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# Informed Consent in Human Research

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## Abstract

The principle of informed consent is not actually a new concept. It indicates the entry point of a human subject to a clinical research without which all the discoveries and recent advancement would have been stopped and the era of human civilization would have come to an end. The aim of this article is to bring out the awareness among researchers to relook into the process of informed consent and to give proper respect to all human subjects including those participating in a research projects rather than treating them as research objects.

**Keywords:** Informed consent, Human Research, Awareness.

## Introduction

Informed consent is the process by which a subject voluntarily confirms his or her willingness in a particular trial, after having been informed of all aspects of trial that are relevant to the subject's decision to participate. This is an ongoing process that begins with initial recruitment of subjects and continues after the initial oral or written agreement form to participate in a research study. It originates from the legal and ethical right the patient has to direct what happens to her body and from the ethical duty of the physician to involve the patient in her health care.[1]

### The Origin of Informed Consent in Human Research

Informed consent emerged from the ethical principle of "Respect for Persons". Individuals should be treated as capable of taking decisions for themselves ("autonomy") andthose with diminished autonomy should be protected.

Before the 20th century, guidelines required physician's need to adhere to acceptable medical standards. Issue of patient's agreement to the research was never discussed.

The principle of consent is not actually a new concept. In fact, already in the times of the Egyptian, Greek and Roman civilization, documents have been found which show how the doctor's intervention had, in some way, first to be approved by the patient. Plato (law IV) had already foreseen the problems, the procedures and the modes of information which are, in synthesis, at the

root of the principles of the present formula of informed consent and correlated the practice of the information and consensus with the quality and social position of the patient.

The first evidence of informed consent was found in **The Tuskegee Syphilis Study** in 1932-72 which formulated the Belmont report. In 1932, the Public Health Service, working with the Tuskegee Institute, began a study to record the natural history of syphilis in hopes of justifying treatment programs for blacks. It was called the "Tuskegee Study of Untreated Syphilis in the Negro Male."In truth, they did not receive the proper treatment needed to cure their illness. In exchange for taking part in the study, the men received free medical exams, free meals, and burial insurance. The study initially involved 600 black men – 399 with syphilis, 201 who did not have the disease. The study was conducted without the benefit of patients' informed consent. The men were never given adequate treatment for their disease. Even when penicillin became the drug of choice for syphilis in 1947, researchers did not offer it to the subjects.[2]

In Nazi Prisoner Research during World War II came out the **Nuremberg Code of 1947**. A trial commenced in Nuremberg, on December 9, 1946, in Nuremberg, Germany and were led exclusively by the United States. Harry Truman approved these trials in January 1946. Most of the suspects escaped punishment for their crimes. Several of the accused argued that their experiments differed little from pre-war ones and that there was no law that differentiated between legal and illegal experiments of Nazi doctors and a code was defined in which the judges, all Americans, clearly emphasized a view of medical research and technology: **science should never transform or consider human beings as an instrument to be employed for scientific purposes.**[3]
In actual fact, documents exist providing evidence that a few decades before the drawing up of the Nuremberg Code, the need had been expressed, in Germany itself to somehow make medical interventions and actions legal by means of the use and practice of consensus.
The expression informed consent has simply been transposed in Italian and roughly translated in an ambiguous fashion into "consensoinformato" when, on the contrary, it should be referred to as "informazione per ilconsenso" "information for consensus" not only to respect the concept but, surely, for a more correct deciphering and a more precise interpretation related to the numerous concepts it presupposes and implies. Information and consent may be compared to the two sides of the same coin. In this respect, it is enough to focus attention on the different cultural traditions and religious routes, on the different doctrinal background, the particular historical origins and the individual legal aspects, all extremely different one from the other. [4]
The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. The Declaration is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs. It is not a legally binding instrument under the international law, but instead draws its authority from the degree to which it has been codified in, or influenced, national or regional legislation and regulations. Its role was described by a Brazilian forum in 2000 in these words "Even though the Declaration of Helsinki is the responsibility of the World Medical Association, the document should be considered the property of all humanity".[5]

## Definition

Informed consent is a key concept in the provision of health care which has **ethical, legal and practical** dimensions.

From an **ethical perspective**, informed consent forms an essential component of the moral right of individuals to autonomy over their own bodies and is based on the principle of free agency. From a **legal perspective**, informed consent is defined in terms of an agreement or process by which the rights of individuals to agree or to refuse treatment are upheld. In **practical terms**, informed consent refers to the process by which a health care provider informs a consumer of their treatment options, and associated risks and benefits, and supports them to make a decision about their care.

Informed consent of a patient or other recipient of services is based on the principles of autonomy and privacy; this has become the requirement at the centre of morally valid decision making in health care and research.

