Marshfield Clinic

Identification Recruitment and Compensation of Research Participants

1. SCOPE

1.1. System-Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. Advertising

- Information intended to be seen or heard by prospective research participants to solicit their enrollment in a research project.
  - ◊ Includes, but not limited to: website, newspaper, radio, TV, bulletin boards, posters, flyers, and recruitment letters intended for prospective research participants.
  - ◊ Not included:
    - Communications intended to be seen or heard by health professionals, such as "dear doctor" letters and doctor-to-doctor letters, even when intent is to solicit for research participants, unless the health professionals are the intended prospective research participants;
    - News stories;
    - Publicity intended for other audiences, such as financial page advertisements directed toward prospective investors, and;
    - Listings of clinical trials when the information provided is limited to the title, purpose of the study, protocol summary, basic eligibility criteria, study site location(s), and how to contact the site for further information;
    - Sponsor created web content, print ads, media campaigns, etc. to be put forward without assistance or input from local research staff.

2.2. Recruitment

- Steps taken by investigators or study staff to attract, screen, and/or contact potential research participants prior to obtaining informed consent

2.3. Compensation

- Payment or non-monetary reward to subjects as remuneration for time and inconvenience of participation, as well as an incentive to participate.

3. PROCEDURE BODY

When approving a research project, Marshfield Clinic Research Foundation Institutional Review Board (MCRF IRB) must determine that the selection of research participants is equitable, a requirement that stems from the concept of "Justice" outlined in the Belmont Report. This document outlines permitted recruitment methods, MCRF IRB submittal requirements, and considerations to be made during IRB review.

3.1. MCRF IRB reviews all plans to recruit research participants to determine whether the recruitment methods are equitable, avoid coercion, undue influence, or deception, and comply with OHRP, FDA, and HIPAA regulations. The IRB may approve recruitment methods for potential participants whose identities will remain unknown until contact is made for enrollment. Examples include some advertising such as posters, approaching people in public settings, snowball sampling, or use of social networks. The IRB may also approve methods that require investigators and/or research staff to learn the identities and/or contact information of potential participants, subject to the requirements set forth below. Whenever possible, the relationship between the potential participant and Marshfield Clinic will be identified in recruitment letters and scripts. If recruitment is disease specific, materials may state that the clinical department has been made aware of the project. For population-based studies, materials may state that individuals are being contacted because they receive health care at Marshfield Clinic. Any recruitment directed toward Marshfield Clinic employees and students must follow the procedure, "Employees, Staff and Students as Research Subjects."

3.2. Pre-Screening / Reviews Preparatory to Research

a. Investigators may want to identify potential participants who meet certain criteria, or who have a specific condition. Medical records, patient registries, and clinical or research databases can be useful resources, so long as the privacy of potential participants is protected and IRB approval is obtained.

b. Under the HIPAA Privacy Rule, investigators can access and view PHI for reviews preparatory to research once a representation is filed. Such preparatory reviews can include viewing PHI to identify prospective research participants before consent and HIPAA authorizations, or waivers of consent and HIPAA authorization, are obtained.

c. Any representation for reviews preparatory to research must be filed as outlined in the document, "Procedures for Use and Disclosure of Protected Health Information for Research."

d. A HIPAA waiver request form must be filed with MCRF IRB when any records, patient registries, and clinical databases exclusive to Ministry Health Care hospitals, will be accessed.

3.3. Advertising

a. In the Food and Drug Administration (FDA) Information Sheet "Recruiting Study Subjects" (2010), the FDA states that it considers advertising to potential research participants to be the start of the informed consent and selection processes, and so requires IRBs to review the methods and materials that investigators propose to use for recruitment. IRBs are to review information in advertisements, and modes of communication, to determine that recruitment procedures do not create undue influence, and do not state or imply a certainty of favorable outcomes, or other benefits beyond what is outlined in the consent document and protocol. IRBs also are to review final copies of printed advertisements to evaluate type size and other visual effects, and of any audio/video tapes.

- Advertising should be limited to information that prospective participants need to determine eligibility and interest. When appropriately worded, the following may be included:

- Name and address of the clinical investigator and/or research facility;
- The condition under study and/or the purpose of the research;
- In summary form, the criteria that will be used to determine eligibility for the study;
- A brief list of participation benefits, if any;
- The time or other commitment required of the participants;
- The location of the research and the person or office to contact for further information; and
- A statement of compensation or incentives as long as the payment or amount to be paid is not emphasized (e.g., larger or bolded text).

b. MCRF IRB requires prior IRB review and approval of all advertising prior to use to ensure that it meets all requirements of this procedure.

- Proposed advertisements should be submitted with the initial IRB application whenever possible; no separate form is needed. If an investigator decides to advertise after initial study approval, or if he or she decides to revise an advertisement, it must be submitted using the IRB "Change or Update to Original Submission" form.
- Investigators must submit the complete, final advertising text and accompanying images or other visual or auditory messages to be used. If an advertisement is to be made via audio or video, MCRF IRB strongly recommends that the accompanying text or script be submitted for pre-review so that any expense of re-taping can be avoided, should changes be required.
- All advertising:
  - Cannot include any exculpatory language.
  - Cannot make claims, either explicitly or implicitly, that any drug, biologic or device is safe or effective for the purposes under investigation, or that any test article is known to be equivalent or superior to any other drug, biologic or device, or that is inconsistent with FDA labeling.
  - Should not use terms such as "new treatment," "new medication" or "new drug" for investigational drug, biologic or device studies without explaining that the test article is investigational.
  - Should not promise "free medical treatment," when the intent is only to say participants will not be charged for taking part in the research.

