MCW IRB Committee Procedures

ADVERTISEMENTS, RECRUITMENT METHODS AND COMPENSATION

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Institutional Review Board Committees

PURPOSE:
The MCW IRB considers advertising or soliciting for subjects to be the start of the informed consent process and subject selection process.

This procedure outlines what IRB Committee Members should consider when reviewing a new project, an amendment or 6-year renewal eBridge submission that includes subject recruitment procedures, advertisements, press releases, and/or proposes to provide compensation to subjects.

DEFINITIONS:
Recruitment: Seeking individuals to enroll or participate in a project.

Advertising: A public announcement usually by a printed notice or voice or data broadcast that describes a project including contact information. Typically, this is used for recruitment purposes for a project.

Coercion: the use of force or intimidation to persuade someone to do something which they are unwilling to do

Undue Influence: (as a term in jurisprudence) is an equitable doctrine that involves one person taking advantage of a position of power over another person. It is where free will to bargain is not possible.

Final Format: an advertisement which has been prepared and is ready for print or to be used for recording. An advertisement which is in "final format" has:

- Identified the mode of advertisement, i.e., print flyer/poster, radio script, video script, website or social media post.
- All text, font and style used is exactly how it will appear to potential subjects.
- Incorporates all images to be used

PROCEDURE:
Investigator's application to the IRB

1. All potential recruitment materials to be used to recruit potential subjects and methods of compensation for research activities must be submitted to the MCW IRB as part of the eBridge SmartForm.
2. Upon submission to the IRB, the IRB Coordinator IIs (C2s) will review the application to ensure that the Investigator has identified and described all methods of recruitment they will use to identify and/or recruit potential subjects.
    a. If any method of recruitment to be used in the project appears as if it will not be conducted in a fair and equitable manner while maintaining respect for the

potential subject and their privacy and confidentiality, it will be noted in the IRB C2's review checklist.

3. Upon assignment of a submission which indicates the use of recruitment materials and methods of compensation; IRB Committee members should review the application to determine if the following guidelines are met and document their findings using the *IRB Member Form: Advertisements and Recruitment Materials Checklist*

Recruitment Methods

Record Reviews

1. Potential subjects may be identified by Investigators using medical records, clinical databases or research databases. This process is often identified as "a record review".
2. IRB Committee members should ensure that Investigators have identified the following within the eBridge SmartForm:
   a. What is the source of records?
   b. Are the potential subjects under their care?
   c. Who will review the records?
   d. What identifying information will be collected to assist with the recruitment process?
3. MCW, Froedtert Health (FH), Versiti and Children's Wisconsin (CW) are considered covered entities and must abide by the federal regulations regarding Health Insurance Portability and Accountability Act (HIPAA). The steps in accessing potential subject records vary if the potential subject is the Investigator's patient or not. For more information, see *IRB Members SOP: Privacy and Confidentiality*.

a. Investigators and project teams should identify if they wish to review and screen subjects via medical records. They must request a "Waiver of HIPAA authorization for Recruitment Purposes" in the eBridge SmartForm.

Inpatient Recruitment:

1. Investigators who wish to approach and recruit inpatient subjects into their projects must obtain the permission from the attending physician.
2. Investigators must describe this process in their eBridge SmartForm and this permission must be documented in the regulatory file for subjects.

Approach Letters:

1. Approach letters are seen as a first step of the informed consent process and the subject selection process and should contain the information as outlined in *IRB SOP: Advertisements.*
2. IRB Committee Members should verify that Approach letters are planned to be printed on either departmental or project-based letterhead and signed by the PI.

Doctor to Doctor Letters or Dear Doctor Letters:

1. Letters providing basic information to physicians affiliated with outside clinics or institutions regarding an Investigator's project do **not** require IRB approval.
2. IRB Committee members should verify that the use of these letters is included within the description of recruitment procedures for the project.

