MCW Office of Research
Standard Operating Procedure

RECRUITMENT METHODS AND COMPENSATION

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

Applies to: Faculty and Staff involved in human research

PURPOSE:
Recruitment methods and materials used to recruit potential research subjects along with methods and amounts of compensation must undergo IRB review and receive approval prior to use of the material.

It is the policy of the Medical College of Wisconsin (MCW) Institutional Review Board (IRB) to review and approve all recruitment methods, materials and compensation for subjects in research conducted under its jurisdiction.

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

Advertisements: forms or pieces of recruitment material used to inform potential subjects about a project. Advertisements can be in many forms and encompass many modes, such as flyers, posters, billboards, bus ads, etc.

Coercion: the use of force or intimidation to persuade someone to do something that 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.

PROCEDURE:
1. When submitting a new research project for IRB review, Investigators should identify all methods of recruitment they will use to recruit and/or identify potential research subjects. Any method of recruitment to be used in a project should be conducted in a fair and equitable manner while maintaining respect for the individual and their privacy and confidentiality. Recruitment, advertisment and consent material must be consistent with the level of data identification.
2. Investigators who propose to use advertisements such as approach letters/phone calls, flyers, posters or social media postings, these documents and/orscripts must submitted for IRB review and approval prior to use. For more information, see *IRB SOP: Advertisements*
3. Investigators who add or change a method of recruitment during the course of the project, the Investigator should submit an amendment via eBridge to the IRB with any revised or new advertising materials if applicable for review and approval.

1. Recruitment Methods

Record Reviews

a. Potential subjects may be identified by Investigators using medical records, clinical databases or research databases. This process is often identified as "a record review" and requires IRB approval prior to review of records.
b. Investigators should identify the following in their eBridge submission:
   i. What is the source of the records (e.g. EPIC, research databank, clinical databank)?
   ii. Are the potential subjects under the care of the Investigators?
   iii. Who will review the records?
   iv. What identifying information will be collected to assist with the recruitment process?
c. The IRB can approve research in which the investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without first obtaining informed consent if either of the following conditions are met:
   i. The information will be obtained through oral or written communication with the prospective subject, OR
   ii. By accessing records or stored biospecimens
d. 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 SOP: Privacy and Confidentiality.*
   i. Investigators and project teams should indicate in their eBridge submission if they wish to screen or recruit subjects from review of medical records prior to consent to request a waiver of HIPAA authorization for recruitment purposes.

Inpatient Recruitment:

Investigators who wish to approach and recruit inpatient subjects into their projects must obtain the permission from the attending physician. This permission must be documented in the regulatory file. Investigators must indicate this in the eBridge SmartForm and describe this as part of their recruitment process.

Approach Letters or Phone calls:

1. Approach letters or phone calls 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. In order to avoid an invasion of privacy, it may be necessary for an investigator to enlist the cooperation of other professionals and organizations as intermediaries in contacting a potential subject and obtaining consent to release his or her contact information to the investigator. This is appropriate when an investigator has not had prior contact with prospective research subjects and has not obtained their names from a publicly available source.
3. Approach letters should be printed on either departmental or project based letterhead and signed by the PI.
4. When obtaining names through a public source, the Investigator should include the name of the source in the initial communication/contact (letter or phone call).

Doctor to Doctor Letters or Dear Doctor Letters:

Letters providing basic information to physicians affiliated with outside clinics or institutions regarding an Investigator's project do not require IRB approval. The use

of these letters should be included in the recruitment procedures to be used for the project and uploaded as reference materials for the IRB.

