**INFORMED CONSENT GUIDELINES**

Informed consent at Pensacola State College refers to the voluntary choice of an individual to participate in research based on an accurate and complete understanding of its purposes, procedures, risks, benefits, alternatives, and any other factors that may affect a person's decision to participate.

**General Requirements**

Informed consent must be prospectively obtained from the subject or legally authorized representative of the subject (if allowed by state law). A subject must be given sufficient opportunity to consider whether to participate. Consent must be given without coercion or undue influence. A subject must not be made to give up legal rights or be given the impression of being asked to do so.

**Competency to Consent**

Informed consent must be legally effective under applicable Florida Statute. Only legally competent adults can give consent. In most cases, minors cannot give consent; only parents or legal guardians can give permission for minors to participate in research. Incompetent adults, such as the developmentally disabled or the cognitively-impaired elderly, cannot give consent. Only legally authorized representatives in accordance with state law can give permission for incompetent adults to participate in research. The evaluation of competence must be made on a case-by-case basis. In addition to obtaining permission from parents or legal guardians, provisions must be made for soliciting the assent of the children or incompetent adults.

**Basic Elements of Informed Consent**

The following specific elements of information must be provided to each prospective subject:

1. A statement that the study involves research, an explanation of the purpose of the research and the expected duration of the subject's participation, a description of the procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

8. A statement that participation in voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

**Research and Procedures**

The information provided to subject should make clear that the activity involves research and describe the overall experience that will be encountered: explain the research activity, including any parts that will be experimental (e.g., extra tests, separate research records, or nonstandard means of management such as flipping a coin for random assignment or other design issues).

**Risks**

All reasonably foreseeable risks, discomforts, inconvenience, and harms that are associated with the research activity, should be described. Investigators should be forthcoming about risks and not underestimate or gloss over reasonably foreseeable risks. 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 contacted again or newly contacted.

**Benefits**

Any benefits that subjects may reasonably expect to encounter should be described. Investigators should be frank about benefits and not overestimate or magnify the possibility of benefit to the subject. There may be no benefit other than a sense of helping the public at large. Payment to subjects should not be listed or described as a benefit.

**Alternatives to Participation**

Appropriate alternatives to participating in the research project, particularly alternatives that may be attractive to the subject, should be described. For example, in drug studies, the medication may be available through a family doctor or clinic without the need to volunteer for the research activity. Researches should be reasonably specific in describing the nature and type of alternatives. It is not sufficient simply to state that "the researcher will discuss alternative treatments" with the subject.

**Confidentiality Protections**

Subjects must be told the extent to which their personally identifiable, private information will be held in confidence. For example, sponsors, funding agencies, regulatory agencies, and the IRG may review research records. Some studies may need sophisticate encryption techniques to prevent confidentiality breaches or a Certificate of Confidentiality to protect the investigator from involuntary release (e.g., under subpoena) of subjects' names or identifiable private information.

**Compensation for Injury**

If there is more than a minimal risk of injury related to a research activity (i.e., physical, psychological, social, financial, or otherwise), an explanation must be given of whatever voluntary compensation and treatment will be provided. Note that injury is not limited to

physical injury. No subject will be required to waive any legal rights or be led to believe that such rights have been waived. Consent language regarding compensation for injury must be selected carefully so that a subject is not given the impression that he or she has no recourse to seek satisfaction beyond the college's voluntarily chosen limits.

**Contact Persons**

One or more individuals must be identified to answer subjects' pertinent questions about the research and their rights as research subjects. Subjects also must be informed as to whom to contact in the event of any injury related to the research. These areas must be stated explicitly and addressed in the consent process and documentation. Questions about the research are usually best answered by the investigator. However, questions about subjects' rights may be answered better by a person not on the research team. Each consent document can be expected to include at least two names with local telephone numbers for contacts to answer questions in these specified areas.

**Voluntary Participation**

Every subject must be informed that participation in any research activity is completely voluntary and that a subject may discontinue participation at any time. It must be clear that there is no penalty or loss of benefits either for declining to participate or for discontinuing participation.

**Additional Elements**

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. 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; and
6. The approximate number of subjects involved in the study.

**WAIVER OF INFORMED CONSENT**

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

## DOCUMENTATION OF INFORMED CONSENT

Informed consent is usually documented by use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

### Long Consent Form

A written consent document that includes all of the required elements is generally required. The document is to be written in language understandable by the subject or representative; technical language is to be avoided. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

### Short Consent Form

A written short form consent document stating that the required elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation.

### Waiver of Consent Form

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern the documentation; or
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.