

Wayne State University Institutional Review Board	
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, Administrative Approval 03/07/07, Administrative Approval 11/30/11, Administrative Approval 2/8/12.

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.***

IRB Policy

The following criteria are used to determine the frequency of the review of protocols by the IRB.

A. If any of the following criteria are applicable, then the IRB *may* require a protocol to be reviewed more frequently than annually:

1. The research involves a high level or unusual types of risk to the participant; or research where many of the risks to humans are unknown.
2. The research involves a high level of complexity or has complex regulatory compliance requirements (such as researcher-held IND or IDE, DoD protocols, etc.).
3. The research is international or is being conducted at an off-site location where WSU is serving as the IRB of record.
4. Research that involves an investigator with a potential conflict of interest for which the IRB feels warrants more frequent reporting and review.
5. The medical conditions of the proposed participants indicate a susceptibility to problems as a result of enrollment in the protocol.

6. 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.
7. There is an increased risk to participants as evidenced by new findings.
8. The research involves new procedures, drugs or devices not previously tested in humans.
9. The study participants are determined to be vulnerable subjects as defined by the various WSU policies regarding vulnerable subjects and federal, state and local laws and regulations.
10. 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 IRB requirements, or ethical principles that guide human participant research.
11. Other factors as deemed relevant by the IRB.

B. Various interval frequencies may be used as determined by the IRB:

1. Specified time period (annual, 6 months, 3 month, etc. review).
2. Requirement to report back to the IRB after a specified number of participants have been enrolled or participated in study interventions.
3. Other points in research meriting more frequent review.

IRB Procedures

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

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.

References and Regulations

DHHS Regulations	FDA Regulations	VA Regulations
45 CFR 46.109	21 CFR 50.25(b)(5)	38 CFR 16.109
45 CFR 46.111	21 CFR 56.108(a)	38 CFR 16.111(b)(5)
	21 CFR 56.109	