## Basic ethical principle

- Autonomy (respect for person /participant)
- Beneficence
- Non-maleficence (do no harm)
- Justice

**Autonomy** means that each person should be given the respect, time, and opportunity necessary to make his or her own decisions. Prospective participants must be given the information they will need to decide to enter a study or not to participate. There should not be pressure to participate. Likewise, there should also be no unrealistic inducements to participate in a study.

**Beneficence** obligates the researcher, to secure the well-being of all study participants. It is the researcher's responsibility to protect participants from harm, as well as ensure that they have an equal opportunity to experience the possible benefits of involvement.

Balancing risks and benefits is an important consideration. The key, according to the 1979 Belmont Report on the protection of human subjects, is to "maximize possible benefits and minimize possible harms."

The concept of **Justice** may be questioned when it is attempted to decide who will be given an opportunity to participate and who (and for what reason) will be excluded. Some classes or persons should not be selected simply because of their availability, their compromised position, or their manipulability while others are not.[6]

Seven criteria define informed consent:

(1) competence to understand and to decide, (2) voluntary decision making, (3) disclosure of material information, (4) recommendation of a plan, (5) comprehension of terms (3) and (4), (6) decision in favour of a plan, and (7) authorization of the plan. A person gives informed consent only if all of these criteria are met. If all of the criteria are met except that the person rejects the plan, that person makes an informed refusal.

## Types of consent

1. **Informed/Express/Explicit**
2. **Implicit/Implied**
3. **Post-hoc**
4. **Proxy**

**Informed consent**, also known as valid, express or explicit consent, entails giving sufficient information about the research and ensuring that there is no explicit or implicit coercion so that prospective participants can make an informed and free decision about their involvement. Typically, the information should be provided in written form. Time should be allowed for the participants to consider their choices and the forms should be signed off by the research participants to indicate consent.

**Implied/implicit consent** differs from express/explicit/informed consent in that it is not gained through formal methods, such as written or verbal approval. An example of this would be where a person completes a questionnaire. By completing the form, they imply their consent to participate.

**Post-hoc consent** is consent that has, as the name implies, been sought and granted after the research has taken place. This is likely to be the case in circumstances where consent needs to be obtained prior to publication or in at the roadside in the event of an accident or at a cardiac arrest or during the early stages of a patient's emergency or admission to an accident and emergency department.

**Proxy consent** for research participants may be necessary when the participant is a vulnerable person. The best interests of the participant must be the highest importance. In sensitive research involving vulnerable populations, particularly children, the competence of the researcher to undertake the research should be considered. Proxy consent should only be used when participants are unable to consent themselves or where it is legally necessary. Care should be taken that consent cannot be sought from the participants and it should not be assumed that children are unable to consent because of their age. When proxy consent is used, agreed criteria should be used to identify signs that the participant is unwilling to take part or wishes to terminate the research interaction, and fully understands to what they are consenting.

## Informed consent process

**"**The process of agreeing to take part in a study based on access to all relevant and easily digestible information about what participation means, in particular, in terms of harms and benefits**."** *(Parahoo, 2006)*

## Informed consent is a process, not a form

It is essential that consent forms be written in plain language that research subjects can understand. The consent document should always be revised if there are changes in the study that might affect the participant or when additional information will improve the consent process.

The informed consent and permission must be obtained by the lead researcher and not by his representative under ordinary circumstances. A life-threatening emergency may dictate otherwise. The physician or surgeon must discuss a number of specific items. The patient should have the opportunity to ask questions to the extent of understanding sufficiently to agree or disagree to have the procedure or intervention performed. Obviously, this may be abbreviated when a life-threatening emergency is present, such as severe trauma and massive bleeding. The patient may not be conscious, and the next of kin may need to give permission. In some situations, there may be no one available to give permission at all and a life-threatening situation may exist requiring immediate treatment to try to save the patient's life. It is always better to stray to the side of giving life-saving, emergency treatment without consent than withholding treatment and risking the patient's life, while waiting on permission.

**Informed Refusal** is an even newer concept, stemming from informed consent in which, after a thorough understanding of the proposed treatment or medical intervention, the patient decides against treatment. It is basically informed consent in which, after all the components have been achieved, the patient decides against any treatment. It includes the basic understanding of the facts and implications of not following recommended treatment. These items must be adequately documented in the medical record. Courts have consistently upheld a patient's right to refuse treatment. After proposing what the physician feels is the best treatment for the patient, it is frustrating when the patient refuses care.[4]

## Consent can be taken by:

- Lead researcher
- Co- researchers
- Nursing staff
- Counselor
- Social worker

## Components of Informed consent

- Nature and Purpose of Proposed Treatment
- Risk and Benefits of Proposed Treatment
- Alternatives Regardless of Cost or Insurance Coverage
- Risks and Benefits of Alternative Treatments
- Risks and Benefits of No Treatment

