UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

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AAHRPP:	Element II.3.C.1. & Element III.1.E.
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Reviewed By:	IRB Chair; IRB; ORIO
Procedure Title:	Recruitment and Screening

1.0 Objective

1.1. To describe the policies and procedures for recruitment and screening offered by the University of Southern Maine (USM) and the USM Institutional Review Board (IRB).

2.0. General Description

2.1. The primary responsibility of the IRB is to ensure the protection of the rights and welfare of research subjects. In performing that responsibility, the IRB must maintain written procedures for research proposals in which a Principal Investigator (PI) will obtain information or biospecimens for the purposes of screening, recruiting, or determining eligibility of prospective subjects.

3.0. Responsibility

3.1. It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Research Compliance Administrator (RCA), Institutional Review Board (IRB), and Principal Investigators to execute this Standard Operating Procedure (SOP).

4.0. Definitions

4.1. **Direct Advertisements** includes, but is not limited to, newspapers, radio, TV, internet ads, audio/video tapes, bulletin boards, posters, and flyers that are intended for prospective subjects.

4.2. **Cold Calling** means the practice of Principal Investigators or research staff, unknown to the potential research subject, initiating contact with the potential subject based on their prior knowledge or private information.

4.3. **Principal Investigator (PI)** means an investigator that accepts overall responsibility for the research activity.

5.0. Procedure

5.1. Recruitment Procedures

5.1.1. Recruitment plans for research projects should be designed to fully encompass racial, ethnic, and gender diversity. Efforts to identify and recruit potential human subjects should be designed to respect personal rights to privacy and confidentiality. Everything possible should be done to avoid coercion of subjects in their recruitment for research study participation. Recruitment of vulnerable subjects must consider and adhere to the regulations at 45 CFR 46, Subparts B, C or D, as appropriate. The IRB will evaluate recruitment processes, including advertisements, to ensure a fair and equitable selection of participants.

5.1.2. Advertising or soliciting to study participants will be considered the start of the informed consent process.

5.1.2.1. The IRB will review the proposed recruitment processes and advertisements to ensure that they do not violate the regulatory requirements of consent.

5.1.3. Cold calling is prohibited for potential research subjects. To avoid cold calling, the research study should be introduced to the potential research subject by an individual who, by virtue of their position, would normally have access to the potential subject's confidential information.

5.1.3.1. If the potential research subject indicates an interest in study participation, they should be instructed to either:
5.1.3.1.1. Contact the PIs directly; or
5.1.3.1.2. Permit the individual who initiated this contact to share with the research team the person's interest in study participation so that the research can subsequently contact the potential subject and provide information about the study.

5.1.4. The Recruitment Material must include:

5.1.4.1. The name and contact information of the PI or research facility;
5.1.4.2. The purpose of the research or the condition under study;
5.1.4.3. The criteria that will be used to determine eligibility for the study;
5.1.4.4. Benefits to the participants, if any;
5.1.4.5. The time or other commitment required of the participants;
5.1.4.6. The location of the research; and
5.1.4.7. A point of contact for further information or questions.

5.1.5. The PI must obtain IRB approval prior to the use of all television, radio, print, e-mail solicitations, letters, telephone, website, and other recruitment methods and materials intended for the recruitment of prospective research participants.

5.1.5.1. The PI must submit any final recruitment materials in advance for IRB approval.
5.1.5.2. Any changes or additional recruitment materials to already approved protocols must be submitted as an Amendment to the IRB for approval prior to the implementation.

5.1.6. While in review, the IRB must ensure the recruitment is equitable while looking through the PI's application. Applications must include:

5.1.6.1. The purpose of the research;
5.1.6.2. The setting in which the research will be conducted;
5.1.6.3. Whether prospective participants will be vulnerable to coercion or undue influence;
5.1.6.4. The selection (inclusion/exclusion) criteria;
5.1.6.5. Participant recruitment and enrollment procedures; and
5.1.6.6. The amount and timing of payment to participants.

5.1.7. In addition, when the IRB is making an assessment about whether selection of participants is equitable, they must take into account:

5.1.7.1. The purpose of the research;
5.1.7.2. The setting in which the research will be conducted;
5.1.7.3. Whether prospective participants will be vulnerable to coercion or undue influence;
5.1.7.4. The selection (inclusion/exclusion) criteria;
5.1.7.5. Participant recruitment and enrollment procedures; and
5.1.7.6. The influence of payments to participants.