Advertisements/Flyers/Posters/Radio

1. The MCW IRB considers advertising or soliciting for subjects to be the start of the informed consent process and subject selection process. IRB Committee members will review advertisements as part of the eBridge PRO SmartForm for initial review and any subsequent amendments to the ongoing project.
2. This review of the advertising will be performed to assure that it is not coercive and does not promise a certainty of cure beyond what is outlined in the consent

and the protocol. This is especially critical when a project may involve subjects who are likely to be vulnerable to undue influence.

3. Federal regulations require IRBs to review television, radio, videotape or print advertisements, e-mail solicitations, websites, social media postings, and other recruitment methods and materials intended to be used for the recruitment of prospective subjects.
4. Advertisements used to recruit subjects include, but are not limited to:
    a. Newspaper
    b. Radio
    c. Television
    d. Bulletin boards
    e. Posters
    f. Social Media posts
    g. Flyers that are intended for potential subjects
5. IRB review is necessary to ensure that the information is not misleading to subjects, especially when the project may involve subjects considered vulnerable.

Internet, Online or Social Media Recruitment

1. IRB Committee members will review the use of the internet (online or social media) for recruitment. This review will include the method and content of the proposed recruitment.
2. Investigators must describe in their eBridge submission where and what listing is being used. Investigators must assure that the information shared for online recruitment is in accordance with their signed clinical trial agreement or grant.
    a. If the proposed recruitment website or social media post includes risks and/or potential benefits or compensation information, the material must be reviewed and receive IRB approval prior to posting.
    b. If the proposed online recruitment process (platform, website, or app) will collect any personal identifiable information from potential subjects, this must be reviewed and approved by the IRB prior to posting, along with a description of how the information will be collected, and protected from breaches of privacy. Investigators should include any terms of services from the platforms, websites or apps.
3. Federal guidance regarding website recruitment states that if a project's recruitment material (e.g. website or social media post) contains only basic descriptive information, IRB approval may **not** required. MCW IRB consider the following posting services to **not** require prospective IRB approval (although the IRB Committee Chair and IRB Committee Members should verify that the use of websites for recruitment is included in the recruitment procedures to used for the project):
    a. the National Cancer Institute's cancer clinical trial listing (PDQ),
    b. the government-sponsored AIDS Clinical Trials Information Service (ACTIS), and
    c. Clinicaltrials.gov, and
    d. Froedtert Hospital website, specifically Clinical Trials on the MCW/Froedtert Campus

Recruitment of Vulnerable Populations

IRB Committee members will ensure that their review includes the additional safeguards and descriptions as outlined in the following procedures:

- *IRB Member SOP: Research Involving Pregnant Women and Fetuses*
- *IRB Member SOP: Research Involving Children*
- *IRB Member SOP: Research Involving Prisoners*

- *IRB Member SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability*
- *IRB SOP: Research Involving Economically or Educationally Disadvantaged Person*
- *IRB SOP: Research Involving Native American or Alaskan Native Tribes*
- *MCW Corporate Policy: Participation as Research Subjects (RS.HS.030)*

Other Federal Agency Requirements:
Several Federal Agencies have additional requirements to ensure the protection of human subjects for projects being funded or conducted under their oversight.

For projects receiving funding from the Department of Defense (DoD) or a component of the DoD, the following elements must be addressed in the eBridge submission:

1. When research involves U.S. military personnel additional protections for military research subjects to minimize undue influence include:
2. Officers are not permitted to influence the decision of their subordinates.
3. Officers and senior non-commissioned officers may not be present at the time of recruitment.
4. Officers and senior non-commissioned officers have a separate opportunity to participate.
5. When recruitment involves a percentage of a unit, an independent ombudsman is present.
6. When research involves U.S. military personnel, limitations on dual compensation:
7. Prohibit an individual from receiving pay of compensation for research during duty hours.
8. US military personnel may be compensated for research if the subject is involved in the research when not on duty.

