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The Informed Consent Process in Clinical Research

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What is the Informed Consent Process?

The process begins when you (as part of the research trial) first approach a potential research subject.

What is the Informed Consent Process?

Contrary to what many believe, the informed consent process does not begin and end with the signing of the informed consent document. It begins with the initial approach of the subject and doesn't end until their involvement in the trial is completely over.

What is the Informed Consent Process?

When addressing the subject, present enough information so that the potential subject can make an objective and voluntary decision as to whether they would like to participate in the trial. The consent document itself should be written at a 7th grade level. The discussion with the subject is dependent upon their level of understanding.

What is the Informed Consent Process?

You do not have to use highly technical language unless the potential subject requests a high level of information.

Assent Document

A consent document for children.

What is the Informed Consent Process?

Be prepared to answer any and all questions or concerns the potential subject may have at that time. If you do not have the answers, state that you will find out for them and contact them at a later time. The potential subject should never walk away confused about their participation in the trial.

What Information Must Be Provided to the Subject?

- Purpose of the research
  - let the subject know what and why the research is being done
  - what is the researcher looking for and why does the subject have the opportunity to be involved in the research

What Information Must Be Provided to the Subject?

- Expected duration of the research
  - the subject needs to know how long they will be expected to be involved in the research study
    - Is it 6 monthly visits?
    - One visit every 3 months?
    - A one hour session where blood will be drawn?
  - let the subject know if it is one hour or one year

What Information Must Be Provided to the Subject?

- Procedures involved
  - the subject needs to know what will happen to them during the research process
    - Will it be usual care with one change?
    - Will it be a questionnaire?
    - Will there be a blood draw?

What Information Must Be Provided to the Subject?

- Procedures involved
  - give the subject as much information as possible so they can best make their decision whether to be involved

What Information Must Be Provided to the Subject?

- Possible risks or discomforts
  - let the subject know that there are risks associated with being a subject in the trial
    - if it is a drug study let them know the possible side effects of the study drug
    - if it is a physical study let them know they could experience a sore back or legs

What Information Must Be Provided to the Subject?

- Possible risks or discomforts
  - this may not help your cause in that it may scare some subjects away from participating in the trial, but the subject must be informed of these issues in order to make a proper decision

What Information Must Be Provided to the Subject?

- Possible benefits
  - if the trial involves a new treatment or study drug, it is possible that participation in the trial could be a benefit
  - if a subject's treatment is part of the research, it is possible that it could be paid for by the study sponsor

What Information Must Be Provided to the Subject?

  - you cannot sell this aspect of the trial to the subject as a reason to be enrolled, but you can inform them of the possibility
  - the possible benefit should never be the reason a subject enrolls in a trial, but they should be informed

What Information Must Be Provided to the Subject?

- The number of subjects expected to be enrolled
  - you should let the subject know how many total subjects will be enrolled in the trial so that they can get an understanding of the scope of the trial

What Information Must Be Provided to the Subject?

  - Is it a big trial going on at many sites across the country with a possible enrollment of 1,000 or 2,000 people?
  - Is it a small trial going on at one place with 3 or 4 enrollments?

What Information Must Be Provided to the Subject?

- Confidentiality of involvement
  - there should be total confidentiality between the subject who has agreed to participate in a trial and those listed as part of the research team

What Information Must Be Provided to the Subject?

  - if identifiers are collected from the subject, then the subject must give approval to do so (HIPAA Authorization Form)
  - informed consent documents and datasheets must be kept in a secure area to ensure privacy of the research subjects

What Information Must Be Provided to the Subject?

- Any potential additional costs
  - there are occasions where being in a research study may add additional costs to the subject (this is very rare)

What Information Must Be Provided to the Subject?

  - If it is a low risk study and the investigator does not have the funding to pay for some procedures involved in the trial, they may ask the subject to pay these costs. This is acceptable as long as the subject is made aware of these additional costs
  - there are times where the subject's insurance will pay for these additional costs but that is happening less and less frequently

What Information Must Be Provided to the Subject?