5.1.8. The IRB must review:

5.1.8.1. The information contained in the advertisement;
5.1.8.2. The mode of its communication;
5.1.8.3. The final copy of printed advertisements; and
5.1.8.4. The final audio or video taped advertisements;

5.1.9. The following criteria must be met in order to gain IRB approval:

5.1.9.1. Advertisements must contain the word "Research";
5.1.9.2. Advertisements cannot state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the protocol and consent document;
5.1.9.3. Advertisements cannot state or imply that the drug, biologic, device or other type of intervention is safe or effective for the purposes under investigation;

5.1.9.4. Advertisements cannot state or imply that the test article or other research intervention is known to be superior or equivalent to any other drug, biologic, device or intervention;

5.1.9.5. Advertisements for recruitment into a research study involving an investigational drug, biologic, or device should not use terms such as "new treatment," "new medication," or "new drug" without explaining that the test article is investigational;

5.1.9.6. Advertisements cannot promise "free medical treatment" when the intent is only to state that subjects will not be charged for taking part in the investigation;

5.1.9.7. Advertisements may state that subjects will be paid but should not emphasize payment of the amount to be paid by such means as larger or bold type. Advertisements aimed at recruitment of children cannot contain the dollar amount of the compensation;

5.1.9.8. Advertisements cannot include exculpatory language through which the participant or their legally authorized representative waive legal rights or releases the PI, the sponsor or institution from liability for negligence; and

5.1.9.9. Advertisements cannot include 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.

5.2. Screening Procedures

5.2.1. Screening procedures start at the moment the PI obtains information about the prospective participant to determine if they are eligible for the research. Screening individuals to obtain and record information to determine eligibility involves obtaining identifiable private information and is considered human subject research subject to 45 CFR 46.

5.2.1.1. Participants must be informed that they may be withdrawn from the study if it is determined that they do not meet the inclusion criteria.

5.2.1.2. Participants who do not meet the screening criteria are to be reported as withdrawals from the study at the time of continuation.

5.2.2. Any screening instruments must be submitted to the IRB for review. Screening may not take place until the IRB has approved the screening instrument and process.

5.2.3. In order to use any data collected from the screening procedures for research purposes, consent must be obtained from the potential research subject, and no sensitive questions may be asked without first obtaining informed consent. The IRB may approve screening procedures without obtaining the prior informed consent of the prospective subject or the subject's legally authorized representative only if:

5.2.3.1. No identifiers can be retained with data from the screening procedure unless informed consent has been obtained, or the IRB has granted a waiver of informed consent and/or waiver of HIPAA authorization for the screening procedure;

5.2.3.2. No data, including aggregated data, can be used for research purposes unless approved in advance by the IRB. Potential subjects still need to be informed that their information can be used for general reporting of how many people completed the screening, how many didn't meet inclusion criteria, and how many decided not to participate in the research study; or

5.2.3.3. No sensitive questions are asked directly.

5.2.4. The PI must not record any identifiable information during the screening process. This includes names, study ID #, gender, etc. The only information the PI may be able to record is eligible yes/no for each subject screened.

5.2.5. Screening may not take place unless one of the following has already been met:

5.2.5.1. Informed consent and (when applicable) HIPAA Authorization have been obtained from the participant;

5.2.5.2. The IRB has determined that consent is not required, a waiver of informed consent has been obtained and either HIPAA does not apply, HIPAA Authorization has been obtained from the participant, or a waiver of HIPAA Authorization has been issued by the IRB; or

5.2.5.3. Waivers of consent and HIPAA Authorization have been issued by the IRB.

5.3. Payment

5.3.1. Payment arrangements can place participants at risk of coercion or undue influence or cause inequitable selection. Ethical conduct of research requires that the participation of all human participants be completely voluntary. The IRB must examine two fee situations;

5.3.1.1. **Finder's Fees** or a referral is a payment from the researcher or sponsor to a person who refers a prospective participant.

5.3.1.1.1. The use of any compensation must be reviewed and approved by the IRB prior to being initiated.

5.3.1.1.2. Payments outside of USM should be structured as a contract and provide reimbursement for actual services rendered by individuals for the recruitment purposes if applicable.

5.3.1.2. **Recruitment Bonuses** are payments from the sponsor to a researcher or organization based on the rate of timing of recruitment.

5.3.1.2.1. It is not permissible to pay or receive bonuses with respect to subject recruitment goals or the competition of a study.

5.3.1.2.2. The use of any bonuses must be reviewed and approved by the IRB prior to being initiated.

5.3.2. When developing payment offers, PIs should first focus on reimbursement and fair compensation, proposing payment as a recruitment incentive only when they wish to offer more than would be justified for reimbursement and compensation.

5.3.3. Acceptable payment arrangements among the sponsor, organization, researcher, and those referring research participants may include:

5.3.3.1. A reasonable amount of payment that is based on the complexities and inconveniences of the study. The amount of payment or compensation should not be based on the risk of study participation.

5.3.3.2. For students, course credit for their participation in a research study. However, the student must be provided with alternate, equitable ways to earn those credits if they decide not to participate in the research study.

5.3.4. All payments for the conduct of a research project must be negotiated at the beginning of the study and not provide any additional payments based on either number or rate of subject enrollment. In addition, all information concerning payments, including the amount and schedule of payments, is set forth in the consent document.

5.3.5. Disbursement of payment must accrue as the study progresses and not be contingent upon the completion of the study. Disbursement of a proportion of the total payment or reward upon completion of the study may be permissible if the amount of the incentive is not a large sum that may unduly induce the subject to remain in the study when they might otherwise withdraw voluntarily.

5.3.6. All payments and compensations must be submitted to the IRB for approval.

6.0 References

6.1. 45 CFR 46.111(a)(3);

6.2. 45 CFR 46.116;

6.3. 45 CFR 17.92;

6.4. OHRP Guidance on Written Institutional Review Board (IRB) Procedures.