

Policy for the Protection of Human Subjects Informed Consent

1. Informed Consent

1.1. Information Provided

1.1.1.Understandable Language

1.1.2.No Waivers for Negligence

1.1.3.Information Content

1.1.4.Additional Applicable Information

1.1.5.Alteration, Elimination, or Waivers of Informed Consent

1.1.6.No Preemption of Required Disclosure

1.1.7.No Limitation on Emergency Medical Care

2. Documentation

2.1. Written Consent

2.2. Informed Consent Form

2.2.1.Types of Consent Forms

2.3. IRB Waiver

2.3.1.Potential Harm to Subject

2.3.2.Minimal Risk

2.3.3.Informing Subject

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1. Informed Consent

Informed consent is a necessary prerequisite for research involving human subjects. Sufficient information about the research and what subjects are anticipated to experience must be provided to a potential subject to allow that person an opportunity to consider the project and consequences of becoming a subject and to make an informed decision about whether or not to participate. This decision must be reached by the subject without coercion or the imposition of undue influence. After receiving the information, the subject or the subject's legally authorized representative must execute an Informed Consent authorization form.

1.1. Information Provided

The subject or subject's representative shall be provided information about the planned research as described below.

1.1.1. Understandable Language

The potential subject or the subject's representative shall be provided information about the research project in understandable language.

1.1.1.1. Under circumstances where the subject does not speak or read English, a consent form should be produced in a language which the subject understands.

1.1.1.2. Alternatively, the information may be presented orally, per **Section 2.2.1.2.**

1.1.2. No Waivers for Negligence

Informed consent shall not include language that explicitly or inferentially waives the subject's legal rights or releases the investigator, sponsor, Whittier College, or any of its agents from liability for negligence.

1.1.3.Information Content

The following lists the necessary elements that must be present in the information provided to potential subjects or their representatives prior to execution of Informed Consent forms.

1.1.3.1. The research statement shall include the following.

- A statement that the study involves research,
- An explanation of the purposes of the research,
- A projection of the expected duration of the subject's participation,
- A description of the procedures that will be followed,
- Identification of the procedures that are experimental.

1.1.3.2. Reasonably foreseeable risks or discomforts to subjects will be listed and described.

1.1.3.3. Reasonably expected benefits to the subject and others will be listed and described.

1.1.3.4. If applicable to the project, disclosure will be made of alternative procedures or treatments that might be effective for the subject.

1.1.3.5. A statement will be made regarding the extent to which the identity of the subject will be kept confidential.

1.1.3.6. For projects that involve more than a minimal risk, there must be an explanation about any compensation or medical treatment that is available in the event that injury to the subject should occur, and what types of injuries might be expected, along with information sources regarding those topics.

1.1.3.7. There must be a designated person indicated as a point of contact for the subject to obtain answers to questions about the research, subject rights, and

questions about whom to contact regarding research related injuries.

- 1.1.3.8. There must be a statement that participation in the project is voluntary, and refusal will result in no penalty or loss of benefits to which the subject might otherwise be entitled. In addition, it must be stated that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject might otherwise be entitled.

1.1.4. Additional Applicable Information

Additional information shall be provided from the following list of items when it is applicable.

- 1.1.4.1. A statement must be included that the particular treatment or procedure may involve currently unforeseeable risks to the subject (or if the subject is or may become pregnant, to the embryo or fetus).
- 1.1.4.2. The subject must be informed of anticipated circumstances where the subject's participation may be terminated without his/her consent.
- 1.1.4.3. Any additional costs that the subject may incur as a result of participation in the research must be indicated.
- 1.1.4.4. The subject must be informed about potential consequences of withdrawal from the research and the procedures that must be followed for orderly termination of participation.
- 1.1.4.5. The subject must be informed of new findings during the research, which may affect his/her willingness to continue participation in the program.
- 1.1.4.6. The subject will be informed about the number of subjects involved in the study.

