

NIH HRPP SOP 13 v1

**HRPP STANDARD OPERATING PROCEDURE/POLICY APPROVAL &
IMPLEMENTATION**

OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

SOP Number: 13

**SOP Title: RECRUITMENT, SELECTION AND COMPENSATION OF RESEARCH
SUBJECTS**

**Distribution: Scientific Directors; Clinical Directors; Clinical Investigators, IRB
Chairs, IRB Administrators, Protocol Navigators**

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SOP 13 RECRUITMENT, SELECTION AND COMPENSATION OF RESEARCH SUBJECTS

13.1 PURPOSE

This policy outlines the responsibilities of NIH IRBs, Principal Investigators (PIs) and other members of the research team related to recruiting, selecting and compensating research subjects.

These procedures are designed to assure:

- A. The equitable recruitment and selection of subjects consistent with the NIH Revitalization Act of 1993, codified at PL103-43 (see Guidance below for a link), aimed at ensuring women and members of minority groups are included as subjects in each project or research (except when inappropriate), and,
- B. That compensation, when it is given to research participants, is appropriate and fair.

13.2 POLICY

During their initial review of protocols, NIH IRBs will review and approve recruitment and compensation plans proposed by PIs. At the time of continuing review, IRBs will evaluate whether the protocol has accrued subjects in accord with the IRB-approved selection criteria.

13.3 SELECTION OF SUBJECTS

13.3.1 GENERAL CONSIDERATIONS

Subjects should be carefully and equitably chosen to insure that certain individuals, or classes of individuals, are not systematically selected or excluded, unless there are scientifically or ethically valid reasons for doing so. Special attention will be given to the enrollment of women, children and minorities in research (see references 1 and 2, below, and SOP 7, "Requirements for the Ethical and Regulatory Review of Research by NIH IRBs", SOP 14A, "Research Involving Vulnerable Subjects", and SOP 14D "Research Involving Children."

13.3.2 PI RESPONSIBILITIES

- A. In their protocol's section on the protection of human subjects, PIs will include: information on the rationale for subject selection as required in SOP 8, "Procedures and Required Documentation for Initial Review of Protocols by a Convened NIH IRB".
- B. The Intramural Initial Clinical Protocol Application must include a Planned Enrollment Table (NIH Application Supplement O) consistent with the NIH Revitalization Act of 1993, PL103-43 (for more information see the link in Guidance below).

13.3.3 IRB RESPONSIBILITIES

- A. Initial Review: The IRB reviews and approves the protocol consistent with SOP 8, including the rationale for research subject selection, the strategies and procedures for recruiting subjects (see 13.4, below, for recruitment materials) and any justification(s) for exclusion of women and/or individuals from particular population categories.
 - 1. In determining if subject selection is equitable, the IRB will consider a variety of factors, including but not limited to: the purposes of the research; the inclusion/exclusion criteria; the setting in which the research will take place; whether prospective subjects are vulnerable to coercion or undue influence, recruitment/enrollment procedures (see 13.4.2, below), and the amount and timing of compensation, if any (see 13.5, below).
 - 2. Exclusions, such as children, may be warranted because of the nature of the disease or condition being studied, or for other justifiable reasons (see, e.g., SOP 14D "Research Involving Children" and link to "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" in Guidance below).
- B. Continuing review: This will include a review of the cumulative number of subjects accrued by gender and ethnic/racial category(ies) (see SOP 9 "Continuing Review by the Convened IRB"). In the course of the continuing review, the IRB may find that the cumulative data are

inconsistent with previously approved targets for subject selection (see Section 13.3.2.C, above). In these cases, the IRB has broad discretion in exercising its judgment on how to proceed. Its actions may include:

1. Continuation of subject accrual, with or without a request that the PI provide a plan for improved accrual, or
2. If necessary, referral of the matter to the IC Clinical Director for evaluation of recruitment strategies and additional resources, or
3. Suspension or termination of the protocol for failure to meet
4. the terms and conditions of IRB approval.

13.4 RECRUITMENT PROCEDURES AND MATERIALS

13.4.1. RECRUITMENT ACTIVITIES OR MATERIALS THAT DO NOT REQUIRE IRB APPROVAL

IRB review and approval is not required for basic descriptive information about a clinical trial if the clinical trial information is limited to the following: title, purpose of the study, protocol summary, basic eligibility criteria, study site location(s), and how to contact the study site for further information (see link to OHRP Guidance on IRB Review of Clinical Trial Websites in Guidance below). Descriptions of clinical trial risks and potential benefits, or solicitation of identifiable information is not considered basic descriptive information, but part of the informed consent process and requires IRB review and approval.

