Advertisements and Recruitment (HRPP Section 7.2 & 7.8)

AUGUST 2025 CONTINUING EDUCATION

MUSC IRB considers advertising to be part of the recruitment and consent process.

All means of advertising, recruiting and notifying individuals of a study for enrollment must be submitted for review and approval!

Advertisements – eIRB Application

Application Checklist Smartform

Select → Recruitment – Advertisements or recruiting materials

Other Study Specifics – Advertisement Smartform populates

1. Describe the mode of recruitment
2. Explain where the advertisements will appear
3. Attach all advertisements to be used for recruitment with MUSC Watermark

Advertisements – What are you looking for?

- Information presented in the advertisement
- Mode of communication
- Printed advertisements as they will be displayed
- Audio/video taped advertisements as they will be broadcast

Advertisements CAN'T:

- Imply benefits beyond what is in the consent and protocol
- Include exculpatory language
- Promise "free treatment"
- Make claims about the drug/biologic/device that are inconsistent with FDA labeling
- Use terms, such as "new treatment/medication/drug" without explaining that the test article is investigational
- Allow 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
- Place emphasis on the payment or the amount to be paid using large or bold type

- Advertisements are limited to the information prospective participants need to determine their eligibility and interest
  - The name of the investigator or research facility
  - Purpose of the research
  - Criteria used for determining eligibility
  - Brief list of benefits (if any)
  - Duration
  - Location
  - Contact information for questions/information

All advertisements should include the following statement:
"A **research** study at the Medical University of South Carolina."

Recruitment – eIRB Application

Study Populations – Study Subjects Smartform

1. Identify targeted subject population
   - Vulnerable populations, Students/Employees, etc.
2. Describe recruitment procedures
   - Must harmonize with the Protocol
3. Cold Contact
   - If yes: Describe the plan, justify why the method is necessary, attach all scripts, MyChart messages, direct mailings, etc. with MUSC Watermark

Recruitment – What are you looking for?

- How will subjects be contacted?
- Who will contact them?
- How will eligibility be determined?
- Will Cold Contact be used?

Recruitment CAN'T:

- Be biased
- Exert undue influence or coercion
- Imply a guarantee of benefit beyond what is in the protocol and consent

Cold Contact Recruitment

- MUSC is an “opt-out” institution

- “Cold calling” is when an individual is contacted by someone they do not know, and the contact is unexpected

- When “Cold Calling” **IS NOT** Approved for a Study
  - Subject’s treating clinician present their patient with information about the research
    - Directly (during an office visit) or indirectly (letter)
  - Can’t be coercive or imply that medical care could be influenced by decision to participate or not
  - If the patient is interested, then he/she contacts the research team for more information

- When “Cold Calling” **IS** Approved
  - PIs or research staff may contact any patients who have not documented an “opt-out” of research contact preference
  - Methods of contact and the recruitment script will need to be approved by the IRB

Other types of Recruitment

- Secondary Recruitment aka Snowball Recruiting
  - When investigators wish to recruit specific groups of participants through friends and family of existing participants
- Recruitment for Research Conducted by Study Sponsors or External Parties
  - MUSC prohibits external parties from directly contacting MUSC patients for purposes of research recruitment
  - It is the study team's responsibility for obtaining IRB approval regarding any use of external parties for recruitment or screening activities
    - GRN
- Future Recontact
  - Documented in the informed consent
  - If participant agrees, it is permissible for the PI to include the name and contact information of that individual for future studies.
  - Decision is separate and distinct from their opt-out research preference included in their medical record

Summary

- Review all recruitment and advertisement information entered in the appropriate eIRB Smartforms
- Confirm that all Advertising and Recruitment information harmonizes (eIRB Smartforms = Protocol = Consent …)
- Advertisements - should be limited to the information needed to decide whether a subject is eligible and wants to participate
- Advertisements – should include a statement: “A research study at the Medical University of South Carolina” & have the appropriate MUSC Watermark attached (Word Doc vs. PDF)
- Advertisements - should not suggest additional benefits than what is included in the study application, offer free treatment, place emphasis on **compensation**.
- Recruitment – should not be coercive or biased
- Is the cold contact recruitment being used? If so, is the plan justified?
  - The IRB does not have to approve Cold Contact Recruitment
- Are any other modes of recruitment being used? If so, are those justified?

What questions do you have?