



## HIC Policy/Procedure

Wayne State University Human Investigation Committee	
<b>SUBJECT</b>	Policy and Procedure Development and Approval
<b>Section</b>	
<b>Form Date</b>	October 14, 2009
<b>Approvals</b>	Administrative Approval 10/23/09, General Counsel Approval 01/20/10, Administrative Approval 02/04/10

### Background:

The Wayne State University Human Investigation Committee (HIC) assures that research involving human participants will be conducted according to high ethical and professional standards and is in line with current best practices for human research. In order to maintain a high quality of review and oversight of research, the HIC utilizes policies and standard operating procedures (SOPs) to ensure effective functioning of the Human Research Protection Program. All HIC policies and SOPs must reflect the most current standards of research compliance and must be revised and/or developed to as needed to meet these standards. This policy sets forth the considerations and procedures for the development, review, approval, and dissemination of revised or new HIC policies.

### Procedures:

The Associate Vice President for Research (AVPR), with advice from the HIC Chair(s), IRB members, administrative staff, and/or investigators, determines when a new or revised policy needs to be established. In most cases, the HIC Education Coordinator or Compliance Coordinator will draft new or revised policies, but any appropriate staff member may do so upon request. Revised or new SOPs can be drafted by any HIC administrative office employee with the requisite expertise, and most SOPs can be approved by the HIC Manager and the Director of the Responsible Conduct of Research after administrative review by the AVPR. The AVPR can recommend further review of SOPs by the HIC Chair or other IRB members if deemed necessary. All WSU policies and SOPs must comply with all relevant federal, state, and institutional regulations. [45 CFR 46; 21 CFR 50 and 56; 38 CFR 46; University Policy 2.41.01

Drafts of all revised or new policies must be reviewed initially and recommended for further action by the following:

- AVPR
- HIC Chair(s)
- Director, Responsible Conduct of Research
- HIC Manager
- HIC Education Coordinator or Compliance Coordinator; or
- Designee for any of the above

The above individuals also render a recommendation to the AVPR regarding whether the revised or new policy represents a major change (i.e. could significantly impact the culture of research or of the IRB at WSU). If the change or new policy is deemed to be minor, the AVPR can administratively approve it after consideration by the above parties. If the change or new policy is deemed to be major or significant, then the IRB membership must consider and vote on it. Voting on revised or new policies will occur at convened meetings of the IRBs when there is a quorum present. Approval of a new or revised policy depends on a majority vote of those members present. If the majority of the committees vote to approve the new or revised policy by majority vote at each meeting, then the policy is sent to the AVPR for final administrative approval. If the policy is not approved by the voting process above, then the AVPR cannot approve it.

### **Review by the Office of General Counsel:**

All new and revised HIC policies must be reviewed by the Office of General Counsel before final approval and implementation.

### **Exception to above procedures:**

If, in the opinion of the HIC Chair and the AVPR, a new or revised policy impacts the safety or well-being of research participants, then the Institutional Official can approve its immediate implementation.

### **Notifications:**

All IRB members and all HIC administrative staff members will be notified when a new or revised policy/SOP is implemented. The new policy/SOP will be posted on the HIC website and investigators may be notified of the change by e-mail, mailings, and/or newsletters.

### **Ongoing review of policies and procedures:**

The HIC Education Coordinator or designee, in consultation with the Office of General Counsel as necessary, will review all policies and SOPs with regard to compliance with federal, state and institutional regulations not less frequently than once every three years.