For projects who are subject to the Department of Justice regulations and guidance:

1. For research conducted within the Bureau of Prisons:
    a. The selection of subjects within any one organization must be equitable.
    b. Incentives may not be offered to help persuade inmate subjects to participate. However, soft drinks and snacks to be consumed at the test setting may be offered.
    c. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are both:
        i. No longer in Bureau of Prisons custody.
        ii. Participating in authorized research being conducted by Bureau employees or contractors

Compensation:

For Subjects:

1. Investigators may choose to provide compensation to subjects participating in their project. Compensation is not a requirement for a project and should be evaluated by both the Investigator and IRB to determine if appropriate for each specific project and subject population. The following compensation methods are permitted, and compensation should be distributed in accordance with *MCW Corporate Policy: Business Purchases, Payments and Reimbursements (BF.PA.010)* and *Office of Research Policy: Subject Payments for Research Participation:*
    a. Monetary compensation. This includes check, cash, gift certificates, and prepaid debit cards.
    b. Parking or travel reimbursement
    c. Meal coupons
    d. Items such as bags, blankets, pens, coolers, calendars, magnets, etc.

e. Wearable Electronics
f. Medical Equipment – if provided to the subjects during the project and allowed to keep it after participation has ended. Examples include, but are not limited to:
    i. Blood Pressure Cuffs
    ii. Glucose meters
    iii. Portable Electronic Devices

2. The IRB reviews and evaluates all compensation plans proposed on a project-by-project basis. In their review, IRB Committee members will evaluate the following components:
    a. If compensation has been pro-rated on a per visit basis
    b. If there is a "completion bonus" offered for the final visit. Completion bonuses are often a visit amount which totals greater than 40% of the total compensation for the project
    c. Evaluate the total compensation being offered in the project to ensure subjects are not subject to undue influence.
    d. Ensure that the compensation method is in line with institutional policies.

Compensation methods not allowed for Investigators or subjects:

1. The following methods are not allowed by MCW IRB as compensation:
    a. Investigators may not receive payment for referrals of potential subjects or offer recruitment bonus to other physicians who refer individuals to a project. See Finder's Fee and Bonus Payments section in this procedure.
    b. Subjects may not receive escalated payments for the purposes of accelerating recruitment or to encourage participation multiple times.

Finder's Fees and Bonus Payments

1. Sponsors may offer to pay Investigators or project personnel an additional fee to encourage subject recruitment efforts and the timely or accelerated opening of projects. In most situations, these payments are prohibited. Each situation should be reviewed to be sure that it complies with Federal regulations, ethical opinions, and MCW IRB policy.
    a. It is impermissible to pay or accept "finder's fees".
        i. Additionally, it is impermissible for MCW or FH faculty, employees or students to accept personal payments from sponsors or other researchers in exchange for accelerated recruitment or referrals of patients.
    b. It is impermissible to accept bonus payments.
        i. It is acceptable to receive compensation for recruitment and screening related activities that are unrelated to whether the subject ultimately enrolls in or completes the project (such as advertising, administrative and personnel costs).
        ii. Investigators should be sure to determine a reasonable budget amount that is directly related to the value of the services provided to the project, and to document how that amount was determined.
            1. For example, individuals could be paid on a flat hourly basis for the time spent recruiting and screening potential subjects (regardless of whether they are successful in recruiting those subjects) and time sheets should be kept documenting this effort. Staff should not be paid a fee for every successful recruitment (e.g., $10 for every subject who signs the consent document to participate in the project).
        iii. This amount should be reflected in a finalized contract that is reviewed by the Grants and Contracts Office (GCO).

This policy is not intended to prohibit renegotiation of contract fees when recruitment is progressing much more slowly than anticipated such that additional time and effort are required for recruitment activities than initially anticipated.

REFERENCES:
N/A

SUPPORTING DOCUMENTS:
MCW Corporate Policy: Participation as Research Subjects (RS.HS.030)
MCW Corporate Policy: Business Purchases, Payments and Reimbursements (BF.PA.010)
Office of Research Policy: Subject Payments for Research Participation
IRB Member SOP: Research Involving Pregnant Women and Fetuses
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IRB Member SOP: Privacy and Confidentiality
IRB Member Form: Advertisements and Recruitment Checklist

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