Informed Consent

Nilakshi Samaranayake

Jt. Secretary / Ethics review Committee

Faculty of Medicine

University of Colombo

Belmont Report

PART C: APPLICATIONS

C. APPLICATIONS

Applications of the general principles to the conduct of research leads to consideration of the following requirements: informed consent, risk/benefit assessment, and the selection of subjects of research.

1. Informed Consent. -- Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness.

Information. Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc.

http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4178b_09_02_Belmont%20Report.pdf

Responsible conduct of research

- Social value
- Scientific validity
- Fair selection of study population
- Favourable risk-benefit ratio
- **Informed consent**
- Collaborative partnership
- Respect for study participants & communities
- Independent review

Where is it assessed?

- Proposal
- Information sheet (IFS)
- Consent form

Informed consent

- Information
- Comprehension
- Voluntariness
- Competence

Components of the IFS

- Introduction to the study

(Title of the research project)

(Version number, date)

INFORMATION SHEET

I am (state name of principal investigator), attached to the (state institute). My current designation is (state the designation). I would like to invite you to take part in the research study on (state the brief non technical title of the project here) conducted by (state the name of the investigator/s) at (state the site of the study here and sponsor if relevant).

Components of the IFS

- Purpose of the study

"Malaria is one of the most common and dangerous diseases in this region. The drugs that are currently used to help people with malaria are not as good as we would like them to be. In fact, only 40 out of every 100 people given the malaria drug XYZ are completely cured. There is a new drug which may work better. The reason we are doing this research is to find out if the new drug ABX is better than drug XYZ which is currently being used. ".

Components of the IFS

- Purpose of the study

Type of research intervention

"This research will involve a single injection in your arm as well as four follow-up visits to the clinic"

Participant selection

"We are inviting all adults with malaria who attend clinic Z to participate in the research on the new malaria drug"

Components of the IFS

- Voluntary participation

"Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will offered the treatment that is routinely offered in this clinic/hospital for disease Z, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier"

Components of the IFS

- Duration, procedures and responsibilities (any procedures which are experimental)

Explain the standard treatment briefly

Unfamiliar procedures

"To confirm the cause of your swelling, a small sample of your skin will be taken. The sample will be taken using a local anesthesia which means that we will give you an injection close to the area where we will take the sample from. This will make the area numb so that you will not feel any pain when we take the sample".

Components of the IFS

- Duration, procedures and responsibilities (any procedures which are experimental)

Description of the process

"In the first visit….

At the next visit, which will be two weeks later, you will again be asked some questions about your health and then you will be given either the test drug or the drug that is currently used for malaria. As explained before, neither you nor we will know whether you have received the test or the dummy/pretend drug".

Duration

"The research takes place over 24 months in total. During that time……."

Components of the IFS

- Potential benefits

“If you fall sick during this period you will be treated free of charge”.

“There may not be any benefit for you but your participation is likely to help us find the answer to the research question”.

Components of the IFS

- Risks, hazards and discomforts (procedures to minimise)

"There is a risk that your disease will not get better and that the new medicine doesn't work even as well as the old one. If, however, the medicine is not working and your fever does not go down in 48 hours we will give you quinine injections which will bring your fever down and make you more comfortable".

Components of the IFS

- Reimbursements

"We will give you [amount of money] to pay for your travel to the clinic and we will give you [amount] for lost work time. You will not be given any other money or gifts to take part in this research".

Components of the IFS

- Confidentiality

"The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information] "

Components of the IFS

- Termination of study participation

"You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way. Please notify the investigator as soon as you decide to withdraw your consent".

Components of the IFS

- Contact information

9. Contact information

If you have questions about any of the tests / procedures or information please feel free to ask any of the persons listed below. (State a list of person/s with contact details from whom the participant can ask questions and clarify any doubts and their contact details. Contact Details should be appropriate to the nature of the study).

Components of the IFS

- Clarifications

This project has been approved by the Ethics Review Committee, Faculty of Medicine, University of Colombo. You may contact the committee if you wish to seek clarifications, record any concerns or make complaints about the study by calling 0112695300 extension 240 (between 9am and 4pm) or by sending an email to info@ethics.cmb.ac.lk.

Additional information

- A statement on risks to the subject which are currently unforeseeable
- A disclosure of any appropriate alternative procedures or courses of treatment
- Circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- 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
- An explanation and description of any compensation and any medical treatments that are available if research subjects are injured
- The approximate number of subjects involved in the study

Informed consent

- Information
- Comprehension
- Voluntariness
- Competence

Ensuring information is understood

- In the language most familiar to participant
- Target reading/writing ability of the audience
- Use active voice, short words
- Break it down
- Quiz the participant
- Don’t rush participant into a decision
- Item by item check in the consent form

Template consent form

To be completed by the participant

The participant should complete the whole of this sheet himself/herself.

