




Campus Institutional Review Board
University of Missouri-Columbia

Recruitment Processes
Policy Number 2876.21

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Board Review

Signed 
IRB Chair

Date December 12, 2007

Administrative Review

Signed 
Associate Vice-Chancellor for Research

Date December 12, 2007

1.0 Policy

The Campus Institutional Review Board (Campus IRB) requires prospective review of the full recruitment plan before any initiation of research or subject contact occurs, to assure that the methods respect the principles of Informed Consent, subject comprehension, and voluntariness.

The Campus Institutional Review Board (Campus IRB) systematically and rigorously examines human subject research recruitment proposals to assure equitable selection of subjects and recruitment processes, reasonable privacy and confidentiality protections, and to ensure the special protections are required for vulnerable subject populations by assuring adequate safeguards are in place to protect their safety and welfare.

2.0 Scope

The guidelines of this policy for recruiting subjects apply to all human subject research being conducted under the jurisdiction of the Campus IRB.

A rigorous examination is applied to all proposed recruitment methods submitted to the Campus IRB in an effort to determine if the proposed research could include vulnerable populations. The Campus IRB will review all files to require the special protections required for vulnerable subject populations.

3.0 Purpose

The Campus IRB is charged with protecting human subjects by providing a comprehensive review of the proposed research methodology, which includes the recruitment methods. When the board does not have at least one person on the IRB with the appropriate scientific and scholarly expertise to conduct an in-depth review of the protocol, a consultant or guest may be invited to provide information in compliance with the “Requesting Information from Consultants or Guests” policy. To effectuate its responsibility, the Campus IRB must prospectively review all aspects of the recruitment campaign as planned or envisioned by the investigator, along with all of the information that the subject will see in the process of deciding whether to participate in the research.

Federal regulations require that the Campus IRB gives special consideration to protecting the welfare of particularly vulnerable subject populations. Research involving vulnerable subjects requires the investigator and the Campus IRB to take the necessary measures to ensure special protections are incorporated into the research methodology to assure the subjects safety and welfare.

4.0 Standard Operating Procedure

I. RECRUITMENT METHODS

Investigators must provide the Campus IRB with the proposed recruitment method materials for review and approval. Throughout the recruitment process, investigators must ensure prospective human subjects receive the information necessary to help them understand the nature of the research so they can knowledgeably and voluntarily decide whether or not to participate.

The Campus IRB will review the proposed recruitment methods and documents submitted in concert with the investigator’s responses review all investigator responses timely submitted prior to the review/approval process. The application and supportive documents will be screened by the

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staff to determine if all materials are present to support initiation of the review process. The Compliance Specialist works directly with the investigator and serves as a conduit between the PI and the reviewer. The specialist forwards all investigator responses to the reviewer or board, and any IRB requests are in turn forwarded to the investigator. The Reviewer assesses the PI's responses and proceeds accordingly to either request more information for approval, or recommend approval.

- A. **SELECTION OF RESEARCH SUBJECTS.** Investigator(s) shall ensure the equitable selection of research subjects. The requirement for an equitable selection of subjects helps ensure that the burdens and benefits of research will be fairly distributed.

The Campus IRB must review the application, recruitment processes and documents, consent materials, and supportive documents and determine that the investigator has documented all of the requirements provided in this policy herein.

In evaluating the *benefits*, the Campus IRB will consider the purpose of the research and whether the subjects selected to participate will be among the population most likely to benefit from the research.

In evaluating the burdens, the Campus IRB must consider whether the selected group of subjects is already burdened by poverty, illness, or institutionalization and whether asking them to assume the additional burdens associated with participating in research is justified.

The equitable "selection process" will require the Campus IRB to make a preliminary assessment of the risks and benefits of research in the context of the particular characteristics of the research subjects. The IRB will take into consideration the inclusion/exclusion criteria to determine if the process is equitable.

The Campus IRB will also take the incentive plan into consideration to determine to what extent of influence, if any, the payments have on participants. The IRB will consider whether the payment makes the subject vulnerable to coercion.

The investigator shall take into account the purposes of the research and the setting in which the research will be conducted. The investigator should be particularly cognizant of the special restrictions present in research involving vulnerable subject populations. If the researcher proposes to recruit vulnerable subject populations, the investigator must comply with the "Recruitment of Vulnerable Subject Populations" and "Informed Consent" Policies. See Policy.

1. **The "Research Selection Process" requires the Investigator(s) to:**

- a. Consider the extent to which a proposed subject population is already burdened by poverty, illness, poor education, or chronic disabilities -- in deciding whether they are a suitable subject population.
- b. Ensure subjects from a variety of locations and circumstances have an equal chance of being selected.

