Guidelines for Drafting Informed Consent Form

Although a sample of informed consent form is attached, additional guidelines are given here in to facilitate the researcher in drafting a simple and acceptable consent form.

1. Every research proposal involving human subjects should have a properly drafted consent form. Research should not be initiated on human subjects without obtaining informed consent before the start of the study.
2. Consent may be obtained in writing or verbally or telephonically. In case of
   (a) unwritten consent, it should be signed by the person taking the consent and witnessed by a second person.
   (b) children, an assent form from children and consent from guardian / parents is needed.
   (c) mentally or physically incapacitated participant, consent should be obtained from immediate guardian or relative such as, wife or husband, father or mother, brother or sister etc.
   (d) In 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.
3. In case of research in other locations such as hospitals and clinics, permission from appropriate authority or physicians should also be obtained.
4. The consent form should be in English, Urdu or other local language if needed. The language should be easy which can be understood by participants (uneducated or literate). Use of technical terms should be avoided.
5. The consent should be written in "second or third person" but not in "first person". For example, "You will be asked to give 10 cc blood" or "you will be asked few questions" etc.
6. 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 participants.
   b) Possible risks and benefits to the participants
   c) Availability of alternate treatment in case of therapeutic trials
   d) Voluntary participation without any compulsion, moral or otherwise and without any incentive.
   e) Right to withdraw from the study at any time without affecting their rights and treatment.
   f) Information provided by the participants will be kept confidential.
   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 participant wants further clarification or information about the research.
   i) Authorization from participants with their signature or thumb impression, signature of witness etc.