§ 27.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, 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.
human subjects, but it is later pro-
posed to involve human subjects in the
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.

§ 27.120 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-
erts 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.

§ 27.121 [Reserved]

§ 27.122 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.

§ 27.123 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 directed the
scientific and technical aspects of an
activity has, 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).

§ 27.124 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.

PART 28—NEW RESTRICTIONS ON
LOBBYING

Subpart A—General

Sec.
28.100 Conditions on use of funds.
28.105 Definitions.
28.110 Certification and disclosure.

Subpart B—Activities by Own Employees

28.200 Agency and legislative liaison.
28.205 Professional and technical services.
28.210 Reporting.

Subpart C—Activities by Other Than Own
Employees

28.300 Professional and technical services.

Subpart D—Penalties and Enforcement

28.400 Penalties.
28.405 Penalty procedures.
28.410 Enforcement.

Subpart E—Exemptions

28.500 Secretary of Defense.

Subpart F—Agency Reports

28.600 Semi-annual compilation.