

		SOP
Department	Title	Dates
Research Integrity and Protection	Study Recruitment	Effective: 2/19/2018
SOP ID		Approved: 2/12/2018
IRB-SOP-905		Last Revised: n/a
		Expiration: n/a

PURPOSE

This procedure establishes the minimal requirements for selection, recruitment, and enrollment of human subjects in research studies.

SCOPE:

This SOP applies to all personnel who conduct research involving human subjects, or assist in the performance of such research activities, where that research is performed at or under the auspices of any Ascension Wisconsin system hospital or subsidiary ministry covered by and Ascension Wisconsin Federalwide Assurance for the Protection of Human Subjects (FWA).

DEFINITIONS

Specialized terms in this SOP are defined in “SOP: Definitions (SOP-001)”.

PROCESS:

1. The IRB will evaluate enrollment procedures, recruitment processes (including any advertisements), and participation arrangements for clinical studies as each relates to equitable selection of subjects and potential for undue influence and/or coercion.
 - 1.1. When making this determination, the IRB will take into account the study purposes, the research setting, and whether potential subjects are vulnerable to coercion or undue influence. The IRB will apply additional safeguards in accordance with federal regulations and institutional policies for vulnerable populations.
2. All recruitment materials (i.e., newspaper ads, posters, flyers) must be reviewed and approved by the IRB prior to distribution. As part of sound study design, investigators should assess enrollment and recruitment practices for fairness and equitable selection. Investigators will provide information to the IRB to make these determinations.
3. The Principal Investigator (PI) should consider equitable selection of subjects in the research design and provide information on the targeted research population for the IRB to make its determinations. Such information will include population characteristics (i.e., age, sex, race, ethnicity), anticipated number of subjects to be enrolled, inclusion/exclusion criteria, and additional information as requested by the IRB.
 - 3.1. The PI must include a sound recruitment plan in their protocol submission. This plan should describe and justify the following information regarding the target population and the proposed recruitment strategy:
 - Number of subjects to be enrolled.
 - Participants’ age range.
 - Participants’ health status.
 - Any requirements for specific gender, race or ethnicity of inclusions.
 - How potential subjects will be identified.

- Assess the need for approval from the subject's health care providers
- How best and who to approach for community projects
- The process to be used to recruit subjects including:
 - Location and setting of contact (i.e., doctor's offices, businesses, other institutions)
 - Methods and materials used for contact (i.e., flyers, letters, videos, etc.)
 - Any compensation for participants, type, amount and payment schedule.
 - How participants are screened for eligibility (i.e., databases, employees, medical records review, etc.)
 - How participants are enrolled.
 - Inclusion/exclusion criteria.
 - Whether vulnerable populations are targeted and any need for added protections.
 - The consenting process to include:
- How consent will be obtained and by whom.
- Time period between informing and soliciting a decision, if applicable.
- Any project-specific information sheets.

3.2. In the Continuing Review, the Principal Investigator should include an evaluation of the recruitment plan and enrollment status including the following:

- Number of subjects enrolled.
- Information on any problems encountered in obtaining informed consent.
- Information on withdrawals and reasons for withdrawal.
- Information on any complaints related to the research.

3.3. The Principal Investigator should submit modifications to the recruitment/selection procedures described in the protocol for review and approval prior to initiation of the changes (i.e., advertisements, changes in eligibility requirements, increase enrollment).

4. Considerations in Recruitment and Advertising for Study Subjects

4.1. Contacting Subjects by phone or mail: In studies where prospective subjects are identified through review of private records, initial telephone contact or mail/internet questionnaire to invite participation in a research study by an unknown investigator (cold call) or direct mailings is not acceptable unless specifically approved by the IRB. A physician who has a treatment relationship with a prospective research subject may approach that patient about participation in any IRB approved protocol. The physician may approach the potential subject about participation in his or her own protocol or on behalf of another investigator. If the protocol is by another investigator, the permission of a potential subject is required before identifying information is given to the study investigator.

4.2. Advertising:

4.2.1. Advertising to be seen or heard by prospective subjects to solicit enrollment into a study must receive IRB review and approval prior to dissemination. Advertisements that are easily comparable to an approved informed consent document may undergo review and approval using the expedited review procedure. For advertisements, the IRB will review the information content and the mode of communication to determine that the procedures are not coercive. The IRB will review the final copy of printed advertisements. For audio and video advertisements, the IRB will review the final taped version. However, the IRB may approve the script of the advertisement prior to taping to preclude re-taping because of inappropriate wording.

