COPD FOUNDATION

BRIDGE Patient to Investigator Training Module 7
Protections for Research Participants Summary Document

Research Protections were developed over time. Strong protections and federal regulations for people participating in research are in place today. They were created to make sure past abuses do not happen again.

Research Ethics Milestones *(click here to read "Summary of Research Milestones", a short history of protections for people who participate in research)*

- Nazi Experimentation (early 1940's)
- Nuremberg "Doctors Trial" (1946-1947)
- Nuremburg Code (1947)
- Willowbrook Study (1963-1966)
- Declaration of Helsinki (1964)
- Tuskegee Syphilis Study (Ended 1972)
- National Research Act (1974)
- Belmont Report (1979) – basic principles for the ethical treatment of people who participate in research
    - Respect: People must have a choice about what happens to them
    - Beneficence: "Doing good": The risks of a study cannot outweigh the possible benefits
    - Justice: The benefits and risks of research should be fairly shared across society

Federal laws are in place for how research should be done

- Protecting people in studies
- Informing people before they decide to join studies
- Reviewing research before it moves forward and while it is going on

The rules were created for everyone doing human subjects research – there are **no** exceptions

Institutional Review Boards (IRBs)

created in 1974 with the National research Act – are the organizations responsible for reviewing, approving and monitoring research and enforcing the rules.

- All research **must be reviewed and approved by an IRB** before starting
- The goal is to ensure that people joining studies will be **protected from unknown harm or risks**
- **IRBs weigh risks vs. benefits**, look at what protections are in place and if people in the study are informed about all the key pieces of the study before they decide to join
- Once a study is approved, **any changes must be reviewed by the IRB before they are put into place**
- IRBs conduct **yearly reviews** of all studies
- Any **unexpected** or **serious study issues** must be **reported to the IRB**
- People in the study can **call the IRB if they are concerned** about something with the study

Informed Consent

A document that outlines what will happen in the study, what is being asked of people who join the study and what the potential risks are. The document provides information on privacy and confidentiality and details what the person's rights are in the study, including the right to stop at any time. The informed consent provides contact information for the study team and the IRB and must be written in clear language that anyone could understand.

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To obtain an informed consent from a person:

- Must be reviewed and explained before a person can do any study activities
- Must be given freely – a person can change their mind at any time
- Must not be forced and ensure the person has enough time to think before agreeing to join the study
- Usually requires a written signature on the informed consent document
    - In some cases consent can be obtained verbally if approved by the IRB
    - In special cases can be provided by the person's legal representative

Privacy and confidentiality for people in a study must be respected at all times. How one's privacy and confidentiality will be protected must be written in the informed consent document and also in the protocol that the IRB reviews and approves.

Privacy - applies to the person	Confidentiality - applies to the data
• An understanding that **information an individual provides will not be shared with others without their permission**. • Involves the **methods and setting used to collect information** from study participants to ensure the information will remain private and **patients' wishes will be respected.**	• Involves **a person's identifiable information and the security in place** on who can see the information. • Involves the **procedures in place to ensure that only *authorized* individuals see the information**— in other words, only seen by people involved in running the research study or other approved people *(regulatory people such as the Food and Drug Administration or the National Institutes of Health).* • **All information is considered confidential**.

The Common Rule

The Common Rule is the short name for the Federal Policy for the Protection of Human Subjects that was published in 1991, recently updated in 2019 and is based on the 1979 Belmont Report (slide 7).
The Common Rule is the minimum standard of ethics that all government funded research in the United States is held to and is codified in the Health and Human Services (HHS) regulations, 45 CFR part 46.

The Health Insurance Portability and Accountability Act (HIPAA) was signed into law in 1996.
It has 3 main focuses:

- **Protect health care insurance coverage for individuals when they lose or change jobs.** (Portability)
- **Address fraud, abuse and waste in health care** insurance and the delivery of health care.
- **Ensure the security and confidentiality of patient information.** (Accountability)

HIPAA required that the U.S. Department of Health and Human Services create "Privacy and Security Rules" that health care organizations and insurance companies must follow.

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