 **IRB Policy & Procedure**

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| **Wayne State University**  **Institutional Review Board** | |
| **Subject** | **Human Research Protection Program: Roles and Responsibilities** |
| **Form Date** | February 2, 2009 (Rev. 06/23/10) |
| **Approvals** | Steering Committee: Rev. 12/07/06, Initial, All IRBs: 02/21/01 Administrative: 2/27/01  General Counsel 11/20/06, Administrative Approval 12/18/06, Administrative Approval  01/30/09, Administrative Approval 09/30/10, Administrative Approval 03, 2015 |

**Background**

Wayne State University (WSU) is committed to the safety and protection of human participants involved in biomedical and social research at our Institution and its affiliates. WSU's Human Research Protection Program (HRPP) meets or exceeds the highest ethical standards for human research required by local, state, and federal laws and regulations and is conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and the Nuremberg Code, and are consistent with Good Clinical Practice (GCP).

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/Assistant Vice President for Research (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 Federal Wide Assurance (FWA 00002460) under which all human participant research will be conducted.

Wayne State University has granted the IRB Administrative Office the authority to determine if an activity is Human Participant Research. An individual can call the IRB Administrative Office to discuss the project or the individual can complete the Human Participant Research Determination Form. If requested, the IRB Administrative Office will provide a written determination. Please see policy 1-4 Human Participant Research: How is it Defined? for the criteria used to make this determination.

**Definitions**

*IRB*: A specially constituted review body established or designated by an entity to protect the welfare and rights of human participants recruited to participate in biomedical or behavioral research.

*IRB Chair*: The individual who directs the proceedings of one of the IRB committees providing expertise and leadership in a wide range of areas related to IRB functions.

**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 the ethical obligations 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 IRB committee members and Chairs. 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/Assistant Vice President for Research [WSU Policy 3-1; 45 CFR

46.107; 45 CFR 46.304; 21 CFR 56.107].

**Responsibilities of the Associate/Assistant Vice President for Research Compliance**

The Associate/Assistant Vice President for Research (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 IRB, 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, this includes but is not limited to legal counsel, conflict of interest, and community outreach.

• Review annually, in consultation with the VPR, the number and composition of IRB committees and ensure that they are adequate and 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:

o Promptly investigating all allegations of attempts to unduly influence IRB members.

o Taking corrective action against anyone investigated and found to attempt to unduly influence an IRB committee member or IRB staff member.

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

• Overseeing the review and approval process.

• Overseeing the educational instruction and training for IRB committee members, investigators, and research and administrative personnel, in conjunction with the Associate Director, IRB Administration, Education Coordinator and Compliance Officer.

• Drafting, reviewing, and approving policies and procedures submitted for approval to the IRB.

• Conducting institutional review of sensitive protocols that have been approved by the IRB.

• 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 liaison between the University community and the public at large on issues related to protecting human participants in research in coordination with the Community Liaison Coordinator.

• Overseeing 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 IRB 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 participants.

**Responsibilities of an IRB Chair**

The individual IRB 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 (i.e., research involving human participation).

* All research protocols should be assessed to ensure that the proposed study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and are consistent with Good Clinical Practice (ICH-GCP) and the applicable regulatory requirements.

• 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).

• Manage activities associated with applications for Single Time Use of a Test Article

(“compassionate use”).

* Review responses to committee-specific minor revision requests.

• Chair the committee meetings.

• Answer questions and complaints from PIs, research staff, the participants or community members, and direct 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 IRB policies.

**Responsibilities of the Principal Investigator (PI)**

The PI is ultimately responsible for those acting on her/his behalf even if any of the PI’s responsibilities are delegated to members of the research team. PI responsibilities are to:

