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BRIDGE Patient to Investigator Training Module 7
Protections for Research Participants Key Terms and Definitions

Belmont Report (1979): The Belmont Report summarizes ethical principles and guidelines for research involving human participants. Three core principles are identified: respect for persons, beneficence, and justice.

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. 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.

Confidentiality: Involves a person's identifiable information and the security and procedures in place to ensure that only *authorized* individuals see this information.

Declaration of Helsinki (1964): The World Medical Association, meeting in Helsinki, Finland, approved principles for ethical research. Important principles are:

- Research plans should be reviewed by an independent committee, such as an institutional review board (IRB).
- Research participants must give their "informed consent" to be in a study.
- Risks of being in a study should not outweigh benefits.

Health Insurance Portability and Accountability Act (HIPPA): HIPPA stands for the Health Insurance Portability and Accountability Act. It provides the ability to transfer and continue health insurance coverage for American workers and their families when they change or lose their jobs, and reduces health care fraud and abuse. HIPPA mandates industry-wide standards for health care information on electronic billing and other processes, and requires the protection and confidential handling of protected health information.

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.

Institutional Review Board (IRB): A group that follows federal regulations, state laws, and institutional policy to review, monitor, and approve research in order to protect the ethical rights and privacy of the participants involved.

National Research Act (1974): The National Research Act required the U.S. government to create rules to protect people in research studies and created a national committee to develop guidelines for ethical research. These guidelines are in the Belmont Report.

Nuremberg Code (1947): In 1946-1947, a U.S. military court in Nuremberg, Germany charged 23 Nazi doctors and officials with war crimes, including unethical medical experiments on concentration camp prisoners. After the Nuremberg Trials, the judges listed important principles of acceptable medical experiments. These principles became known as the Nuremberg Code. Important principles are:

- Research participation must be voluntary.
- Research participation cannot put people at high risk for disability or death.
- Participants can quit a study at any time.

Privacy: An understanding that information an individual provides will not be shared with others without their permission and that the methods and setting used to collect information will ensure the information remains private and patients' wishes are respected.

Protected Health Information (PHI): any information held by a covered entity which concerns health status, the provision of health care, or payment for health care that can be linked to an individual.