

Human Research Protection Program: Roles and Responsibilities

Background

In order to adequately protect the rights of human participants in research an effective Human Research Protection program requires an institutional organizational structure in which authority and responsibilities are clearly defined. The President of Wayne State University (WSU) has given the Vice President for Research the authority to designate the Associate Vice President for Research Compliance (AVPR) as the University's chief regulatory compliance officer for research. The AVPR also oversees inquiries and investigations of alleged violations of University policies and state and federal regulations related to human subject's protections. Wayne State University's commitment to the highest standards in human participant research also requires the cooperation and commitment of all components of the University that are involved with the conduct or oversight of human research protection; each has a distinct and critical role to play. [VHA Handbook 1200.5 7]

Authority

Wayne State University has granted the Institutional Review Board (IRB) the authority to approve, require modifications in (to secure approval), or disapprove all research activities, to suspend or terminate approval of research not being conducted in accordance with IRB requirements; observe or have a third party observe, the consent process and the conduct of the research; and the Office of Human Research Protection (OHRP) has granted the WSU IRB a Federalwide Assurance (FWA 00002460) under which all human participant research will be conducted.

Definitions

Chair: the individual who directs the proceedings of one of the HIC committees or the HIC in its entirety, and who provides expertise and leadership in a wide range of areas related to IRB functions.

HIC: Human Investigation Committee, which is the name of the IRB at WSU, refers to the five committees separately or jointly.

HIC Chair: the individual who directs the proceedings of the HIC in its entirety and who has administrative authority in a wide range of areas related to IRB functions.

IRB: a specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

Responsibilities of the Vice President for Research

On behalf of Wayne State University, the Vice President for Research (VPR) serves as the Institutional Official and assumes the obligations of the Institution's Federal Wide Assurance including signing the FWA documents. The VPR is primarily responsible for setting the level of the institutional culture of compliance, for instilling respect for human research participants and ensuring effective institution-wide communication and guidance on human participant research.

The Vice President for Research is also responsible for the appointment of HIC committee members, Chairs, and the HIC Chair. In addition, the VPR is responsible for the creation of the budget and resource allocation necessary to ensure that there are sufficient resources, space, and staff to support the IRB's review and record keeping obligations. The VPR must ensure respect for the authority of the IRB and its decisions and must ensure that the IRB is free from inappropriate influence. The VPR has delegated research compliance responsibility to the Associate Vice President for Research. [WSU Policy 3-1; 45 CFR 46.107; 45 CFR 46.304; 21 CFR 56.107)

Responsibilities of the Associate Vice President for Research Compliance

The Associate Vice President for Research Compliance (AVPR) oversees the Office of Research Compliance and Regulatory Affairs and is responsible for all areas of research compliance, including research utilizing human participants, biosafety, radiation safety, conflict of interest, scientific misconduct, and non-compliance in research. The AVPR has the authority and responsibility to support, supervise and manage selected units within the division that concern human participant research. These include the HIC, the Office of Environmental Health and Safety, and the Financial Conflict of Interest Committee [45 CFR 46.107; 45 CFR 46.304; 21 CFR 56.107; VHA Handbook 1200.5.3.].

The AVPR has the responsibility to:

- Ensure compliance with the FWA, federal regulations, state statutes, local law, IRB decisions, institutional policies, and international ethical principles for protecting human participants in research.
- Review, at least annually, in consultation with the VPR, the resources provided to the human research protection program and ensure that they are adequate.
- Review annually, in consultation with the VPR, the number and composition of HIC committees and ensure

that they are adequate to ensure that reviews are accomplished in a thorough and timely manner

- Plan improvements based on the annual review of the Human Research Protection Program
- Implement planned improvements
- Ensure that the IRB process is free of inappropriate influence by:
 - Promptly investigating all allegations of attempts to unduly influence IRB members
 - Taking corrective action against anyone investigated and found to attempt to unduly influence an HIC committee member or staff

The AVPR has the responsibility to provide oversight to the HIC by:

- Oversight of the review and approval process
- Oversight of the educational instruction and training for HIC committee members, investigators, and research

and administrative personnel in conjunction with the Education Coordinator and Compliance Officer.

