

Standard Operating Procedures		
SOP #510.2 Revision 2	TITLE: Advertisement and Recruitment for Human Research	Effective Date: 3/1/2019
Approved By: OIRB Director	Signature 	Date 3/1/2019
Approved By: IRB Chair	Signature 	Date 3/1/2019

PURPOSE

This policy ensures the equitable recruitment of potential research participants by providing information regarding appropriate methods and mechanisms for recruiting research volunteers. This policy applies to all researchers who conduct recruitment activities for projects under the purview of the UNM IRB.

REVISIONS FROM PREVIOUS VERSION

Revise the scope of the purpose of the policy and administrative corrections

POLICY

It is UNM policy to evaluate for approval all planned protocol recruitment methods including appropriateness of materials, inclusion and exclusion criteria, and compensation components. Researchers and the IRB must ensure that recruitment activities are free of bias, do not exert undue influence on or coerce a potential participant to volunteer, or to imply a guarantee of benefits beyond what is outlined in the protocol and consent form approved by the IRB. Researchers should make reasonable efforts to assure open access to research opportunities. However, efforts to be broadly inclusive and representative are only required if there is potential direct benefit to those participating in the research.

RESPONSIBILITIES

Execution of SOP: Researchers, IRB.

PROCEDURE

Equitable Recruitment and Selection

1. All recruitment/advertisement methods must be thoroughly described in the protocol. The researcher must carefully consider the targeted research population, research aim(s), participant privacy, and potential for bias and influence when designing recruitment activities for specific protocols. For example, faculty/teachers who also serve as researchers and wish to enroll their students into research must ensure that recruitment methods do not cause undue influence or inappropriately promise or suggest benefit to the participant beyond what is written in the protocol and consent form.
2. Researchers wishing to recruit their own students or staff to participate in research must ensure that the recruitment plan minimizes any perception of coercion or undue influence. The recruitment plan must assure the potential participant that their job, promotion, grade, etc., is not dependent upon their participation. An acceptable way to address this issue is to utilize a third party to present the research information to potential participants.
3. The IRB evaluates the planned recruitment and selection procedures for fairness. Generally, both the risks and benefits of potentially beneficial research should be shared equitably by those most likely to benefit from the research.

4. Any inclusion or exclusion criteria should be intended to minimize potential risks and distribute potential benefits to participants by fair means (e.g. not intentionally excluding underrepresented groups or difficult to include groups for convenience); persons who are unable to comprehend English must not be excluded from research opportunities solely on that basis if there is the potential for direct benefit to the participants.
5. Recruiting and selection methods, including compensation components should be free from the appearance and fact of coercion and undue influence, especially if a prior relationship with the researcher exists (e.g. employer, course instructor, social network, etc.) – see SOP 503 Compensating Participants.
6. Participants targeted for enrollment should be appropriate for answering the research question.
7. If vulnerable populations are included in the research, additional protections from risks should be included as appropriate (see Guidance on Assessing and Minimizing Risks).

Advertising Materials

1. All advertisements planned for the recruiting of research participants must be approved by the IRB prior to use. The IRB reviews final copies of printed, audio or video taped advertisements. Any changes made following approval must be re-approved prior to implementation.
2. The key features evaluated include the following:
 - a. Materials clearly state that research participation is being solicited.
 - b. Materials do not contain misleading statements. Statements describing potential risks or benefits from participation in research, or from research results, are accurate and consistent.
 - c. Materials neither include exculpatory language nor promise “free treatment” when the intent is only to say participants will not be charged for taking part in the research.
 - d. Incentives or compensation for participation are not inappropriately emphasized (e.g. larger or bold type).
 - e. Communication materials and processes are culturally sensitive and appropriate.
3. Advertisements should be limited to information prospective participants need to determine their eligibility and interest, such as:
 - a. The name of the researcher, location of research, and address of the research facility.
 - b. The purpose of the research.
 - c. A summary of eligibility criteria.
 - d. The procedures, time or other commitment required of participants.
 - e. Compensation for participation, if applicable.
 - f. The person or office to contact for more information.
4. IRB review and approval of posting research projects on the Internet is not required when the information provided is limited to the following:
 - a. The title and purpose of the project;
 - b. Protocol summary;
 - c. Basic eligibility criteria;
 - d. Research site location(s); and
 - e. Site contact information.
5. For online recruitment, projects may use teaser ads placed on social media sites (e.g. Facebook, Twitter, Tumblr, Vimeo, etc.) where character length is limited as long as:
 - a. the teaser mentions that it is a research project;
 - b. the teaser does not use inflammatory language or misleading statements;
 - c. the teaser refers the potential participant to a full flyer; and

- d. the teaser and any hashtags are not misleading and do not emphasize compensation.
6. For FDA regulated research, advertising may not make claims, either explicitly or implicitly, about the drug or device under investigation, that are inconsistent with FDA labeling. Advertising may not use terms, such as “new treatment,” “new medication,” or “new drug,” without explaining that the test article is investigational. Advertising may not allow compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price for the product once it has been approved for marketing.

Identification of Potential Participants through Existing Data (e.g. school records, medical records)

1. IRB review and approval is required in addition to the review and approval from sources holding existing data prior to a research team member reviewing existing data sets for the identification of individuals who may be eligible to participate (examples: medical records, UNM student academic records, etc.). Data sources that are not publicly available may be subject to additional institutional or regulatory requirements prior to access, such as the Family Educational Rights and Privacy Act of 1974 (FERPA) and HIPAA requirements. Access to such data will be approved by the IRB only when the proposed recruitment plan is compliant with these additional requirements, such as HIPAA waivers of authorization (45 CFR §164.512(i)(1)(i)) or limiting access to only those data elements allowable under FERPA. The IRB may also require a letter of support from the providing institution noting their willingness to share private information.
2. Persons who have been identified as possibly qualifying for a project without their knowledge should be initially contacted by an individual known to the potential participant. For example, persons identified through a medical record review should be contacted via their treating clinician or other health care provider or students identified through their academic record should be contacted by school personnel. Researchers may seek approval from the IRB to contact the potential participant directly. However, such approval will only be granted when the IRB considers it impracticable for researchers to have potential participants contacted by an individual known to them.

Use of Third Party for Recruitment of Potential Participants

IRB review and approval is required when a third party is used to inform potential participants of a research opportunity. Examples of a third party would include community physicians or school administrators who are asked to provide their patients or students with information regarding a research project. Third parties may also include commercial entities hired to aid in recruiting research volunteers.

IRB review and approval is also required of all materials used by the third party to inform potential research participants of the project, such as “Dear Colleague” or “Dear Patient” letters. Third party recruiters may provide the research contact information directly to the potential participant. The collection of additional research-related information used to determine eligibility cannot be conducted by the third party. The use of currently enrolled research participants to recruit additional research participants (sometimes referred to as “snowball sampling”) may be approved by the IRB; IRB review and approval is required for materials used with snowball recruitment as well. Providing finder’s fees or bonus payments for participant referrals is strictly prohibited.

REFERENCES

- 45 CFR 46.111(a)(3)
- 21 CFR 56.111(a)(3)