

What does research governance mean...

... if I'm asked to take part in research?

Hopefully you will feel more confident that any research that you are asked to be part of, is a good and necessary piece of research. The research should be explained to you in a clear, understandable way and once the study has finished you should be told about results.

...if I want to do my own research?

If your research does not need any funding, then it will depend on what your research is and who you need to take part. If your research involves asking people to take part from a particular hospital clinic, GP surgery or in hospital or GP premises or through social services, then you will still need to work within the research governance framework.

If your research involves people from your user group or support group, then you are not currently required to follow the steps of research governance. For further information regarding ethical issues, contact COREC (Central Office for Research Ethics Committees), details of which can be found on the back of this leaflet.

Useful contacts:

Department of Health website

www.doh.gov.uk/

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Exeter & North Devon NHS
**Research &
Development**
Support Unit



research governance in health made simple

A brief introduction to the Research Governance Framework for Health and Social Care 2001

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What is research governance?

Research governance is about the rules and procedures drawn up by the Department of Health to make sure that all NHS, medical or social care organisations (e.g. hospitals, GP surgeries and day centres) involved in research are aware of, and take responsibility for, all the research going on.

Why do we have research governance?

There is a need to have clearly laid out rules for good quality research, which has the respect of the patient clearly at the centre. The scandal at Alder Hey hospital (in Liverpool) where organs were systematically removed from hundreds of dead children without their parents' knowledge or consent is a good example of the need for research governance.

What happened before research governance?

- someone (such as a doctor, nurse, service user or carer) had a bright idea
- all the idea needed was some of their time
- they may/may not have sought ethical approval even if patients were involved in the research
- they went ahead and did their research possibly without the hospital, practice/day centre even knowing about it.

What happens now?

- someone (such as a doctor, nurse, service user or carer) has a bright idea
- all the idea needs is some of their time
- their research idea must be considered worth investigating (by an independent scientific review)
- they have to seek ethical approval if the research involves NHS patients or staff
- an approved organisation (sponsor) must accept responsibility for the quality of the research
- the host institution must allow the research to take place within it.

Only when they have ethical approval, and a sponsor to agree to take responsibility for the research can the research go ahead.

What is an independent scientific review?

Before the research is allowed to go ahead the proposal (what the research is about and how it will be done) must have been read and approved by a professional researcher who is not involved in the project. They decide if the proposal:

- is a good one!
- is worth doing
- has involved patients in the design
- will be done in the right way to find out the answer
- is looking at all the relevant things.

What is ethical approval?

All research which involves NHS/social care service users and staff requires ethical approval. Research proposals go to a Research Ethics Committee (REC). The committee is made up of lay people and health professionals who look at the research and decide whether it could possibly cause any harm (emotional as well as physical) to the participant. The ethics committee will only give approval for the research project when:

- risks to anyone taking part are negligible or minimal
- everyone agreeing to take part understands what is expected of them
- everyone understands that they can refuse to take part or leave the study at any time.

What is an approved organisation?

In 2000 the Department of Health set strict criteria which NHS organisations, universities and charities have to meet in order to become a sponsor. A sponsor ensures that the research is of high quality and has suitable checks in place to make sure that all the research is known about and carried out properly.