopment/A-Z/DH_4002132

Further information about sponsorship

http://www.rdforum.nhs.uk/docs/sponsorship_principles_280705.doc

and

<http://www.rdforum.nhs.uk/docs/sponsorshipfaq.doc>

National Research Ethics Service

<http://www.nres.npsa.nhs.uk/>

Health Research Norfolk and Waveney

<http://www.norfolkhealthresearch.nhs.uk/nhr/index.html>

Mental Capacity Act 2005 – Code of Practice

www.opsi.gov.uk/acts/en2005/ukpgaen_20050009_en_cop.pdf

A simple guide to the Mental Capacity Act 2005 in relation to research

http://www.rdforum.nhs.uk/docs/mca_guidance.doc

Clinical Trials Toolkit

<http://www.ct-toolkit.ac.uk/>

Data and Tissues Toolkit

<http://www.dt-toolkit.ac.uk/home.cfm>

A Draft document – “Consent for Consent”

http://www.dt-toolkit.ac.uk/_db/_documents/Consent_for_Consent_DRAFT.pdf

Research Passports

http://www.ukcrc.org/PDF/RESEARCH_PASSPORT_LEAFLET_vUUK.pdf

UK Panel for Research Integrity in Health and Biomedical Sciences

www.ukrio.org

Research in the NHS: indemnity arrangements

www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4125281

Clinical trials for medicinal products – MHRA

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=101

Clinical trials for medical devices - MHRA

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=194