WAYNE STATE UNIVERSITY

HIC Policy/ Procedure

Wayne State University Human Investigation Committee	
Subject:	Criteria for Determining Frequency of IRB Review
Section:	
Form Date:	02/2007
Approvals	Office of the General Counsel 01/05/07, Steering Committee 02/05/07, Admin Approval 03/07/07

Background

Federal regulations require that an Institutional Review Board (IRB) have the authority to review, approve or disapprove and monitor human subject research to ensure the protection of the rights and welfare of human participants. The IRB must determine whether or not a specific protocol requires review more often than annually at the time of initial protocol review, at continuation, and when there is sufficient reason to believe that there is an increased risk to participants [45 CFR 46.109 and 46.111, 38 CFR 16.109 and 16.116(b)(5), 21 CFR 50.25(b)(5), 21 CFR 56.108(a) and 56.109]. *Research may not proceed without the approval of the IRB.*

HIC Policy

The following criteria will be used by IRB members, chairs, vice chairs and the Human Investigation Committee (HIC) chair when reviewing protocols to determine the frequency of review. (See HIC Policy/Procedures: "IRB Review of Initial Research Proposals", "Continuation/Renewal of Protocol"). If any of the following criteria exist, then the IRB may require that a protocol be reviewed more often than annually:

- The research involves a high level of complexity or unusual types of risk to the participant,
- The medical conditions of the proposed participants indicate a susceptibility to problems as a result of enrollment in the protocol,
- The nature and frequency of adverse events observed in similar research at WSU and other facilities indicate that participants will likely experience serious adverse events,
- There is an increased risk to participants as evidenced by new findings,
- The research involves new procedures, drugs or devices not previously tested in humans,
- The study participants are determined to be vulnerable subjects as defined by the various WSU policies regarding vulnerable subjects (e.g. see Children as Research Participants and Cognitively Impaired and Mentally Disabled) and federal, state and local laws and regulations,

- The principal investigator or other members of the research team have minimal qualifications, limited experience and/or a history of continuing noncompliance in adhering to federal and HIC requirements, or ethical principles that guide human subject research,
- Other factors as deemed relevant by the IRB.

HIC Procedures

When initial submissions, continuations, or amendments are submitted to the HIC and reviewed by the IRB, the criteria described under HIC Policy section above are used to determine whether or not the protocol must be reviewed more frequently than once a year.

When an IRB requires a review and approval period more frequently than annually, the IRB may define the period with either a specific time interval or a maximum number of participants.

The decision to review a research protocol more frequently than once a year is included on all approval memos generated after IRB review. It is the responsibility of the PI to take careful note of the approval and expiration dates on those memos.

The determination of the frequency of review and approval for each study must be clearly described in the meeting minutes of the IRB.