
Recruiting Human Research Participants: Guidance

A Western Michigan University Homer Stryker M.D. School of Medicine (WMed) Human Research Protection Program (HRPP) Guidance Document

Purpose

This guidance document defines the standards and parameters for utilization of advertisements and other recruitment materials in research studies. Advertisements and recruitment materials targeting research participants should be thought of as the beginning of the informed consent process. These materials should be limited to the information prospective subjects need to determine their eligibility and interest.

Regulations/Guidance

[45 CFR 46.111](#) Require that the IRB review all research documents and activities that have a direct impact on the rights and welfare of the human subjects in the proposed research and must ensure that subject selection is fair and equitable.

The preparatory research provision permits covered entities to use or disclose protected health information (PHI) for purposes preparatory to research, such as to aid study recruitment. However, the provision at [45 CFR 164.512](#) does not permit the researcher to remove PHI from the covered entity's site. As such, a researcher who is an employee or a member of the covered entity's workforce could use PHI to contact prospective research subjects.

[FDA Recruiting Study Subjects - Information Sheet](#)

Discussion

Recruitment of subjects is one of the most challenging aspects of research involving human subjects. Recruitment of subjects must be equitable and include racial, ethnic, educational, socioeconomic, and gender diversity appropriate to the condition or situation that is studied. All recruitment efforts must respect personal rights to privacy and confidentiality, be compliant with Health Insurance Portability & Accountability Act (HIPAA) regulations or other privacy regulations where applicable and avoid coercion or undue influence of subjects.

Recruitment Plan Content Guidance

A plan for identifying and recruiting participants should be outlined for the IRB's review and approval. A general recruitment plan may be outlined in a multi-site protocol. However, when the local site is involved in recruitment, the general plan may be insufficient. This also applies to external researchers seeking to recruit participants at WMed. In such cases, a supplemental recruitment plan must be submitted to the WMed HRPP, clearly detailing the recruitment activities specific to the WMed site.

The protocol or the application should clearly note the following:

- **How** participants will be identified
- **Who** at the local site will approach potential participants
- **What** information will be presented to potential participants (i.e., use of any recruitment materials) prior to beginning the consent process
- **When** recruitment will happen (i.e., context)
- **Where** recruitment will happen (i.e., setting)

Methods of recruitment should be outlined in the recruitment plan. Methods may include one or more of the following methods:

- Direct potential participant approach (e.g., in-person visit)
- Phone calls
- Direct messaging
- Social media
- Advertising / Marketing

Initial Contact Guidelines

Letter

- **Mailed recruitment letters:** Letters, whether or not they precede a phone call, should be clear regarding why the potential participants are being contacted and how the individual(s) sending the letter have identified the potential participants. Letters sent to patients should be signed by someone who, by virtue of their position, patients would reasonably expect has access to their health information (see [Clinical Recruitment Guidelines](#)).
- **Recruitment of subjects from a previous study for a follow-up or other related study:** Letters should refer to the study in which the individual has already participated and state how the new study is related to it.
- **Recruitment of children through their school or WMed programming:** Letters should be addressed to parents/guardians; it can be provided in a packet that children take home with them.

Phone

If you plan to recruit or screen potential participants by phone, the IRB requires you to use a script to ensure consistency and completeness in the information that potential participants are given about the study or screening questions. You will need to upload these scripts as part of the IRB application. The IRB generally requires that phone calls to patients are preceded by a letter (see [Clinical Recruitment Guidelines](#)).

For additional guidance on drafting recruitment letters, phone scripts, and eligibility screening scripts, please see <https://wmed.edu/hrppforms>.

Email Recruitment Guidelines

Only secure email accounts should be used, such as @wmed.edu. Personal email accounts, such as @gmail.com, may not be used. Use encrypted email if possible.

- Email addresses must not include references to health information or other potentially sensitive, private information (e.g., parkinsonsresearch@wmed.edu).

