Recruitment Communications

I. Statement

Communications play a critical role in recruiting research study participants. There are two types of content that appear in research-related recruitment communications: **study-specific** communications that require IRB approval and communications that do not require IRB approval.

According to federal regulations, an IRB is required to protect the welfare of human participants participating in research and, specifically, to determine that the selection of participants to participate in the project is equitable and free from coercion. As an essential part of this process, the IRB must review and approve any advertisement for recruiting research participants to a research project before it can be distributed to potential participants. Materials should encourage the participants of diverse backgrounds to review the information.

Some of the recruitment materials include, but are not limited to:

- Flyers
- Web content
- Brochures
- Social media posts
- Direct mailings
- Emails
- Newspaper, radio, tv and digital advertisements
- Scripts

Review the guidance below to determine if your recruitment communication materials need IRB approval and for tips on what to include.

Researchers who are conducting non-exempt research must follow this guidance. Researchers who are conducting exempt research are strongly encouraged to reference this guidance.

This guidance does not apply to studies ceded to a non-UM IRB since the IRB-of-record is responsible for approving recruitment materials.

II. Study-Specific Recruitment Communications

Recruitment communications are usually study-specific and not generic statements about research conducted in a particular setting or for a given group of conditions.

Recruitment communications are designed to be conveyed to potential participants, either directly or through an intermediary (e.g. referring physician, school, nursing home, etc).

A. Content to Include in Study-Specific Communications

Recruitment communications are normally limited to the information needed to determine potential participants' initial eligibility and pique their interest. Most importantly, the details should be worded in such a way as to be informative without being coercive, overly enticing, or promising benefit. Be careful to use language most individuals will understand (i.e., 8th grade reading level) and spell out acronyms. Keep materials accessible by using accessibility checks, high color contrast, and use of headers and lists.

Required:

- Study team contact information
- HUM#
  When a U-M IRB is the single IRB and the Multi-Site (MSR) application is used, use the HUM# of the MSR IRB application

Expected as applicable:

- Condition under study and/or the purpose of the research (NOT specific aims or scientific objectives of the research)
- Inclusion and exclusion criteria
- A brief list of significant risks, if any
- A brief description of benefits of participation, if any
- A brief description of elements of participation (e.g., imaging, genetic testing, behavioral tests, etc)
- Payment, if applicable
- Time commitment required
- The location of the research

B. Additional Information for FDA-Regulated Research

When creating advertising materials for FDA-regulated research, researchers must adhere to additional guidelines set out by the Food and Drug Administration (FDA). Per the FDA guidelines, FDA considers direct advertising to research participants to be part of the informed consent process and subject selection process. Any patient-facing materials must be submitted to the IRB for

approval. This includes, but is not limited to recruitment letters where the study team is recruiting the doctor to be a subject.
In addition to the above bulleted information, researchers must include the following:
(1) Whether or not the investigational agent is FDA-approved for the given indication and
(2) Whether the study participant may receive a placebo or similar.

1. **The following information must <u>be avoided</u>:**
   - Claims, either explicitly or implicitly, that the experimental agent/intervention is known to be safe or effective, or equivalent or superior to any currently available treatment or other drugs, biologics, or devices
   - Terms such as "new treatment," "new medication," or "new drug" without explaining that the study product is investigational
   - Promises of "free treatment" when the intent is to convey that participants will not be charged for taking part in the study
   - Claims of free access to the investigational product once FDA approved

2. **Materials that do not have to be submitted to the IRB for review:**
   - Communications intended to be seen or heard by health professionals, such as "dear doctor" letters and doctor-to-doctor letters (even when soliciting for study subjects),
   - News stories and
   - Publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.

   This FDA guideline contains samples of some of the most common Dear Doctor letters and provides recommendations on: (1) when to issue a Dear Healthcare Provider (DHCP) letter, (2) the types of information to include in a DHCP letter, (3) how to organize that information so that it is communicated effectively to health care providers, and (4) formatting techniques to make the information more accessible.

3. Web Content

University IRBs encourage researchers to employ web-based or other recruiting mechanisms. However, researchers are reminded that any such advertisements require IRB review and approval, and when modified, the IRB must approve the modification prior to use and posting. If an advertisement or posting is modified, the researcher would have to provide the IRB with the text of the modified advertisement before it is posted on the website. If the text on the website is identical to text being used in flyers or newspaper advertisements, then the IRB only needs to receive one ad with appropriate indications that this ad will be displayed as a flyer in the department's waiting rooms, as an ad in the local news, and on the departmental website.

