Module 3

Designing a Patient Centered Consent and Study Protocols

Key Questions:

What rules and laws protect people taking part in research studies?

What do people need to know before they decide whether to take part in a research study?

research protocols

contain all the things the team will do to perform the study

explain how the rights of people taking part in the study will be protected

RESEARCH RIGHTS:

- right to keep medical information private
- right to be informed of any risks for harm
- right to be treated ethically

developing a research protocol

the plan and procedures the study team will follow to conduct the study

KEY QUESTIONS:

Who will be in the study?
Where, when, and how will information be collected?
How will participants be protected?

protocols help keep the research team on track

protocols help document the planning that went into developing a study

components of a research protocol

REASONS FOR THE STUDY

why is this important?

RESEARCH QUESTION

what will we study?

METHODS

study design, PICOTS

PROCEDURES

plans for recruitment, data collection, data analysis, and data safety

PROTECTIONS

informed consent, risks & benefits, compensation, privacy & confidentiality

SHARING RESULTS

dissemination

patients and caregivers

have an important role to play in developing research protocols

experiences
and
points of view

help make sure the study plans and all the materials used are designed with patients in mind

clinicians and health educators also contribute important perspectives on protocols

research protocols might need to change when studies

- need more people
- need new ways to recruit more patients
- find an additional site
- need more or less time for the study
- change the intervention or treatment

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protecting rights

The Institutional Review Board (IRB) is key!

The IRB evaluates:

- possible risks to study participants
- protections against these risks
- potential benefits of the research for participants and others
- importance of the knowledge to be gained by doing the study

- universities and research institutions all have IRB's
- research team undergoes training to make sure they know how to keep people safe in research

why so many *precautions?*

history has proven it necessary

medical research didn't always put the rights of participants first

some participants ...

- were forced to participate without giving consent
- were not warned of the dangers of the study
- did not give consent and did not get care during the study or after it was over

3 famous cases led to many of the rules that researchers now follow

while extreme cases, the issues are the same and can still happen today without these rules

ethical violation	historical example
research participants forced to participate without giving consent	Nazi medical experiments on prisoners (1939-1945)
research participants not warned of the dangers of the study	experiments to understand the effects of radiation on the human body (1944-1974)
research participants did not consent or did not get care during the study or after it was over	Syphilis study of African American men at Tuskegee University (1932-1972)

health and safety of the participants must always come before the goals of the research

declaration of Helsinki

- a formal statement developed by the World Medical Association
- provides ethical guidelines for conducting research using human subjects
- widely cited in international research study publications

Belmont Report

the basis for the rules and ethical principles that guide modern research

- Respect for persons
- Beneficence
- Justice

Common Rule

a federal regulation that applies to all government supported research

- How research institutions make sure research is safe and ethical
- How an IRB is made and how it operates
- How to protect vulnerable groups
- What information people need to know before consenting to participate in a study

HIPAA

Health Insurance Portability and Accountability Act

1996

- protects patient health information such as diagnosed conditions you might have, what medicines you take, and what doctors you see
- applies to everyone who can see your medical information
- prohibits giving any of your health information to anyone without your consent

informed consent

- a person understands and is informed of details of the study
- gives permission to researchers to collect information

4 KEY ASPECTS:

the person in the study understands...

- everything that is being done in the study
- how privacy is being protected
- the risks and benefits of participating in the study
- they can stop participating in the study at any time

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sometimes there are *changes*

consent form and IRB need to address changes

needs and interest change and participants can withdraw at any time

changes in the study may require additional IRB review and require additional consents from participants

consent form should tell patients…

- What is the purpose of the study?
- How long will it last?
- How do I leave the study if I change my mind?
- What parts of the study are experimental?
- Are there any likely risks or discomfort expected?
- What benefits might someone get from being in the study
- How might the study help others?
- What other treatments may be available besides the ones in the study?
- How will personal information be kept confidential in the study?
- If there’s more than minimal risk of harm, is there any compensation available?
- Is there treatment for any injury that might occur? How is the treatment provided?
- Who can answer questions about the research and participants’ rights?

consent form

- every participant should be able to review the consent form in advance
- consent should be at an appropriate reading level and in appropriate languages
- someone should be available to answer questions about the study

assent form

- assent is a child's affirmative agreement to participate in research.
- sometimes as young as 7 but usually 11
- should use simple language that can be understood by the child

preparing a research protocol and planning to submit it for review by the IRB are crucial steps

studies should be focused on patients' needs and respect them as study participant

as members of a research team, patients, caregivers, and other stakeholders have a vital role to make sure research studies are safe and fair and that people invited to join the study understand the risks and benefits of doing so