13.4.2 PI RESPONSIBILITIES

- A. The PI describes in the protocol who will participate in the identification and recruitment of prospective research participants.
- B. The PI will provide the IRB with the materials to be used to identify participants, including recruitment activities/methods, advertisements, and/or other media announcements (such as internet sites), etc. The contents of advertisements/recruitment materials will be limited generally to information needed by prospective subjects to determine their eligibility and interest, such as:

1. The name and address of the researcher or research facility.
 2. The condition under study and the purpose of the research.
 3. A brief summary of the criteria that will be used to determine eligibility.
 4. A brief list of risks and benefits, if any, to participants.
 5. The time or other commitment required of participants, and
 6. The location of the research and the contact person/office for more information.
- C. If the PI intends to recruit subjects or obtain any identifying information *via* internet sites he/she must be compliant with NIH Policy Manual 2805 “NIH Web Privacy Policy”, and other NIH policies, e.g., the Paperwork Reduction Act (see link to NIH Policy Manual 1825 “Information Collection from the Public” in References below), as applicable.
- D. PI’s should also be aware of and comply as needed with the NIH Policy Manual 2809 “NIH Social and New Media Policy” and NIH Policy Manual Chapter Appendix 1, “NIH Office of Intramural Research (OIR) Guidance for Use of Social Media for Recruitment of Subjects to Clinical Trials” (see a link to the NIH Manual Chapter 2809 in References below).

13.4.3 IRB RESPONSIBILITIES

The IRB will review and must approve recruitment materials before they are used. This includes the information contained in the materials, how the information is to be communicated, and the planned venue(s) for distribution (for example, newspaper, radio, or flyer). For audio/video tape, the IRB may review and approve the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording. The IRB will review the final copy of printed and/or electronic advertisements and the final version of audio- or videotaped advertisements and may use expedited procedures for final approval.

- A. Verification of information and institutional logos: The IRB will verify that all information included in the recruitment materials is consistent with the protocol. DHHS, NIH, and IC logos must be used consistently with NIH Policy Manual 1186, “Use of NIH Names and Logos”.

- B. Recruitment Materials: As part of its review of recruitment materials, the IRB will ensure that materials do not:
1. State or imply a favorable outcome or other benefits beyond what is stated in the protocol and the consent document.
 2. Include exculpatory language.
 3. Emphasize monetary compensation or the amount to be paid by such means as larger or bolder type.
 4. Promise “free treatment” when the intent is only to say participants will not be charged for taking part in the investigation.
 5. IRBs should pay particular attention to risk and potential benefit information to ensure it is presented in a balanced and fair manner. If identifiable private information of prospective subjects is to be collected via a clinical trial website, the IRB should review plans for protecting the confidentiality of that information. The IRB should ensure that the website clearly explains how identifiable private information might be used. For further guidance, see OHRP Guidance on IRB review of Clinical Trial Websites (see Guidance below for a link).
- C. Recruitment Materials related to FDA-regulated research: As part of its review, the IRB will ensure that recruitment materials are consistent with FDA regulations and applicable guidance, e.g., “Recruiting Study Subjects - Information Sheet: Guidance for IRBs and Clinical Investigators” (see link in Guidance below).

13.5 COMPENSATION OF RESEARCH SUBJECTS

13.5.1 GENERAL CONSIDERATIONS

- A. At the NIH, compensation may be offered to persons participating in research protocols. Compensation is one way to acknowledge research subjects’ contributions; however, proposed payments should be commensurate with the expected contributions of the subject and should not be so much as to constitute (or appear to constitute) undue influence to participate.

