Title: RECRUITMENT/ADVERTISING

1.0 Purpose:

The purpose of this Standard Operating Procedure (SOP) is to describe the policy and procedure for recruitment of human research participants and provide guidance for recruitment, especially when advertising.

2.0 Policy:

2.1 All Recruiting and Advertising Materials Must be Approved by the IRB. The IRB must assure that appropriate safeguards exist to protect the rights and welfare of research participants. In fulfilling these responsibilities, the IRB must review all of the research documents and activities that bear directly on the rights and welfare of the participants of proposed research, including the methods and materials that Investigators propose to use to recruit participants.

2.1.1 For example, the Investigator must obtain IRB approval for all television, radio, video recorded or print advertisements, e-mail solicitations, Internet websites, and other recruitment methods and materials intended for the recruitment of prospective research participants. All methods of advertisement require approval from the IRB prior to their use.

2.1.2 The IRB considers advertising or soliciting for study participants to be the start of the informed consent process and subject selection process. Advertisements must be reviewed and approved by the IRB as part of the package for initial review. When the Investigator decides after the initial approval to advertise for participants or to change the advertisement, the advertising is considered an amendment to the ongoing study.

2.1.3 When advertising is to be used, the IRB must review the information contained in the advertisement and the mode of its communication, to determine that the procedure for recruiting participants is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol. This is especially critical when a study may involve participants who are likely to be vulnerable to undue influence. The IRB must review the final copy of printed advertisements to evaluate the relative size of type used and other visual effects. When advertisements are to be recorded for broadcast, the IRB must review the final audio or video recording. The IRB may review and approve the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording. The review of the final recorded message prepared from IRB-approved text may be accomplished through expedited procedures.

2.2 Advertisements. Any advertisement to recruit participants should be limited to the information the prospective participants need to determine their eligibility and interest.

2.2.1 Advertisements should include:

2.2.1.1 The purpose of the research;

2.2.1.2 A statement that the solicitation is for *research* participation;

2.2.1.3 In summary form, the criteria that will be used to determine eligibility for the study;

2.2.1.4 The time or other commitment required of the participants; and

2.2.1.5 The location of the research, facility or institution, and the person or office to contact for further information.

2.2.2 Advertising materials should not:

2.2.2.1 State or imply a certainty of a favorable outcome or other benefits beyond what was outlined in the consent document and the protocol;

2.2.2.2 Use catchy words like “free” or “exciting”;

2.2.2.3 Emphasize the payment or the amount to be paid, by such means as larger type.

2.3 Receptionist Scripts. The first contact prospective study participants make is often with a receptionist who follows a script to determine basic eligibility for the specific study. The IRB must review the procedures to assure that they adequately protect the rights and welfare of the prospective participants. The IRB must have assurance that any information collected about prospective participants will be appropriately handled.

2.4 Internet Recruitment. For Internet recruitment sites, IRB review and approval is required to assure that the information does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document. In addition, the Investigator must assure that the information shared for Internet recruitment is in accordance with their signed clinical trial agreement or grant.

2.5 Syracuse University Mass Communication E-mail. Advertising submitted through mass email solicitation at SU should be simple, readable, and understandable. It should meaningfully and respectfully convey a message to a broad spectrum of the SU community. The following format is recommended when utilizing this method of recruitment or advertisement:

2.5.1 A headline that describes the study and volunteers needed;

2.5.2 Use sentences and paragraphs;

2.5.3 Paragraph 1 – include enough information to help readers self-select;

2.5.4 Paragraph 2 – purpose of the study;

2.5.5 Paragraph 3 – requirements of participation;

2.5.6 Paragraph 4 – benefit to the participant or a statement there is no benefit; and

2.5.7 Paragraph 5 – a contact person “for more information”.

2.6 Data Base/Primary Care Physician Recruitment. Often times Investigators request to use search methods of particular databases looking for potential participants that may be eligible for their research projects (e.g., disease, age, sex, etc.), or they request to contact primary care providers (PCP) for access to potential participants from the PCP’s patient population. These recruitment methods require IRB approval prior to initiation.

2.7 Inclusion of Women, Children and Minorities. The inclusion of women, children, and minorities in research is important, both to ensure that they receive an appropriate share of the benefits of research and that they do not bear a disproportionate burden. To the extent that participation in research offers direct benefits to the participants, under-representation of children, women or minorities denies them the opportunity to benefit. Moreover, for purposes of generalizing research results, Investigators must include the widest possible range of population groups.

