

## **Research Governance and Ethics**

### **Research Governance Framework for Health and Social Care**

The research governance framework aims to enhance the scientific and ethical quality of research, to promote good practice, reduce adverse incidents and prevent poor performance and misconduct. More details regarding the research governance framework is available from the Dept. of Health ([www. Dh.gov.uk](http://www.Dh.gov.uk)). All research projects undertaken with NHS patients or staff must obtain approval from both the Research Governance and Ethics committees. The details of these committees in Norfolk and Suffolk are detailed below.

### **Study Requirements and Researchers Responsibilities**

The research governance framework sets standards that all research studies must achieve. They generally fall within 5 categories, ethics, science, information, health and safety and finance & intellectual property. All researchers are obliged to show that they adhere to the research governance framework, by meeting the standards set. Researchers also have responsibilities and accountability for all research they undertake.

The ethical requirements of any study include the following points: informed consent is taken; the study undergoes an independent review; the consent of relatives is obtained if deceased persons tissues or organs are used; confidentiality is maintained; there is patient public involvement in the research study; the multicultural nature of our society is accounted for.

The scientific requirements are to ensure that a systematic review has been performed, the protocol has been peer reviewed, the medicine control agency has been informed if new medicines are used and there is provision for data archiving. The main information requirement is that the outcome of the study should be published or disseminated. There is also a requirement to protect the safety of staff and subjects. Finally, compensation must be available to participants if they are harmed due to negligence.

Researchers bear the day to day responsibility for the conduct of the research study. They must ensure the protocol is adhered to and that participants receive appropriate care. All confidential information should be protected and any adverse events, such as drug reactions or suspected misconduct should be reported. The principal investigator has additional responsibility. They must take responsibility for the conduct of the research and is accountable for this to their employer and to the sponsor of the research and care organisation within which the research takes place or through which participants, their organs, tissue or data are accessed. All of this information is available in more detail in The Research Governance Framework, available from the Dept. of Health ([www. Dh.gov.uk](http://www. Dh.gov.uk)).

## Central Office for Research Ethics Committees (COREC)

COREC issue guidelines outlining the new ethics committee procedures. In brief, all new submissions must be made on the electronic REC application form. Depending upon the design of your study, you will need to call either your local REC or the COREC central allocation system to obtain a reference no. prior to submitting your application. For example, if your study is a clinical trial of a new medicinal product or is taking place in more than one domain then you must apply via the central allocation system (Tel: 0845 270 4400). Web page: [www.corec.org.uk](http://www.corec.org.uk), [comments or queries to queries@corec.org.uk](mailto:comments_or_queries@corec.org.uk).

## Patient Information Sheets and Consent Forms

If appropriate to the design of your study you may be required to provide copies of your patient information sheet and consent form with your ethics application. COREC issue guidelines for researchers on how to design these forms, available on their webpage. RD direct also provide a sample consent form ([www.rdinfo.org.uk/flowchart/ConsentForm.htm](http://www.rdinfo.org.uk/flowchart/ConsentForm.htm)).

## What Makes Clinical Research Ethical?

When designing your study you should ensure that the dignity, rights, safety and wellbeing of your participants is a primary consideration. When submitting your study for ethical approval you should be aware of the ethical issues that can arise. The points stated below give some indication of the ethical requirements of all health care research.

Emmanuel, Wendler & Grady (2000), suggest that all healthcare research should fulfil 7 ethical requirements. These are:-

- (1) social or scientific value – enhancements of health or knowledge must be derived from the work,
- (2) scientific validity – the research must be methodologically rigorous,
- (3) fair subject selection – scientific objectives, not vulnerability or privilege should determine selection of subjects,
- (4) favourable risk-benefit ratio – risks must be minimised, potential benefits enhanced, and the potential benefits to individuals and knowledge gained for society must outweigh the risks,
- (5) independent review – unaffiliated individuals must review the research and approve, amend or terminate it,
- (6) informed consent – individuals should be informed of the research and provide their voluntary consent,
- (7) respect for potential and enrolled subjects – subjects should have their privacy protected, the opportunity to withdraw, and their well being monitored. These ethical requirements are listed in chronological order from conception of research to its formulation and implementation.

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