**Informed consent = Patient Information Document+ Informed Consent form**

## Information to the participants of a research (Patient Information Document)

- the purpose of the research
- how long their participation will last
- who is involved in the research
- the practicalities and procedures involved in participating
- the possible benefits and risks of participation and, when appropriate, the alternative therapies
- how data about them will be managed and used
- how long and where the data will be stored
- the purpose of the consent form
- what is expected of them if they agree to participate in the research
- how information will be provided to them
- throughout the research that their participation is voluntary
- they can withdraw from the study at any time, without giving any reason and without compromising their future treatment
- the insurance indemnity arrangements for the conduct of the research where appropriate
- the research has been approved by a research ethics committee.
- contact details, should they have further questions or want to withdraw
- details of the research sponsor and funding body.
- uses language appropriate to the potential participant group, avoiding the use of technical language
- includes diagrams, pictures, tables and flowcharts if these contribute to explaining the research

## Informed consent in special circumstances

## Vulnerable

- Children and minors
- Pregnant women
- Foetuses and human in vitro fertilization
- Cognitively impaired persons
- Prisoners

## Special

- Students
- Residents
- Employees
- Terminally ill patients
- Minorities

Every potential subject who is a physically and mentally able adult (defined as anyone age 18 or over) must provide consent to participate in research prior to the conduct of any activities that constitute the research encounter. This is the most general case and applies to all research. Minors or special adult populations who are being recruited as research subjects may be compromised in their ability to provide truly informed and voluntary consent and therefore require special safeguards to ensure that their rights are protected in the informed consent process.

**Children**: Obtaining permission to conduct research involving children (persons under age 18) requires special attention to the child's age, his/her ability to understand what is asked of him/her, and his/her relationship to parents/guardians. If research subjects are wards of the state, further safeguards are required as outlined in 45CFR46. In all cases, the investigator must demonstrate respect for the rights of the subject within the proposed consent procedures, which should be developmentally appropriate to the age and circumstances of the child (see IRB Forms for Sample Child Assent Form).

a. Parental Consent: Parental permission or consent in writing is required for all minors under the age of 18 who participate in research except for emancipated minors.
b. Adolescent's Written Assent: From about junior high or middle school onward, a child's written assent is needed (in addition to parental consent), because children in this age group usually can read and comprehend a well-constructed assent form. However, the investigator should use supplementary verbal explanations whenever needed.
c. Child's Assent: For elementary school aged children, the investigator should obtain (in addition to parental consent) the child's assent to participate. The explanation to the child should contain elements of consent expressed in a form the child can understand. A conversational question-and-answer setting is often necessary to achieve this goal. In addition, the child's assent should be positive, that is, not merely lacking of dissent. If the child is old enough to render a signature, investigators are required to obtain a signed assent form.
d. Very Young Child's Assent: For children below school age (e.g., infants, toddlers, and preschoolers) the investigator should give explanations that match the level of understanding. In many instances, the children's nonresistant behaviour may be interpreted as assent, but the investigator must use special care to discontinue the participation of children who appear to experience undue stress from the research procedures. A verbal script must be submitted as part of the protocol.

**Prisoners:** Obtaining the informed consent of prisoners to participate in research requires attention to their circumstances. The research should not provide the prisoners with advantages that would unduly influence their ability to weigh the risks involved in the research. Moreover, the consent form should make it clear to prisoners that participation would have no direct effect upon their parole or treatment. An advocate is required. See 45CFR46.

**Individuals with mental disabilities:** In obtaining informed consent from individuals who are mentally disabled, additional protection is necessary. The research protocol must clearly demonstrate how the research intends to ensure that the interests of patients are protected.

**Fetuses, pregnant women, and human in-vitro fertilization:** Special safeguards may be required depending upon the research.

**Other groups:** Vulnerable and special populations include subjects who, as outlined in federal regulations, must be provided extra protection. Other groups such as racial minorities, the elderly, the economically disadvantaged and the very sick are described as vulnerable populations by The Belmont Report, and are therefore provided similar protection when sought as research subjects.

## Importance

Gaining informed consent for research which involves invasive procedures is considered to be a legal requirement. The emotional, psychological, and physical dangers that can occur when researchers fail to communicate adequately with their subjects/

**Lack of Informed Consent ≡ Breach of Duty ≡ Negligence**

## Conclusion

Obtaining consent is not only an ethical obligation, but also a legal compulsion. While the turn of the 21st century sees new doubts surfacing about informed consent, the resilience of other parts of the requirement is striking. A good informed consent does not only avoid legal litigations on the part of the medical professionals, it also increases the bond and reciprocal respect between doctor and patient and thus enhances the efficacy and benefits of the entire health care system.

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