Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Recruitment Process

Recruitment Process

Effective Date: January 21, 2019
Original Approval Date: January 21, 2019
Revision Date:

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1.0 Purpose

To aid in assuring knowledge and compliance of all persons involved in any aspect of human subject research by documenting the requirements for subject recruitment methods and compensation of participants.

2.0 Scope

The SOP applies to all non-exempt human subject research falling under the purview of the University of Missouri Institutional Review Board.

3.0 Policy/Procedure

45 CFR 46.111(a)(3) requires selection of subjects to be equitable. In making this assessment, the IRB will take into account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of research recruiting vulnerable populations.

The recruitment process and materials are reviewed by the IRB to assure that potential subjects are not unduly coerced or influenced, and the recruitment strategies respect an individual's reasonable expectation for privacy. The inclusion and exclusion criteria are reviewed to determine the subject population is appropriate for the study objectives, and the methods of recruitment are acceptable.

Recruitment Advertisement Requirements:

1. A recruitment advertisement must be limited to the following information the prospective subjects need to determine their eligibility and interest:

- The name and address of the investigator or research facility
- A statement the study involves research, and the condition under study or the purpose of the research
- In summary form, the criteria that will be used to determine eligibility for the study
- A brief list of participation benefits, if any
- The time or other commitment required of the subjects
- The location of the research and the person or office to contact for further information

2. The advertisement cannot:
   - State or imply a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the protocol
   - Make claims, either explicitly or implicitly, that the drug, biologic or device was safe or effective for the purposes under investigation
   - Make claims, either explicitly or implicitly, that the test article was known to be equivalent or superior to any other drug, biologic or device
   - Use terms, such as "new treatment," "new medication" or "new drug" without explaining that the test article was investigational
   - Promise "free medical treatment," when the intent was only to say participants will not be charged for taking part in the investigation
   - Include exculpatory language
   - Emphasize the payment or the amount to be paid, by such means as larger or bold type

   All final recruitment ads must be submitted for IRB review and approval, including but not limited to, newspaper, television, radio, scripts, emails, social media, letters, and flyers. Depending on the location of recruitment, if permission is required from the site(s), the investigator must maintain the records of permission. Unless requested by the IRB, permission does not need to be uploaded to the study for IRB record keeping.

<u>Identifying Subjects through their Medical Record:</u>

If an investigator is utilizing the medical record to identify and contact subjects in a study, there must be a treating relationship with a research team member listed on the IRB application, or the research team members must work directly with providers that have a treating (patient-provider) relationship to consult before contacting potential subjects. HIPAA regulations apply to the screening process and access to protected health information. The IRB will review requests for HIPAA waivers or alterations if necessary.

<u>Subject Compensation:</u>

Although it is common, it is also not required for subjects to be compensated for reimbursement for time and/or expenses incurred as part of the research study. The IRB will determine on a case-by-case basis whether the amount of compensation is

appropriate, and upon review, may request changes in the amount or method of compensation. The IRB will consider:

1. The amount of payment and the proposed method and timing of disbursement neither is coercive nor presents undue influence and is reflective of the degree of risk, inconvenience, or discomfort associated with participation.
2. Credit for payment accrues as the study progresses and not be contingent upon the participant completing the entire study.
3. Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.
4. All information concerning payment, including the amount and schedule of payments, is set forth in the consent document.

Compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing is prohibited.

Investigators must work directly with their department's fiscal office to ensure compliance with the MU Business Policy and Procedure for Research Participation Payments found here: https://bppm.missouri.edu/policy/research-participation-payments/?_ga=2.23105082.1689524572.1539115672-2052305340.1537195229

Recruitment Assistance:
Institutions/organizations whose employees or agents only participate in the following ways are not engaged in the research and do not need to be added to the IRB application as key personnel:

1. inform prospective subjects about the availability of the research;
2. provide prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but do not obtain subjects' consent for the research or act as representatives of the investigators;
3. provide prospective subjects with information about contacting investigators for information or enrollment; and/or
4. seek or obtain the prospective subjects' permission for investigators to contact them.

An example of this would be a clinician who provides patients with literature about a research study at another institution, including a copy of the informed consent document, and obtains permission from the patient to provide the patient's name and telephone number to investigators.

See OHRP Engagement Guidance for more information:
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html

Finder's Fees and Bonus Payments

University of Missouri IRB does not permit the payment of finder's fees and / or bonus payments (monetary or in kind) in any form, due to the potential that such a practice could be perceived as coercive and bordering on unethical research subject recruitment. In addition, several professional associations and groups have stated that this practice is unethical (e.g., **AMA**, **APA**).

References:

Combined Policy January 21, 2019:
Subject Compensation

Approval Dates: October 1, 2004; December 1, 2005; December 1, 2006; June 10, 2010; July 1, 2011; March 1, 2015; July 1, 2015; June 8, 2017