Policy 302 Subject Recruitment and Compensation – Policy Overview

This document summarizes changes in *Policy 302 Subject Recruitment and Compensation* (referred to as Policy 302 in this document) that NIH investigators should be aware of, from the SOP(s) mentioned below.

NIH investigators are responsible for reviewing Policy 302 and complying with the requirements of the policy.

Note: Text from the policy and other policy titles are italicized.

Policy 302 Subject Recruitment and Compensation	**SOP(s) superseded by Policy 302**
Policy 302 Subject Recruitment and Compensation fully supersedes:	**SOP 13 - Recruitment, Selection and Compensation of Research Subjects**

Applicability of Policy 302 – This policy applies to:

- The requirements for research subject recruitment, to assure that recruitment will promote the fair and equitable selection of subjects and to ensure scientific validity of the research.
- The requirements for research subject compensation, to assure that compensation will minimize the possibility of coercion or undue influence.
- *NIH investigators when conducting human subjects research at an NIH site, regardless of whether the NIH Institutional Review Board (IRB) or an external IRB is the Reviewing IRB.*
- *NIH investigators when conducting human subjects research at a non-NIH site, when the NIH IRB is the Reviewing IRB.*
- *Non-NIH investigators when the NIH IRB is the reviewing IRB.*

Policy Requirement	**SOP Requirement**
Recruitment – Section C.1. – *Recruitment of subjects will not commence prior to IRB approval of the research protocol.*	**SOP 13, Section 13.4.3.** – *The IRB will review and must approve recruitment materials before they are used.*
Recruitment – Section C.2. – *The plan for recruitment of subjects will promote the fair and equitable selection of subjects*.	**SOP 13, Section 13.3.1.** – *Subjects should be carefully and equitably chosen to ensure that certain individuals, or classes of individuals, are not systematically selected or excluded, unless there are scientifically or ethically valid reasons for doing so.*
Recruitment – Section C.3. – *The plan for recruitment of subjects will be described in the protocol and the relevant recruitment material will be provided to the IRB for review.* **Section E.1.a.I.** – *Include a description of the recruitment plan that is fair and*	**SOP 13, Section 13.4.2.** – This section of the SOP described what the PI must submit to the IRB for recruitment.

equitable in the protocol (e.g., intended populations and cohorts, and methods for recruitment). NIH investigators should review the Policy 302 Guideline to learn more about NIH IRB requirements.	
Recruitment – Section C.5. – *NIH investigators, or their supporting ICs, are not permitted to provide or receive finder's fees (e.g., payment in exchange for referrals of individual prospective research subjects, which are sometimes referred to as "recruitment incentives"), from any source in connection with research at NIH.*	NA
Recruitment – Section C.5.a. – Individuals *or entities may be compensated for recruitment services, consistent with terms of the contract and/or appropriation rules*. NIH investigators may use professional recruitment services to recruit subjects, so long as the services provided are consistent with the contract/federal procurement requirements. NIH investigators should consult their ICs for more information on procuring such services.	NA
Recruitment – Section C.6. – *No NIH investigator may receive recruitment bonuses from study Sponsors (e.g., a bonus payment for achieving a subject recruitment threshold).*	NA
Recruitment – Section E.1.a.II.i-ii. – NIH PIs must review this section to learn what must, and must not, be included in recruitment materials.	**SOP 13, Section 13.4.2.** – This section of the SOP described what the PI must submit to the IRB for recruitment.
Recruitment – Section E.1.a.II.iii. – For FDA-regulated research, NIH PIs must review this section to in order to comply with FDA requirements for recruitment materials.	**SOP 13, Section 13.4.3.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"
Recruitment – Section E.1.a. II. iv. – NIH PIs should review this section to learn what recruitment information that will be posted on a clinical trial website that *does not* require prospective IRB approval. These requirements have not changed from SOP 13. Such recruitment material must include *only* basic descriptive information, such as the information included on clinicaltrials.gov, otherwise prospective IRB review and approval is required.	**SOP 13, Section 13.4.1.** – *IRB review and approval is not required for basic descriptive information about a clinical trial website 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 per the" OHRP "Guidance on IRB Review of Clinical Trial Websites." 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. All other recruitment materials will be submitted to the IRB per 13.4.2 below.*
Recruitment – Section E.1.a.II.v. – *The NIH PI/Lead Site Investigator does not need to seek IRB review or approval of media releases, statements or interviews.* (Emphasis added.)	**Section 13.4.2.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.*
Recruitment – Policy 302 does not specify any requirements related to the NIH Revitalization Act of 1993 (e.g., inclusion of women and minorities and children in research and the submission of inclusion/enrollment tables). These requirements are outside the scope of the NIH IRB. For more information, NIH investigators should consult their Institute/Center (IC) Scientific Director or designee or review https://nih-extramural-intranet.od.nih.gov/d/nih/topics/inclusionwo_main.htm.	**SOP 13** specified requirements for compliance with the NIH Revitalization Act of 1993 (PHS Act sec. 492B, 42 USC 289a-2), also known as the NIH Policy on Inclusion of Women and Minorities as Subjects in Clinical Research, and the NIH Policy on the Inclusion of Children as Participants in Research Involving Human Subjects.
Recruitment – Policy 302 does not discuss the NIH Web Privacy Policy. This requirement is out of the scope of the NIH IRB. However, as with other NIH policy requirements, NIH investigators should be familiar and comply with this NIH manual	**SOP 13, Section 13.4.2.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 and the NIH*

