

Recruiting for Human Research	Effective	
	Revised	3.23.2020

1.0 Purpose: The purpose of this standard operating practice (SOP) is to ensure that a participant's decision to take part in human research is truly voluntary. The University and Medical Center Institutional Review Board (UMCIRB) considers advertising to be the first step in the informed consent process. The UMCIRB must review and approve all recruitment materials and payment schedules for incentives or reimbursement to ensure there is no undue coercion or influence on a participant's decision to enroll in a research study.

2.0 Persons Affected:

- 2.1 Investigators and study team members
- 2.2 UMCIRB Chairpersons and members
- 2.3 UMCIRB Office staff members

3.0 SOP: The UMCIRB must review both the information contained in recruitment material, and the mode of its communication. This review determines that the procedure for recruiting participants is not coercive, and that the recruitment material does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the research plan.

Additionally, any participant payments should not be contingent upon completing the entire study and should be prorated when appropriate. In studies with very short participation windows and involving minor procedures/inconveniences it may be appropriate to provide the compensation in one lump sum at the end of the study. The UMCIRB is particularly sensitive to any effects that recruitment strategies may have on vulnerable populations such as students, economically disadvantaged individuals, or individuals who may have experience with sensitive research topics being studied.

When research involves children (<18 year old), incentives for participation should be appropriate to their ages and the nature of the study. Incentives (e.g., toys, coupons for food) should usually be given to the child participants, not the parents. Parents may be reimbursed or paid for expenses such as travel.

4.0 Definitions:

4.1 Recruitment material: includes print advertisement (flyers, newspaper/magazine ads), electronic advertisement (websites, forums, social media) and scripts used to recruit participants.

5.0 Responsibilities:

- 5.1 Investigators/study team members have the responsibility to:
 - 5.1.1 Provide a copy of all recruitment materials and a description of recruitment methods for IRB review and approval prior to use.
 - 5.1.2 Adhere to the ECU processes of obtaining approval from University Marketing.
 - 5.1.2.1 ECU University Marketing must review advertisements for the criteria required for marketing, including content and logo use.

- 5.1.3 Seek approval from owners of social media outlets to be used for recruitment (i.e., listservs, Facebook accounts, etc.).
- 5.1.4 For research topics that may be sensitive (such as assault, abuse, illegal behavior, or other topics that could trigger a negative response by a potential participant), add an explanation statement at the beginning of recruitment material explaining how individuals were selected to receive recruitment information.
- 5.1.5 Clearly outline the participant payment and payment process, when applicable.
- 5.1.6 After initial approval, seek IRB approval for any further changes to recruitment methods or materials prior to use.
- 5.2 UMCIRB Office staff members are responsible for
 - 5.2.1 Ensuring recruitment materials match the human research activities being reviewed.
 - 5.2.2 Ensure the recruitment materials follow guidelines listed in the Procedures section below.
 - 5.2.3 Providing assistance to study team member that may be developing recruitment materials, especially related to sensitive research topics.
- 5.3 UMCIRB/UMCIRB Chairperson (or designee) will
 - 5.3.1 Ensure the information presented does not mislead, for example, by promising benefits or implying a benefit beyond that potentially provided by the research.
 - 5.3.2 Ensure the content of recruiting materials makes clear that it is for research.
 - 5.3.3 Assess the types of incentives, if any, which are being offered to prospective participants with the goal of reducing undue influence on their decision about participation in the study.
 - 5.3.4 Review recruitment processes that ask respondents to provide identifiable private information to determine recruitment eligibility in order to decide whether plans for informed consent and protecting the confidentiality of that information are acceptable and clearly explained.
 - 5.3.5 Ensure recruitment material for sensitive research topics have a clear and accurate introduction letting individuals know why they have been selected to receive this material.

6.0 Procedures

- 6.1 Generally, advertisements should be limited to information prospective participants need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements:
 - 6.1.1 When recruiting for research studies that may involve sensitive topics, a description of why the individual is receiving recruitment material and/or how the study team got their name or contact information should be added as one of the first things the individuals sees or hears..
 - 6.1.2 The purpose of the research (e.g., the condition under study or goal of the project).
 - 6.1.3 A summary of inclusion/exclusion criteria that will be used to determine eligibility for the study.
 - 6.1.4 The time or other commitment required of the participants for participation in the study.
 - 6.1.5 A brief list of participation benefits, if any.
 - 6.1.5.1 Payment should not be listed as a benefit of participating in the

research.

- 6.1.6** Advertisements may state that participants will be paid, but they should not emphasize the payment by such means as larger or bold type.
- 6.1.7** The words “research study” must appear within the advertisement.
- 6.1.8** Advertising for recruitment into investigational drug, biologic or device studies should not use terms such as “new treatment”, “new medication” or “new drug” without explaining that the test article is investigational. A phrase such as “you will receive new treatments” incorrectly implies that all study participants will be receiving newly approved products of proven worth. Advertisements should not promise “free medical treatment” when the intent is only to say participants will not be charged for research procedures.
- 6.1.9** The name and address of the Principal Investigator and the research facility (e.g., East Carolina University), the location of the research and the person or office to contact for further information
- 6.2** All recruitment material and any scripts to be used should be provided by the study team in the IRB application required for approval.
 - 6.2.1** For recruitment material that may be recorded or filmed, the study team can provide the IRB with a draft of the plan and wording for approval before actually recording to keep from needing to record multiple times secondary to any changes the IRB may request to the recruitment plan.
- 6.3** Anytime a website or phone script will be used to collect protected health information about a potential participant for recruitment purposes, the IRB should be consulted to determine the acceptability of the informed consent and confidentiality practices (depending on the sensitivity of the data gathered, including personal, medical and financial information) for this purpose. Some items to consider and include in the IRB application include:
 - 6.3.1** A description of the proposed management of the data (paper and electronic) that is collected during this recruitment process.
 - 6.3.2** Disclosure about whether the data are gathered by a marketing company or will be sold to others.
 - 6.3.3** Verification of whether names of non-eligible respondents are maintained in case they would qualify for another study.
- 6.4** An investigative site may post basic clinical trial information to be viewed by the general public on a website, such as: title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information.
 - 6.4.1** However, any descriptive information will require consultation with the UMCIRB to determine if review and approval is necessary. Information posted on a website may not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document.
- 6.5** An internal web site may be used by an investigative site to keep physicians and other staff within the organization abreast of clinical trial opportunities for potential participants. This practice would simply be an electronic mechanism to provide the necessary information to determine that one of his/her patients may be eligible for an available clinical trial. Such an internal website would not require review and approval by the UMCIRB.

Revision History:

Date	Change	Reference Section(s)
1.21.2016	Created standalone SOP	All
1.21.2019	Revised office name from ORIC to UMCIRB	2.0, 5.0
9.16.2019	Clarified what information about payment can be included in advertisements	6.1.6
3.23.2020	Added information related to recruiting individuals to research studies of sensitive topics	3.0, 5.1.4, 5.2, 5.3, 6.1, 6.2

References:

US DHHS. Guidance on Institutional Review Board Review of Clinical Trial Websites:

<http://www.hhs.gov/ohrp/policy/clinicaltrials.html>

US FDA. Recruiting Study Subjects - Information Sheet. Guidance for Institutional Review Boards

and Clinical Investigators: <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm>