SOP 2.3.1 **Participant Recruitment**

General Description:

Recruitment for subjects is often seen as the first step in the informed consent process as recruitment materials present the research to potential participants for the first time. Recruitment is how potential participants learn of the research project. Recruitment materials may come in the form of an invitation email/letter, in-person or in-class verbal script, flyers/posters, telephone recruitment script, or webpage announcement (e.g. SONA).

Before the Principal Investigator (PI) or any team member may begin to recruit human subjects for a specific study, both the recruitment methods and materials are subject to IRB review and approval. The IRB must review the information contained in all recruitment materials, as well as the method of communication, to determine whether the procedure for recruiting subjects affords adequate protection.

When recruiting potential research participants, the PI must consider the risks and ethical aspects of the method of contact, as well as of the research study itself. The PI should choose the least intrusive and coercive method of recruitment that is consistent with successful research and should explain in the protocol application to the IRB why such a method is appropriate.

Procedures:

IRB Review of Recruitment Process

The PI may not begin any recruitment measures before he or she receives IRB approval of the recruitment methods and materials. The PI shall submit such information with the protocol application or via a protocol amendment.

The following provides guidance for researchers as to the specific information that must be submitted for IRB review:

1. Context
    a. Description of the mode of communication
        i. PI must inform the IRB of the type of the medium/media (e.g., newspaper, website, e-mail) and the target audience.
    b. For printed or written electronic advertisements, the final copy text
    c. For audio/video tape recruitment (such as TV or radio advertisements), the final version of the content
2. Advertisement
    a. Does not state or imply a certainty or favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
    b. Does not promise “free” when the intent is only to say subjects will not be charged for taking part in the research
    c. Does not include exculpatory language
    d. Does not overemphasize the payment or the amount to be paid, by such means as larger or bold type (See SOP 2.3.2 “Providing incentives to participants” for more information).
    e. The advertisement contains the information prospective subjects need to determine their eligibility and interest, such as:
        i. The contact information of the investigator or research facility
        ii. The condition under study or the purpose of the research

iii. In summary form, the criteria that will be used to determine eligibility for the study
iv. A brief list of participant benefits, if any
v. The time or other commitment required of subjects
vi. The location of the research and the person or office to contact for further information.

The IRB will then decide if the merits of the research, the potential benefits to participants, the risks of the study, and the risks of the recruitment method(s) are in such balance as to allow approval of the recruitment method(s).

IRB Review of Changes to Recruitment Materials

If a PI modifies a recruitment method or the text of an advertisement, he or she must submit an amendment request to the IRB for review and approval before use.

Related Forms, Guidance, and SOPs:

- 2.3.2 Providing incentives to participants

Responsibility:

Principal Investigators
Research Team Members
IRB staff
Institutional Review Board

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

Date First Effective:	06/25/2014
Revision Date:	N/A
Current Version #:	1

Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Research Development, Integrity and Assurance	06/25/2014
Greg Guagnano	IRB Chairperson	06/25/2014