GUIDE TO WRITING A CONSENT FORM

The process of obtaining informed consent must comply with the requirements of 45 CFR 46.116**.** The documentation of informed consent must comply with 45 CFR 46.117**.** The following comments may help in the development of an approach and proposed language by investigators for obtaining consent and its approval by IRBs:

- Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. 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", (i.e. 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.
- Use of the first person (e.g., "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.

Informed Consent/Assent

The consent and assent sections of the reviewer worksheet are divided into four sections:

1) the consent document, which includes a list of required elements;
2) assent and witness requirement;
3) the consent/assent process;
4) any waivers or alterations of informed consent requirements.

1) The consent document. General federal requirements for informed consent are provided in 45 CFR 46 Section 116. The checklist provided below combines the informed consent requirements of the Department of Health and Human Services. Each element listed must be included in the informed consent, unless it is not applicable.

1. Statement that the study involves research.
2. Purpose of research stated in plain language and reason why subject is asked to participate.
3. Study procedures or treatments, including duration.
4. Potential risks or discomforts to the subject.
5. Potential direct benefits to subjects or benefits to society.
6. Compensation or reimbursement. If applicable, additional costs associated with participating—who will pay for what.
7. How confidentiality will be protected; who has access to the data.

8. Statement that participation is voluntary and subject may withdraw and, if applicable, anticipated circumstances under which a subject's participation may be terminated.
9. Appropriate contact information.

2) Assent and witness requirement. Unlike the consent document, no federal regulations exist for assent documents. However, many institutions still require separate assent documentation, whereas others require a child's co-signature on a parental permission form. For protocols that involve children, each IRB must determine whether the obtainment of assent is required and, if so, an appropriate mechanism for obtaining and documenting assent. The IRB must also determine whether the permission of one or both parents should be obtained. Assent obtainment and documentation requirements need to be considered on a per-protocol basis. The following reviewer worksheet questions prompt the IRB members to make this special determination when required.

3). Process of obtaining informed consent/assent. Although the regulations require the inclusion of certain elements in the informed consent document, they do not provide rules or requirements for the process of obtaining informed consent. Investigators and reviewers are urged to consider the following general recommendations and suggestions when proposing or reviewing a method of obtaining consent.

- Who?
  It is important to consider what type of relationship exists between the subject and the person approaching the subject for consent.
- When?
  When potential subjects are being educated or informed about the research opportunity available to them, timing is very important. The IRB should consider when subjects would be approached regarding participation in a research study.
- Where and How?
  The IRB should consider where the informed consent process will take place and how it will be conducted.

4) Waiver or modification of informed consent. Federal regulations permit the waiver or alteration of the informed consent document if a protocol meets very specific criteria. In order for the IRB to determine whether a protocol meets the criteria, it is essential that investigators seeking the waiver or alteration provide adequate justification for the request. The worksheet questions here help IRB reviewers to look for the appropriate justification if a waiver or alteration is requested.

- **Describe the overall experience that will be encountered**. Explain the research activity, how it is experimental (e.g., 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.
- **Describe the benefits that subjects may reasonably expect to encounter**. 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.
- **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.
- **The regulations insist that the subjects be told the extent to which their personally identifiable private information will be held in confidence**. 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 (e.g.,subpoena) of the names or other identifying characteristics of research subjects. The IRB will determine the level of adequate requirements for confidentiality in light of its mandate to ensure minimization of risk and determination that the residual risks warrant involvement of subjects.
- **If research-related injury (i.e. physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk (see 45 CFR 46.102[g]), 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.
- **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.
- **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. These questions could be addressed to the IRB, an ombudsman, an ethics committee, or other informed administrative body. Therefore, each consent document can be expected to have at least two names with local telephone numbers for contacts to answer questions in these specified areas.

- **The statement regarding voluntary participation and the right to withdraw at any time can be taken almost verbatim from the regulations** (45 CFR 46.116 [a][8]). 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 intervention to maintain normal function.
- Don't forget to ensure provision for appropriate **additional requirements** which concern consent. Some of these requirements can be found in sections 46.116(b), 46.205 (a)(2), 46.207(b), 46.208 (b), 46.209(d), 46.305 (a)(5-6), 46.408(c), and 46.409 (b). The IRB may impose additional requirements that are not specifically listed in the regulations to ensure that adequate information is presented in accordance with institutional policy and local law.