NOTE: An investigator must receive Campus IRB approval PRIOR to implementing the "selection or recruitment of subjects".

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2. The (3) criteria to consider when assessing the equitability of the Research Selection Process the proposal must include:
 - a. The purpose of the research
 - b. The setting in which the research will be conducted.
 - c. The special problems of research involving vulnerable populations and whether they are vulnerable to coercion or undue influence.

3. The Campus IRB Review of the proposed “Selection Process.”

The Campus IRB must take participant recruitment and enrollment procedures into consideration when reviewing the recruitment process. The will comprehensively review the application, CRR, Amendment and any other proposed processes and require the investigator to describe the following:

 - a. Define the study population.
 - b. The description of the study population reasonably related to the purpose of the research.
 - c. The *Inclusion* and *Exclusion* criteria for the study population.
 - d. The Rationale for the *Inclusion* and *Exclusion* criteria.
 - e. Whether prospective participants were vulnerable to coercion or undue influence.

B. THE RECRUITMENT PROCESS

The Investigator(s) shall ensure the IRB that the recruitment process is equitable by describing the following in their submissions for approval:

- a. The purpose of the research
- b. Setting in which the research would be conducted
- c. Whether prospective participants were vulnerable to coercion or undue influence.
- d. The inclusion/exclusion criteria
- e. Participant recruitment and enrollment processes
- f. Incentives Plans
- g. Approval from Accounting Services for the cash or cash value incentive plan.

The Campus IRB will review all applications and submissions from the investigator to assure the investigator has done the following:

The investigator must address (4) areas when developing their recruitment process:

- **CONSENT (On-going process):** The subject may be informed through a dynamic continuous process of Informed Consent. The investigator must comply with the “Informed Consent” policy.
- **COERCION (Equitable incentive offerings, venue or message):** The incentive, venue or message offered shouldn’t be so enticing that the subject is in a vulnerable decision making position.
- **CONFIDENTIALITY (Addressing privacy issues)** The subject’s participation should remain a private matter, and not relinquished based on whether there is participation.
- **COMPLETENESS (Accuracy of truthfulness versus deception)**

The process must exhibit that there are adequate resources to conduct the research and addresses the following:

- There is access to a population that allows recruitment of the required number of participants.
- There is sufficient time to conduct and complete the project within the research period.
- There are adequate numbers of qualified staff.
- A plan is in place to assure research team members have adequate training about their research related duties and function.

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- A plan is in place that provides access to medical or psychological resources if required as a consequence of the research.

C. Recruitment Methods Requirements

The Campus IRB will review all applications and submissions from the investigator to assure the investigator has provided a statement and assurance of the following:

1. The purpose of the research
2. Setting in which the research will be conducted
3. Whether prospective participants are vulnerable to coercion or undue influence.
4. The subject inclusion/exclusion criteria.
5. Participant recruitment and enrollment processes.
6. Incentives Plans
 - a. The amount is fair and equitable.
 - b. The proposed payment schedule is appropriate to the subject's participation
 - c. The payment reasonable.
 - d. The payment is no so large as to unduly influence the subject to stay in the study.
7. Documentation of approval from Accounting Services for monetary incentive plans.
8. The time commitment involvement.
9. The benefits of participation.
10. The risks associated with participation.
11. The IRB must review the FINAL version of the recruitment ad, flyer or documents the subject will view.

NOTE: The IRB will not approve unreasonable bonuses that coerce subjects to finish the project, or finder's fees.

1. Verbal recruitment (telephonically or in-person):

- a. An investigator will be required to provide the Campus IRB with a script of the verbal recruitment process, detailing the intended "contents" of the delivery. The Campus IRB may require a letter of permission from an authorized individual at the research site.
- b. An investigator must ensure the absence of coercion, particularly when recruiting in-person or through a personal acquaintance.

2. Electronic recruitment (e-mail, website, or listserves):

- a. An investigator may be required to provide the Campus IRB with access to the proposed web address.
- b. The investigator is prohibited from changing the approved recruitment process without prior Campus IRB approval, regardless of external arrangements.
- c. An investigator may be required to provide the Campus IRB with a letter of permission from an authorized individual at the site whereby subjects will be contacted for recruitment.
- d. The investigator may be required to give the subject, or potential subject, frequent opportunities to reassert consent.
- e. The IRB must review the FINAL version of the recruitment ad, flyer or documents the subject will view.

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3. Recruitment by mail:
 - a. Investigators shall provide the Campus IRB with the complete recruitment campaign and the proposed mode of communication.
 - b. The IRB must review the FINAL version of the recruitment ad, flyer or documents the subject will view.

