



## Employees, Staff and Students as Research Subjects

### 1. SCOPE

#### 1.1. System Wide

### 2. DEFINITIONS & EXPLANATIONS OF TERMS

#### 2.1. Coercion

- When a person is compelled to act or comply by use of, or perceived use of, overt or implicit threat of harm, intimidation, or other pressure or force by another.

#### 2.2. Human Subject

- A living individual about whom an investigator conducting research obtains:  
1) data through interaction with the individual or 2) identifiable, private information.

#### 2.3. Research

- A systematic investigation including research development, testing and evaluation, designed to contribute to generalizable knowledge.

#### 2.4. Undue Influence

- When a person is compelled to act or comply because another takes advantage of a position of authority or power by offering an excessive, unwarranted, inappropriate or improper reward.

### 3. RESOURCE GUIDE BODY

This guidance outlines considerations for investigators and the Marshfield Clinic Research Foundation Institutional Review Board (MCRF IRB) for circumstances where Marshfield Clinic employees and/or students (including residents) are to be recruited and enrolled in human subjects research. MCRF IRB considers employee and student research subjects to be vulnerable to coercion or undue influence (real or perceived), and to have increased risks to privacy and confidentiality, and therefore will consider additional safeguards to protect their rights and welfare.

#### 3.1. Source Guidance

##### a. The Belmont Report

- The ethical principle, "Respect for Persons," requires informed consent to be a process involving a voluntary decision to participate, free of coercion and undue influence.

##### b. Department of Health & Human Resources (DHHS) Office of Human Research Protections (OHRP)

- A "Human Research Protections FAQ," highlights the potential for coercion and undue influence, and the need to protect confidentiality, when employees enroll in research.
  - "Employee participation raises questions about the ability of employees to exercise free choice, for example, because of the possibility that a decision to participate could affect performance evaluations or job advancement, even if it is only the employee's perception that this is the case. In the case of coercion, refusal to participate might result in a loss of benefits (e.g., salary increases, time off). In the case of undue influence, a decision to participate could result in a job promotion. Employees are likely to view their employers as authority figures to whom they must show deference, which could undermine the freedom of their choice."
- OHRP also discusses employees under the heading of "Special Classes of Subjects" in its IRB Guidebook, and recommends avoiding individual solicitations to participate.

### 3.2. Avoidance of Coercion and Undue Influence

- a. Marshfield Clinic investigators must strive to prevent even the appearance of coercion and undue influence when recruiting and enrolling employees and/or students in research.
  - When an investigator wants to specifically include employees and/or students as part of a study subject population, he or she must identify them as part of the subject population in an IRB application or amendment form for IRB consideration. If an investigator plans to enroll only employees and/or students, he or she must provide a rationale for restricting the study population, other than convenience. The potential for incidental enrollment of employees or students who otherwise meet study inclusion criteria does not need to be identified to the IRB.
  - Recruitment materials must be reviewed by MCRF IRB prior to being used, in accordance with "IRB Initial Review." Recruitment materials that are directed to a larger audience are preferred over those that are directed to employees and/or students, individually or as a group.
  - Employee and/or student participation in research must be voluntary.
    - Employees and students shall not be required to participate in research as a condition of employment or to maintain student status. Research participation is also not considered to be part of employee or student responsibilities at Marshfield Clinic.
    - A voluntary decision not to participate or to stop participation shall not affect a subject's employment or student status, performance evaluations, or any benefits of his or her employment or student status.
    - When an investigator specifically includes employees and/or students as part of a study's subject population, he or she must make the voluntary nature of their participation especially clear.
  - Participation by employee or student subjects is not compensable beyond the remuneration or costs approved by the MCRF IRB to be paid to, or on

behalf of, every other subject enrolled the study. Participation must also only be done on the employee or student's own time ("off the clock")

- Investigators should avoid directly recruiting or enrolling any employee or student that works under the investigator's supervision, or for whom the investigator has authority to give instructions, evaluate performance, recommend pay raises and/or promotions, or hire, discipline, or terminate. A third party other than the investigator should recruit, obtain informed consent and collect data from such subjects. If this is not feasible, the IRB must approve a method of obtaining consent and collecting data that minimizes the possibility of coercion or undue influence.

#### 4. ADDITIONAL RESOURCES

- 4.1. References:
- None

#### 5. DOCUMENT HISTORY

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1.0	New Document in Document Control transferred from Policy & Handbook Library - #5108.0. (no changes made).
2.0	
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#### 6. DOCUMENT PROPERTIES

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