3.4. Contacting Potential Participants

a. Clinicians' Own Patients

- If a Marshfield Clinic investigator wants to target his or her own patients for research recruitment, he or she must disclose the plan to do so to MCRF IRB in the description of proposed recruitment methods. He or she should describe any plans to minimize the possibility that patients will feel obligated to participate (e.g., emphasize voluntariness of participation and

explain the decision to not participate will not affect care; initially contact patients about the research in writing, and allow patients to make further inquiry if interested).

- Marshfield Clinic investigators and practitioners are prohibited from accepting payment for enrolling patients in research studies. See the document, "Compensation for Identifying and Enrolling Subjects."

b. Investigators commonly seek to contact potential participants over the telephone, or via in-person or written communications, to determine their interest in research. IRB approval of contact methods is required. A representation for reviews preparatory to research must also be filed unless the IRB has granted a waiver of authorization for such contact.

c. Investigators and the IRB should consider whether a preliminary contact by the individuals' health care provider to introduce the research and/or assess the individual's interest in learning more about the research would be important in honoring the individual's privacy. Preliminary contact by a health care provider, either verbally or in writing, can be particularly important when the research involves sensitive topics or diseases.

d. For use of third-party calling centers/centralized screening centers, the HIPAA Privacy Rule prohibits individuals or institutions outside of Marshfield Clinic from contacting potential participants for recruitment on the Clinic's behalf unless HIPAA authorizations are obtained, a Business Associate Agreement is in place authorizing the disclosure, or MCRF IRB grants a request to waive authorization.

e. Information from prospective participants who were pre-screened but not enrolled can be retained so long as it is not identifiable. In order to retain identifiable information, investigators must obtained signed authorizations, or request a waiver of authorization from the IRB to retain the information.

3.5. Participant Compensation and Incentives

a. Federal Guidance

- IRBs are responsible for ensuring that research participation is voluntary, and consent is sought under circumstances that minimize the possibility of coercion or undue influence (45 CFR 46.116 and 21 CFR 50.20). Federal guidance suggests that in order to ensure this, proposed compensation must receive IRB review and approval.

b. MCRF IRB requires prior IRB approval of financial compensation to be paid to research participants in any amount, and of incentives such as token gifts, gift certificates, free medicine, etc. valued at greater than $20 per study.

- Proposed compensation and incentives should be submitted with the initial IRB application when possible; no separate form is needed. If known, proposed compensation and incentives should be described in the consent form provided to the IRB. If an investigator decides to pay participants compensation or incentives after initial study approval, or if he or she decides to change or revise compensation or an incentive, he or she must submit the compensation or incentive using the IRB "Change or Update to Original Submission" form prior to payment.

c. MCRF IRB considers compensation or incentives on a study-by-study basis, considering variables such as patient population, time to be spent, and inconvenience. When participants are compensated or given incentives, the compensation or incentive should be adequate, but not be so great as to influence them to participate in the research when contrary to their interests or values. Compensation should be based upon a reasonable amount for time spent in preparation for, participation in, and recovery from a particular research intervention, including travel time as well as any potential discomfort they may experience. The amount should not be based upon the degree of risk of the study.

d. Travel expenses, as well as compensation for the time of required travel companions, may be compensated.

e. Credit for payment may accrue as the study progresses, but payment may not be contingent upon the participant completing the entire study.

f. Any amount to be paid as a bonus for study completion must be deemed reasonable by the IRB, and may not be so large as to unduly induce participants to stay in the study when they would have otherwise withdrawn.

g. Sponsors may not offer participants discounts on the purchase price of the investigational product being tested in the research, if it becomes approved for marketing.

h. Compensation or Incentives for Parents of Minor Research Participants

    - If compensation and/or incentives are being proposed for research involving children, the parent(s) and child may be compensated separately for their efforts. Parents may be compensated for travel time and inconvenience in taking the child to appointments and time completing study procedures such as diaries. Rather than cash payments, the IRB recommends compensating children for their time with a small gift such as a book or toy.

i. Any approved compensation should be disclosed in the informed consent document, including amounts to be paid and the points at which payment will occur. Incentives will be included in the consent form at the IRB's discretion.

j. Compensation or incentives may not be highlighted or otherwise stressed in advertisements or consent documents. Compensation and incentives also may not be given more emphasis during the informed consent process than discussion of the purpose, risks, benefits, and alternatives of the study.

k. According to the Internal Revenue Services (IRS), payment to a participant is considered income and if the compensation is in the amount of $600 or more in a calendar year, the participant must complete a W-9. The MCRF Fiscal Dept. will then send the participant an IRS Form 1099 – MISC at the end of the year for tax filing purposes.

    - When compensating a participant the IRS templated language needs to be incorporated into the informed consent along with the amount or type of compensation being provided to the participant

4. ADDITIONAL RESOURCES

4.1. References:
- None]

4.2. Supporting documents available:
- Change or Update to Original Submission

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control System transferred from Policy & Handbook Library - #1532.8. Update IRB title of ARU form to Change or Update Form.
2.0	Sect. 3.5 (c) Removed recommended $25 per hour amount for compensation and reworded what the compensation amount should be based upon.
3.0	Sect.2.3 Add definition of compensation. Sect.3.5.k Add IRS requirement & MCRF process for $600 or greater compensation.
4.0	Change DCS file to match title of this document.

6. DOCUMENT PROPERTIES

Primary Author: Scheller, Lori A
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