Human Subjects Research

A human subject is defined as any living individual about whom an investigator is conducting research, either through intervention or interaction with the individual, or using identifiable biospecimens or private information. Human subject protection in research became a global priority beginning in 1947 with the Nuremberg Code and in 1964 with the Declaration of Helsinki. In 1978, the United States created a National Commission that released the "Ethical Principles and Guidelines for the Protection of Human Subjects of Research." These guidelines became known as the Belmont Report, named after the Smithsonian Institution Belmont Conference Center, the site of the Commission meeting. The Belmont Report identified three fundamental ethical principles for all human subjects research – respect for persons, beneficence, and justice.

Respect for persons asserts the ethical conviction that persons should be treated as autonomous agents and shown respect for their decisions and opinions. If a person's autonomy is diminished by immaturity or incapacitation, the person is entitled to additional protection. This principle demands that patients enter into research voluntarily and with adequate information.

Beneficence refers to the ethical obligation of researchers to not harm patients and to maximize possible benefits and minimize possible harms. In research, one should never consider injuring one person, regardless of the benefits that might come to others.

Justice refers to the ethical obligation to treat persons fairly and to distribute benefits and burdens equally. In research, exploitation of one group for the benefit of another is absolutely intolerable. The Tuskegee syphilis study in the 1940's is a historical example of injustice in research where the disadvantaged were exploited. Selection of research subjects must be carefully examined to avoid exploitation or manipulation of persons who are disadvantaged or financially, socially, or physically compromised.

The Belmont Report provided guidance for informed consent, risk/benefit assessment, and the selection of subjects of research. Based on this report, the United States Department of Health and Human Services (HHS) revised its regulations for protection of human subjects in the 1980's in the code of federal regulations (45 CFR part 46, subparts A through D). In 1991, 14 other federal departments and agencies joined the HHS and adopted a uniform set of regulations known as the Federal Policy for the Protection of Human Subjects, informally known as "The Common Rule." The Common Rule describes the activities of Institutional Review Boards (IRBs) in protecting human subjects and assuring compliance with federal regulations.

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An IRB is formally designated by an institution to review research involving human subjects. Since 2003, the Health Insurance Portability and Accountability Act (HIPAA) has granted IRBs additional authority to consider and act upon requests for a partial or complete waiver or alteration of an Authorization to use or disclose protected health information (PHI), under the conditions described below (Link). For HIPAA compliance, a covered entity may use either a local IRB, an off-site IRB, or a central IRB, or another type of review body called a Privacy Board. Approval for use of PHI may be through a full review, or an expedited review if the request represents minimal risk to the privacy of individuals. Documentation of approval requires identification of the IRB, date of approval, the specified criteria for approval, a brief description of the PHI for which use or access has been determined, whether it was a full or expedited review procedure, and the signature of the IRB chair or chair's designee. An IRB's action related to access to PHI may be determined by considerations of both the Common Rule's concern with human subjects and the Privacy Rule's concern with a subject's protected health information. IRBs are not legally responsible for enforcing the Privacy Rule but are expected to review issues and enforce regulations regarding the protection of human subjects. Sentara presently uses the EVMS IRB and a variety of other IRBs. More information regarding the EVMS IRB may be obtained at https://www.evms.edu/research/human_subjects_protection/