at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.


(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 is in accordance with §225.116. The IRB may require that information, in addition to that specifically mentioned in §225.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with §225.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(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.

(Approved by the Office of Management and Budget under control number 0990–0260)

[56 FR 28012, 28020, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

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

(a) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(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. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §225.108(b).

(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.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

[56 FR 28012, 28020, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 225.111 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 sub-
jects to risk, and (ii) whenever appro-
priate, by using procedures already
being performed on the subjects for di-
gnostic 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 distin-
guished from risks and benefits of
therapies subjects would receive even if
not participating in the research). The
IRB should not consider possible long-
rangage 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 in-
volving vulnerable populations, such as
children, prisoners, pregnant women,
mentally disabled persons, or economi-
cally or educationally disadvantaged
persons.

(4) Informed consent will be sought
from each prospective subject or the
subject’s legally authorized representa-
tive, in accordance with, and to the ex-
tent required by §225.116.

(5) Informed consent will be appro-
priately documented, in accordance
with, and to the extent required by
§225.117.

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

(7) When appropriate, there are ade-
quate provisions to protect the privacy
of subjects and to maintain the con-
identiality 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 in-
cluded in the study to protect the
rights and welfare of these subjects.

§225.112 Review by institution.

Research covered by this policy that
has been approved by an IRB may be
subject to further appropriate review
and approval or disapproval by officials
of the institution. However, those offi-
cials may not approve the research if it
has not been approved by an IRB.

§225.113 Suspension or termination of
IRB approval of research.

An IRB shall have authority to sus-
pend or terminate approval of research
that is not being conducted in accord-
ance with the IRB’s requirements or
that has been associated with unex-
pected serious harm to subjects. Any
suspension or termination of approval
shall include a statement of the rea-
sons for the IRB’s action and shall be
reported promptly to the investigator,
appropriate institutional officials, and
the department or agency head.

(Approved by the Office of Management and
Budget under control number 0990–0260)

§225.114 Cooperative research.

Cooperative research projects are
those projects covered by this policy
which involve more than one institu-
tion. In the conduct of cooperative re-
search projects, each institution is re-
sponsible for safeguarding the rights
and welfare of human subjects and for
complying with this policy. With the
approval of the department or agency
head, an institution participating in a
cooperative project may enter into a
joint review arrangement, rely upon
the review of another qualified IRB, or
make similar arrangements for avoid-
ing duplication of effort.

§225.115 IRB records.

(a) An institution, or when appro-
priate an IRB, shall prepare and main-
tain adequate documentation of IRB
activities, including the following:

(1) Copies of all research proposals re-
viewed, scientific evaluations, if any,
that accompany the proposals, ap-
proved sample consent documents,