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-
agnostic 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-
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 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 confi-
dentiality 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,