Ymchwil Iechyd
a Gofal Cymru
Health and Care
Research Wales

Ariennir gan
Lywodraeth Cymru
Funded by
Welsh Government

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 care research plays an important role in all our lives.

It seeks to find answers about the best options to improve health and care for all of us.

Research can find answers to things that are unknown, filling gaps in knowledge and changing the way health and social care professionals work.

Research is an everyday part of the NHS, community and social care. High-quality research helps the NHS and social care providers to improve future care and treatment outcomes saving time and money.

What is research governance?

Research governance is all about setting and maintaining standards in how we manage our research.

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

Who does it apply to?

Research governance applies to everyone connected to health and social care research that involves humans their tissue and or data. Whether as a scientist leading on a study, a care professional working with the people taking part or support staff.

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Can be stored in site file as evidence of staff training.

Regulations in the UK

The Mental Capacity Act 2006

The Children's Act 1989/2004

Drug studies, these must comply with Good Clinical Practice (GCP), GCP ensures the rights, safety and wellbeing of the people taking part in the research are protected and the results of the research are credible. Additional standards for drug studies are set into UK law under the Medicines for Human Use (Clinical Trials) Regulations.

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 every stage of the process.

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.

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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, or different form of therapy/care) this must be delivered safely, as set out in the study documents.

SCAN ME

For more information and training scan the QR code or visit our website:
www.HealthandCareResearchWales.org/support-and-guidance/training-courses

or contact Health and Care Research Wales by email:
HealthandCareResearch@Wales.NHS.UK

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