Policy on Amendments

Effective date: 12/14/2018

I. Background
Once IRB approval or exempt determination is received, the study must be carried out as described in the application. Any changes must get submitted and receive approval before enacting the change unless when “necessary to eliminate immediate hazards to the subject” per 45 CFR 46.103(b)(4). This policy outlines amendments for non-exempt research. Please see Policy on Exemptions for how to amend exempt studies.

II. Definitions
a. Amendments/modifications/changes: Any change made to an approved protocol except for correcting a typographical error. This can be anything else related to the study such as change in recruitment, population, procedures, study sites, instruments, funding, personnel, informed consent, etc.

b. Minor changes: Changes that, if considered independently from the overall research, involve no significant alteration in research design or fall into one or more categories allowing expedited review, or a determination of exemption, and involve no more than minimal risk to the human subjects.

III. Amendment Submission Requirements and Procedures
a. Researchers: The Principal Investigator/Faculty Sponsor is required to submit a Modification/Amendment Request Form for IRB review outlining each change made in the description, along with your modified protocol and/or any applicable supplemental materials (e.g., recruitment materials, consent documents unless requesting waivers, study instruments, data collection forms, Requests to Review Research for Another IRB, etc.). Highlight all changes within your protocol and supplement materials. Approval is needed before any changes begin unless when “necessary to eliminate immediate hazards to the subject (health or livelihood of subject in jeopardy-PI must submit an event form in such case).” The researcher must respond to any comments sent from either the administrative review or IRB review before it moves forward to the next action.

b. ORCA: ORCA does an administrative review of protocols in the order of receipt, sends comments to researchers as appropriate, and once response to comments are received, ORCA sends expedited reviews to the Chair or their designee, and schedules a full committee meeting for amendments that are not considered “minor” for greater than minimal risk studies.
IV. IRB Review and Actions
   The IRB will review the amendment to ensure the changes still allow the study to meet the criteria for IRB review in DHHS or FDA regulations, or equivalent when applicable.
   a. Expedited review: The IRB Chair or their designee conducts the review. The expedited reviewer can approve it, require modifications, or refer it to the full board.
   b. Full committee review: A quorum of the IRB meets to discuss the protocol and reviews it based on the criteria for IRB review. The Board can approve it, require modifications if the comments are specific and direct, defer it if they cannot determine whether criteria for approval is met until response to comments are returned, or disapprove the research if risks outweigh benefits.

V. Criteria for IRB Approval (DHHS) and Ethical Principles (Belmont Report)
   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.
   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.

b. The IRB also is guided by the three ethical principles described in the Belmont Report of the National Commission for the Protection of Human Subjects:

Respect for persons—researchers should obtain the informed consent of all human subjects invited to participate in research. In order to respect subject autonomy, the consent process should include giving subjects full and comprehensible information about the research and provide clear assurances of the subjects' voluntary participation.

Beneficence—the risk of harm to subjects should be the least possible, and that the sum of benefits to the subjects and the importance of the knowledge to be gained should so outweigh the remaining risk of harm to the subject as to warrant a decision to allow this risk.

Justice—the selection of human subjects should be fair and equitable and that the risks and benefits of research should be distributed among subjects in a fair and equitable manner, with particular concern for subjects whose personal status or condition as children, prisoners, patients, impoverished persons places them in a vulnerable or dependent status.

VI. Documentation
The IRB will document and notify the researcher of the approval date, any newly granted waivers of consent, and any new approval for inclusion of special
populations. Full committee meetings will record controverted (debated) issues and their resolution in the minutes. Once approval is received the changes may begin as written. If any further changes are needed, they first must be submitted and approved before enacting them unless to prevent immediate hazard to subjects.

VII. References
45 CFR 46