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**Boston
Children's
Hospital**

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Applicability Boston Children's
Hospital- Policies
& Procedures

Recruitment: Special Circumstances Policy/Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

This policy describes considerations for the recruitment of populations with additional vulnerabilities. This guidance on recruitment includes, but is not limited to:

1. Minorities and Underrepresented Communities
2. Foreign Populations
3. Recruiting in Schools
4. A Research Team Member or an Investigator's Child
5. Staff or Students of an Investigator

Policy Statements

The Institutional Review Board (IRB) recognizes an investigator's desire to optimize recruitment; however, the rights and welfare of the subject and the need to avoid undue influence and/or coercion are the IRB's priority.

Procedures

The following are some specific guidelines to consider when developing and evaluating recruitment practices with vulnerable populations and/or other special circumstances.

Minorities and Underrepresented Communities

All potential subjects regardless of race, creed, color, religion, or economic status are to be treated equally. In the context of research, equal treatment requires that all individuals be accorded the autonomy to decide whether to participate in research.

1. Minorities, underrepresented communities, and non-English speaking individuals are not to disproportionately bear the burdens and risks of research and they are to be assured they share the benefits of the research.
2. In addition, special efforts should be made to include them in research protocols.

If the research protocol holds out the prospect of benefit, minorities, and non-English speaking individuals are not to be excluded from the research unless there are sound medical or scientific justifications for such exclusion. In addition, special efforts should be made to include them in research protocols. Each protocol is considered on its own merits.

The IRB is responsible for independently assessing the investigator's opinion of risk/benefit and inclusion/exclusion criteria. The IRB has the right to require that minorities and non-English speaking individuals be included. Specifically, this may require that the written informed consent and the verbal consent for obtaining informed consent be rendered in a language and a manner that ensures the participant's understanding. This may require the translation of informed consents and/or the use of interpreters with a short form translation.

Foreign Populations

Boston Children's Hospital has long been recognized as a significant force in medical care and research, both in this country and internationally. Owing to their expertise, investigators may be provided opportunities to study foreign populations with unique disease entities (e.g. tropical diseases, malaria, etc.).

As a leading research institution, Boston Children's Hospital recognizes that cultural differences and varying standards of medical care exist and that it is not always possible to ensure that researchers will be subject to the same regulations that apply in the United States. In such situations, the investigator and the IRB must make extraordinary efforts to ensure that the rights of these populations are protected in accordance to culturally and socially acceptable standards.

1. The IRB requires evidence that the investigator has considered the regulations and the needs of the host country.
2. Proposed procedures must be sensitive to the population and compliant with the sponsoring government.
3. Research conducted at foreign sites will require local IRB review in addition to review by Boston Children's Hospital

Federally funded studies that involve a foreign population are required by regulation to negotiate an assurance of compliance between the foreign site and the Office of Human Research Protections. For specific information see IRB policy: International Research and Cross-Cultural Research and Community

Based Participatory Research.

Recruiting in Schools

All conduct of research by Boston Children's Hospital investigators at schools or targeting school populations require the written permission of the school board and/or superintendent of the school system involved. This must occur before the study begins.

1. It is the investigator's responsibility to obtain approval from the individual school system.
2. Investigators must also consider special arrangements for recruiting subjects, obtaining parental consent, teacher involvement, and feedback on individual results. These issues are to be addressed in the protocol application.
3. Investigators are advised that school system requirements vary and that ample be allowed to address these issues.

A Research Team Member's or an Investigator's Child

Research Team Member's Child

If a research team member would like their child to participate in a study they are supporting, then the team member must approach the Principal Investigator (PI) about participation, based on knowledge of the research. The PI must not directly or actively recruit the team member's child.

Investigator's Child

Criteria: An investigator may involve their own child in their research project only in accordance with all the following criteria and stipulations:

1. The consent process is conducted by an individual other than the PI.
2. The other parent/guardian must provide parental permission. However, if there is only one parent/guardian, the IRB office should be contacted for approval.

IRB Requirement: For research when there is **no** potential for direct benefit:

1. The research must be minimal risk.
2. The child must be of age and mind to provide assent.

Possible IRB Requirement: For research that presents a potential for direct benefit, the IRB may require that a child assent be obtained if the child is capable.

Staff or Students of the Investigator

Investigators may not recruit staff or students under their supervision.

It is generally suggested that such individuals be recruited outside the department of the investigator through public postings. In this manner, interested individuals can approach the investigator and will not feel coerced or unduly influenced, as they might if approached by the investigator.

Related Content

- IRB Policies
 - International and Cross-Cultural Research
 - Community Based Participatory Research
 - International Research
 - Recruitment: Methods
 - Recruitment: Responsibilities and Requirements

Approval Signatures

Step Description

Approver

Date

Applicability

Boston Children's Hospital- Policies & Procedures

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