

RECRUITING METHODS, RECRUITMENT MATERIALS, AND PARTICIPANT COMPENSATION

1. Overview

Methods used to recruit and compensate research participants must be free from coercion or undue influence, respect the privacy rights of prospective participants, and provide for their fair and unbiased selection. As with the informed consent process, investigators and IRBs must consider the content, comprehensibility, and voluntariness of the methods used to recruit participants.

The purpose of this policy is to describe recruiting methods, recruitment materials, and participant compensation plans that minimize the possibility of coercion and help ensure equitable selection of participants. Recruiting methods, recruitment materials, and plans for participant compensation used in human subjects research must first be approved by the IRB (except for certain recruitment materials identified below).

2. Definitions

Recruiting Methods: Materials, compensation, and other practices or procedures used to inform potential participants about research. *Note: Methods for recruiting research participants are generally distinguished from those of marketing, advertising, or public relations' efforts, which have promoting a product, service, or idea as goals.*

Recruitment Materials: Announcements; advertisements; flyers; posters; scripts for telephone or other oral communication; letters or email messages; bulletin board tear-offs; Internet postings; newspaper, radio, television, or video broadcasts, or other media used to attract potential participants for research.

Compensation: Payment, merchandise, class credit, or other gift or service provided to research participants or their legally authorized representatives to reimburse them for their time, effort, and/or for any out-of-pocket expenses associated with research participation. *Note: Compensation is sometimes distinguished from an **incentive** or **inducement**, which is generally thought of as a payment or other offering that is "over and above" reimbursement and intended to encourage research participation.*

Finder's Fee: Payment made by an investigator or sponsor to an organization or individual (including non-research personnel or a research participant) for identifying and/or referring potential participants for research.

Recruitment Bonus: Payment, merchandise, or other gift or service offered by a sponsor as an incentive or reward to an organization, investigator, or key personnel conducting research designed to accelerate recruitment that is tied to enrollment rate, timing, or numbers.

3. General Information on Participant Recruitment

As a criterion for approval, IRBs are required to assure that selection of participants is equitable, taking into account the purpose(s) of the research and the setting in which the study will be conducted. This assessment also requires consideration of whether any potential subjects are vulnerable to coercion or undue influence. Investigators and IRBs will consider the participants likely to respond to the type(s) and location(s) of recruitment efforts, as well as proposed incentives, to avoid potential inequalities in participant selection and to balance protection of participants who might be considered vulnerable with their opportunity to participate in the research.

4. Recruiting Methods

- A. Participants may be recruited from a variety of sources including medical centers, businesses, schools, churches, support groups, and health fairs, using a variety of methods, such as referral, telephone solicitation, Internet posting, flyer, and media announcement or advertisement. Individuals involved in recruitment of participants, beyond providing information about the availability of the study and contact information for the investigator, are considered to be “engaged in research” and must have IRB approval to perform this activity.
- B. Recruiting methods (including the proposed inclusion and exclusion criteria) will be designed to ensure that vulnerable participants are not systematically selected solely due to ease of availability, compromised positions, or manipulability.
- C. Recruitment should result in the selection of participants accurately reflecting the question under study and not disproportionately involving participants from groups unlikely to be among the beneficiaries of future applications of the research.
- D. The IRBs will consider the medical, employment, and educational status of participants, as well as available financial, emotional, and community resources when determining whether participants can be recruited fairly, informed adequately, and appropriately compensated.
- E. Offering or accepting a finder’s fee for identification and referral of potential participants is not permitted because of the potential for coercion of participants or conflict of interest on the part of the individual making the referral. Note: Several professional associations, including the American Medical Association (Council on Ethical and Judicial Affairs Code of Ethics, E-6.03) and American Psychological Association (Ethical Principles of Psychologists and Code of Conduct) consider the use of finder’s fees to be unethical.
- F. Paying or accepting a recruitment bonus or other incentive tied to the timing or rate of enrollment or number of enrolled participants is not permitted.