4.2.2. IRB review of advertisements will assure that advertisements DO NOT INCLUDE:

- Any language that would contribute to therapeutic misconception (research subject's belief that enrolling in study will contribute to direct therapeutic benefit)
- Any language which states or implies a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

- Exculpatory language
- Claims about the efficacy, safety or superiority of investigational agent, or the security of confidential information
- Enticing or inducing terms such as “free,” “new,” “exciting,” “opportunity,” “limited opportunity,” “you deserve to feel better”
- Inducing phrases such as “limited enrollment,” “call today” or “study ends soon”
- Overemphasis on compensation. The payment or the amount to be paid should not be emphasized by such means as larger or bold type. If the payments will be prorated, the ad should make this clear. For example, instead of stating “\$300 compensation,” the ad should state that subjects will receive \$50 for each of six completed visits.
- Links to sites/resources that are not IRB approved
- For FDA-regulated research:
 - o Claims, either explicitly or implicitly, about the drug, biologic or device under investigation that are inconsistent with FDA labeling.
 - o Compensation for participation in a trial offered by a sponsor to involve a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

4.2.3. Advertisements to recruit subjects should be limited to information prospective enrollees need to determine their eligibility and interest. When appropriately stated, the advertisements SHOULD INCLUDE the following items:

- Name and location of the institution and center/department conducting the research
- Name of the PI or department if appropriate
- The word “research”
- Statement or condition under study and brief description of the purpose of the research
- Brief list of the procedures involved
- Brief list of participation benefits, if any
- Brief summary of the eligibility criteria
- Statement of approximate time commitment required, if appropriate
- Brief description of the compensation/reimbursement
- Contact for further information with telephone number

4.3. Internet Listings: IRB review and approval of listings of clinical trials on the internet would provide no additional safeguard and is not required when the system format limits the information provided to basic trial information, such as: the title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information. However, when the opportunity to add additional descriptive information is not precluded by the data base system, IRB review and approval may assure that the additional 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.

4.4. Screening Tests/Interviews: Screening procedures (including interviews) that are performed solely for the purpose of determining if individuals are eligible for participation in a research protocol are subject to IRB oversight including the requirement for written informed consent. With respect to screening interviews/surveys, written informed consent must be obtained prior to conducting the interview/survey if: 1) the interview/survey is being performed for research purposes; 2) the individual’s responses to the interview/survey could place him/her at risk of civil or criminal liability or be potentially damaging to his/her employability or reputation; and 3) subject identifiers are recorded with the interview/survey responses.

4.5. Incentives/Payments: Subjects may be paid or otherwise rewarded for their time and inconvenience associated with participation in a research study. Payment of human research subjects is not, however, considered a benefit; it is a recruitment incentive. Financial or other incentives are frequently used when the benefit of study participation is remote or non-existent. The amount of payment, if any, should be reasonable based on the complexities and inconveniences of the study and the subject population. The amount of payment should NOT be

based on the risk of study participation. The amount of payment or reward and the proposed method and timing of its disbursement must not be coercive or present undue influence for initial or continued participation in the study.

- 4.5.1.** Information concerning the remuneration of human research subjects, including the amount of payment or nature of reward and the schedule of its disbursement, is subject to initial and continuing review by the IRB. This information should appear in the Costs and Payments section of the research protocol and informed consent document(s). It should not be included as a benefit of study participation.
- 4.5.2.** Any payment or reward should accrue as the study progresses and not be contingent upon the human research subject completing the entire study. Disbursement of a proportion of the total payment or reward contingent upon study completion is acceptable, provided that the amount of this incentive is not so large as to unduly induce subjects to remain in the study when they might otherwise withdraw voluntarily.
- 4.5.3.** Payments to professionals in exchange for referrals of potential subjects (“finder’s fees”) are prohibited.
- 4.5.4.** Payments to subjects in exchange for referrals of potential subjects (“finder’s fees”) are prohibited, unless they are judged not to increase the possibility of coercion or undue influence on subjects by using unreasonable compensation or unreasonable conditions for distribution of compensation.
- 4.5.5.** Payments designed to accelerate recruitment that are tied to the rate or timing of enrollment (“bonus payments”) are prohibited, unless they are judged not to interfere with providing prospective subjects with sufficient opportunity to consider whether to participate and do not increase the possibility of coercion or undue influence on investigators or subjects.

REFERENCES:

- 21 CFR 56.107(a)
- 21 CFR 56.111(a)(3)
- 21 CFR 56.111(b)
- 21 CFR 50.20
- 21 CFR 50.25
- FDA Information Sheet: Recruiting Study Subjects

RELATED MATERIAL:

NONE

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	12/5/17	New- Initial Integration Update	J. Blundon