

Donnelly, Janet

From: OC GCP Questions
Sent: Tuesday, October 22, 2019 2:00 PM
To: [REDACTED]
Subject: RE: Criteria for IRB disapproval of a new study

Dear [REDACTED] -

Thank you for your question. I can speak to the FDA regulations, but if you have questions about interpretation and application of the HHS regulations at 45 CFR 46 for the protection of human subjects in research, you can contact OHRP at OHRP@HHS.gov.

FDA's regulations on the criteria for IRB approval can be found at 21 CFR 56.111 (see <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=56.111>). In order to approve research covered by the FDA regulations the IRB must determine that all of the requirements found in 21 CFR 56.111 are satisfied.

FDA's regulations for IRB review of research at 21 CFR 56.109 (see <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=56.109>) state an IRB must review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by the regulations. These regulations also say that the IRB must notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it must include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. IRB decisions to disapprove a research activity must be made at a meeting of the convened IRB.

If the IRB determines that a research activity does not meet all of the criteria for approval under 21 CFR 56.111, the IRB is not permitted to approve it, but may either disapprove it or require modifications in order to secure approval (21 CFR 56.109(a)).

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at <https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/replies-inquiries-fda-good-clinical-practice> since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----

From: [REDACTED]
Sent: Saturday, October 19, 2019 10:46 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>; OC GCP Questions <gcpquestions@fda.hhs.gov>
Cc: [REDACTED]
Subject: Criteria for IRB disapproval of a new study

Hello FDA,

I am trying to find documentation regarding the criteria for an IRB to disapprove a new study. The requirements for the IRB to approve a new study is clear (see below) but not to disapprove it. I recall seeing somewhere that disapproval is simply that the study doesn't meet any of the specified criteria for approval. Can you help me locate the documentation for criteria for disapproving a study. I looked through the OHRP and multiple sites.

§46.111 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 that are consistent with sound research design and that 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.

(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. 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 (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(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. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(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.

(5) Informed consent will be appropriately documented or appropriately waived in accordance with §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(i) The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

(8) For purposes of conducting the limited IRB review required by §46.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations:

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §46.116(a)(1)-(4), (a)(6), and (d);

(ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §46.117; and

(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Thank you

