

**§46.101 To what does this policy apply?**

(a) Except as provided in paragraph (b) of this section, this policy applies to **all research involving human subjects** conducted, supported or otherwise subject to regulation by any federal department or agency...

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are **exempt** from this policy:

(1) Research conducted in established or commonly accepted educational settings, **involving normal educational practices**, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless**: (i) information obtained is recorded in such a manner that **human subjects can be identified**, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be **damaging to the subjects'** financial standing, employability, or reputation...or if: (3)(i) the human **subjects are** elected or appointed **public officials** or candidates for public office; or (3)(ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or **study of existing data**, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

**§46.102 Definitions.**

(f) Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

(i) **Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life** or during the performance of routine physical or psychological examinations or tests.

**§46.107 IRB membership.**

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution...

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

**§46.109 IRB review of research.**

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent...

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

**§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.**

(b) An IRB may use the **expedited review procedure** to review either or both of the following:

(1) Some or all of the research appearing on the list and found by the reviewer(s) to involve **no more than minimal risk**,

(2) **Minor changes in previously approved research** during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review **may be carried out by the IRB chairperson** or by one or more experienced reviewers designated by the chairperson from among members of the IRB.

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

**§46.111 Criteria for IRB approval of research.**

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) **Risks to subjects are minimized:** (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) **Risks to subjects are reasonable in relation to anticipated benefits**, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) **Selection of subjects is equitable.** In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) **Informed consent will be sought** from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) **Informed consent will be appropriately documented**, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate **provision for monitoring the data collected to ensure the safety of subjects.**

(7) When appropriate, there are adequate **provisions to protect the privacy of subjects and to maintain the confidentiality of data.**

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

#### **§46.113 Suspension or termination of IRB approval of research.**

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

#### **§46.115 IRB records.**

(b) The **records required by this policy shall be retained for at least 3 years**, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection...

#### **§46.116 General requirements for informed consent.**

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an **explanation of the purposes** of the research and the expected **duration of the subject's 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**;

(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 and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A **statement that participation is 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.

(c) An 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 requirement to obtain informed consent provided the IRB finds and documents that:

(2) The research could not practicably be carried out without the waiver or alteration.

#### **§46.117 Documentation of informed consent.**

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the 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.**

(b) Except as provided in paragraph (c) of this section, the **consent form may be either of the following:**

(1) A written consent document that embodies the elements of informed consent required by §46.116. ...

(2) A short form written consent document stating that the elements of informed consent required by §46.116 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.** Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the **short form itself is to be signed by the subject** or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A **copy of the summary shall be given to the subject** or the representative, in addition to a copy of the short form.

(c) An 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; 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.**