Informed Consent In Research

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ABSTRACT

Background: *Ethical problems most often arise in research. One of the most important ethical rules governing research on humans is that participants must give their informed consent before taking part in a study. Informed consent is therefore a vital part of the research process, and as such entails more than obtaining a signature on a form. Most researchers however, do not have the requisite knowledge of the importance of informed consent in research. This paper attempts a synopsis of the place of informed consent in research study.*

Method: *A review of literature on informed consent in research. Literature search was done using Google search engine as well as international and local journals.*

Result: *Informed consent as an aspect of medical ethics, balances autonomy and beneficence, and provides adequate assurance of voluntary and autonomous participation without negative repercussions on access to study benefits. The search showed that this if adhered to in research, will surely maintain the dignity of man and the integrity of research as a field of human endeavour.*

Conclusion: *Researchers must therefore ensure that potential research participants be given sufficient information about a study, in a format they understand, to enable them to exercise their right to make an informed decision whether or not to participate in a given research.*

Keywords: *Informed consent, Research.*

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INTRODUCTION

Informed consent is a process in which a person learns key facts about a clinical trial, including potential risks and benefits, before deciding whether or not to participate in a study[1]. Informed consent continues throughout the trial. Informed consent is a legal procedure to ensure that a participant or client knows all of the risks and costs involved in an intervention or study.[2] In order for informed consent to be considered valid, the client must be competent and the consent should be given voluntarily.[2]

The elements of informed consent include informing the participant or client of the nature of the intervention or study, possible alternatives, and the potential risks and benefits of the intervention or study. There are three elements of informed consent, viz: information; comprehension and volition. Informed consent is a process, not just a form[3]. Information must be presented in a manner that is well understood. This is to enable persons to voluntarily decide whether to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through the provision of thoughtful consent for a voluntary act.[3]

PROVIDING INFORMATION TO PARTICIPANTS

Effective communication is the key to enabling potential participants to make informed decisions about their involvement in research. Research participants should be given opportunities to ask questions about the study to help them decide if they want to take part in the research or not.[4,5]

Before being recruited into a study, potential participants should be given information about the study and the possible implications of their participation. This information may be presented verbally or in a written format. For most research projects, it is appropriate to have a leaflet or sheet summarising key information about the study.[4,5.]

The information sheet should be given to the person when they are approached about the study. The content of the information sheet should address the likely concerns of participants. The text contained in the information sheet should be presented in a clear and easy to understand format. The wording should be accessible to participants in terms of both language and style. Information should be translated into the likely language(s) of the participants or an interpreter provided.[4,5.]

BASIC ELEMENTS OF INFORMED CONSENT

The verbal and written briefing of the participants should include the following information about the study:[5-9.]

The identity of researchers: The name(s) and contact details of the researcher(s) involved in the study should be made available to allow participants to obtain more information about the study if required. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

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The purpose of the research: The goals and objectives of the research should be presented to participants in a simple way. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

Complex procedure(s) explained: The design of research projects can be complicated, so the exact procedures that will occur during the study should be clearly explained. Also, a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

Explain the research activity, how it is experimental. For example, a new drug, extra tests, separate research records, or nonstandard means of management, such as flipping a coin for random assignment or other design issues. Inform the human subjects of the reasonably foreseeable harms, discomforts, inconvenience and risks that are associated with the research activity. If additional risks are identified during the course of the research, the consent process and documentation will require revisions to inform subjects as they are recontacted or newly contacted.

For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

Identity of others associated with the research: The details of other health professionals involved in the study or the funding organisation supporting the project should be made available to participants.

Reason/s why the participant has been selected: The reasons or methods for the selection of participants should be outlined.

Harms and benefits: A description of any reasonably anticipated and potential foreseeable benefits and/or risks to the subject or to others, of participating in the research project should be highlighted to participants in a clear way. There may be none other than a sense of helping the public at large. If payment is given to defray the incurred expense for participation, it must not be coercive in amount or method of distribution.

