Informed Consent

Outline

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Definition of Informed consent

- **Informed consent** is a process for getting permission before conducting a healthcare intervention on a person, for conducting some form of research on a person, or for disclosing a person's information.

History of Informed Consent

Tuskegee Study

- Research Done The Wrong Way – The Tuskegee Syphilis Study Longest non-therapeutic experiment on human beings in medical history: The progress of untreated syphilis (1932-1972).

❑ 399 poor African-American sharecroppers in rural Macon County, Alabama, USA.

❑The men were told they were being treated for “bad blood”.

❑ Even after penicillin was discovered and found to be a miracle cure, the men were not treated or even told what they had.

❑ US government officials went to extreme lengths to insure that they received no therapy from any source. Presidential apology, May 1997

* Tuskegee Syphilis Study Legacy Committee Final Report of May 20, 1996

Nazi Prisoner Research During World War II

- Research Done the Wrong Way – Nazi Prisoner Research During World War II (1939- 1945)
- Objectives of various trials:

❑Effect of cold, heat, chemicals on men, women and children.

❑"Time to death" testing in response to stressors in healthy "volunteers".

❑Organ transplant experiments on healthy "volunteers".

❑Any information given is irrelevant because prisoners were forced to participate.

Outcome: 23 German scientists taken to court, 7 acquitted, 9 imprisoned, 7 given death. sentence Nuremberg Code of 1947.

Tuskegee Study

- **1932**, the “Tuskegee Study of Untreated Syphilis in the Negro Male. "starts. The study was conducted without the benefit of patients’ informed consent
- **1972,** first news articles condemn studies. Study ends.

The result is the creation of what is called an IRB (Institutional Review Board). Which we'll talk about in a minute. The thing that these IRBs, these review boards will monitor is a process called informed consent. And the idea is that if any research is conducted on a human subject, then this human subject must be informed about the experiment.

Biomedical Research in Humans Guidelines for Informed Consent

- The Nuremberg Code, 1947
- The Declaration of Helsinki, 1964 (2000)
- The Belmont Report, 1979ϖ
- ICH GCP, 1997
- ICMR Guidelines, 2000

Informed Consent as A Process

Informed consent is a communication process:

- between the researcher and the participant.
- starts before the research is initiated.
- continues throughout the duration of the study.

Basic Principles:

- Informed Consent Process
- Autonomy
- Beneficence
- Justice

Autonomy

- Autonomy means that each person should be given the Respect, Time and Opportunity necessary to make his or her own decision. They will need to decide to enter a study or not to participate. There should not be pressure to participate.

Beneficence

- Beneficence obligates the investigator to secure the well-being of all study subject. It is the responsibility of the investigator to protect subject from harm, as well as ensure that they experience the possible benefits of investigator.
- The key is to “Maximize possible benefits and Minimize possible harm.

Justice

- The principle of justice requires that the study subjects should not be selected on the basis of Class, Socioeconomic status. The basis of including or not including a study subject in a study should be explained and justified by the investigator.
- Fair distribution of the benefits and burdens of research.

Basic Elements of Informed Consent

- In seeking Informed Consent, the following information shall be provided to each subject:

❑ A statement that the study involves research, an explanation of the purposes of the research and the expected duration of subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

❑Obtaining informed consent from each study subject.

❑Obtain the informed consent before the start of the study.

❑Obtain approval of the informed consent from the IRB (INSTITUTIONAL REVIEW BOARD).

Basic Elements of Informed Consent- Continued

- The person receiving the information and giving consent must sign and date the consent form.
- In a situation where the study subject is incapable of providing informed consent (e.g.- subject is unable to write or understand the consent document) or the study subject is in a “vulnerable” population (children, elderly) the informed consent document should be signed by the study subject’s legally acceptable representative.
- The person who provides the information and obtains consent (usually the investigator) must sign the consent form. The signatories (study subject, investigator and any other person involved in the consent process) should personally date the information consent document.

Basic Elements of Informed Consent- Continued

- Neither the investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial.
- The language used in the oral and written information about the trial, including the written informed consent form, should be as nontechnical as practical and should be understandable to the subject.
- If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. The witness should sign and personally date the consent form.
- Prior to participation in the trial, the subject or the subjects legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects.

Special protections for vulnerable populations

- Special Protections for Vulnerable Populations Federal regulations involving human subjects research include specific protections for children, pregnant women, fetuses, and prisoners.
- In addition, the IRB expects the investigator to provide additional information regarding cognitively impaired individuals in research or others who are likely to be vulnerable to coercion or undue influence

Informed consent in children

- "Children" are persons who have not attained the legal age for consent to treatment or procedures.
- Parental permission is generally required.θ Assent from children is required when, in the judgment of the IRB, the children are capable of providing assent.
- If there is any risk at all involved there must be a direct benefit to the minor subjects
- Informed consent for a prisoner would state that participation will not be considered in parole consideration.
- Must state that risks for prisoner in this study same as for a non-prisoner.
- If a prisoner is treated in a research study and the IRB is not aware or does not have a prisoner advocate on the committee, federal regulatory bodies must be notified.

Inform consent in pregnant women

- Researchers should obtain informed consent from both the pregnant woman and the father.
- Consent of the father is not necessary if:

❑The purpose of the study is to meet the health needs of the mother.

❑The identity or whereabouts of the father cannot be reasonably ascertained.

Informed Consent In Illiterate Persons

- An investigator may enroll individuals, who can speak and understand English, but cannot read or write. The potential subject must be able to place a written mark on the consent form. θ The subject must also be able to:

❑Comprehend the concepts of the study and understand the risks and benefits of the study as it is explained verbally, and

❑Be able to indicate approval or disapproval for study enrollment.

Summary

- The Investigator is primarily responsible for the ethics and practice of informing persons about their participation in research.
- The Investigator should communicate the importance of the Informed Consent Process to the research staff and expect them to maintain high ethical standards.
- The ultimate aim is to protect the rights of the study subjects.

- A health care provider may ask a patient to consent to receive therapy before providing it,
- A clinical researcher may ask a research participant before enrolling that person into a clinical trial, and
- A researcher may ask a research participant before starting some form of controlled experiment.
- Informed consent is collected according to guidelines from the fields of medical ethics and research ethics.

- Obtaining informed consent is not always required:

- ❑An individual is considered unable to give informed consent, another person is generally authorized to give consent on his behalf, e.g., parents or legal guardians of a child (though in this circumstance the child may be required to provide informed assent) conservators for the mentally disordered
- ❑Consent can be assumed through the doctrine of implied consent, e.g., when an unconscious person will die without immediate medical treatment.

- The United States Department of Health and Human Services (HHS) defines a human research subject as a living individual about whom a research investigator (whether a professional or a student) obtains data through 1) intervention or interaction with the individual, or 2) identifiable private information).
- As defined by HHS regulations

❑**Intervention** – physical procedures by which data is gathered and the manipulation of the subject and/or their environment for research purposes.

❑**Interaction** – communication or interpersonal contact between investigator and subject.

❑**Private Information** – information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

❑**Identifiable information** – specific information that can be used to identify an individual.