chapter, as applicable, and consult with the Manual Chapter point of contact as needed.	*Policy Manual 1825 "Information Collection from the Public" in References below), as applicable.*
Recruitment – Policy 302 does not discuss social media guidelines. NIH investigators should review the accompanying Guideline for Policy 302 for more information. However, as with other NIH policy requirements, NIH investigators should be familiar and comply with this NIH manual chapter, as applicable, and consult with the Manual Chapter point of contact as needed.	**SOP 13, Section 13.4.2.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 2809* (NIH Policy Manual 2809 – NIH Social and New Media Policy: http://oma1.od.nih.gov/manualchapters/management/2809/)
Recruitment – Policy 302 does not discuss NIH guidelines for use of names and logos. However, as with other NIH policy requirements, NIH investigators should be familiar and comply with this NIH manual chapter, as applicable, and consult with the Manual Chapter point of contact as needed.	**SOP 13, Section 13.4.3.** – *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"*
Compensation – Section B.5 – This policy does not address the reimbursement of travel, lodging, or per diem for research subjects. Consult your IC about any IC policy regarding reimbursement for travel, lodging or per diem	**Section 13.5.1.B.** – *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. below). Such compensation may be given in addition to reimbursement for travel, meals, lodging, parking, or other expenses. See Appendix A - Guidance for Monetary Compensation for Clinical Research Volunteers for more information.*
Compensation – Section C.7. – *When applicable, the compensation plan, including the method, the timing of distribution, and the amounts for compensation of research subjects must be described in both the protocol and the informed consent form(s).* *Alternatively, both the protocol and the informed consent form(s) must describe that compensation will not be provided.*	**Section 13.5.1.B.** – *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.*

Compensation -**Section E.2.a.** – NIH PIs should review this section to comply with NIH and FDA requirements for what must, and must not, be included in a compensation plan.	**Section 13.5.1.** – This section described compensation requirements for NIH PIs.
Compensation -**Section E.2.a. II.** – NIH PIs should *"Not state or imply to subjects that compensation is a "benefit" of the research."*	**Section 13.5.3.D.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.*
Compensation -**Section E.2.a.III.** – NIH PIs should, "*Eliminate or reduce, to the extent possible, undue influence or coercion, regarding the amount of payment, timing and disbursement of compensation."* NIH PIs should review this section to learn more about methods of compensation that will reduce coercion or undue influence.	**Section 13.5.1.** – *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.*
Compensation -**Section E.2.a.III.i.** – *Whenever possible, compensation must accrue over the course of the study and be provided to participants in a prorated manner (e.g., rather than being made in a single payment at the end of the study).*	**Section 13.5.3.B.1.** – *As appropriate, credit for compensation payments accrue as the study progresses and are not contingent upon the participant completing the entire study*
Compensation -**Section E.2.a. IV.** – *For FDA-regulated research, subjects cannot be compensated via a coupon or a discount on the purchase price of the test article once it is approved for marketing.*	NA