WAYNE STATE UNIVERSITY

HIC Policy/Procedure

Wayne State University Human Investigation Committee	
SUBJECT	Costs Associated with Research Participation
Section	
Form Date	
Approvals	11/12/97 Steering Committee, 12/97 All IRB Committees, 4/25/98 Administrative

Background

Information about "any additional costs to the subject that may result from participation in the research" is considered to be one of the "additional elements of informed consent" that, when appropriate, must be provided to each participant (subject) [45 CFR 46.116]. The Food and Drug Administration (FDA) regulations governing research with products regulated by the Agency [21 CFR 50.25] concur with the general regulations that expense incurred because of participation in research should be explained to the participant at the time that informed consent is being obtained. Furthermore, the FDA urges Institutional Review Boards (IRBs) to consider that some insurance and/or other reimbursement mechanisms may not fund care that is delivered in a research context (FDA Information Sheets, October 1, 1995).

The additional costs addressed in these parts of the code are distinct from any costs associated with unforeseen *injury* to the research subject during participation in a research study. The institution has the authority to regulate compensation for injury due to research participation, although its policy must be stated in the consent document and cannot appear to waive any of the subject's legal rights. According to 21 CFR 50, the subject must be told whether any compensation and any medical treatment(s) are available if a research-related injury occurs and, if so, what they are and who to contact for further information.

HIC Policy

If there are not costs that could be incurred by the subject because of participation in the research, this should be stated in the consent form. If there is any possibility that research participants might incur *additional costs* as a result of participating in a research study, the consent document must explicitly state this. If appropriate, the consent form must also mention that *some insurance plans* may not fund care that is delivered in a research context. In this case, the consent form should include a statement recommending that the subject inquire about his/her insurance coverage when deciding about participation. If the study is a clinical trial of a drug, the consent form should state *whether the drug is being provided* to the subject free of charge.

When the investigator has reason to believe that additional costs to the subject of participation in the research will be substantially greater than standard clinical care, then some estimate or description of the anticipated costs should be provided. This could be in the form of a range of anticipated total costs, or a descriptor of the

total such as "minimal", "modest" or "substantial" extra costs that could result from participation. If known, the specific procedures or tests that may not be covered by insurance and their approximate costs should be listed.

Other Considerations

If it has been stated that there are no costs to the research subject, then it should be clear from the protocol and information provided in the Protocol Summary Form that this is the case. If the reviewers have reason to believe that costs *may* be incurred by someone, and a source of funding for these has not been identified, then the IRB should ask the investigator for clarification.