Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2011 – 006.0
Policy Title: Additional Protections for Certain Populations: General Policy

Purpose

The purpose of this policy is to set forth the requirements of HSPP for review and approval by the Institutional Review Board of non-exempt studies involving population that may be vulnerable to undue influence or coercion or for which additional protections have been set forth in regulation...

Definitions

See policy 2011-007.0 for definitions of the following:

Pregnancy	Children
Fetus	Neonate
Pregnant Woman	Prisoner

Policy

Certain populations (e.g. pregnant women, fetus, neonates, prisoners, children, individuals with impaired decision making capacity, economically disadvantaged, or educationally disadvantaged,) may only be the target population for research when their inclusion in the research is justified (i.e., scientifically necessary, not for convenience). The research must be relevant to the population and not otherwise capable of being carried out with another population. Adequate procedures must be in place to minimize the risks related to harm (e.g. physical, psychological, legal, economic, societal) and to protect the rights and welfare of these subjects.

As applicable to the population being studied, the IRB will fulfill the additional duties required by federal regulations and/or internal policies, for initial review and continuing review, and when reviewing modifications to add one of the aforementioned populations. Once a study qualifies for continuation through expedited review because the remaining activity is limited to long-term follow-up or data analysis the IRB will presume that the previous determinations made by the IRB satisfied the criteria for inclusion of that population, but the IRB reserves the right to require additional information.

For studies requiring full board review, for the initial review to include one of the aforementioned populations a member or consultant who is knowledgeable about or experienced in working with the population to be studied must review all material and provide comments (in person, via teleconference, or other means that allows for two way communication). Excluding studies that may involve prisoners as subjects, giving consideration to the nature of the study, the IRB may determine on a case-by-case basis that an exception to the requirement to obtain special expertise may be made.

For full board continuing reviews, and reviews of modifications that affect study design or populations; a member or consultant with expertise will be assigned to review the material and be expected to be present at the meeting. However, excluding studies involving prisoners and providing there have not been substantive changes to the study or new information that significantly alters the risks of the study, for continuing reviews the IRB may make an exception and rely upon the comments previously provided by the member with expertise or consultant with expertise. The IRB may also make an exception for studies prospectively reviewed under subpart C (i.e. non-prisoners are recruited but the population is at higher risk of becoming incarcerated), that if not present at the meeting, favorable review by the prisoner representative will be a contingency for granting final continuing approval.

The IRB may also require additional protections for any other group not specified in policy but determined to be vulnerable in the opinion of the IRB. Such additional protections may include, but are not limited to, the witnessing of the consent process, more frequent continuing review, or additional review by someone with a specific expertise.

The IRB reserves the right to require additional protections for research that is exempt from the federal requirements for the protection of human subjects in research.

Procedure

The Principal Investigator must identify within the IRB application any vulnerable group that is to be the focus of recruitment or that pregnant women will be included in the research

The Principal Investigator must then complete and submit the corresponding IRB form that addresses the special protections required for the specific subject population identified that will be included in the research.

The assigned reviewer(s) must review this form and determine whether the requirements have been met.

- For expedited reviews:
  - the reviewer must document the permissible category
  - the reviewer must document whether the additional protections have been satisfied
- For studies requiring review by the convened board:
  - the IRB Chair may use the IRB roster to identify members and/or standing consultants to assign reviewers with specific expertise
    - if necessary the Chair may seek an ad-hoc consultant if a standing consultant is not available
  - the IRB Coordinator will document in the minutes the determinations for the required findings.

Related Policies

2011-006.1 – Additional Protections for Certain Populations, Pregnant Women, Fetuses or Neonates
2011-006.2 – Additional Protections for Certain Populations, Prisoners
2011-006.3 – Additional Protections for Certain Populations, Children
2011-006.4 – Additional Protections for Certain Populations, Other Groups
2011-006.5 – Additional Protections for Certain Populations, Fetal Tissue Transplant
2011-009.3 – Institutional Review Board – Review by Expedited Procedures
2011-009.5 – Institutional Review Board - Review by the Convened Board
2011-009.6 – Institutional Review Board - Consultants
2011-007.0 – Definitions Applied to Policies

Basis

45 CFR 46
21 CFR 50

Document Attributes

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Reviewed and Approved By:

Signed by Richard H. Simon ***3/8/2017***
Richard Simon, MD **Date**
Director Human Subjects Protection Office