- B. Who may receive compensation: Generally, at the NIH, when compensation is offered for research participation, it is offered to healthy volunteers or to persons with diseases or disorders who participate in research that offers them little or no prospect of direct benefit. However, if justified by the PI and approved by the IRB, compensation may be given to patient subjects (persons with diseases or disorders who participate in research that offers them a prospect of direct benefit). For fairness reasons, all participants taking part in a particular research protocol should be offered the same amount of compensation for the same type of contribution. NIH Institutes and Centers may have additional policy on this topic (see 13.6).
- C. Types and calculation of compensation: Compensation may include check payments, gift cards, or other items. All forms of compensation must be specifically mentioned in the protocol and consent document (see 13.5.2). Such compensation may be given in addition to reimbursement for travel, meals, lodging, parking, or other expenses.
- D. Compensation amounts for healthy volunteers at the Clinical Center will be based on time, and in some instances, inconvenience of participating in the research using NIH/CC guidelines (contact NIH Program for Healthy Volunteers at 301-496-4763, see References for a link to the site). NIH investigators at non-Clinical Center intramural sites will abide by site guidelines in addition to this policy's requirements.
- E. Tracking of compensation: Compensation will be tracked and processed through the Clinical Research Volunteer Program (CRVP) for studies conducted in the Clinical Center and in accord with any required IC or outside site procedures for studies conducted at NIH non-CC sites.

13.5.2 PI RESPONSIBILITIES

- A. The Principal Investigator (PI) will make a preliminary decision about whether or not to offer compensation to the participants in his/her protocol.
- B. Protocol-specific calculation of compensation: PIs will follow the recommended NIH/CC guidelines taking into account the time, and, in some instances, inconvenience required to participate in the protocol.

1. Deviations from these guidelines are permissible, but require written justification to and approval of the IRB (and possibly other IC/CC officials).
 2. NIH investigators at non-Clinical Center intramural sites will rely on this policy and use site-appropriate guidelines as approved by the IRB.
- C. Contents of the written protocol: The PI will include a section on compensation containing the type, amount and conditions of payment.
- D. Description of compensation in consent forms:
1. Compensation will be discussed in the consent document under a separate section labeled "Compensation." It will not be listed or discussed as a benefit of participation in research.
 2. Information will include what is being compensated, when and in what manner the compensation will be given, including the total amount the subject may potentially receive and how the amount will be prorated.

13.5.3 IRB RESPONSIBILITIES

- A. General considerations: The IRB shall review the justification for compensation to ensure it is appropriate given the particular study and the population to be recruited, and that the compensation payments are reasonable, equitable, and do not constitute coercion or undue influence. In making this decision, the IRB should consider the potential vulnerabilities of the targeted subject population and the proposed methods for assessing subjects' knowledge of risks and benefits and their ability to make voluntary, autonomous decisions. It should also take into account the amount, schedule, and method of disbursement of compensation payments.
- B. Review and approval of the proposed compensation plan: The IRB reviews and determines that the amount of payment and the proposed method and timing of compensation is appropriate (does not present undue influence). In making that determination, the IRB shall verify that:
1. As appropriate, credit for compensation payments accrue as the study progresses and are not contingent upon the participant completing the entire study, and

2. Any amount paid for completion of the study is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.
- C. The IRB shall be satisfied that the NIH/CC (or local non-CC) guidelines for calculating amounts have been followed, or that justification provided for any deviation is appropriate.
 - D. Review and approval of the consent document language: The IRB shall assure that all relevant information concerning compensation, including the amount and schedule of payments, is set forth in the consent document.

13.6. ADDITIONAL COMPENSATION POLICIES

NIH Institutes or Centers (ICs) may have compensation policies specific to their research activities. Such policies may be in addition to, but may not conflict with, the policies described above.

REFERENCES

1. NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended, October, 2001:
http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm
2. NIH Revitalization Act of 1993, PL103-43:
http://grants.nih.gov/grants/funding/women_min/women_min.htm
3. NIH Policy and Guidelines on the Inclusion of Children as Participants In Research Involving Human Subjects: <http://grants.nih.gov/grants/guide/notice-files/not98-024.html>).
4. NIH Policy Manual 2805 - NIH Web Privacy Policy:
<http://oma.od.nih.gov/manualchapters/management/2805/>
5. NIH Policy Manual 2809 – NIH Social and New Media Policy:
<http://oma.od.nih.gov/manualchapters/management/2809/main.html>
6. NIH Policy Manual 1186- Use of NIH Names and Logos:
<http://oma.od.nih.gov/manualchapters/management/1186/1186.pdf>
7. NIH Program for Healthy Volunteers:
http://clinicalcenter.nih.gov/participate/studies/healthy_vol_prg.shtml#compensation

GUIDANCE

1. OHRP Guidance on IRB review of Clinical Trial Websites:
<http://www.hhs.gov/ohrp/policy/clinicaltrials.pdf>
2. FDA guidance “Recruiting Study Subjects- Information Sheet: Guidance for IRBs and Clinical Investigators”:
<http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm>)