Table 1—Framework for Equivalent Protections

Specific Protection	Example Procedures	45 CFR 46 Authority
INSTITUTIONAL RESPONSIBILITIES		
Establish norms of ethical conduct and due diligence in review and performance of research within the institution	-Institutional statement of principles -procedures for review -procedures s for reporting to Research Ethics Committee (REC) -procedures for REC record keeping -Statement of investigator responsibilities -Effective dissemination of REC submission procedures -investigator training	**46.103(a)**; **46.103 (f)** establish and satisfy terms of assurance **46.103 (b)(1)** develop or adopt statement of principles governing institution's human subjects protections responsibilities **(46.103 (b)4)** ensure initial and continuing review of research; determine necessary frequency of review for each study; determine where external verification is necessary that no material changes have occurred since last IRB review; establish procedures for IRB reporting of findings and actions to institution and investigator(s) **46.103 (b)5**) establish and **46.108 (a)** follow written procedures for prompt reporting to IRB and Institutional officials of: -unanticipated problems involving risk to subjects or others, or non-compliance with the policy -suspension or termination of IRB approval **46.103 (b)4** ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject **46.103 (b)5** Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval **46.115** An institution, *or when appropriate an IRB*, shall prepare and maintain adequate documentation of IRB activities. The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the Department or Agency at reasonable times and in a reasonable manner.
Protect against biased decision making and arbitrary decisions in research ethics review	-documentation of REC authority - REC member(s) unaffiliated with the institution	**46.109 (a)**; **46.109 (e)** grant and ensure necessary authority for IRB, including: discretion to review, approve, require modifications, or disapprove protocols; increase information for informed consent, observe, or have third party observe consent process and research **46.112** 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 officials may not approve the research if it has not been approved by an IRB **46.113** An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. **46.110 (b)** 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 §46.108(b). **46.107 (d)** Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

Specific Protection	Example Procedures	45 CFR 46 Authority
RESEARCH ETHICS COMMITTEE (REC) RESPONSIBILITIES		
Appropriate Scope and Quality of Review		
Protection from biased decision making and arbitrary decisions in research ethics review	-Public accessibility of REC membership and affiliation within institution -Institutional policy on REC conflict of interest -REC membership to reflect: independence, unaffiliated member(s)	**46.103 (b)3** A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations. Disclosure of any employment or other relationship between each [IRB] member and the institution **46.107 (a)** IRB membership. (see 45 CFR 46 for specific criteria) **46.107 (b)** Gender balance **46.107 (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 **46.107 (d)** Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. **46.107 (e)** No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB
Ensure sufficient quality and comprehensiveness of review	-REC membership to reflect competence, comprehensiveness of review; adequate expertise for study population; diversity of representation; gender balance	**46.107 (b)** Gender balance **46.107 (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 **46.107 (d)** Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. **46.107 (f)** An IRB may, in its discretion, invite 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 **46.108 (b)** Except when an expedited review procedure is used (see §46.110), review proposed research at convened meetings at which a majority of the members 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 majority of those members present at the meeting

Specific Protection	Example Procedures	45 CFR 46 Authority
REC RESPONSIBILITY (cont'd)		
Ensure research ethics review and oversight are commensurate with risks to subjects and vulnerability of the study population	-procedures for continuing review and monitoring commensurate with risk -procedures for evaluating risk and benefit -procedures for reviewing selection of subjects and safeguards provided -procedures for IRB reporting to investigators	**46.109 (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. **46.110 (b)** Expedited Review **46.111 (2)** In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished 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. **46.111 (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 involving vulnerable populations, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantaged persons. **46.113** Any suspension or termination or approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Department or Agency head
Protection against unnecessary or unjustified risk throughout the course of the study	-REC membership policy reflects adequate expertise and experience -policy has provisions for supplementing expertise, experience and disciplinary perspective as required -procedures for review of minimization of risk -procedures for reviewing selection of subjects and safeguards provided -procedures for continued oversight and monitoring	**46.107 (a)** If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects. **46.111 (1)** Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. **46.111 (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. **46.111 (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 involving vulnerable populations, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantaged persons **46.111 (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 included in the study to protect the rights and welfare of these subjects. **46.111 (6)** When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. **46.109 (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.

Specific Protection	Example Procedures	45 CFR 46 Authority
REC RESPONSIBILITY (cont'd)		
Informed and Voluntary Participation		
Ensure voluntary participation after adequate disclosure of information related to the study	-policies on obtaining verifiable informed consent -policies on types of information to be disclosed in the informed consent process	**46.116** Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative…An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence **46.111 (4)** Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116. **46.111 (5)** Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. **46.109 (a)** Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative **46.109 (b)** An IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, 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. **46.109 (c)** An IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117. **46.109 (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. **46.111 (4)** Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116. **46.116 (1-8)** Necessary elements of disclosure **46.116 (b)(1-6)** Necessary elements of disclosure **46.116 (c)(1-2)** Waiver of informed consent **46.116 (d)(1-4)** Approval of alternate consent procedures or waiver **46.117(a)** Written informed consent