- Drafting, reviewing and approving policies and procedures submitted for approval to the HIC
- Conducting institutional review of sensitive protocols that have been approved by the HIC
- Overseeing random protocol reviews and for-cause audits in coordination with the Process Improvement/Compliance Coordinator.
- Suspending or terminating protocols on behalf of the institution for non-compliance with the FWA or Wayne

State University policies and procedures.

- Notifying federal agencies and sponsors regarding compliance issues
- Instituting corrective action plans based upon audit findings.
- Serving as a liaison between the University and the community at large on issues related to protecting human

participants in research in coordination with the Community Liaison Coordinator

- Oversight of the Conflict of Interest Committee in coordination with the Conflict of Interest Coordinator
- Ensuring communication among all components of the human research community. This includes attending meetings of University wide and affiliate committees and sharing minutes and other communications between the HIC and affiliate institutions.

In keeping with WSU's education mission, the AVPR also oversees the development and presentation of University-wide educational programs and on-line training related to research compliance. These include: student and faculty awareness of human participant research, ethical obligations and compliance requirements; training of investigators and key personnel and administrative staff; participant outreach and education on the rights and responsibilities of human subjects.

Finally, the AVPR serves as a liaison between the University community and the public at large on issues related to protecting human participants in research.

Responsibilities of the HIC Chair

The HIC Chair is responsible to:

- Assist the AVPR in ensuring that HIC activities are compliant with pertinent federal, state and local regulations and institutional policies.
- Review and approve new protocols and amendments to existing protocols that meet criteria for expedited review
- Decide whether to concur that research protocols are exempt from IRB review
- Manage activities associated with applications for Single Time Use of a Test Article ("compassionate use")
- Provide approval for Humanitarian Use requests for drugs or devices
- Serve as the contact person for research questions that may arise from study participants, as listed in consent forms.
- Provide leadership to the committees and the committee Chairs on regulatory and policy issues
- Participate in the development of new policies, procedures and process improvement initiatives

Responsibilities of a Committee Chair

The individual HIC committee Chairs, or Vice Chair if the Chair is unavailable, have the following responsibilities:

- Pre-review each protocol to determine if a full board review is necessary
- Assign protocol reviewers based upon expertise
- Ensure that there is a permanent continuation reviewer on each committee
- Serve as reviewer when he/she has appropriate expertise
- Review Unexpected Problems to determine if further committee action is necessary (See Unexpected Problem Policy)
- Review responses to committee-specific minor revision requests
- Chair the committee meetings
- Answer questions and complaints from PI's, research staff, the participants or community members, directing issues to the appropriate resource person.
- Participate in the ongoing evaluation of the performance of committee members
- Propose and review new policies and procedures
- Help to ensure that committee activities comply with pertinent laws and HIC policies

Responsibilities of the Deans and Department Chairs

The College Deans and/or Department Chairs and other authorized signatories ("signatory officials") are required to certify that the Principal Investigator has the necessary expertise, facilities, resources and staff to conduct the research as described in the protocol. Signatory Officials must also affirm that the research protocol is consistent with sound research design. An affirmation statement signed by signatory official is included in the HIC forms (Medical Exempt Form, Medical/Behavior Protocol Summary Form and Amendment Form) and certifies that the above criteria have been met.

In signing the certification on the HIC forms, signatory officials ensure that the research has scientific merit and that:

- The research uses procedures consistent with sound research design.
- The research is designed to answer the proposed question
- The knowledge reasonably expected to result from the research is important
- Sufficient resources, facilities and staff to conduct the research are available

Research conducted by a principal investigator whose signatory official does not have sufficient expertise to ensure the above statements should also be reviewed and certified by an official or committee with the necessary expertise to determine the merits and probable success of the research. [38 CFR 16; 45 CFR 46; 21 CFR 56; VHA 1200.5 7]

Responsibilities of General Counsel

A representative from the Office of General Counsel (OGC) holds a position as a voting member of an HIC committee and provides legal expertise to the Human Investigation Committee as necessary. [45 CFR 46.116; 45 CFR 46.102; 38 CFR 46.116; 38 CFR 46.102]

Policy Review

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.

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 are promptly reported to the HIC Compliance Officer, the HIC Chair, or the AVPR. Further discussion and review of revisions to HIC policies are conducted with dissemination of the information to each of the committees. (See the HIC website for the General Counsel SOP).