Human Research Protection Program
UNIVERSITY OF GEORGIA

Participant Selection and Recruitment

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1. PURPOSE

1.1. All ***human research*** conducted at the University of Georgia (UGA) must adhere to the basic ethical principles described in the Belmont Report. The selection of ***human subjects*** for research must demonstrate adherence to the principle of justice. This document describes the ***policy*** and ***procedure***s that the UGA Institutional Review Board (IRB) will use to evaluate the equitable selection of subjects and to review proposed participant recruitment methods and materials, and payment arrangements in order to determine whether such arrangements are fair, accurate, and appropriate.

2. DEFINITIONS

2.1. ***Autonomy***: the personal capacity to consider alternatives, make choices, and act without ***undue influence*** or interference of others.

2.2. ***Equitable selection***: the process of defining the appropriate group of subjects for a research project using methods that will encourage a broad cross-section of subjects and will evenly distribute the burdens of research.

2.3. ***Finder's Fee:*** a 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.

2.4. ***Justice***: one of the basic ethical principles in the Belmont Report requiring fairness in distribution of burdens and benefits; that is, one group in society should not bear the costs of research while another group reaps its benefits.

2.5. ***Recruitment Bonus:*** a payment, merchandise, or other gift or service offered by an Investigator or Sponsor as an incentive or reward to an organization, investigator, or key research personnel designed to accelerate the rate, timing, and/or number of participant recruitment.

2.6. ***Recruitment Materials***: any information that prospective subjects will hear or see during the process of recruitment to announce the research or invite individuals to participate in the research.

2.7. ***Vulnerable population***: a population whose members may have limited autonomy and/or who are at risk for ***coercion*** or undue influence.

3. POLICY

3.1. The IRB must determine that the plan for selection of subjects adheres to the principle of justice and is equitable. That is, the process for recruiting individuals to participate in research should not pressure certain classes of individuals to participate or entice them to subject themselves to extraordinary risk through any aspect of the research.

3.2. The process for recruiting subjects must be reviewed and approved by the IRB prior to implementation.

3.3. Where a group of individuals may have limited autonomy, there must be additional measures to protect these individuals from undue influence or coercion. If a vulnerable population is targeted, the rationale must be provided in the submission and approved by the IRB.

3.4. If a gender or racial group is excluded, the rationale must be provided in the submission and approved by the IRB.

3.5. For non-***exempt*** research, final versions of all recruitment materials, in any format (e.g., printed or oral scripts, audio or video recording, web site) must be reviewed and approved by the IRB prior to use.

3.6. For non-exempt research, the recruitment materials must include, at a minimum, the information necessary to determine eligibility and to gauge interest (see *WORKSHEET: Advertisements*), unless IRB allows variation for specific methods (e.g., SONA listings for student research pools, HIT listings for Amazon Mechanical Turk).

3.7. Recruitment methods and/or materials must not be misleading, inaccurate, exculpatory, coercive or unduly influential.

3.8. The recruitment materials may not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and protocol.

3.9. Recruitment materials that include a description of ***incentive*** payment must state amount of payment and the proposed method and timing of disbursement in a way that does not draw undue attention to the payment by means such as larger font or bold type.

3.10. The recruitment method and materials that are used in FDA-regulated ***research*** cannot:

3.10.1. Make claims either explicitly or implicitly about the drug, biologic or device under investigation that are inconsistent with FDA labeling; or

3.10.2. Use terms, such as “new treatment,” “new medication,” or “new drug,” without explaining that the test article is investigational.

3.10.3. Offer any incentives, finder’s fees, or bonuses of any type in exchange for referral of potential participants or to accelerate the rate, timing, and/or number of participant recruitment.

3.11. When the research is conducted under Department of Defense requirements:

3.11.1. Officers and senior non-commissioned officers have a separate opportunity to participate;

3.11.2. Additional criteria to minimize undue influence will be included (see *WORKSHEET: Additional Federal Criteria, Section 9*).

