

Wayne State University Human Investigation Committee	
SUBJECT:	Policy and Procedure Development and Approval
Section:	
Form Date:	September 20, 2006
Approvals	Approved by Steering Committee 6/12/97, Approved by All IRB Committees 8/97, Administrative Approval 4/25/98, Steering Committee 9/20/06, Administrative Approval 3/28/07

Background

The Wayne State University (WSU) Human Investigation Committee (HIC) assures that research involving human participants will be conducted according to high ethical and professional standards and are in line with current research practices in the field. To maintain this high level of review, the HIC utilizes policies and standard operating procedures (SOP) to ensure an effective functioning human participant research protection program. Utilizing well thought-out policies, clear and concise definitions, and standard procedures that fit well into the actual work process, the HIC provides a base for maintaining a program that is in compliance with the federal regulations, state laws and university policies. Policies and SOPs must reflect the most current standards for quality research and compliance and must be revised and/or developed to meet this need.

Procedures

The Assistant Vice President for Research at WSU, with advice from HIC Chair, HIC staff, IRB members and/or investigators determines when a new or revised policy or SOP needs to be established. In most cases, the HIC Process Improvement/Compliance Coordinator and/or the Education Coordinator are responsible for writing policies and SOPs. However, any HIC administrative staff member may draft a policy or SOP based on his/her specialization. All policies and SOPs are in compliance with federal, state, and institutional regulations. [45 CFR 46.101(e), 38 CFR 16.102(c), 21 CFR 50, 56, 312, 812; 38 CFR 46] [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)].

Drafts of all new policies/SOPs must be reviewed according to the following steps:

- Initial administrative review which will include review by:
 - the Assistant Vice President for Research,
 - HIC Chair,
 - Program Project Coordinator
 - Education Coordinator or Process Improvement/Compliance Coordinator,
 - A Research Compliance Administrator,

- And/or designee for one of the above
- Once the policy or SOP meets the standards of the HIC, it is forwarded to the Office of General Counsel 2 weeks prior to the Steering Committee's consideration to determine if it complies with all federal, state, and local laws and University policy.
- If the proposed policy/SOP meets the approval of General Counsel, it will be sent electronically to all HIC Steering Committee members for review. Representatives of the affiliate institutions (i.e., John D. Dingell Veterans Administration Medical Center and the Detroit Medical Center) are members of the HIC Steering Committee and determine if the proposed policy/SOP is acceptable to their institution and compatible with their institutional policies.
- After review and discussion, the Steering Committee will vote to:
 - Approve the policy/SOP as written,
 - Approve the policy/SOP with proposed changes, or
 - Request that clarifications be returned to the HIC Steering Committee for review at a later date.
- The approval can be obtained by a vote at a convened HIC Steering Committee meeting or through electronic review of the policy or SOP and electronic vote. Either process is applicable unless a policy or SOP impacts the culture of research at this Institution, a consideration that is part of the review process. In that case, review by a convened Steering Committee and review by all four IRB committees would be required.
- If any member of the Steering Committee determines that a policy or SOP requires review and a vote at a convened Steering Committee meeting, the document will be sent to that committee meeting. A majority vote (i.e., greater than half of the membership) is required for approval.
- If any member of the Steering Committee determines that a policy or SOP requires review and a vote from all IRB members, the document will either be sent to all IRB Committee members electronically or to a convened IRB meetings, utilizing the same processes as described above.
- The policy/SOP is then forwarded to the Vice President for Research or designee for review and approval.
- A policy/SOP will be implemented only after undergoing the above-delineated process and Institutional Official approval. If a policy or SOP impacts the safety or well-being of research participants, the Institutional Official may approve its immediate implementation prior to being sent to a convened meeting.
- All HIC administrative staff members will be notified when a policy/SOP is implemented. When a new or revised policy/SOP is implemented, all IRB members will be provided this information via email, included in their IRB review packets or distributed at the IRB meetings.
- All changes to policy/SOP will be reflected on the HIC website and notification of changes will be sent to the research community through a variety of educational initiatives or via e-mail (e.g., listserv).
- All policies and SOPs will be reviewed on a yearly basis through HIC Administrative review and General Counsel to ensure that they reflect the best current practices and comply with all relevant University policy, laws and regulations.