WAYNE STATE UNIVERSITY

Wayne State University Human Investigation Committee	
SUBJECT	Vulnerable Participants: Normal Volunteers
Section	
Form Date	
Approvals	Steering Committee 7/8/98, All IRB Committees 8/98, Administrative Approval 10/30/98

Background

There are no federal regulations that specifically address the participation of normal volunteers in research protocols. However, this class of subjects could be considered vulnerable, and special precautions must be taken to ensure that their rights and welfare are adequately protected.

Normal volunteers are vulnerable in that they may be unduly influenced by the offer of monetary compensation or may feel coerced by one-on-one personal recruitment by a person in a position of authority. In particular, subjects who are financially or educationally disadvantaged may be unduly influenced to participate in a research study. Volunteers must be made aware that there may be unknown long term effects from test agents (e.g., new drugs or classes of drugs). Confidentiality of data may also be of special concern to this class of research subjects who otherwise might not have data on file at an institution.

HIC Policy Procedures

Research protocol*:* The manner in which normal volunteers will be contacted and recruited for participation in research must be specified, and any advertisements or scripts must be submitted for IRB review prior to beginning the study. It is recommended that general announcements or advertisements be utilized for recruitment in order to minimize the possibility of undue influence resulting from person-to-person recruitment. Research involving normal volunteers should involve low or minimal risk, and any foreseeable risks must be minimized. Justification must be provided for involving normal volunteers in protocols involving greater than minimal risk. The protocol form must specify how the confidentiality of the data will be ensured.

Consent form: There must be a statement in the consent form that participation is voluntary and that the subject has the choice of not participating in the research. The issue of costs to the research subject must be specifically addressed: there must be no medical costs to the participant (i.e. only those costs related to meals and transportation during the study visits are acceptable). Any known or unknown long term risks

must be addressed in the consent form. There must be a specific plan regarding compensation for injury that might result from participation in the research, included in the consent form.