GUIDELINES FOR DRAFTING AN INFORMED CONSENT FORM

Although a sample of informed consent form is attached, additional guidelines are given here in order to help and facilitate the researchers in drafting a proper, acceptable consent form.

1. All studies involving human subjects should have a properly drafted consent form. No study should be done on human subjects without obtaining informed consent and sufficiently before the start of the study, at an appropriate time, and not at a time when s/he is under stress such as surgical procedure, and is unable to understand the study.
2. Consent may be written or verbal or telephonic. In case of unwritten consent, it should be signed by the person taking the consent and witnessed by a second person.
3. In case of children, an assent form from children and consent from guardian / parents is needed.
4. In case of mentally or physically incapacitated subject, consent should be obtained from immediate guardian or close relative
5. In case of community studies, community leaders, elders, local political leaders, religious leaders (in certain cases), and governmental officials should be taken into confidence, and a written consent should be obtained.
6. In case of doing a study in other locations such as other hospitals and clinics, permission from appropriate authority or physicians should also be obtained.
7. The consent form should be in English and Urdu with translation into other local language if needed. These should be identical in such a way that the translation of one into other is similar. The language should be easy which can be understood by study subjects (uneducated or primary passed). Use of technical terms should be avoided.
8. It should be written in “second or third person” and not in “first person”. For example, “You will be asked to give 10 cc blood” or “you will be asked few questions” etc.
9. A properly drafted consent form should contain the following important points
    a. Information sheet. There should be one paragraph or page giving information about the nature of study, its purpose and need, possible benefits of the study, and procedures to be carried out on the study subjects.
    b. Possible risks and benefits to the study subjects
    c. Availability of alternate treatment in case of therapeutic trials
    d. Voluntary participation without any compulsion, moral or otherwise and without any financial incentive or coercion. However, financial assistance or reimbursement for time and traveling may/should be provided to study subjects; which should commensurate with the time spent, and should not be too high.

e. Right to withdraw from the study at any time without affecting their rights and treatment.
f. Confidentiality
g. If any specimen is to be stored, its time of storage and permission to use it in further research.
h. Name and contact number of the investigator in case the study subject wants further clarification or information about study.
i. Authorization from study subjects with their signature, thumb impression, signature of witness etc

Important Notes

I. Studies should not be done on patient's expenses.
II. If any new or additional tests are to be done as a requirement of study, their cost should be supported by the study.
III. If a new treatment is compared with an existing and established one OR two treatment modalities are being evaluated and compared, cost of treatment or difference in cost of treatment should be borne by the study. In addition, any expected or unexpected complication arising as a result of new treatment should also be supported by the study.
IV. Studies which are unlikely to produce any significant results because of faulty design are often considered not to be ethical as such studies cause wastage of time and resources. These should be avoided unless there is strong justification.