- Compensation
  - in order to assist the subject for travel reimbursement or for their time, the subject can be given a certain amount of funds for being a research subject (these are given as a reimbursement and not as payment for involvement)

What Information Must Be Provided to the Subject?

  - the amount should always be reasonable so as not to coerce or entice the subject to be involved in the trial
  - subject payment should be specifically explained in the informed consent document as to amounts, time of payment, and type of payment (cash, check, or gift card)

Subject Payment

- Federal law - if a research subject receives over $600 in a calendar year from a research study, that money has to be taxed (becomes income at that point)

What Information Must Be Provided to the Subject?

- Medical treatments available if injury occurs
  - this can vary by institution, but most will provide medical treatment to the subject if injury occurs from the study (this is something to be discussed during the consent process and depends upon the level of risk for the study and whether it is a sponsored trial)

What Information Must Be Provided to the Subject?

- How research results (if any) will be made available
  - most of the time the results from a clinical trial are not known for many years

What Information Must Be Provided to the Subject?

- How research results (if any) will be made available
  - if, however, there is a questionnaire or study involved in the research, the subject may be able to get the results in a timely manner; this will need to be explained during the consent process

What Information Must Be Provided to the Subject?

- Whom to contact if questions arise with contact numbers?
- The informed consent process does not end at the time the subject signs the document

What Information Must Be Provided to the Subject?

- Questions may arise and they need to be able to contact someone with questions or even to report discomfort
- It is also acceptable to give the potential subject the consent form, allow them to take it home to read it, and call back with any questions

What Information Must Be Provided to the Subject?

- Participation is voluntary (this cannot be stressed enough)
  - it does not matter the reason if the potential subject does not wish to be a part of the study
  - there is nothing wrong with asking the subject why they don't want to be in the research

How to Document Informed Consent

- The consent document is a written form signed and dated by the subject and a research representative

How to Document Informed Consent

- The informed consent document will contain all of the elements noted earlier
- The document must be:
  - explained to the potential subject (they can either read it at the time or take it home)

How to Document Informed Consent

- The document must be:
  - signed and dated by both parties (this documents that the subject understands the research trial and wishes to participate)
  - signed and dated at the same time

How to Document Informed Consent

- if the subject cannot read, there is also a signature line for a witness who will acknowledge that the subject has been given verbal informed consent and that the subject understands
- if the subject speaks a different language (very important to have an informed consent document in the language that the individual speaks)

How to Document Informed Consent

- All informed consent documents:
  - must be approved by the institutional review board (IRB)
  - will go through the process of being reviewed by the IRB

How to Document Informed Consent

- The IRB is a group of medical doctors, scientists, and community members whose job it is to approve research involving human subjects. It is their job to protect the rights of human volunteers.
- all research involving humans must be approved by some kind of IRB

How Does the Informed Consent Process Differ for Minors and Children?

- When research involves subjects under the age of 18, consent of parents or guardians must be obtained

How Does the Informed Consent Process Differ for Minors and Children?

- Also, the researcher must obtain and document the assent of the minor who is capable of deciding whether they wish to participate in the research (ages 8-17)
  - an assent document is an informed consent document for subjects between the ages of 8-17

How Does the Informed Consent Process Differ for Minors and Children?

  - it is a much more basic document that explains what will happen to the subject during the research

How Can the Researcher Help the Potential Subject Understand?

- The informed consent document should be written at a 7th grade reading level (the documents should be easily understood)
  - any kind of scientific jargon should be as limited as possible

How Can the Researcher Help the Potential Subject Understand?

  - the subject should be able to understand the research and what is expected of them just from the informed consent document alone

How Can the Researcher Help the Potential Subject Understand?

- The informed consent should also be provided in the different languages of your community. By not doing so, the researcher runs the risk of excluding certain members of the community for the research.

Points to Remember

- The informed consent process begins when you first approach a potential subject and doesn't end until they are finished with the trial
- The subject should be given enough information to make an objective decision as to whether they would like to contribute or be part of your research

Points to Remember

- It is the potential subjects' decision, and theirs alone, as to whether they wish to contribute
- Coercion and anything close to it should be kept at a minimum

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