Wayne State University Human Investigation Committee	
Subject:	Determining Projects that Require Additional Verification
Section:	
Form Date:	12/06
Approvals	Office of the General Counsel 1/05/07, Steering Committee 2/05/07, Administrative Approval 3/8/07

Background

The Institutional Review Board (IRB) has the authority to determine when additional information is necessary, from sources other than the Principal Investigator (PI), to ensure that no unreported material changes have occurred in a study since the last IRB protocol review and that a research study complies with all federal regulations [45 CFR 46.103(b) (4) and (5)], 38 CFR 16.103(b) (4) & (5), state and local laws, and Wayne State University (WSU) policies and procedures. The IRB will obtain such verification in the following cases:

- Complex projects involving unusual levels or types of risk to subjects,
- Projects conducted by investigators who have previously failed to comply with IRB or Federal regulations or
- concerns have been raised about material changes occurring without IRB approval based on information provided in continuing review reports or other sources (See below)
- Randomly selected projects.

Non HIC Causes for Requesting Additional Information

Review of supplementary information may be required as the result of reports, complaints, suggestions or queries from sources outside of the Human Investigation Committee (HIC). Examples include:

- An inquiry from other compliance committees (e.g., Animal Investigation Committee, Scientific Misconduct Committees, Conflict of Interest Committee, Biosafety Committee, Radiation Safety Committee),
- An inquiry from WSU's Sponsored Program Administration (SPA) Office regarding concerns about the administration of a grant,
- An inquiry from WSU's Office of the Vice President for Research (OVPR), other universities and/or other offices at WSU and/or the affiliated health care facilities (e.g., Pharmacy),
- An inquiry from a sponsor that raises concerns to the HIC administration or the IRB committees,
- An inquiry from a research participant about their involvement in a research protocol,

- An inquiry from a coordinating center about a multi-center application that is being conducted at the University,
- An inquiry from an employee of WSU and/or individual from the community surrounding WSU about research being conducted at WSU,
- An inquiry from the Office of Human Research Protection (OHRP), Food and Drug Administration (FDA) and other federal compliance organizations, and
- An inquiry from the news media concerning a research protocol being conducted by faculty members at WSU.

HIC Policy/Procedure

The Assistant Vice President for Research, in consultation with the HIC Chair and/or the IRB committee chairs, determines if any of the following activities are necessary:

- An audit of the research protocol conducted by the Human Investigation Committee Process Improvement/ Compliance Coordinator (See the HIC Policy/Procedure "For-Cause Audit")
- The research protocol is suspended, and/or
- Additional administrative actions need to be taken.

In addition, the HIC Process Improvement/Compliance Coordinator will conduct random quality assurance reviews of active protocols. These random reviews will be conducted after the HIC Process Improvement/Compliance Coordinator has conferred with the Chair of the HIC, the Chairs of the individual IRBs, and/or the AVPR to determine the selection criteria [e.g., informed consent forms, Health Information Portability and Accountability Act (HIPPA) compliance]. The HIC Process Improvement/Compliance Coordinator will notify the HIC Steering Committee that a random audit has been completed. If the Process Improvement/Compliance Coordinator finds that the study is in compliance with regulations, HIC policies and procedures, and ethical guidelines, then the study will be allowed to continue. If there is evidence of non-compliance from the random audit, the HIC Process Improvement/ Compliance Coordinator will conduct a for-cause audit of the study at the request of the AVPR, the HIC Chair, or any of the IRB Chairpersons (See the HIC Policy/Procedure: "For-Cause Audit", "Identifying, Defining, and Managing Non-Compliance in Human Research".)

All unexpected problems, suspensions, terminations, or continuing or serious noncompliance will be reported as specified by the HIC Policy/Procedures "Reporting of Unanticipated Problems, Suspensions, Terminations, and Continuing and Serious Noncompliance" & "Suspensions and Terminations of Research Protocols".