

**South Carolina Department of Mental Health  
Institutional Review Board**

**GUIDELINES FOR AN INFORMED CONSENT FORM TO BE USED IN  
RESEARCH PROJECTS INVOLVING HUMAN SUBJECTS**

No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

No informed consent may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, sponsor, the institution, or its agents from liability for negligence.

**ELEMENTS OF AN INFORMED CONSENT**

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subjects' participation, a description of the procedures to be followed, and identification of any 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 and that notes the possibility that the Food and Drug Administration may inspect the records.
6. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject.
7. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
8. 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.

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 (or to the embryo or fetus, if the subject is or may become pregnant) 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 that may relate to the subject's willingness to continue participation will be provided to the subject.

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### **Research and Procedures**

The information provided to subjects should:

- Make clear that the activity involves research and describe the overall experience that will be encountered;
- Explain the procedures, including any parts that are 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);
- Include the expected length of time it will take for study visits or scheduled procedures, as well as, the total expected length of participation.

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### **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 understate 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 recontacted or newly contacted.

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### **Benefits**

- Any benefits to subjects or others which may reasonably be expected from the research should be described.
- Investigators should be frank about benefits and not overestimate or magnify the possibility of benefit to the subject. If there is no reasonable expectation of benefit, the subject should be told this..
- Payment to subject should not be listed or described in the Benefits section.

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## Alternatives to Participation

- Appropriate alternatives to participating in the research project, particularly alternatives that might be advantageous to the subject, should be described. 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.
- Investigators should be reasonably specific about describing the nature and type of available alternatives. It is not sufficient simply to state that "the researcher will discuss alternative treatments" with the subject.

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## Confidentiality Protections

The regulations require that subjects be told the extent to which confidentiality of research records identifying the subject will be held in confidence. For example, sponsors, funding agencies, regulatory agencies, and the IRB may review research records. Some studies may need sophisticated encryption techniques to prevent confidentiality breaches or a Certificate of Confidentiality to protect the investigator from being compelled to release (e.g., under subpoena) subjects' names or identifiable private information.

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## Compensation for Injury

If research-related injury (i.e., physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk, an explanation must be given as to whether any compensation and treatment will be provided and if so, what these consist of and where further information may be obtained. **Note that the regulations do not limit injury to "physical injury." This is a common misinterpretation.**

The regulations prohibit

- (i) Requiring subjects to waive any of their legal rights, and (ii) leading subjects to believe they are waiving their rights. Consent language regarding compensation for injury must be selected carefully so that subjects are not given the impression that they have no recourse to seek satisfaction beyond the institution's voluntarily chosen limits.

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## Contact Persons

The regulations require the identification of contact persons to answer subjects' questions about the research and their rights as research subjects. Subjects must also be informed as to whom to contact in the event of any research-related injuries.

These areas must be explicitly stated and addressed in the consent process and documentation.

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## Contact Persons

A single contact person is not likely to be appropriate to answer questions in all areas. This is because of real or apparent conflicts of interest. Questions about the research are frequently best answered by the investigator(s). However, questions about the rights of research subjects may best be referred to persons not on the research team. These questions could be addressed to the IRB, an ombudsperson, an ethics committee, or other informed individual or committee.

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.

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### **Voluntary Participation**

The regulations require statements regarding voluntary participation and the right to withdraw at any time. Subjects must be informed that:

- Participation is voluntary;
- Subjects may discontinue participation at any time;
- There is no penalty or loss of benefits for refusing to participate or discontinuing participation.

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### **Additional Protections for Vulnerable Populations**

- The regulations identify three populations as needing additional protections. These are Subpart B Additional DHHS Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research; Subpart C Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects; and Subpart D Additional DHHS Protections for Children Involved in Research. The provisions of these subparts must be met for research to be approved.
- Incompetent adults cannot give consent – this may include the developmentally disabled, the cognitively-impaired elderly, and unconscious or inebriated individuals. Only legally authorized representatives in accordance with state law can give permission for incompetent adults to participate in research.
- In addition to the population described above, when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as economically or educationally disadvantaged persons or subordinates, additional safeguards shall be included to protect the rights and welfare of the subjects.

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### **Waiver of Consent**

Under certain circumstances specified in the HHS regulations, the IRB may approve a consent procedure that does not include some or all of the elements of informed consent, or may waive the requirements for obtaining informed consent. To do so, the IRB must find and document that:

- The research involves no more than minimal risk to subjects;
- The waiver will not adversely affect the rights and welfare of subjects;
- The research could not practicably be carried out without the waiver; and
- Whenever appropriate, the subjects will be debriefed – provided with additional pertinent information – after they have participated in the study.
- NOTE – FDA regulations do not provide for a waiver of consent, except in emergency situations.

## **The Consent Process**

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### **Documentation of Consent**

The information that is given to the prospective subject, or his/her representative, must be in language understandable to the subject or representative.

Consent forms should be written at a level appropriate to the understanding of the subjects to be enrolled; technical language should be avoided.

OHRP strongly discourages use of the "first person" in consent documents (e.g., "I have been fully informed about ..."). Such statements unfairly ask subjects to make statements that the subject is not in a position to verify (e.g., the subject has no way to verify that the investigator has provided full and complete information).

Except as allowed below, the informed consent must be documented by the use of a written consent form approved by the IRB and signed by the subject or legally authorized representative. A copy shall be given to the person signing the form.

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### **Waiver of Documentation of Consent**

The IRB may waive the requirement for written documentation of consent in cases where:

- The principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research; and the consent document is the only record linking the subject with the research; each subject will be asked if they want documentation to remain with them or with the research and the subject's wishes will govern;

OR

- The research presents no more than minimal risk and involves procedures that do not require written consent when performed outside of a research setting.