1. Have you read the information sheet? (Please keep a copy for yourself) YES/NO

2. Have you had an opportunity to discuss this study and ask any questions? YES/NO

3. Have you had satisfactory answers to all your questions? YES/NO

4. Have you received enough information about the study? YES/NO

5. Who explained the study to you?/……

6. Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting your future medical care? YES/NO

Template consent form

Purpose of this study was thoroughly explained to me verbally by the principle investigator. I went through the information sheet provided to me by principle investigator regarding the study and satisfied with the information provided in the information sheet.

I confirm that the study has been explained to me and I have had ample time and opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time. I can decline to answer any of the questions if I am not comfortable.

Informed consent

- Information
- Comprehension
- Voluntariness
- Competence

Vulnerable populations

- Women
- Children
- Elderly
- Prisoners
- Differently abled
- Refugees
- Unconscious / sedated patients
- Patients who are desperately ill (“therapeutic misconception”)

Proxy Consent

- Make decisions for an incompetent patient
- Commitment to incompetent persons welfare
- Ability to make a reasoned judgment
- Define the limits on the kinds of research risks that the surrogate decision maker can accept on behalf of a non competent subject?

Assent

- Express willingness to participate in research
- By persons not legally authorised or lacks sufficient understanding for giving consent competently
- A mark of respect for a child's evolving maturity
- Age limit?
- Not a substitute for consent

Types of informed consent

"I don't need informed consent to give you a sponge bath."

Types of informed consent

Written

- Preferred method
- Participants sign a consent form to indicate that they agree to participate in a study

Verbal (Waiver of Documentation of Consent)

- Phone interviews, online surveys
- Alternative methods of proof

Waiver of consent

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects
- The research could not practicably be carried out without the waiver
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation
- ***Needs to be justified***

Consent		Applicable		Protocol Section Number	Reviewer checked
		Yes	No		
1.	The procedure for approaching the relevant community	☐	☐		
2.	The information (written/oral) provided to the community	☐	☐		
3.	The procedure for initial contact of participants	☐	☐		
4.	The information (written/oral) provided to participants	☐	☐		
5.	The procedure for obtaining informed consent	☐	☐		
6.	The procedure for ensuring that participants have understood the information provided	☐	☐		
7.	The procedure for obtaining proxy consent	☐	☐		
8.	The procedure for obtaining assent	☐	☐		
9.	The procedure for consenting if the child reaches consenting age during the study	☐	☐		
10.	The procedure for consenting if the participant acquires capacity to give consent during the study	☐	☐		
11.	The procedure for re-consenting if data or specimens that have been collected are to be used for other research projects that may be in the same (Extended Consent) or a different (Unspecified Consent) field of study	☐	☐		
12.	The procedure for withdrawing consent	☐	☐		
13.	The justification for waiver of consent or waiver of written consent	☐	☐		
14.	Incentives/rewards/compensation/reimbursement provided or not provided to participants and their accompanying persons	☐	☐		
15.	The procedure for re-consenting if the research protocol changes during the course of research	☐	☐		

How is Informed Consent obtained?

- The investigator or a person designated by investigator must obtain informed consent
- before non-routine screening procedures are performed and/or before any change in the subject's current medical therapy is made for the purpose of the clinical trial
- A conversation with the prospective participant
- Allows ample opportunity for the prospective participant to ask question

How is Informed Consent obtained?

- One time activity?
- Order of signatures
- A copy of the signed consent form must be kept at the site
- All versions of approved consent forms must be kept in the site study file; only the current ERC approved version may be used to consent new patients

Challenges in informed consent process

- Language Barriers
- Religious Influence
- Patient perceptions
- Vulnerable groups
- Cultural differences

What documentation is required?

- ❑ Information sheet
- ❑ Information for Assent
- ❑ Consent /Assent form
  - ❑ Participant's signature
  - ❑ Investigator’s signature
  - ❑ other

Role of the ERC

- Review by main Committee +/- Sub Committee
  - Review of the protocol – risks and benefits
  - Review by a non-medical member
  - Suggestions for improvement
- Cannot be modified without approval from ERC
- Observe the process of obtaining consent (site visit)

Resources

Language aids

http://www.lib.umich.edu/plain-language-dictionary

Guidance /training documents on Informed Consent

http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm#revision

https://medicine.umich.edu/medschool/research/office-research/institutional-review-boards

Policy & regulations

http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy

http://www.cioms.ch/final_draft_CIOMS_guidelines-10_september_2015-WITH_WATERMARKS.pdf