

**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 required by policy and 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 (e.g. because the remaining activity in an FDA regulated study is limited to long-term follow-up or data analysis and continuing review is required by regulation, or the IRB otherwise determined and justified that continuing review is a requirement) 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, at the time of initial review of a study proposing 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 for which prisoners are the intended population, 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 example, if a study is comparing two established and accepted methods of treatment special expertise may not be required.

For full board continuing reviews, and reviews of modifications that affect study design or populations; preference will be that a member or consultant with expertise review all material and provide comments (in person, via teleconference, or other means that allows for two way communication). As with initial review, 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. In addition, providing there have not been substantive changes to the study or new information that significantly alters the risks of the study, the IRB may

make an exception and rely upon the determinations previously provided by the member or consultant with expertise when granting subsequent approvals.

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 are intended to 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 will document the permissible category on the reviewer form
  - the reviewer will document on the reviewer form 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 Regulatory Specialist will document in the minutes the determinations for the required findings. For continuing reviews the determination may be made by reference to the initial review.

### ***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***

**Date Created:** 2/5/2018

**Replaced Version:** 3/8/2017

**Reviewed and Approved By:**

*Richard H. Simon*

*5-Feb-18*

---

**Richard Simon, MD**  
**Director Human Subjects Protection Program**

**Date**