

Wayne State University Human Investigation Committee	
SUBJECT	General Counsel: Roles and Responsibilities
Section	
Form Date	10/26/06
Approvals	10/25/06 Office of General Counsel, 11/17/06 Steering Committee, 12-05-06 Administrative Approval

Background

Wayne State University is committed to assuring that human participant research is conducted according to the highest ethical standards and all applicable laws and regulations. Research is governed by federal laws, regulations and standards [45 CFR 46.101(e), 38 CFR 16.102(c), 21 CFR 50, 56, 312, 812; 38 CFR 46]. Federal regulations also require that human participant research conducted, wholly or in part, within the state must comply with pertinent state and local laws and regulations [38 CFR 16.101(e)-(f), 38 CFR 15.102(c); 45 CFR 46.101(e)-(f), 45 CFR 46.102(c), 45 CFR 46.402(d)-(e)]. State law must take precedence when it provides a higher level of protection than federal regulations.

Michigan has no specific statute concerning human participant research. However, both the Michigan Mental Health Code and the Michigan Public Health Code require the protection of human participants in research. In addition, various other local and state laws and regulations may apply.

The following WSU Human Investigation Committee (HIC) policy outlines general and specific guidelines for the availability and function of legal counsel to ensure that the Institutional Review Board's (IRB) policies, activities, reporting, investigations, and legal interpretation comply with all applicable laws and regulations.

Scope

This HIC Policy/Procedure applies to all Human Investigation Committee policies/procedures governing human participation research at Wayne State University and its medical affiliates.

General Counsel Responsibilities to the Human Investigation Committee

A representative from the Office of General Counsel (OGC) holds a position as a voting member of an IRB committee and the HIC Steering Committee and provides legal expertise to the Human Investigation Committee and Institutional Review Boards as necessary.

Policy Review

A designated member of the OGC reviews all new Human Investigation Committee policies for compliance with federal, state and local laws and University policy, including relevant definitions (e.g. child, legally authorized representative, legal guardian, emancipated minor). New or revised policies are forwarded to the OGC two weeks prior to their being submitted to the HIC Steering Committee for review and final approval. If no necessary revisions are identified, the OGC certifies that the policy meets legal and regulatory requirements. If the policy requires revisions in order to meet compliance requirements, the policy will be returned to the HIC Administration with suggested revisions. When the revisions are complete the OGC will review the policy again and if all compliance requirements are met it will be sent to the next Steering Committee meeting. *Policies cannot be approved by the Steering Committee without first being reviewed and approved by the OGC.*

Existing policies are reviewed by the OGC on an ongoing basis, but not less than annually.

Relevant changes in state and local laws are reviewed on a regular basis by the OGC. Laws that require the immediate attention of the HIC Administration are promptly reported to the Compliance Officer and the HIC Chair. Further discussion and review of revisions to HIC policies are conducted by the HIC Steering Committee, with subsequent dissemination of the information to each of the IRB committees and the research community.

Consultation

The Office of General Counsel is available for consultation on issues of non-compliance, scientific misconduct and export control.