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.

§ 16.109 IRB review of research.
(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.
(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §16.116. The IRB may require that information, in addition to that specifically mentioned in §16.116, 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.

§ 16.111 Criteria for IRB approval of research.
(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:
(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 approved by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.
(b) An IRB may use the expedited review procedure to review either or both of the following:
(1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,
(2) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.
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 §16.108(b).
(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.
(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution’s or IRB’s use of the expedited review procedure.

(56 FR 28012, 28021, June 18, 1991, as amended at 70 FR 36328, June 23, 2005)

§ 16.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
(a) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.
(b) An IRB may use the expedited review procedure to review either or both of the following:
(1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,
(2) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.
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 §16.108(b).
(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.
(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution’s or IRB’s use of the expedited review procedure.

(56 FR 28012, 28021, June 18, 1991, as amended at 70 FR 36328, June 23, 2005)