

Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2011-006.4
Policy Title: Additional Protections for Certain Populations: Other Vulnerable Groups

Purpose

The purpose of this policy is to set forth the requirements of the HSPP for review and approval by the Institutional Review Board of non-exempt studies intending to involve other vulnerable groups as subjects.

Definitions

See policy 2011-007.0 for definition of Decisionally Impaired

Policy

Other vulnerable groups (e.g. economically disadvantaged, educationally disadvantaged, employees, persons with an impaired ability to make decisions, students, terminally ill) may qualify for exempt status or expedited review if the research falls within one of the regulatory defined categories.

The additional protections for other vulnerable groups will apply to non-exempt research when the research calls for focused recruitment of a specific group, involves an intervention or interaction with that group, and the additional conditions noted under the group, if any, are met (for example the teacher-student or supervisor-employee dynamic.).

Economically and/or Educationally Disadvantaged

Economically disadvantaged individuals are considered vulnerable because they may be more inclined to participate due to financial incentives without regard for the risks involved in the research. Educationally disadvantaged are considered vulnerable because they may have difficulty understanding the consent form and procedures involved in the research, thereby potentially reducing their appreciation for the risks involved in the research.

Students

Students are considered vulnerable when the focus of recruitment and when a direct relationship exists with the Principal Investigator (e.g. student – teacher). While a PI may use his/her own students as subjects if necessary the preference of the IRB is that the PI recruit students with whom the PI does not have a direct relationship (i.e. non-vulnerable students).

Students should not be asked to participate in any study that will interfere with their curricular activities and obligations. A student's decision to participate or not participate cannot have any bearing on grades awarded by the instructor.

If extra credit is awarded for participation in a study, other comparable means of earning the same amount of extra credit must be available to those students who choose not to participate.

Employees

Employees are considered vulnerable when the focus of recruitment and the relationship of the PI with the employees is such that it may create undue influence, e.g. supervisor-subordinate. While a PI/supervisor may use his/her own direct report employees as subjects if necessary, the preference of the

IRB is that the PI recruit employees with whom the PI does not have a direct relationship (i.e. non-vulnerable employees).

Employees should not be asked to participate in any study that will interfere with their job obligations. An employee's decision to participate or not participate cannot have any bearing on the employee's performance evaluation.

Decisionally Impaired

When reviewing proposals that focus on decisionally impaired subjects the IRB will make a determination as to whether the target subject population is capable of providing consent or whether a legally authorized representative must provide consent and the subject provide assent. The IRB may also require additional protections such as a witness to the consent process or requiring the PI to determine and document on an individual basis whether an individual is capable of providing consent, e.g. the IRB may require that the PI ask the subject to articulate in his/her own words the purpose of the study, the risks involved with the study, the benefits of the study and may request that those responses be documented. If the subject cannot answer such questions consent from a legally authorized representative must be obtained.

The IRB will use the additional protections set forth in regulation regarding the inclusion of children in research as guiding standards for the review process. Legally authorized representative will be substituted for reference to parent or guardian. The IRB may still elect to approve research that does not fall into one of the categories for research involving children.

Terminally Ill

When a study focuses on a terminally ill population, special attention will be paid to the recruitment and consent process. The IRB may require, for example, a witness to be present, a legally authorized representative to provide consent and that the subject provide assent, or that the IRB or HSPO observe the consent process.

The informed consent must clearly state that:

- there may be no benefit to the subject in terms of quality or length of life
- as an alternative, the subject has the right not to participate
- that the subject may in fact experience a decline in health status

Procedure

See policy 2011-006.0 – Additional Protections for Certain Populations: General

In addition the PI and IRB staff and reviewers use the informed consent checklist to ensure that required elements of consent have been addressed.

Related Policies

2011-006.0 - Additional Protections for Certain Populations - General

2011-006.3 – Additional Protections for Certain – Children

2011-007.0 – Definitions Applied to Policies

2011-008.3 – Informed Consent – Assent

2011-008.5 – Informed Consent – Providing and Obtaining Informed Consent

2011-009.2 – Institutional Review Board – Exemptions
2011-009.3 – Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board – Review by Convened Board

Basis

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