

## **DHS INFORMED CONSENT POLICIES**

Where informed consent is required, the Researcher shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative. If the subject is a child or an adult with a legally authorized representative or guardian, but the subject is nevertheless capable of consenting to the research project, the Researcher must also obtain the informed assent of that child or adult. (As used in the following provisions of this policy, the term "subject" includes both the subject and the subject's legally authorized representative, if any.)

The Researcher shall give each subject a written informed-consent form that explains the study in simple, easily-understood language and easy-to-read type. The Researcher shall give each subject a reasonable opportunity to read the form and ask questions before signing the form.

## **DHS INFORMED CONSENT REQUIREMENTS**

**At a minimum, the informed-consent form shall comply with the following requirements:**

- A. The informed-consent form shall not include any exculpatory language that requires or appears to require the subject to waive any of the subject's legal rights, nor may the form release or appear to release the Researcher, investigator, sponsor, the institution or their agents from liability for negligent or intentional harm.
- B. The Researcher shall provide the subject with sufficient information and opportunity to consider whether or not to participate in the study.
- C. The Researcher shall ensure that the possibility of coercion or undue influence is minimized.
- D. The Researcher shall give the subject a written statement that clearly explains the following:
  - 1. That the study involves research
  - 2. The purposes of the research
  - 3. How long the subject's participation will last
  - 4. The procedures that the Researcher will use
  - 5. Whether any of procedures the Researcher plans to use are experimental, and if so, which ones
  - 6. The approximate number of subjects who will be involved in the study.
  - 7. That participation in the research study is voluntary, and that refusal to participate in the study will not result in any penalty or loss of benefits to which the subject is otherwise entitled; and

8. That the subject may withdraw from the study at any time without penalty and without loss of any benefits to which the subject is otherwise entitled.
- E. The Researcher shall give the subject a written description of any reasonably foreseeable risks, discomforts or consequences that the subject might experience as a result of participating in the study.
- F. For research involving more than minimum risk, the Researcher shall give the subject a written explanation of:
  1. Whether the subject may obtain compensation for any injuries or damages arising out of such risk;
  2. Whether any medical treatment is available for such injuries or damages, and if so, what those treatments are and whether the Researcher will provided them free of charge to the subject; and
  3. Whom the subject should contact to obtain further information about the risk of injury or damage or about compensation or treatment.
- G. The Researcher shall give the subject a written description of any additional costs that the subject may incur as the result of participating in the research study.
- H. The Researcher shall give the subject a written description of any benefits that the research project will provide to the subject or others.
- I. The Researcher shall give the subject a written disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the subject.
- J. If any of the Researcher's treatments or procedures poses currently unforeseeable risks to the subject or to an embryo or fetus if the subject becomes pregnant, the Researcher shall notify the subject in writing about this risk. (The Department will not approve any studies that involve foreseeable risk to a pregnant subject or to the subject's embryo or fetus.)
- K. The Researcher shall give the subject a written statement describing the extent to which the Researcher will maintain confidentiality of records.
- L. The Researcher shall notify the subject in writing whom the subject should contact if the subject has questions about the research or the subject's rights, including the DHS IRB contact.
- M. The Researcher shall give the subject a written statement listing the anticipated circumstances in which the Researcher may terminate the subject's participation in the research study.

- N. The Researcher shall give the subject a written description of the consequences of a subject's decision to withdraw from the research study, and a description of the procedures for orderly termination of the subject's participation in the study.
- O. The Researcher shall give the subject a written statement indicating that if the Researcher makes significant new research findings which relate to the subject's willingness to continue participation in the research project, the Researcher will notify the subject about those findings during the study.
- P. The Researcher shall give the subject a written statement indicating that if the subject discloses any actual or suspected abuse, neglect or exploitation of a child, disabled adult or elder adult, the Researcher must report this abuse to the authorities, as required by federal and state laws.
- Q. If the subject is a child and the State has guardianship over the child, the Researcher shall give the subject a written statement indicating that the child is represented by the Office of the Guardian Ad Litem. To facilitate access to the Guardian Ad Litem, the statement shall also include the Guardian Ad Litem's phone number: (801) 578-3962.
- R. The informed consent must disclose if the research is being conducted to fulfill the requirements for a master's thesis or doctoral dissertation.