Human Subject Research Recruitment Guidance for UnityPoint Health – Meriter

Recruitment Plans and Materials

1. **Recruitment Plans** including all materials and methods must be reviewed and approved by the reviewing IRB and the Meriter Research Integrity Office before recruitment can take place at Meriter.

2. **Recruitment Materials**
    a. Posters, flyers, brochures, and other informational media such as advertisements in electronic, written or oral media that a prospective study participant might encounter. These media should include:
        i. The name and address of the researcher/clinical institution;
        ii. The condition under study or the purpose of the study;
        iii. Inclusion/Exclusion criteria for subjects in summary form;
        iv. A brief list of procedures involved;
        v. Time or other commitment required (number of visits, duration of visits, etc.);
        vi. Compensation/reimbursement, if any;
        vii. Location of research and contact person for further information.
        viii. Will not promise "free medical treatment," when the intent is to say participants will not be charged for taking part in the investigation.
    b. Screening questionnaires, scripts, emails, letters, texts, used by research staff. These items may include the same information as a. above.
    c. Social Media guidelines
        i. Use only the reviewing IRB and Meriter-approved content for posts/ads.
        ii. Do not use personal social media accounts for official study recruitment
        iii. Do not collect or request private health information (PHI) through public comments or messages, rather direct interested individuals to a secure/approved contact method.
        iv. Assume posts can be forwarded beyond the intended audience. Avoid language that could unintentionally reveal private health information or sensitive information about prospective study participants.

d. This is not an exhaustive list of recruitment materials.

First Approach to Meriter Patients in Clinics and Hospital Units

1. A **member of the patient's care team** or an appropriate clinic, unit, or department representative makes the initial in-person approach to obtain the patient's permission for a researcher to contact them. The person doing the first approach is not expected to know more than the health condition being studied and who is doing the study when asking whether a patient would like to speak to study staff to learn more.

    a. **Permission to Contact** – The care team may obtain the patient's oral or written permission to release their name and contact information to the study team for later contact. Written permission to contact is recommended if the future contact will be after hospital discharge. Oral permission is acceptable if the study team will be contacting the patient while they are still in the hospital or clinic. The Permission to Contact form should be HIPAA compliant. There's a template on the Meriter Research Integrity website.

Other Methods of Patient Contact for Recruitment

1. **Email and Text Messaging**
    a. Inform the prospective subject of the risks associated with the use of regular email before seeking permission to communicate in that way.
    b. Use encrypted email to communicate with prospective subjects. Do not include any PHI or sensitive information in the email. Do not request PHI or sensitive information in emails or texts such as medical conditions or test results.
    c. Verbal permission from the prospective subject to use unencrypted email for regular study communications and exchange of PHI is acceptable.
    d. Email/text should state that the email/text is being sent on behalf of Meriter and the treating provider. The message must clearly state the identity of the sender (e.g., UW Principal Investigator) if this is a first contact.
    e. Use only organization-approved accounts/systems for study communications (e.g., such as @unitypoint.org, @wisc.edu, @medicine.wisc.edu or @uwhealth.org accounts). Do not use personal accounts (e.g., Gmail, Yahoo)

2. **Recruitment Letters** may be sent to Meriter patients who meet inclusion criteria. The letter must:
    a. Be on Meriter letterhead, preferably the letterhead reflecting the department or unit the patients are recruited from. You can get this from the Meriter-employed manager who will be signing the letter.
    b. Be signed by a Meriter manager or director with their title after their name as well as a treating provider. This should be someone the patient would reasonably expect to have access to their health information.
    c. Clearly explain why the patient is being contacted, how they were identified as eligible for the study, and how to contact the study team.
    d. State how the person may opt out of further communication.
    e. Clearly state if there will be a follow-up call from the study team if the patient doesn't opt out.

2. **Phone Calls –** The study team may call someone who was sent a recruitment letter if the person did not opt out of further communication.
    a. A reasonable amount of time (at least two weeks) should be allowed for the letter recipient to respond before the study team performs follow-up phone calls.
    b. The study team may call and leave a general message regarding the research. Meriter would like to see an IRB approved phone script to ensure consistency and to make sure confidentiality is adhered to.
    c. The study team is allowed one conversation with a person who then says during the phone call they do not wish to participate. However, if the person wishes to participate, additional contact for informed consent, etc. may move forward.
    d. Study teams are asked to track calls and opt outs over the life of the study to avoid re-contacting someone who does not wish to be contacted.
    e. Cold calling prospective subjects who are not expecting contact and where there's been no previous attempt to introduce the person to the research are generally not allowed.

Opting Out of Research Recruitment

1. Prospective subjects must always be given a method for opting out of future contact at any point during the recruitment process. The study recruitment plan should describe how prospective subjects can opt out.
2. Letters, emails, texts, phone calls, etc. must provide information on how the prospective subject can opt out of further contact from the study team.
3. Once someone asks not to be contacted again, the study team must honor that person's right to opt out immediately.
4. The study team may keep a list of those who have opted out until study recruitment has ended to ensure they don't re-contact anyone who has opted out.

Eligibility Screening and HIPAA Compliance

HIPAA Preparatory to Research clause allows researchers to look at and collect identified private health information (PHI) to determine eligibility. Under this clause, the PHI may not leave Meriter. This means electronic PHI cannot be taken off of Meriter's servers and PHI that is written on paper cannot be removed from Meriter's physical premises.

A **HIPAA Waiver of Authorization** may be granted to allow researchers who need to remove PHI (for example, names and phone numbers or email addresses) from Meriter for eligibility screening.

PHI Disposal if person turns down research - Screening information from prospective subjects who are not eligible or choose not to participate is destroyed; however, one or more identifier (e.g., MRN) may be temporarily retained to ensure someone who says "no" is not inadvertently contacted again. Investigators may keep some identifiers of non-participants until recruitment permanently closes.