

Research Awareness Factsheet

This factsheet has been developed specifically for people who are not undertaking any direct study activities but are working in a research active environment and need an understanding of what is going on around them.

Why does research matter?

Health and social care research matters to us all.

Research is essential to find out which treatments could be better for patients. It plays an important role in discovering new treatments, and making sure we use existing treatments in the best possible ways. Research can find answers to things that are unknown, filling gaps in knowledge and changing the way health and social care professionals work.

Research and clinical trials are an everyday part of the NHS, community and social care. People being cared for in the NHS benefit from past research, and continue to benefit from research that is currently being carried out. Ultimately, high-quality clinical research helps the NHS to improve future healthcare.

From paracetamol and chemotherapy, to physiotherapy and treatments for depression; without research, many of the treatments and types of care we receive today wouldn't be available.

Research governance is all about how we manage that research.



What is research governance?

Research governance is one of the core standards for health and social care and involves a broad range of regulations, principles and standards of good practice that exist to achieve, and continuously improve, research quality in the UK and worldwide.

Who does it apply to?

Research governance applies to everyone connected to health and social care research. Whether as a scientist leading on a study, a care professional working with the participants or support staff helping at a site.

By research, this means any health or social care related research that involves humans, their tissue and/or data.

What is Good Clinical Practice?

Good Clinical Practice (GCP) is the international ethical and scientific quality standard that all research involving human participants must follow. Compliance with this standard provides the public assurance that the rights, safety and wellbeing of the people taking part in the research are protected and that the clinical trial data coming out is credible.

Regulations in the UK

The UK Policy Framework for Health and Social Care Research is a UK-wide document. It sets out the principles of good practice in the management of health and social care research in the UK which must be followed for all research involving human participants.

Additional standards for drug studies are set into UK law under the Medicines for Human Use (Clinical Trials) Regulations 2004.

But ... what does this all mean practically?

Documentation

- It is really important that everything we do in research is clearly documented so we can prove exactly what happened at the beginning, middle and end.
- This protects the people taking part in the research and makes sure the results of the study are high quality so people receiving this treatment or care in the future are protected too.
- All data collected must be complete. Any missing or incorrect information must be clearly documented by the research team.
- Any updates or corrections must clearly show the original entry and identify the person making that change and when. Reasons for the change must be clearly documented and show the lead researcher is involved.
- The best research practice is, “if it’s not written down it didn’t happen”.

Confidentiality

- People taking part in research have the right for their data to be collected and stored securely.
- Participants are given an ID number when they start a research study and all the data collected about them is identified by this number along with other things like their date of birth and initials.
- There will be a document which lists patient names and ID numbers together. This should be the only record of this information and must be stored securely at the site.
- Patient identifiable information such as names or addresses should not be listed on any study documentation that gets sent to the study sponsor for processing (unless specifically approved for that study).

Participant rights, safety and wellbeing

- We all have a duty of care towards our research participants, their data and any human tissue. Their rights, safety and wellbeing must always take priority.
- All participants have the right to freely choose to take part in research, having been given all the information they need to make an informed decision.
- If a participant chooses not to take part in a study this must not affect their care.
- Consent is an ongoing process and they are free to withdraw at any time.
- If a patient experiences any illness or injury these must be reported, even if it doesn't appear to be linked to the study.
- If a study involves a change to usual care (known as an intervention – such as being given a new drug, using a medical device, new exercise regime, different form of therapy) this must be delivered safely, as set out in the study documents.

Always check with your research team if you have any questions or concerns.

For more information visit: www.healthandcareresearchwales.org



3