



SUBJECT: Investigator Responsibilities for Fair and Equitable Subject Recruitment

POLICY: RA:HRPP:10.07

DATE EFFECTIVE:

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I. POLICY

The Principal Investigator and research staff members are required to recruit in a fair and equitable manner, weighing the potential benefits of the research to the subjects against their vulnerability and the risks to them.

II. ACCOUNTABLE EXECUTIVE AND REVIEWER(S)

- A. Accountable Executive: Chief Academic Officer/Institutional Official for the Federalwide Assurance
- B. Department Responsible for Review: Office for the Protection of Human Subjects
- C. Committee Responsible for Review: Institutional Review Board Executive Committee
Research Policy/Procedure Working Group

III. APPROVAL

Approved by:

_____ IRB Executive Committee

_____ 10/01/2009

Date

_____ Research Policy/Procedure Working Group

Date

_____ Mark L. Batshaw, M.D., Chief Academic Officer

Date

IV. APPLICABILITY

Areas where the policy and procedure applies: Children's Research Institute, Children's National Medical Center

Persons to whom the policy and procedure applies: Investigators, research staff members

V. REVIEW OR REVISION DATE

Original:

VI. REFERENCES

AAHRPP Element(s):

Federal Regulations: U.S. Department of Health and Human Services (DHHS) 45 CFR 46.111(a)(3); 45 CFR 46.116.
Food and Drug Administration (FDA) 21 CFR 56.111(a)(3); 21 CFR 56.20

FDA Information Sheets: Recruiting Study Subjects, Payment to Research Subjects

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PROCEDURE: RA:HRPP:10.07P

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I. PROCEDURE

- A. The Principal Investigator (PI) is responsible for the equitable selection of research subjects and must consider the purposes of the research and the setting in which the research will be conducted. The PI should be cognizant of the special problems of research involving populations vulnerable to coercion or undue influence (such as children, pregnant women, economically disadvantaged and cognitively impaired persons) and the potential need for additional protections.
1. Consideration must be given to whether subject selection is likely to equitable.
 2. If a research protocol includes a population(s) that is (are) potentially vulnerable to coercion or undue influence, appropriate additional protections must be described by the investigator in the submission to the Institutional Review Board (IRB).
 3. The Principal Investigator should describe subject recruitment in terms of who, where, and how.
 4. Recruitment processes used by investigators and research staff must be fair and equitable.
 5. The PI should consider whether payment and reimbursements are excessive as to introduce coercion to participate. (See RA:HRPP:08.08 and 08.08P, *Payment to Research Subjects*)
- B. The Principal Investigator must submit a detailed description of recruitment strategies and procedures, including recruitment and advertising materials, to the IRB for review and approval (RA:HRPP:08.06 and 08.06P, *Equitable Selection and Recruitment of Human Research Subjects*).
- C. The investigator must submit for IRB review the exact wording for all recruitment tools such as flyers, audio or videotaped advertisements, print advertisements, email solicitations, internet websites, scripts and other recruitment methods and materials intended for the recruitment of prospective research subjects.

- D. Prior to submission to the IRB, all recruitment materials to be used in public settings including (but not limited to) flyers and brochures, audio- or video-recorded advertisements, print advertisements, and internet website postings require approval from the Children's National Medical Center (CNMC) Public Relations and Marketing Department.
- E. The following examples do not qualify as an advertisement:
1. News stories, so long as they are not intended for recruitment purposes (e.g., a phone number at the end to contact for more information to participate in a particular study, full details of inclusion/exclusion criteria of a particular study, etc.); and
 2. Publicity intended for other audiences (e.g., media releases regarding types of services available or offered by a particular clinic, institute or physician).

II. **REVIEW OR REVISION DATE**

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Policies and Procedures: RA:HRPP:08.06 and 08.06P, *Equitable Selection and Recruitment of Human Research Subjects*
RA:HRPP:08.08 and 08.08P, *Payment to Research Subjects*