

1. Informed Consent Guidelines

"Informed consent" provides the subject the opportunity to exercise free power of choice without undue inducement, as to whether or not he/she chooses to participate in the research project. It is the investigator(s) responsibility to provide a concise, yet complete explanation to the subject concerning what is expected from his/her involvement in the investigation. Each of the following *Basic Elements of the Informed Consent* must be included:

1. A concise, yet complete explanation of the procedures to be followed, including the duration of the subject's participation. Identification of experimental procedures must be revealed.
2. A description of any risks or discomfort that can be reasonably expected.
3. A description of any benefits that can be reasonably expected.
4. A disclosure of alternative procedures, especially therapeutic procedures that may be advantageous for the subjects(s).
5. A statement explaining the extent of confidentiality of data and records.
6. A statement allowing the subject to withdraw consent and/or discontinue participation in the project at any time without intimidation or prejudice.
7. An explanation as to whether compensation or medical treatment is available if physical injury occurs as a direct result of the study.
8. The name and telephone number of whom to contact for answers to pertinent questions about the research, research subject's rights, or whom to contact in case of a research-related injury.

Additional elements of the informed consent that may be included are:

- Subject criteria: age, gender, medical conditions, number of subjects needed, etc.
- Circumstances under which the subject's participation may be terminated.
- Financial obligation of the subject that may result from participation in the study.
- Participants should receive a copy of the consent form.