If research-related injury such as physical, psychological, social, financial, or otherwise is possible in research that is more than minimal risk, an explanation must be given of whatever voluntary compensation and treatment will be provided. Note that the regulations do not limit injury to "physical injury". This is a common misinterpretation.

Privacy, anonymity & confidentiality: Details should be provided about what will happen to any personal data collected during the study. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained, and when applicable.

Future use of information: Any potential future use or processing of data collected in the study should be outlined to participants. For example, some studies require disclosure of information to other parties. Some studies inherently are in need of a certificate of confidentiality which protects the investigator from involuntary release (subpoena) of the names or other identifying characteristics of research subjects **Right not to participate and withdraw:** Participants should be informed about their right to decline participation or to withdraw consent at any stage of the research with no consequences to their future care or treatment. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Describe any alternatives to participating in the research project. For example, in drug studies the medication(s) may be available through their family doctor or clinic without the need to volunteer for the research activity.

Time to reflect: Participants should be given sufficient time to reflect, before and after making a decision to join a study. **The regulations provide for the identification of contact persons who would be knowledgeable to answer questions of subjects about the research, rights as a research subject, and research-related injuries. These three areas must be explicitly stated and addressed in the consent process and documentation.** Furthermore, a single person is not likely to be appropriate to answer questions in all areas. This is because of potential conflicts of interest or the appearance of such. Questions about the research are frequently best answered by the investigator(s). However,

questions about the rights of research subjects or research-related injuries (where applicable) may best be referred to those not on the research team.

It is important not to overlook the need to point out that no penalty or loss of benefits will occur as a result of both not participating or withdrawing at any time. It is equally important to alert potential subjects to any foreseeable consequences to them should they unilaterally withdraw while dependent on some interventions to maintain normal function.

The regulations prohibit waiving or appearing to waive any legal rights of subjects. Therefore, for example, consent language must be carefully selected that deals with what the institution is voluntarily willing to do under circumstances, such as providing for compensation beyond the provision of immediate or therapeutic intervention in response to a research-related injury. In short, subjects should not be given the impression that they have agreed to and are without recourse to seek satisfaction beyond the institution's voluntarily chosen limits.

When appropriate, the following information must be provided to each subject:[10]

A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

Any additional costs to the subject that may result from participation in the research;

The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and the approximate number of subjects involved in the study.

ESTABLISHING CAPACITY TO MAKE DECISIONS

Participants should also be deemed legally competent to make an informed decision. You must work on the presumption that every adult has the capacity to decide whether to consent or refuse to participate in a study, unless it is shown that they cannot understand the information presented to them.[4] The recently published EU Directive: Medicines for Human Use (Clinical Trials) 2003 describes regulations for obtaining consent from a person who may be incapable of giving consent to participate in a trial due to a mental health condition, dementia or a disability.[4] In these circumstances, consent to participate in research may be obtained by a 'legal representative' of the person unable to give informed consent. The person taking on the role of legal representative should be a person close to the patient although a doctor responsible for the care of the patient may fulfil this role unless they are connected with the trial. The legal representative of the patient is expected to base their decision on the person's 'presumed will'.

There are particular requirements for consent for participation in research for some individuals including children and vulnerable groups such as people with mental health conditions or learning disabilities. The parents or guardians of children under the age of 16 years must provide consent for the child's participation in a study. It should be noted that proxy consent from one adult for another's participation in a research study is unacceptable.

ELEMENTS OF GAINING CONSENT FROM RESEARCH PARTICIPANTS

The main elements of gaining consent from research participants are:[3,11,12.]

Consent should be voluntary: Consent for participation in research is voluntary only if it is given without any direct or indirect coercion or inducement.

Consent should be informed: Participation in research should be based on an informed decision after sufficient information about the study has been provided.

Consent should be in writing: Informed consent for participation in a research project should involve participants giving written consent. If participants are unable to give written consent, oral consent in the presence of a witness is acceptable.

Seeking informed consent : All researchers obtaining consent from potential participants should have sufficient knowledge of the study in order to adequately brief individuals.