4. Recruitment with the assistance of a third party:
 - a. Investigators shall ensure coercion is absent at all times by overseeing the recruitment process.
 - b. Investigators shall maintain the subject's confidentiality and protect the privacy of the prospective participants by overseeing the recruitment process.
 - c. The IRB must review the FINAL version of the recruitment ad, flyer or documents the subject will view.

5. Recruitment through existing records:
 - a. Investigators must have permission to access such records.
 - b. Investigators may be required to provide the Campus IRB with a letter of permission from an authorized individual at the record site, to access such records.
 - c. The Campus IRB must have access to all research records.
 - d. Investigators shall maintain confidentiality of the records and protect the privacy of each prospective participant.
 - e. Investigators must obtain informed consent to use the data for research purposes and to publish the research data.
 - f. The IRB must review the FINAL version of the recruitment ad, flyer or documents the subject will view.

NOTE: If the records contain private health information, the investigator must comply with the Health Insurance Portability and Accountability Act (HIPAA) of 1996. Investigators are encouraged to contact the Campus IRB office for compliance directives when accessing private health information. The Campus IRB will assure the investigator is HIPAA compliant.

6. Recruitment by advertisements:
 - a. Investigators must provide the Campus IRB with a copy of the final advertisements, flyers, and ads to recruit subjects for research purposes.
 - b. Investigators must provide the Campus IRB with a copy of the final audio/video taped advertisements.
 - c. The advertisement(s) must accurately reflect the research project in the absence of misleading, coercive, or deceiving information.
 - d. The advertisement is limited to the information necessary to determine whether to participate in the research proposal.
 - e. The IRB must review the FINAL version of the recruitment ad, flyer or documents the subject will view.

D. Recruitment Incentives

Investigators often use "incentives" to promote the recruitment of subject participants in research. Many methods include offering tokens of appreciation in the forms of vouchers, chance offerings in drawings, or gift certificates. If a recruitment campaign involves incentives in other forms, the researcher should contact the Campus IRB for further directives.

The Campus IRB will also take the incentive plan into consideration to determine to what extent of influence, if any, the payments have on participants. The IRB will consider whether

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the payment makes the subject vulnerable to coercion. Incentive plans should be reasonable for the participation efforts. Payment should be a reasonable representation of the percentage of participation.

SUBJECTS: Receiving Payment Reimbursement

Investigators must provide the Campus IRB a full description of the intended incentive campaign

1. Submit a copy of the incentive recruitment ad to the Campus IRB.
2. Include the source of the funding, dollar amount of the incentive, method for disbursement, and the subject's responsibilities for receiving the incentive;
3. The incentive plan must propose an absence of misleading, coercive, or deceiving information.
4. The incentive proposal shall be for the purpose of reimbursement for the amount of participation, and provide an opportunity for the subject to withdraw without coercive undertones. An equitable incentive plan permits reimbursement for the amount of participation delivered.
5. Investigators must contact Accounting Services at the University of Missouri-Columbia to confirm the payment method complies with the University of Missouri-Columbia's Policies. The investigator must upload correspondence from the Accounting Services Department documenting compliance;
6. The proposed Informed Consent process must include a description of the payment incentive, the degree of risk for participation, any inconveniences, proposed time commitment, possibly the size of subject population, and any foreseeable discomforts associated with participation;
7. Investigators shall maintain the confidentiality of any private information obtained from the subject for the purposes of payment.
8. The investigator must comply with any applicable Privacy requirements set forth by the Campus IRB, Accounting Services Department, and University of Missouri-Columbia.
9. Investigators must ensure that the subject receives the payment as promised.

STUDENTS: Receiving Extra-Credit Points

Investigators must provide the Campus IRB with a full description of the intended extra-credit incentive campaign.

1. The investigator shall submit a copy of the extra-credit incentive ad to the Campus IRB.
2. The campaign should specify the following:
 - a. The student may decline to participate in the research, but obtain extra-credit by alternate assignment methods.
 - b. The student who chooses to participate in the research will be informed of the "specific" requirements to obtain extra-credit for participating in research.
3. The extra-credit campaign must be proposed in the absence of misleading, coercive, or deceiving information.
4. The extra-credit campaign must assure ALL STUDENTS that they will not be penalized or their grade will not be adversely affected by their decision to participate in the research.

II. RECRUITMENT OF VULNERABLE SUBJECT POPULATIONS

The Investigator proposing to recruit vulnerable subjects must comply with the “Recruitment of Vulnerable Subject Populations” and “Informed Consent” policies. See Policy. If the investigator has a question about a target population, they should contact the Campus IRB to receive a determination of whether the group is included in the categories of vulnerable subject entitled to special protections.

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