

Wayne State University Human Investigation Committee	
SUBJECT	Vulnerable Participants: Students, Trainees and Employees
Section	
Form Date	
Approvals	10/13/99 Steering Committee, 11/04/99 Approved by all IRB Committees, 02/20/00 Administrative Approval

## Background

There are no federal regulations that specifically address the inclusion of students/trainees/employees in research protocols. However, these classes of subjects are vulnerable in that they may be unduly influenced by the expectation that participation or nonparticipation in a research protocol may affect their academic or employment status.

Special precautions must be taken to avoid coercion or the appearance of coercion when including students/trainees/employees in research. Similarly, it is important to avoid the appearance of any special treatment or any penalty of individuals in these categories based on their decision to participate or not to participate in a research protocol. Finally, confidentiality of data may be of special concern to these classes of research subjects.

## Definitions:

*Student/Trainee* – Any individual who is enrolled in a graduate or undergraduate program at Wayne State University and those individuals who are in training programs conducted by Wayne State University.

*Employee* – All individuals, including faculty and house staff officers, employed by Wayne State University and its affiliated health care institutions, the Barbara Ann Karmanos Cancer Institute, Children's Hospital of Michigan, Detroit Receiving Hospital/University Health Center, Sinai-Grace Hospital, Harper Hospital, Huron Valley/Sinai Hospital, Hutzel Hospital, Rehabilitation Institute of Michigan, and the John D. Dingell Veterans Administration Medical Center.

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## **HIC Policy:**

Students/trainees/employees have the same rights as any other potential subjects to participate in an HIC approved research project, irrespective of the degree of risk, provided all of the following conditions are met:

1. All students/trainees/employees must be offered the same inducement as other participants in the research project.
2. Research must not offer students/trainees/employees any competitive academic or occupational advantage over others who do not volunteer nor impose any academic or occupational penalty on those who do not volunteer. If only one protocol is available, the student should be allowed to participate and receive credit after the study has received full board review and approval. If credit is offered to students for research participation, alternative methods of gaining credit that require an equal time commitment must be offered to non-participating students. The alternative method(s) of obtaining credit must be disclosed to the IRB.
3. Students/trainees/employees must not be systematically treated differently from non-institutional participants as a result of their participation in a research study.

Extra precautions must be taken to ensure the confidentiality of data files for students/trainees/employees. If data to be collected are of a sensitive nature, someone other than the investigator(s) must manage subject recruitment and data collection (interviews et. al.). The protocol form must specify how the confidentiality of the data will be ensured.

*Recruitment:*

1. A researcher may not recruit a student/trainee/employee directly under his/her supervision or one who is expected to be under his/her supervision as a result of their student status or whose grade or performance evaluation requires input from the researcher.
2. A student/trainee/employee may participate in a research project if their participation is in response to a general announcement or if there is potentially direct medical benefit to the participant and condition #1 above is met.
3. It is left to the Human Investigation Committee's discretion to determine if the recruitment methods fall within WSU policy guidelines.
4. The mechanism for equal access to all potential protocols must be provided. Individuals who accept monetary compensation for participation in research projects should be aware that loss of confidentiality to supervisors and Wayne State University personnel result because of IRS and other reporting requirements.

## HIC Policy Procedures