JOHNS HOPKINS
BLOOMBERG
SCHOOL of PUBLIC HEALTH

Informed Consent: What It Is and What It Includes

Anant Bhan, MBBS, MHSc
Ethical Social and Cultural Program for the Grand Challenges in Global Health Initiative

Objectives of This Session

- Why informed consent is important
- Identify the elements of informed consent
- Identify specific categories of information to include in the disclosure of the informed consent process and form; regulatory requirements
- Identify strategies to improve the consent form

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Section A

Introducing Informed Consent

Why Informed Consent?

Public Domain

What Is Informed Consent?

- It is a process of communication between a research participant and researcher that results in the participant's authorization or agreement to undergo a specific research intervention (modified from the AMA definition)

Informed Consent (IC)

- Is an expression of the ethical principles of “respect for persons” and “autonomy”
- Persons have the opportunity to choose “what shall and shall not happen to them”
- Those with diminished autonomy need to be protected

Source: NIH. (2000). OHSR guidelines for writing informed consent forms.

Walter Reed Commission

The undersigned, Antonio Benino Antonio Benino being more than twenty-five years of age, native of Cereeda, in the province of Corima , the son of Manuel Benino and Josefa Castro here states by these presents, being in the enjoyment and exercise of his own very free will, that he consents to submit himself to experiments for the purpose of determining the methods of transmission of yellow fever, made upon his person by the Commission appointed for this purpose by the Secretary of War of the United States, and that he gives his consent to undergo the said experiments for the reasons and under the conditions below stated.

The undersigned understands perfectly well that in case of the development of yellow fever in him, that he endangers his life to a certain extent but it being entirely impossible for him to avoid the infection during his stay in this island, he prefers to take the chance of contracting it intentionally in the belief that he will receive from the said Commission the greatest care and the most skillful medical service.

It is understood that at the completion of these experiments, within two months from this date, the undersigned will receive the sum of $100 in American gold and that in case of his contracting yellow fever at any time during his residence in this camp, he will receive in addition to that sum a further sum of $100 in American gold, upon his recovery and that in case of his death because of this disease, the Commission will transmit the said sum (two hundred American dollars) to the person whom the undersigned shall designate at his convenience.

The undersigned binds himself not to leave the bounds of this camp during the period of the experiments and will forfeit all right to the benefits named in this contract if he breaks this agreement.

And to bind himself he signs this paper in duplicate, in the Experimental Camp, near Quemados, Cuba, on the 26th day of November nineteen hundred.

The contracting party,
Antonio Benigno

On the part of the Commission:
Walter Reed
Maj. & Surg., U.S.A.

Nuremberg Code

- The voluntary consent of the human subject is absolutely essential
  - Legal capacity to consent
  - Be able to exercise free choice
  - “Should have sufficient knowledge and comprehension … to make an understanding and enlightened decision”

ICMR Guidelines and IC

- Indian Council for Medical Research (ICMR) guidelines and IC
  - Necessary to obtain IC for any form of research (from participant or from legal guardian if participant is unable to consent)
  - Informed consent document has two parts
    1. Informed consent form which both researcher and participant sign
    2. Study information sheet

Informed Consent Is Not Just the Document

- IC is a process and not just a requirement to get a signature/thumb imprint on a form

- Starts before research is begun and continues throughout the duration of the study

ICMR Guidelines and IC

- Participation must be voluntary
- Participants must be “fully apprised of the research”
- The investigator must obtain informed consent
  - Responsibilities and information that must be provided
- Assent be obtained, where possible, for minors
- Requirement for consent can be waived by an ethics committee if risk is minimal (e.g., collecting data from subjects’ records)

Elements of Informed Consent

- Disclosure
- Comprehension → documentation
- Voluntariness

IC

- IC is a process wherein …
  - All relevant information about the study is provided to the participant
  - The participant understands the information and clarifies any doubts/questions, and
  - Decides to participate voluntarily in the study

IC and Language

- Use simple wording that is not too technical
- In a language that the person understands (need for trained personnel and translations of the consent forms)
- Discussed in detail by a study team member well versed with the research protocol