- Protocols must describe how email will be used, including the source of email lists, targeted populations, frequency of emails, and methods for potential participants to remove themselves from the email list.
- The following disclosure language should be included in all recruitment materials that invite participants to contact the study team via email and at the end of all email communications with subjects for studies that may collect sensitive or health related information:
 - Email is generally not a secure way to communicate sensitive or health related information as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email.
- You will need to provide email scripts or templates used for recruitment purposes. The subject line and content of these emails should not contain any references to health information or request health information from the subject through email.
- WMed allows researchers to use email to send its faculty, staff, and students information about research opportunities. Information about the mass email distribution is available at: [Research Survey Distribution Approval Process](#)
- To recruit subjects through the Bronson email system please contact Bronson Research Compliance at mitckath@bronsonhg.org or research@bronsonhg.org.
- For external organizations interested in recruiting research participants through the WMed email system, please contact irb@wmed.edu and include the following materials with your request:
 - IRB determination or approval letter
 - Email template intended for distribution
 - Consent Form
 - Survey or questionnaire (if applicable)
 - Target population (e.g., students, residents, etc.)

Clinical Recruitment Guidelines

In addition to the general recruitment guidelines, these guidelines apply to research studies that identify potential participants from the electronic health record or will identify and recruit participants in a clinical health care setting (i.e., patients). **The guidelines apply regardless of the reviewing IRB.** Please note, other healthcare entities outside of WMed Health may have additional guidelines or policies that apply.

- **Initial contact by letter, phone, email, and MyChart**
 - Initial contact by letter or phone should come from someone who, by virtue of their position, patients would reasonably expect has access to their health information. The list below is provided as examples and is not intended to be exhaustive:
 - A member of the potential participants' clinical team.
 - An administrator from the clinic where the potential participant receives care.
 - An individual, such as a research coordinator acting as a designee of a clinical researcher involved in the potential participants' care.
 - An individual, such as a research coordinator who works within a clinic, department, or center where a potential participant has or will receive care (e.g., from the Department of Surgery for a patient who has an upcoming surgery scheduled);
 - The administrator of a database housed within a clinic, department, or center where a potential participant has or will receive care (e.g., from a

recruitment database or registry within the department or clinic where the patient has been seen for clinical care).

- “Cold calling” of potential participants by phone is generally not permitted. “Cold calling” is a planned communication with a potential participant by the study team when not known to the potential participant or not expected to have access to their PHI.
- The IRB generally requires telephone calls to be preceded by a letter that alerts potential participants that a WMed researcher will call them about the study. The letter should provide contact information for the individual to opt-out if they do not want to receive a phone call or further contact.
- Use of patient email addresses in MyChart for research recruitment is not permitted.
- Use of MyChart for recruitment purposes is permitted if conducted with approval from Bronson and/or WMed and the WMed IRB.
- **In-Person Contact (including virtual visits)**
 - How and who initiates contact with patients in a clinical setting depends on the circumstance. Any patients in private clinic rooms or hospital rooms should first be approached by someone who is part of their care team or an administrator who is part of the clinic or department in which the study is being conducted.
 - Unless a member of the care team is also a member of the study team, potential patient-subjects should provide oral or written permission to be approached by researchers in this private setting.
 - Researchers who are employees of the covered entity or members of its workforce for research purposes may use PHI to recruit participants as a [preparatory to research activity](#).
 - For all other researchers, the IRB may grant an altered authorization to permit an abbreviated written authorization or to permit an oral authorization process (see suggested template language below).

Permission to Contact template language:

The HIPAA Privacy Rule requires this clinic to get your permission to release your name and phone number to Dr. _____ and their research team at Western Michigan University Homer Stryker M.D. School of Medicine (WMed) so that they can contact you about taking part in this study. Your information will only be used for this purpose and not be shared with anyone other than the WMed research team. If you decide to provide your name and contact information, you can still decline to participate in the research study. You do not have to give your name and contact information if you don't want to. If you don't want to provide your name and contact information, it will not affect your health care at this clinic.