Research Ethics Committee approval: All research involving patients, service users, care professionals, volunteers, their tissue or data must be reviewed by an ethics committee before it can commence to ensure that ethical standards have been met. This is to protect the rights, dignity and well being of the research participants. The ethics committee will ask for detailed information about how participants will be recruited and how consent will be obtained.

WRITTEN CONSENT

After the participant has been given the information sheet outlining the study and the consent form has been read, the participant must sign the consent form. At this stage, the participant should be given time to ask questions about the study and the nature of the data collected. Signed consent forms should be dated, with a copy being given to the participant, a copy stored in the medical notes and the original kept with the research data in a locked filing cabinet.

THE PROCESS OF INFORMED CONSENT OF RESEARCH SUBJECTS

Informed consent is a vital part of the research process, and as such entails more than obtaining a signature on a form. Investigators must educate potential subjects to ensure that they can reach a truly informed decision about whether or not to participate in the research. Their informed consent must be given freely, without coercion, and must be based on a clear understanding of what participation involves. [13]

The process of educating subjects about the study begins during initial contact and continues for the duration of their participation. Thus, information conveyed through advertisements, recruitment letters, pre-screening phone calls, study description sheets as well as written informed consent documents and discussions must be understandable to the subjects. [13]

Non-English speaking subjects must have information presented in a language they understand. The consent discussion should begin sufficiently in advance of the initiation of study-related procedures to allow potential subjects time to reflect on the potential benefits and risks and possible discomforts of participation. Though clearly it may need to be tailored to the circumstances of individual studies and may not be appropriate or feasible in all situations. [13]

First, potential subjects are given general information about the research (for example, through advertisements, information sheets, letters or discussion with their treating physicians), and if they are interested in learning more about the study, they contact study staff. The investigator then meets with the potential subject to review and to discuss the details of the research study using the informed consent document as a guide. This discussion should include all of the required elements of informed consent, for example, the purpose of the research, the procedures to be followed, the risks and discomforts as well as potential benefits associated with participation, and alternative procedures or treatments, if any, to the study procedures or treatments.

Preferably, potential subjects are then given a copy of the informed consent document to take home so that they can carefully read the document and discuss the research with their family, friends and/or physician and develop questions to ask at their next meeting with the research staff. Subjects must always be given the opportunity to ask questions and have them answered by the investigator and, whenever possible, to consult with friends/family and/or their physicians. Once they have read the consent document and their questions are answered, if they agree to participate in the research, they sign and date the informed consent document.

Special consideration must be given to the timing of the consent process when the subject population includes patients who will be same-day admissions for surgical procedures or who present for diagnostic or other tests, such as cardiac catheterizations or radiological examinations. Clearly, the time frame for the consent process will be more limited in these situations. Generally, the investigator should allow potential subjects at least 12 hours to consider participation. [13]

With few exceptions, the informed consent of subjects, whether patients or healthy volunteers, must be obtained and documented in writing before the start of any study-related procedures, including screening tests and exams done solely to determine their eligibility for the study. Once the informed consent document has been signed, subjects are considered enrolled in the study.

INDIVIDUALS WHO CAN OBTAIN INFORMED CONSENT

For most studies involving more than minimal risk and all studies involving investigational drugs/devices, a licensed physician investigator listed on the protocol must obtain informed consent. Study nurses or other study staff may assist in the consent process, but investigators should be actively involved in the consent discussions and should not

delegate this vital investigator function. It is the investigator's responsibility to ensure that proper informed consent is obtained from every subject.