3.12. The recruitment process must comply with any additional State and Federal laws, including, but not limited to, FERPA (Family Educational Rights and Privacy Act), HIPAA (Health Insurance Portability and Accountability Act), and NSLA (National School Lunch Act). See *Policy and Procedure: FERPA* and *Policy and Procedure: HIPAA*.

4. PROCEDURES: Researchers

4.1. Complete the submission form through the IRB's electronic application system.

4.2. Answer all relevant questions pertaining to recruitment and subject selections, specifically the following:

4.2.1. Research Methods and Procedures page (description of study purpose and complete description of study procedures including setting);

4.2.2. Human Research Participants page (target population general description, inclusion/exclusion criteria, and plan for compensation/incentive payment);

4.2.3. Vulnerable Participants page (selection of vulnerable/special populations, assessment of working relationships or other influences over voluntariness such as payment, and measures to reduce undue influence and coercion);

4.2.4. Recruitment Methods and Materials page (description of recruitment methods) for non-exempt research. Upload all recruitment materials and advertisements (e.g., flyers, emails, follow-up emails) where prompted. Use *TEMPLATE: Recruitment/Advertisement* as a guide.

4.3. When the selection and recruitment processes involve collection of information to determine eligibility, the researcher will consider all State and Federal laws for obtaining such information for research purposes, including but not limited to FERPA, HIPAA, NSLA, and copyright laws regarding trademarks. It is the researchers' responsibility to know, understand, and comply with the Federal, State, and local laws for the jurisdiction within which the research activities are conducted. *WORKSHEET: NSLA Compliance* and *WORKSHEET: FERPA Compliance* may be used for reference.

5. PROCEDURES: Institutional Review Board

5.1. The IRB will review the submission to determine that selection of participants is equitable considering the purpose of the research, the setting in which the research will be conducted, potential vulnerability of the target population to undue influence or coercion, and selection criteria.

5.1.1. When appropriate, an IRB Member conducting scientific review or a ***consultant*** providing additional review will provide additional determination regarding equitable selection

based on knowledge and experience with similar population and study procedures, and review of plans for analysis. See *Policy and Procedure: Scientific and Scholarly Review*.

5.2. The IRB reviews recruitment materials and/or advertisements to ensure congruence with the policy in Section 3. See *WORKSHEET- Advertisements*.

5.3. IRB Staff will document determinations that the requirements of this policy have been met on the review checklist corresponding to the type of review being completed (for ***non-committee review***) or in the meeting minutes by recording the motion to approve (for committee review).

6. MATERIALS

6.1. Checklist: Expedited Review
6.2. Checklist: Subject Matter Review
6.3. TEMPLATE: Recruitment/Advertisement
6.4. WORKSHEET: Additional Federal Criteria
6.5. WORKSHEET: Advertisements
6.6. WORKSHEET: FERPA Compliance
6.7. WORKSHEET: NSLA Compliance

7. REFERENCES

7.1. Belmont Report
7.2. DHHS: 45 CFR 46.111(a)(3); 45 CFR 46.116
7.3. DoD: Instruction 3216.02 11; Dual Compensation Act, 24 U.S.C 301; DoD 3216.2, para. 4.4.4; SECNAVINST 3900.39D, para. 6a(6)
7.4. FDA: 21 CFR 56.111(a)(3); 21 CFR 50.20; 21 CFR 56.111(a)(3); FDA Information Sheets: Frequently Asked Questions: Informed Consent Document Content, Frequently Asked Questions: IRB Organization, A Guide to Informed Consent, Recruiting Study Subjects
7.5. Policy and Procedure: Family Educational Rights and Privacy Act (FERPA) and Use of Education Records
7.6. Policy and Procedure: Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule
7.7. Policy and Procedure: Scientific and Scholarly Review

Revision History:
04/17/2015: REV0 New Document
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