

Wayne State University Human Investigation Committee	
SUBJECT:	Policy and Procedure Development and Approval
Section:	
Form Date:	November 2008
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, Administrative Approval 11/21/08, Office of General Council 12/04/08

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. The HIC provides a base for maintaining a research program that is in compliance with the federal regulations, state laws and WSU policies by utilizing well thought-out and thoroughly reviewed policies, clear and concise definitions, and high quality standard procedures that fit well into the actual work process. All WSU policies and SOPs must reflect the most current standards for quality research and compliance and must be revised and/or developed to meet these standards.

Procedures

The Associate Vice President for Research at WSU, with advice from HIC Chair, IRB Chairs, IRB members, HIC staff 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 WSU 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 following:
 - the Associate Vice President for Research;
 - HIC Chair;
 - HIC Manager;

- Education Coordinator or Process Improvement/Compliance Coordinator;
 - Research Compliance Administrator; and or
 - a designee for any of the above individuals.
- A decision will be made by the majority vote of those listed above, as initial administrative reviewers, to determine if the draft of a new policy/SOP or revisions to a current policy/SOP are major (impacts the culture of research at WSU) or minor changes.
- Once the draft policy/SOP or revised policy/SOP has been reviewed by the administrative review personnel listed above, then the policy/SOP or revision is forwarded to the Office of General Counsel to determine if it complies with all federal, state, and local laws and University policy.
- If the proposed policy/SOP or revision meets the approval of General Counsel and the revisions have been determined to be minor, the AVPR can approve the proposed policy/SOP **OR** the AVPR can elect to send the policy to an IRB sub-committee for review. The IRB sub-committee consists of the following:
 - IRB Committee Chairs;
 - IRB Committee Vice-Chairs;
 - Office of General Counsel representative;
 - One alternate from each IRB committee; and
 - the AVPR (as ex-officio).
- After review and discussion, the IRB sub-committee will vote (by majority) to:
 - Approve the policy/SOP as written; or
 - Approve the policy/SOP with proposed changes; or
 - Disapprove the policy/SOP; or
 - Determine that the revision or the policy/SOP is major and therefore should go to the individual IRB committees' members for a vote.
- If approved, the policy/SOP or revision is forwarded to the Vice President for Research (Institutional Official) or designee for review and approval.
- A new or revised policy/SOP will be implemented only after undergoing the above-delineated process and receiving Institutional Official approval. If a new or revised policy or SOP impacts the safety or well-being of research participants, the Institutional Official may approve its immediate implementation after consultation with the AVPR and the HIC Chair or designee.
- All HIC administrative staff members will be notified when a new or revised 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 scheduled 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 WSU research 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 and regulations, and all relevant federal and state laws and regulations.