However, for minimal risk studies and very carefully selected studies involving more than minimal risk (but not investigational drugs/devices), it may be appropriate for study nurses or other study staff to obtain consent, with "back up" provided by licensed investigators. [13] If subjects are to be enrolled from among the investigator's own patients, consent procedures must be put in place to ensure that subjects do not feel obligated to participate because the investigator is their treating physician. There is always concern about the possibility of patients feeling obligated to participate because it is their physician who is doing the asking. One can have a nurse or colleague re-contact the patient after the investigator has had the consent discussion and offer them an opportunity to ask additional questions, raise concerns, or opt out, with someone who is not their physician. [13]

In addition to permission of the parent(s) or guardian, assent to participate in the study must be obtained from each child age 7 years or older who, in the opinion of the investigator, is able to provide assent based on their age, maturity or psychological state. This however varies from one country to another. For instance, in Massachusetts, "Emancipated" minors, that is, those who are married, widowed or divorced, or have a child or are pregnant (or believe themselves to be), are in the armed forces, or living apart from their parents and managing their own affairs, can provide informed consent for their own medical care. [13]

USE OF A SUBJECT ADVOCATE

The subject advocate is an individual who has no vested interest in the research and who agrees to act as an impartial third party in the consent process. When a subject advocate is appointed, the subject advocate is expected to act in the best interests of the subject by sharing in discussions with the investigator and with those responsible for giving consent. Individuals who might fulfill this role include the subject's primary care physician or other health care professional not involved in the research. The subject advocate is responsible for ensuring that the subject understands the research procedures and the risks and potential benefits of participation and that his/her consent is free and voluntary. When a subject advocate is used, the subject advocate must sign and date the consent form. Situations in which the use of a subject advocate may be required include:[13] when the risks to subjects are significant and the subject is the patient of the investigator and, as such, may feel obligated to participate; or when consent is to be obtained in the emergency room or in an emergency situation when the time frame to obtain consent prior to start of study-related procedures is limited; or when surrogate consent is to be obtained for research involving more than minimal risk with the potential for direct benefit to the subject.

DOCUMENTATION OF INFORMED CONSENT

In almost all cases, investigators must document the informed consent process by use of a written consent document (research consent form) signed and dated by the subject or his/her legally authorized representative (or surrogate) and the investigator (or study staff) who obtained the subject's consent.[13]

Usually, three copies of the signed and dated research consent form are needed. The original signed and dated research consent form should be retained in the research records. A copy of the signed and dated research consent form must be given to the subject and a copy placed in the subject's medical record, if relevant to his/her ongoing medical care. If the study involves sensitive research, (e.g., alcohol or drug use, some genetic studies) a copy of the research consent form ordinarily should not be placed in the subject's medical record. [13]

It is noteworthy that any informed consent, whether written or oral, must not include exculpatory language such that the subject is made to waive, or appear to waive, any of his or her legal rights or to release the institutions or its agents, the investigators, from liability or negligence. Examples of exculpatory language: By agreeing to this use, you will give up all claim to personal benefit from commercial or other use of these substances; I voluntarily and freely donate any and all blood, urine, and tissue samples to the researcher and hereby relinquish all right, title, and interest to said items; By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research; I waive any possibility of compensation for injuries that I may receive as a result of participation in this research; The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand.[13]

Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language" which is understandable to the people being asked to participate. The written presentation of information is

used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process. [13]

Use of the first person (for example, "I understand that ...") can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject. Use of scientific jargon and legalese is not appropriate. Think of the document primarily as a teaching tool not as a legal instrument. [13]

INFORMED CONSENT IN DEMOGRAPHIC HEALTH SURVEILLANCE (DHS)

Stringent requirements for voluntary informed consent have been developed to protect the autonomy of human subjects in research activities, and the close interaction between surveillance systems' individual-level data collection and associated research studies makes the process of consent appropriate with DHS participants. However, the complications in the consent process specific to surveillance activities-related to conception of autonomy, the position of individuals within households and communities, and the multi-generational nature of longitudinal surveillance have received only slight attention in the surveillance ethics literature.[14-19.]

CONCLUSION

When conducting research one should ensure that the research will be of benefit to humanity; the research would not in any way compromise the dignity and integrity of the human being; the research would not result in harm to the human subject; every subject of the research is fully aware of the procedure and consequences of the research; every subject of the research gives an informed consent for the research; a subject is not coerced or blackmailed into submitting to the research; a subject's ignorance or mental incompetence is not exploited; the research does not offend societal norms and morals, even if there are willing subjects. Adherence to informed consent will guide the researcher in addressing ethical dilemmas.

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