- Recruitment of potential participants in waiting areas or other similar space requires permission from the institution or clinic to ensure minimal interruption of workflow.
 - WMed Health clinics do allow WMed research teams to utilize digital signage. The request can be submitted using the Project Request Form, which can be found on the Branding and Communications portal page at <https://portal.wmed.edu/sbranding-and-communications>.
 - For recruitment at Bronson, please contact Bronson Research Compliance at mitckath@bronsonhg.org or research@bronsonhg.org.

My Chart Guidelines

Studies using Epic and with a study record in Health Link may be eligible to recruit subjects through MyChart, WMed's patient portal. Study teams should describe this as a recruitment modality in IRB application materials and include invitation language using the approved WMed invitation template (see below). Note, while IRB approval to recruit through MyChart is a requirement, study teams must also comply with Bronson requirements for such MyChart use. Please contact the Research Navigator at morgan.brown@wmed.edu on the process for obtaining approval and submitting a request.

Study teams should consider the following in determining whether MyChart is an appropriate recruitment modality for a given study:

Sensitivity of the research. Many patients allow proxy access to MyChart. Any recruitment invitations would be visible to both the patient and any proxies to whom they have granted MyChart access. Study teams should consider whether this creates a confidentiality concern.

Adequate study population with MyChart Access. Only a subset of patients actually use MyChart. Study teams should consider whether this will unintentionally limit diversity of recruitment and potentially impact generalizability of data.

Once Bronson and/or WMed and WMed IRB approval is in place, study teams will submit a recruitment request through Data Analytics Services Unit (DASU). They will assist in determining whether there is an adequate study population with MyChart access and if so, identify potentially eligible subjects based on parameters provided by the study team. Only those patients identified through DASU can receive a research study invitation through MyChart.

The following is suggested language study teams may use to describe the use of MyChart recruitment in IRB materials:

One recruitment modality we plan to use is MyChart, WMed's patient portal. We will obtain all needed approvals from Bronson and the DASU and follow the required workflows. We will/have created an Epic study record that is interfaced with Health Link and will track individual level recruitment in Epic. Once approvals are in place, the IRB-approved invitation will be posted to invited participants' Research Studies page in MyChart and patients will initiate contact with study team if interested.

The following patient-facing invitation language should be edited by study teams and included in IRB materials:

Bold text in brackets to be filled in by study team.

You are invited to participate in a research study: **[Patient-facing Title of Study]**. The lead researcher is **[Principal Investigator name and credentials]** with **[Principal Investigator’s affiliation/department]**.

The purpose of this research study is **[Brief Description]**.

If you are interested in participating or have questions about the study, please click on the “I’m interested” button below and a study team member will reach out to you, or you may contact the study team at **[Information on how to contact study team]**.

[For studies using external links, replace the paragraph above with the following]:

If you are interested in participating, please click on this external link **[insert link here]** which will take you out of MyChart to **[choose one: a questionnaire to determine your eligibility / the study survey / information about the study and an electronic consent]**.

If you have questions about the study, you may select the “I’m interested” button below and a study team member will reach out to you, or you may contact the study team at **[information on how to contact the study team]**.

How to opt out of receiving messages about this research study

If you are not interested in participating and you would no longer like to receive MyChart messages about this study, please click on “No, thank you” below.

How to opt out of receiving recruitment messages for any or all research studies

If you would no longer like to receive messages about research opportunities at WMed, please call the Center for Clinical Research at 269-337- . You will be asked for your information such as name, date of birth and address so we can make sure you are added to the list of patients who do not want to receive research recruitment messages. This information will be stored in a secure location.

If you opt out of receiving messages about research opportunities, your health care team may still contact you about clinical research for which you might be eligible.

Social Media Recruitment Guidelines

- It is the responsibility of the research team, when designing a protocol, to understand the social media site terms of use. In addition, study teams should be aware of any research or recruitment-related restrictions on the social media sites through which they intend to conduct their recruitment activities. This includes a site’s advertising, privacy and prohibited content policies.
- It is the responsibility of the research team, when designing a protocol, to understand the various privacy and data security provisions of social media sites and ensure that these provisions are consistent with the IRB’s privacy and confidentiality guidelines.

