category of subjects, such as children, prisoners, pregnant women, or handi-
capped or mentally disabled persons, consideration shall be given to the in-
clusion of one or more individuals who are knowledgeable about and experi-
enced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB
consists entirely of men or entirely of women, including the institution’s con-
sideration of qualified persons of both sexes, so long as no selection is made
to the IRB on the basis of gender. No IRB may consist entirely of members
of one profession.

(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.

(d) Each IRB shall include at least one member who is not otherwise affili-
ated with the institution and who is not part of the immediate family of a
person who is affiliated with the institution.

(e) No IRB may have a member par-
ticipate in the IRB’s initial or con-
tinuing review of any project in which
the member has a conflicting interest, except to provide information re-
quested by the IRB.

(f) An IRB may, in its discretion, in-
vite individuals with competence in
special areas to assist in the review of
issues which require expertise beyond
or in addition to that available on the
IRB. These individuals may not vote
with the IRB.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3,
3474; and 42 U.S.C. 300v–1(b))

§ 97.108 IRB functions and operations.

In order to fulfill the requirements of
this policy each IRB shall:

(a) Follow written procedures in the
same detail as described in §97.103(b)(4)
and, to the extent required by,
§97.103(b)(5).

(b) Except when an expedited review
procedure is used (see §97.110), review
proposed research at convened meet-
ings at which a majority of the mem-
bers of the IRB are present, including
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 ma-
jority of those members present at the
meeting.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3,
3474; and 42 U.S.C. 300v–1(b))

§ 97.109 IRB review of research.

(a) An IRB shall review and have au-
thority to approve, require modifica-
tions in (to secure approval), or dis-
approve all research activities covered
by this policy.

(b) An IRB shall require that infor-
mation given to subjects as part of in-
formed consent is in accordance with
§97.116. The IRB may require that infor-
mation, in addition to that specifically mentioned in §97.116, be given to
the subjects when in the IRB’s judg-
ment the information would meaning-
fully add to the protection of the rights
and welfare of subjects.

(c) An IRB shall require documenta-
tion of informed consent or may waive
documentation in accordance with
§97.117.

(d) An IRB shall notify investigators
and the institution in writing of its de-
cision to approve or disapprove the pro-
posed research activity, or of modifica-
tions required to secure IRB approval
of the research activity. If the IRB de-
cides to disapprove a research activity,
it shall include in its written notifica-
tion 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 pol-
icy at intervals appropriate to the de-
gree of risk, but not less than once per
year, and shall have authority to ob-
serve 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, 28021, June 18, 1991, as amended
at 70 FR 36328, June 23, 2005]

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3,
3474; and 42 U.S.C. 300v–1(b))

§ 97.110 Expedited review procedures
for certain kinds of research involv-
ing no more than minimal risk, and
for minor changes in approved re-
search.

(a) The Secretary, HHS, has estab-
lished, and published as a Notice in the