1.1.5. Alteration, Elimination, or Waivers of Informed Consent

The IRB may approve a consent procedure that differs from the standard informed consent process, either by the elimination or alteration of elements of Informed Consent, or by the waiver of the requirement to obtain informed consent if the following items are identified and documented.

1.1.5.1. Individual informed consent requirements may be modified by the IRB when the research or demonstration project is conducted by or subject to the approval of state or local government officials, and it is designed to study, evaluate, or otherwise examine one of the following.

- Public benefit or service programs.
- Procedures for obtaining benefits or services under those programs.
- Possible changes in or alternatives to those programs or procedures.
- Possible changes in methods or levels of payment for benefits or services under those programs.

1.1.5.2. Informed consent requirements may be modified, eliminated, or waived by the IRB if it finds and documents that the research could not be carried out practicably without the waiver or alteration.

1.1.5.3. Informed consent requirements may be modified, eliminated, or waived by the IRB when the IRB finds and documents that the following is true.

- The research involves no more than minimal risk to the subjects.
- Waivers or alterations will not adversely affect the rights and welfare of the subjects.

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

1.1.6.No Preemption of Required Disclosure

The requirements under **45 CFR Part 46** do not preemptively reduce any other applicable federal, state, or

local laws as to the required information that must be disclosed for legally effective informed consent.

1.1.7.No Limitation on Emergency Medical Care

Physicians are not precluded under **45 CFR Part 46** from providing emergency medical care, to the extent they are permitted under applicable federal, state, or local laws.

2. Documentation (**45 CFR 46.117**)

2.1. Written Consent

The form approved by the IRB, per **Section 2.2**, shall be utilized in obtaining informed consent, except for circumstances listed in **Section 2.3**. The document will be signed by the subject or the subject's legally authorized representative. A copy shall be provided to the person signing the document.

2.2. Informed Consent Form

The IRB shall approve a standardized form for use in obtaining documentation of informed consent.

2.2.1.Types of Consent Forms

The Consent Form may be either of the following two types.

2.2.1.1. A written consent document that captures the elements of informed consent as specified in **45 CFR 46.116** and **Section 1** of this procedure. The form may be read to the subject or the subject's legally authorized representative. In any case, the researcher shall assure that the subject or the subject's representative has sufficient time to read and understand the document before it is signed.

2.2.1.2. A short form written consent document may be used to document that required information according to **45 CFR 46.116** and **Section 1** of this procedure have been presented orally to the subject or the subject's legally

authorized representative. When this method is used, it must include the following.

- Someone must witness the oral presentation of the information.
- A written summary of the planned presentation to the subject or the subject's representative must be pre-approved by the IRB.
- The summary must be signed by both the witness and the researcher obtaining the consent.
- The short informed consent form must be signed by the subject or the subject's representative and the witness.
- A copy of the signed short form and the summary shall be given to the subject or the subject's authorized legal representative.

2.2.1.3. For circumstances where the subject does not speak or read English, the following elements are specified.
(See Attachment 1, per Division of Human Subjects Protections, OPRR, inter-office memo.)

- In the event that the oral presentation is done in a language other than English, the witness must be fluent in both English and the language of the subject.
- The short form written document should be provided in the language of the subject.
- The IRB-approved English language consent form may serve as the summary.
- The short form must be signed by the subject and the witness.
- The summary document (IRB-approved English language consent form) must be signed by the researcher and the witness.

2.3. IRB Waiver

The IRB may waive the requirement for the researcher to obtain a signed informed consent form for some or all subjects of a research project for either of the reasons provided in **Sections 2.3.1** and **2.3.2**.

2.3.1.Potential Harm to Subject

The only record of the subject's participation would be the consent form, and there is the potential of harm to the subject if ever there should be a failure in confidentiality. The subject shall be asked whether or not he/she wants the documentation of his/her participation in the project. If the subject does not want the documentation to exist, no consent document will be created.

2.3.2.Minimal Risk

The research is projected to be of minimal risk to the subjects, and no procedures that would normally require written consent will be involved.

2.3.3.Informing Subject

The IRB may require that the researcher provide a written statement about the research to the subjects who waive documentation.