research, the research shall first be re-
viewed and approved by an IRB, as pro-
vided in this policy, a certification sub-
mitted, by the institution, to the de-
partment or agency, and final approval
given to the proposed change by the de-
partment or agency.

§ 46.120 Evaluation and disposition of
applications and proposals for re-
search to be conducted or sup-
ported by a Federal Department or
Agency.

(a) The department or agency head
will evaluate all applications and pro-
posals involving human subjects sub-
mitted to the department or agency
through such officers and employees of
the department or agency and such ex-
perts and consultants as the depart-
ment or agency head determines to be
appropriate. This evaluation will take
into consideration the risks to the sub-
jects, the adequacy of protection
against these risks, the potential bene-
fits of the research to the subjects and
others, and the importance of the
knowledge gained or to be gained.

(b) On the basis of this evaluation,
the department or agency head may
approve or disapprove the application
or proposal, or enter into negotiations
to develop an approvable one.

§ 46.121 [Reserved]

§ 46.122 Use of Federal funds.

Federal funds administered by a de-
partment or agency may not be ex-
pended for research involving human
subjects unless the requirements of
this policy have been satisfied.

§ 46.123 Early termination of research
support: Evaluation of applications
and proposals.

(a) The department or agency head
may require that department or agency
support for any project be terminated
or suspended in the manner prescribed
in applicable program requirements,
when the department or agency head
finds an institution has materially
failed to comply with the terms of this
policy.

(b) In making decisions about sup-
porting or approving applications or
proposals covered by this policy the de-
partment or agency head may take
into account, in addition to all other
eligibility requirements and program
criteria, factors such as whether the
applicant has been subject to a termi-
nation or suspension under paragraph
(a) of this section and whether the ap-
plicant or the person or persons who
would direct or have have directed the
scientific and technical aspects of an
activity has have, in the judgment of
the department or agency head, mate-
rially failed to discharge responsibility
for the protection of the rights and
welfare of human subjects (whether or
not the research was subject to federal
regulation).

§ 46.124 Conditions.

With respect to any research project
or any class of research projects the de-
partment or agency head may impose
additional conditions prior to or at the
time of approval when in the judgment
of the department or agency head addi-
tional conditions are necessary for the
protection of human subjects.

Subpart B—Additional Protections
Pertaining to Research, Devel-
opment, and Related Activi-
ties Involving Fetuses, Preg-
nant Women, and Human In
Vitro Fertilization

SOURCE: 40 FR 33528, Aug. 8, 1975, unless
otherwise noted.

§ 46.201 Applicability.

(a) The regulations in this subpart
are applicable to all Department of
Health and Human Services grants and
contracts supporting research, develop-
ment, and related activities involving:
(1) The fetus, (2) pregnant women, and
(3) human in vitro fertilization.

(b) Nothing in this subpart shall be
construed as indicating that compli-
ance with the procedures set forth
herein will in any way render inappli-
cable pertinent State or local laws
bearing upon activities covered by this
subpart.

(c) The requirements of this subpart
are in addition to those imposed under
the other subparts of this part.