- In social media or other Internet-based research settings, recruitment information can be forwarded or otherwise accessible to other individuals who may not be part of the intended participant pool. Research teams, therefore, must exercise caution to appropriately identify the targeted participant population and to ensure the equitable selection of participants.
- The IRB will review the content of social media recruitment materials according to existing IRB guidelines for traditional media recruitment such as flyers.
- Recruiting via public and private groups is permitted. Study teams must be aware of any site restrictions or group-specific rules or restrictions on recruiting participants via groups.
- Study teams are discouraged from using their personal social media accounts to purchase or place initial recruitment materials for studies.

Eligibility Screening

- Collection of identifiable private information to determine study eligibility is considered a research procedure. Obtaining oral permission prior to the research screening interview is usually acceptable.
- For HIPAA Privacy Rule purposes, screening may constitute a preparatory to research activity. See [Preparatory to Research Activities](#). There may be some variation in how our affiliates (i.e. Bronson, Integrated Services of Kalamazoo (ISK), etc.) interpret 'preparatory to research'. Screening for research studies may require a partial waiver or alteration of authorization.
- In most cases, screening information from individuals who take part in the study is kept as part of study records, while screening information from individuals who are not eligible or choose not to participate is destroyed. Researchers proposing to retain contact information and/or identifiable data collected during screening for future recruitment or other purposes should specify what information will be retained, and how long, how the information will be stored, how the information will be used, and who will have access to the information. In addition, researchers will need to either obtain informed consent and authorization (for studies that fall under HIPAA regulations) from subjects to retain the identifiable screening data or request waivers of informed consent and authorization from the IRB.
- Retention of sensitive screening information from subjects who are ineligible (e.g., data about illicit or stigmatizing behavior; social security numbers) is discouraged.
- The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:
 1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, OR
 2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.
 - The research protocol should include information about how potential subjects will be identified and recruited in order for the IRB to be able to determine whether informed consent for these activities is required.

- Contact the IRB Office with additional questions or for further guidance regarding the requirement to obtain HIPAA authorization or a waiver to obtain HIPAA authorization for recruitment purpose.

Recruitment at WMed by External Research Teams

WMed will consider recruitment at WMed by non-WMed faculty on a case-by-case basis.

WMed requires a local context review from the WMed HRPP/IRB for all external recruitment materials. This review goes beyond simply confirming the external IRB's approval. It's a crucial step to make sure your materials and methods won't conflict with our policies, cause any issues or be seen as coercive by our community. This dedicated internal process ensures we protect our community and adhere to our own standards, bridging the gap between external ethical approval and local suitability.

WMed retains the discretion to decline any request to post research advertisements. Priority is given to WMed-related requests, and due to the volume of internal submissions, there may be limitations on the ability to accommodate external postings.

To initiate a request, please submit an application to the WMed IRB through [iMedRIS, our electronic system](#). Under 'study documents', include your IRB approval letter, any recruitment plan at WMed, recruitment materials, the IRB approved informed consent form and anything else you think would be applicable to the request. If you do not have a WMed single sign-on username please complete the [New User Request Form](#) or contact the Office of the IRB at irb@wmed.edu or 269-337-4345.

Summary

Recruiting human subjects is a complex and critical aspect of research. Recruitment must be equitable, reflecting appropriate diversity (racial, ethnic, educational, socioeconomic, and gender) relevant to the study. All efforts must respect privacy, comply with HIPAA or other applicable regulations, and avoid coercion or undue influence.

Recruitment Plan Requirements:

- A recruitment plan must be submitted for IRB review and approval.
- Multi-site protocols may include a general plan, but a **supplemental recruitment plan** is required by the WMed IRB.
- This also applies to **external researchers** recruiting at WMed.

When in doubt, contact the Office of the IRB if you have questions about recruitment irb@wmed.edu or by phone 269-337-4345.

Supplemental Information

Bronson Policy on Recruitment & Screening of Subjects
Data Analytics Services Unit Data Management Policy
Center for Clinical Research (CCR) SOP Subject Recruitment