2.8 Finder’s Fees and Bonus Payments. Finder’s fees and bonus payments are compensation of any type (cash, office or medical supplies, educational stipends, gift certificates, priority in authorship listings, travel reimbursement, or anything else of value) to a professional (i.e. health professional, teacher, faculty member, study coordinator) made in exchange for referral or recruitment of a participant to a research study. The SU IRB does not permit the payment of finder’s fees (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.

2.9 Referral fees-Research participants may be offered a nominal fee to assist with participant recruitment efforts (i.e., respondent driven sampling). Researchers must include information in the IRB protocol, such as the amount of the fee and the circumstances under which fees will be paid. The IRB must ensure that there is no coercion on referred individuals to participate, and no coercion on current participants to provide referrals.

3.0 References and Reference Documents:

Amdur, R. and Bankert, E. *IRB Management and Function*. Jones and Bartlett Publishers, Inc., 2002.
SOP 014, Amendments to Previously Approved Applications or Claims for Exemption

4.0 Procedure:

This procedure provides guidance for advertising associated with the recruitment of human participants for research.

4.1 Investigator Responsibilities.

4.1.1 The Investigator will submit all types of advertisements (e.g., television ads, radio, video recordings, print advertisements, e-mail solicitations, and Internet websites) associated with the recruitment of research participants to the SU IRB for review and approval. This includes any sponsor-provided advertisements or Investigator-drafted advertisements.

4.1.2 Advertisements must be submitted to the IRB in their final form in order to receive final IRB approval for use.

4.1.3 The SU IRB considers advertising or soliciting for study participants to be the start of the informed consent and participant selection processes. Therefore, advertisements must be included as part of the initial "IRB Application for Full/Expedited Review."

4.1.4 IRB review and approval for additional advertisements or changes in currently approved advertisements or recruitment methods will be submitted in the form of an amendment to the IRB for approval prior to implementation. (See *SOP 014*).

4.1.5 For recruitment of students:

4.1.5.1 Investigators are to advertise and recruit student participants generally, rather than recruiting individual students directly;

4.1.5.2 An exception to this rule may be allowed when the use of one's own students is integral to the research. For example, research into teaching methods may be allowed by the IRB when sufficient precautions have been taken to protect the student-participant (e.g., using a third party to obtain informed consent).

4.1.6 For student participation as a class component:

4.1.6.1 Students should be recruited through general announcements, bulletin board postings or advertisements, rather than individual solicitations;

4.1.6.2 Research interventions should not be conducted during class time;

4.2 IRB Committee Responsibilities.

4.2.1 The IRB will review and approve all advertisements or means of soliciting participants in human subjects research to assure that the rights and welfare of the prospective participants are protected and that information collected about prospective participants will be appropriately handled.

4.2.2 The IRB must review the final copy of printed advertisements to evaluate the relative size of type used and other visual effects.

4.2.3 When advertisements are to be recorded for broadcast, the IRB must review the final audio or video recording prior to approval.

4.2.4 The IRB may review and approve the wording of an advertisement prior to recording to preclude re-recording because of inappropriate wording. The review of the final recorded message prepared from the IRB approved script may be conducted via expedited procedures.

4.2.5 The IRB Committee Chair or designated Committee Member may review changes to advertisements. However, the Chair or designated Committee Member may refer the advertisement to the full, convened IRB Committee if the advertisement contains subjective material which in his or her opinion needs further review.

Examples for Recruiting Potential Participants into Research

Advertisements/Recruitment Tools	Examples/Information
Flyers Posters Brochures Ads	Departmental or community bulletin boards; Soliciting participation on a website; Soliciting participation through the mail, newspaper, magazine, television, face-to-face, etc.
Recruitment scripts	Telephone, face to face encounters, informational group settings, introductory meetings, etc. *If writing a recruitment script for a child, a shorter recruitment script may be needed depending on the child's age.*
Recruiting subjects by word of mouth or by using the snowball method	Submit talking points or script that will be used when discussing the study with the initial contact. Provide a copy of the contact card or sheet that will be used for participants to put information down to contact about the study. Specify a method in the application for collecting contact information for potential study participants. Provide a script for the follow-up.
Recruitment by a mass email	Submit a copy of the document that will be emailed. Specify in the application where and how contact information is being obtained.

SOP 036: RECRUITMENT/ADVERTISING

Approved by:

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6-14-10
Date

Kathleen King, Ph.D.
Chair of the Institutional Review Board
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Director of Office of Research and Integrity Protections
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6-11-
Date