- G. To avoid potential invasions of privacy, investigators may not directly contact potential participants identified from privately held sources (e.g., physicians' practices, teachers' class lists, previous research participation) without the participants' (or their legally authorized representatives') permission. This does not include listservs or other lists without a reasonable expectation of privacy (e.g., magazine subscribers, professional organization members). Whenever possible, methods of contact that are the "least intrusive" should be considered, e.g., allowing interested potential participants to initiate contact with the research team.
- H. The IRBs must evaluate the appropriateness of recruiting methods that propose enrollment of participants such as employees or students who are directly supervised or taught by the investigator(s) to ensure voluntary participation and equitable selection. Investigators proposing to recruit participants from their own patient, student, or client populations must also consider strategies to avoid the possibility of coercion or undue influence.
- I. For studies that require participant identification or referral by a primary family study participant (i.e., proband in genetic studies), consideration must be given to the privacy interests and the potential for coercion of family members.
- J. Investigators must ensure that methods for reviewing and/or obtaining protected health information from medical records or clinical databases during the recruitment of potential participants are compliant with the requirements of the HIPAA Privacy and Security Rules and OSU policy [e.g., University Hospitals Policy 09-11: Use of Patient Information by Hospitals and Medical Staff].
- K. The proposed use of student education records for identifying and recruiting potential participants must comply with the requirements of the [Family Educational and Rights Privacy Act \(FERPA\)](#).
- L. Use of University computing resources to recruit potential participants must comply with OSU policy [[Policy on Responsible Use of University Computing and Network Resources](#) and [Policy on Institutional Data](#)].
- M. Individually identifiable records of individuals who decline research participation or do not meet study entry criteria (e.g., screening logs) can be retained as necessary to generate a "do not contact" list, provided that the individuals are informed of the list and appropriate confidentiality of the data is maintained. When this information is requested by sponsors to verify enrollment efforts, data provided must not be individually identifiable.
- N. Recruiting methods will be described in the application form, "Initial Review of Human Subjects Research," including the inclusion/exclusion criteria of participants. Changes in approved recruiting methods or the proposed participant population are amendments to

the research and must be submitted to the IRB for review and approval before initiating these changes.

5. Recruitment Materials

- A. Recruitment materials are considered to be part of the informed consent process and must follow the requirements for informed consent described in OSU HRPP policy [[Informed Consent Process and the Elements of Informed Consent](#)].
- B. Recruitment materials must meet the following general requirements:
- Purpose indicates that the activity is research
 - Potential benefits of participation are not coercive or misleading
 - Compensation is not overly emphasized, coercive, or misleading
 - Free of deception and exculpatory language
 - Font size or other visual effect is not coercive or misleading
 - Language and terminology is appropriate for the intended audience.
- C. Information included in recruitment materials (including oral recruitment scripts) should usually be limited to information prospective participants need to determine their eligibility and interest, such as:
- Name and contact information of the investigator, research facility, and/or the organization conducting the study
 - Brief description of the condition or concept being studied and/or the purpose of the research
 - Summary of criteria that will be used to determine study eligibility (or exclusion)
 - Brief list of any benefits of participation
 - Time or other commitment required of the participants
 - Location of the research
 - If payment is being offered:
 - Statements about payment should not be emphasized by **LARGE** or **bold** type relative to other statements (if in writing)
 - The amount of payment should be preceded by “up to” (e.g., “up to \$100”) if not all participants will receive the full amount
 - Person or office to contact for further information.
- D. For FDA-regulated research, recruitment materials must **NOT** include any of the following:
- Any direct or implied claim that the purpose of the study is to provide treatment for a condition or disease, or that the research will improve a participant’s medical condition

- Any claim (directly stated or implied) that a drug, biologic, or device being studied is safe and effective, or equal or superior to, an existing treatment
 - Any claim (explicit or implicit) about a drug, biologic, or device being studied that is inconsistent with FDA labeling
 - Any statement (direct or implied) that the research is approved by the FDA
 - Statements that promise “free medical treatment,” when the intent is that participants will not be charged for participation
 - Use of terms such as “new treatment,” “new medication,” “new drug,” or “new device” without explaining that the drug, biologic, or device is investigational
 - For studies involving a placebo, descriptions of study design, drug allocation, or potential benefits without acknowledging the possibility that participants may receive a placebo
 - Exculpatory language (e.g., releasing the investigator or sponsor from liability).
- E. When advertisements are to be used, the IRBs will review the following:
- Information contained in the advertisement
 - Mode of its communication
 - Final copy of printed or Internet advertisements
 - Script and final audio/video recording of recorded advertisements (see below).
- F. The “final” version of recruitment materials, along with a description of how, where, and by whom these materials will be distributed should be submitted to the IRB at the time of initial protocol submission, when possible. Recruitment materials developed or revised after IRB approval must be submitted to the IRB as an amendment and approved prior to use.
- G. The following types of recruitment materials do **NOT** require IRB review:
- Listings of IRB-approved studies, including Internet registries, when the information provided in the listing is limited to basic information, such as the title of the study, basic eligibility criteria, study site location(s), and information on how to contact the site for further information.

