Issuing Department: Human Subjects Protection Office (HSPO)
Policy Number: 2011-009.12
Policy Title: Institutional Review Board (IRB) - Criteria for Approval

Purpose

The purpose of this policy is to set forth the criteria that the IRB must ensure are satisfied prior to granting IRB approval to an investigator to conduct a non-exempt research protocol.

Definitions

See policy 2011-007.0 for definition of IRB Approval

Policy

In order for the IRB to grant approval the IRB must find that the following criteria are met at the time of initial approval and sustained through continuing review and requests for modifications/addendums:

- 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;
- 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 (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility;
- 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.
- 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 regulations (Or a request to waive or alter the elements of consent must be approved);
- informed consent will be appropriately documented, in accordance with, and to the extent required by regulations;
- when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;
    - At its discretion, the IRB may require that a plan be in place for minimal risk studies and studies presenting a slight increase over minimal risk.
    - At its discretion, the IRB may require that a data safety monitoring board (DSMB) or independent monitor be in place for moderate to high risk studies. The DSMB or independent monitor may be internal or constituted by the sponsor. In determining whether an internal board or independent monitor is required the IRB will take into consideration the length of the study, the number of subjects to be enrolled in the

study, overall subject exposure and other mechanisms for monitoring already in place, e.g. adverse event reporting requirements, access to information from safety divisions etc.
    - Issues that should be addressed within the area of data safety monitoring include the frequency of the monitoring, who will conduct the monitoring, what data will be monitored, how the data will be interpreted and analyzed, what actions will be taken upon the occurrence of specific events or end points, and how communication from the DSMB to the IRB will occur.
- when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. (This criterion applies to all studies).
    - Privacy refers to the individual. Therefore the PI must ensure that the consent process and study activities are conducted in a setting that affords sufficient privacy to the subject. Confidentiality refers to the data related to the subject. Confidentiality encompasses the storage of electronic and paper files and biological samples.

Procedure

The Principal Investigator (PI) must complete the IRB application, inclusive of supporting documents such as the appendices, consent form, data safety monitoring plan, etc., and in so doing address the regulatory criteria for approval.

The standard screening and review procedures used for expedited and convened board review apply.

Designated IRB staff prepare the appropriate letter to communicate the determinations of the IRB to the investigator.

The Research Compliance Monitor verifies in audit that the regulatory criteria for approval continue to be satisfied, e.g. that the plans to protect privacy and confidentiality, as submitted to the IRB, are in fact being followed.

Related Policies

2009-005.0 – Monitoring of IRB Approved Studies
2011-006.0 – Vulnerable Populations – General
2011-007.0 – Definitions Applied to Policies
2011-008.0 – Informed Consent – Forms
2011-008.1 – Informed Consent – Process
2011-008.2 – Informed Consent – Waivers and Alterations
2011-008.5 – Informed Consent – Providing and Obtaining Informed Consent
2011-009.3 – Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board – Review by Convened Board
2011-009.7 – Institutional Review Board – Assignment of Status Codes

Basis

45 CFR 46.111
21 CFR 56.111

Document Attributes

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Replaced Version: Section in HSPO manual dated 7/8/2011

Reviewed and Approved By:

Signed RS 5/12/13

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