Web postings providing details of eligibility criteria and study procedures in lay language, those describing potential benefits of the research (as opposed to the specific aims or scientific objectives of the research), and descriptions of compensation all would be viewed by the IRB as elements of an advertisement. Advertisements for recruiting are designed (at least in part) to solicit a response from potential participants, and hence, provide contact information to reach individuals responsible for entry into that study. Statements such as "To see if you are eligible to participate, call..." or "For more information about participating in this study, contact..." would be viewed by the IRB as elements of an advertisement. A generic statement such as "Speak to your doctor if you are interested in participating in a cancer clinical trial" or "To hear more about the research efforts of the Department of Radiation Oncology..." would not, in and of itself, constitute an advertisement for recruiting.

4. Social Media Kits

In some circumstances, the IRB may approve a social media kit. This may include a single document that has a variety of phrases, talking points, and images/artwork that study teams may mix in various combinations on various platforms without having to have each use approved by the IRB. Keep in mind the content expectations noted above. This will allow the flexibility of alternating advertisements based on how/where the recruitment will take place.

5. **Content to avoid in study-specific communications (should also be avoided in non-specific study communications)**
    - Characterizing payment as a benefit, emphasizing payment by using a larger font, different color, or bold type compared to the main body of the text, or promising a bonus for completion of the study
    - Stating or implying a certainty of a favorable outcome or other benefits beyond what is outlined in the consent documents
    - Including exculpatory language that waives or appears to waive the rights of research participants or indicates that the investigator or university cannot be held liable for research-related harms.
6. **Emails**

    When conducting research utilizing emails, researchers must use secure email platforms for communication and collection of data. If you want to conduct a research study utilizing emails, please refer to ITS guidelines for additional information as listed below.
    1. Requesting Targeted Email or Data Files for Research Purposes
    2. Getting Started with Targeted Email
    3. Targeted Email: Approval Process

III. General Recruitment Communications

General recruitment communications include materials that do not specifically relate to an IRB-approved study/protocol/program. These materials are typically general in nature. They serve to raise awareness of research generally, convey information about becoming a research participant, and provide links to IRB-approved solicitations for participation in specific research studies. Typically, these materials do not require IRB review/approval.

Examples include:

- Non-study-specific web portals matching participants to specific studies and registries such as UMHealthResearch.org or ClinicalTrials.gov
- Generic information for prospective participants, such as OHRP's About Research Participation, on-hold telephone scripts
- Materials that promote research in general and are intended to inspire interest among prospective participants, such as the Rogel Cancer Center's Research web page and Office of the Vice President for Research (OVPR's) Michigan News.
- Print pieces promoting general research participation, such as a UMHealthResearch.org brochure, flyer, or advertisements and press releases.

IV. Additional Information

A. Instructions about requesting Patient Portal use for screening/recruitment:

IRBMED Frequently Asked Questions (FAQ) | University of Michigan Medical School
level-2 login required.

B. Study Flyers and Brochures:

The Michigan Institute for Clinical Health and Research (MICHR) provides assistance to study teams with recruitment strategies. See more information in their Participant Recruitment Toolkit.

C. Press Releases:

For detailed information on best-practice implementation and press releases, contact:

- Michigan Medicine: Contact the Media Team
- Campus: UM Social Vice President for Communications

D. Logo Usage:

For detailed information on the use of logos, contact:

- Michigan Medicine: For consultation regarding advertising and logo usage, contact the Department of Communication: 734-764-2220
- Campus: For information on logo usage and campus advertising, consult the Brand Office.

V. Resources

- FDA guidance on recruitment: Recruiting Study Subjects: Guidance for Institutional Review Boards and Clinical Investigators, January 1998
- FDA guidance on Dear Health Care Provider Letters: Guidance for Industry and FDA Staff: Dear Health Care Provider Letters: Improving Communication of Important Safety Information
- NIH/NIMH: Points to Consider about Recruitment and Retention While Preparing a Clinical Research Study
- Additional related guidance outlined below is available on the Coordinated Services & Practices (CSP) – Human Research Protection Program webpage
    - CSP_CP201.Ceded.What.When.Where...