6. Participant Compensation

- A. Participants or their legally authorized representatives may be reimbursed for out-of-pocket expenses such as parking or travel costs and/or compensated for time, effort, or other commitment associated with research participation. Compensation may be in the form of payment, merchandise, class credit, or other offering that is intended to encourage or reward research participation.

- B. Investigators may compensate participants using any (one or combination) of the following models: “reimbursement,” “hourly wage,” “market” (higher pay for high risk/low benefit studies), “fair share” (fixed proportion of the per-subject reimbursement to investigators), or other method, provided undue inducements and inequitable selection are avoided.
- C. Compensation to a participant (or to the participant’s legally authorized representative) for research participation is to be considered by investigators and the IRBs as a recruitment incentive rather than a benefit.
- D. The IRBs will consider the cultural, financial, and educational status of study participants when determining whether proposed compensation plans are appropriate. When payments are offered, the IRBs will review the amount of payment and proposed method and timing of disbursement to ensure that each is not coercive and does not present undue influence.
- E. In reviewing proposed payments, the IRBs will determine that compensation for research participation meets the following criteria:
- The amount of reimbursement is comparable to other research projects involving similar time, effort, and inconvenience. Payments are not so large as to induce participants to accept risks that they would not otherwise undertake, i.e., consent to participate “against their better judgment.”
 - As appropriate, credit for payment accrues as the study progresses and is not contingent upon the participant completing the entire study.
 - Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in a study when they would otherwise have withdrawn.
 - All information concerning payment, including the amount and schedule of payments, is described in the informed consent process.
- F. Gift certificates, gift cards, and merchandise are acceptable forms of compensation if the certificate, card or merchandise meets the criteria above. Investigators should not provide participants with products containing a corporate sponsor’s name, slogan, logo, or other marketing materials as a form of payment.
- G. Payments to research participants will be provided and documented (including appropriate use/storage of social security numbers) as described in OSU policy [Policy on Payments to Research Subjects; Managing Research Subject Payments]. When participants who do not complete the entire study are to be paid, payments may be made as follows:
- Payment to a participant who withdraws from a study may be made at the time that the participant would have completed research participation (or completed a phase of the research) had he/she not withdrawn.

- For short-term studies (e.g., lasting only a few days or weeks), a single payment at the end of the study is acceptable, even for participants who have withdrawn before then.

- H. For research involving children, investigators will specify to whom payment will be provided (i.e., participants, their parent(s) or legal guardian, or both). Proposed incentives should generally be offered to participants, if appropriate based on age and circumstances, with reimbursement for time and expenses provided to a parent or legal guardian.

- I. Opportunities to participate in drawings or other games of chance are acceptable forms of compensation in accordance with Ohio law (ORC Sections 2915.04 and 3763.01), provided that all participants are eligible, including those who withdraw from the study.

- J. Coupons good for a discount on the purchase price of an investigational drug or device once the drug or device has been approved for marketing may not be used.

- K. Information describing when and how payments will be made to participants should be described in the protocol and informed consent process and submitted to the IRB for review and approval at the time of initial review, when possible. Compensation plans proposed or revised after IRB approval must be submitted to the IRB as an amendment and approved prior to use.

7. Applicable Regulations/Guidance

21 CFR 50.20, 21 CFR 56.111, 34 CFR 99, 45 CFR 46.111, 45 CFT 46.116, 45 CFR 160, 45 CFR 164, ORC 2915.04, ORC 3763.01, FDA Information Sheets: “Recruiting Study Subjects” and “Payment to Research Subjects,” OSU “Policy on Institutional Data” (10/18/07), OSU “Policy on Responsible Use of University Computing and Network Resources” (05/10/00), OSU “Policy on Payments to Research Subjects” (07/21/08) and “Managing Research Subject Payments” (10/28/08), University Hospitals Policy 09-11: “Use of Patient Information by Hospitals and Medical Staff”