

Research Ethics and Governance

Background

All research carried out in NHS premises must be approved by the institutions that are hosting the research. This is known as research governance approval or NHS R&D management approval. In addition, research ethics approval is required if the research involves any of the following:

- patients and users of the NHS, and participants recruited by virtue of the patient's or users past/present treatment
- participants identified due to status as relatives/carers of above
- NHS staff (professional or voluntary)
- access to data/tissue

Applying for research governance and ethical approval

Applications for research governance approval are made to the R&D Office or Lead of the NHS institution(s) in which the research is to take place. Where research is to be confined to one site and is not a clinical trial of a medicinal product, applications for ethical approval are made to the local Research Ethics Committee (LREC). Multi-site research studies apply via the Central allocation system. It is recommended that conditional funding is secured and research governance approval obtained before applying for research ethics approval as this will ensure that research proposals/protocols are finalised and agreed before undergoing REC review.

Research governance

Research governance systems are the responsibility of NHS institutions and are concerned with improving research quality and safeguarding the public by:

- enhancing ethical and scientific quality;
- promoting good practice;
- reducing adverse incidents and ensuring lessons are learned; and,
- preventing poor performance and misconduct.

This ensures that all research is carried out according to the principles of good governance.

Research ethics

Research Ethics Committees are in place to protect the dignity, rights, safety and well-being of all actual or potential research participants. They provide independent advice on compliance with ethical standards to participants, researchers, funders, sponsors, employers, care organisations and professionals. Issues addressed by the REC application form are:

- scientific design and conduct of the research;
- recruitment of research participants;
- care and protection of research participants;
- protection of research participants' confidentiality;
- informed consent process; and,
- community considerations.

Useful websites

Guidance and application forms for research governance approval (R&D form) are to be found at www.rdforum.nhs.uk. Extensive guidance and application forms for ethical approval are to be found at the website of the Central Office for Research Ethics

Committees (COREC) website www.corec.org.uk. Applicants are required to register with the COREC or R&D websites to obtain a username and password. This only needs to be done at the first application. Once a username and password is accepted, they can be used each time the researcher makes an application. The application forms can be completed and submitted electronically. They need not be completed at one sitting, as the system saves progress every time a page is completed. In addition, when the A and B forms on the COREC form website are completed satisfactorily, data relevant to the application for research governance approval can be transferred to the R&D form saving duplication of effort. Guidance to all of these procedures is to be found on the websites above.

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