Advertisements/Flyers/Posters/Radio

1. Federal regulations require IRBs to review the information contained in advertisements to determine that the procedures for recruiting subjects are not unduly influential or coercive and do not promise a certainty of cure beyond what is outlined in the consent and the protocol. See *IRB SOP: Advertisements* for specific language which may or may not be allowed in advertisement materials.
2. 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
    g. Flyers that are intended for potential subjects
3. 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. Investigators who choose to use the internet for recruitment, IRB review and approval of the method and content is required. Investigators must describe in their eBridge SmartForm where (websites, online platforms, social media) and what listing is being used.
2. Investigators must assure that the information shared for recruitment is in accordance with their signed clinical trial agreement or grant (if applicable). Refer to *IRB SOP: Advertisements* for a description of what information may be included with internet recruitment.
    a. When 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 considers the following posting services not to require prospective IRB approval (although the use of websites for recruitment should be included in the recruitment procedures to be 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

Projects which will include or target vulnerable populations must include the appropriate safeguards to ensure the rights; welfare and safety of these subjects are protected. For more information about these safeguards and vulnerable populations refer to the following procedures:

- *IRB SOP: Research Involving Pregnant Women and Fetuses;*
- *IRB SOP: Research Involving Children;*
- *IRB SOP: Research Involving Prisoners;*
- *IRB SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability*
- *IRB SOP: Research Involving Econcomically 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 SmartForm:

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

2. <u>Compensation</u>:

For Subjects:

a. Investigators may choose to provide compensation to subjects for the time, effort or inconvenience associated with 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 may be permitted and compensation should be distributed in accordance with *MCW Corporate Policy: Business Purchases, Payments and Reimbursement (BF.PA.010)* and *Office of Research Policy: Subject Payments for Research Participation:*

i. Monetary compensation. This includes check, cash, gift certificates, and prepaid debit cards.
ii. Parking reimbursement
iii. Meal coupons
iv. Items such as bags, blankets, pens, coolers, calendars, magnets, etc.
v. Medical Equipment – if provided to the subjects during the course of the project, and allowed to keep it after participation has ended. Examples include, but are not limited to:
   - Blood Pressure Cuffs
   - Glucose meters
   - Portable or wearable Electronic Devices

b. The IRB reviews and evaluates all compensation plans proposed on a project by project basis. In their review the IRB will evaluate the following components:
   - If compensation has been pro-rated on a per project visit basis
   - If there is a "completion bonus" offered for the final visit, completion bonuses are often an amount which totals greater than 40% of the total compensation for the project
   - If the total compensation being offered in the project to subjects is not unduly influential.

Compensation methods not allowed for Investigators or subjects:
The following methods are not allowed by MCW IRB as compensation:

- Investigators may not receive payment for referrals of potential subjects, or offer recruitment bonus to other physicians who refer individuals to a project, or offer to provide additional compensation for submitting data or addressing queries. See Finder's Fee and Bonus Payments section in this procedure.
- Subjects may not receive escalated payments for the purposes of accelerating recruitment or to encourage participation multiple times.

Finder's Fees and Bonus Payments

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 HRPP policy.

- It is not permissible to pay or accept "finder's fees". Additionally, it is impermissible for faculty, employees or students to accept personal payments from sponsors or other researchers in exchange for accelerated recruitment or referrals of patients.
- It is impermissible to accept bonus payments.

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).

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. 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). Further, this amount should be reflected in a written agreement that is reviewed by the Office of Grants and Contracts.

- 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 SOP: Advertisements
IRB SOP: Research Involving Pregnant Women and Fetuses;
IRB SOP: Research Involving Children;
IRB SOP: Research Involving Prisoners;
IRB SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability
IRB SOP: Research Involving Econcomically or Educationally Disadvantaged Person
IRB SOP: Research Involving Native American or Alaskan NativeTribes
IRB SOP: Privacy and Confidentiality

Effective Date:	07/01/2023
Version number:	5.0
Previous Version/date:	4.0, 06/15/2018
Responsible Office:	HRPP Office
Approval Date:	05/29/2023

Approved By
HRPP Authorized Official: Ryan Spellecy, PhD, Director, HRPP
Human Research Protections Program (HRPP)
Office of Research
Medical College of Wisconsin