* Oversee the research process and be responsible for the conduct of the investigators and research staff at all study sites. Ensure compliance with research protocols, and applicable federal, state, and local laws and regulations, WSU University policies, and IRB policies and procedures
* Protect the safety and welfare of research participants. Ensure compliance with the protocol's data and safety monitoring plan and report adverse events to the respective IRB, study sponsor, and appropriate federal agencies.
* Ensure that informed consent is appropriately obtained from all participants and that participants are treated with respect and dignity.
* Complete all required human research training, and if applicable, HIPAA training, and ensure that investigators and key study personnel complete required training.
* Ensure professional training and expertise (including, but not limited to, appropriate training education, expertise, credentials and, when relevant, privileges) of co-investigators and research personnel is appropriate to perform the procedures assigned to them during the study. Review all pertinent IRB policies and procedures as part of the required initial training for conducting human research. Routinely review the Human Research Protection Program (HRPP) website for new or revised policies and procedures.
* Review scientific literature to ensure that protocol interventions are consistent with current research data and do not place subjects at unnecessary risk.
* Responsible for the adequacy of all submissions to the IRB including protocol applications, amendments, and the reporting of adverse events and/or unanticipated problems.
* Ensure the timely continuing review of protocols and the submission of all re-approval applications before the protocol's expiration date. Report protocol expirations promptly to the appropriate IRB.
* Submit proposed changes to the research in the form of protocol amendments to the appropriate IRB before the changes are implemented, except when such changes must be implemented immediately to ensure the health and wellbeing of research participants.
* Protect participants' privacy and confidentiality according to applicable HIPAA policies, WSU policies, and IRB policies and procedures.
* Maintain all study-related documentation in accordance with WSU policies, IRB policies, and federal regulations.

**Responsibilities of Study Coordinator/Research Staff/Nurse**

Individuals working on a research project under the supervision and direction of a Principal Investigator (PI). Study Coordinator, Research Staff and Nurse must:

* Perform all research-related interventions in accordance with the IRB-approved study protocol.
* Obtain, when delegated, appropriate informed consent and/or ensure continued informed consent from all participants, and treat participants with respect and dignity.
* Complete all required human research training, and, if applicable, HIPAA training.
* Comply with the IRB-approved research protocols, applicable federal, state, and local laws and regulations, WSU policies, and IRB policies and procedures.
* Comply with the protocol’s data and safety monitoring plan and report adverse events to the PI and, as appropriate, to the IRB, study sponsor, and appropriate federal agencies.
* Protect subjects’ privacy and confidentiality according to applicable HIPAA policies, WSU policies, and IRB policies and procedures.
* Maintain all study-related documentation in accordance with WSU policies, IRB policies, and federal regulations.
* May act as an intermediary between the PI and the IRB, Sponsored Programs Administration office, and study sponsor.

**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 officials is included in the IRB 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 IRB 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 (i.e., yield the expected knowledge).

• The knowledge reasonably expected to result from the research is important.

• Sufficient resources, facilities and staff to conduct the research are available.

• Provide in writing to the IRB any comments or feedback related to the scientific review, if applicable.

Research conducted by a principal investigator whose signatory official does not have sufficient expertise to ensure the above statements should 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 IRB

committee and provides legal expertise to the IRB as necessary. [45 CFR 46.116; 45 CFR 46.102; 38 CFR 46.116; 38 CFR 46.102]. In addition, the OGC:

• Reviews new policies/SOP’s to determine if they comply with all federal, state, and local laws and

University policy.

• Review all research policies and SOP’s.

• Review relevant changes in state and local laws on a regular basis.

**Responsibilities of the IRB Administrative Staff**

Administrative and professional staff support and facilitate the IRB processes:

* Provide guidance regarding the interpretation of regulations, laws, and policies to researchers, staff, and WSU administrators.
* Ensure compliance with the terms of WSU's Federalwide Assurance (FWA) as well as with WSU policies and procedures, federal regulations, and state and local laws related to the review of human research.
* Participate in the development and subsequent implementation of WSU's human research protection policies and procedures.
* Perform quality assurance monitoring of research protocols and investigate matters of non-compliance. Implement corrective action(s) as needed in accordance with federal regulations, WSU policies, and IRB policies and procedures.
* Provide human research protection training for investigators, key study personnel, IRB members, and IRB staff.
* Complete all training requirements and stay informed of current research-related and regulatory developments.
* Monitor federal regulatory websites and other research-related resources to stay current with regulatory changes in human research protection guidelines and policies. Communicate pertinent information to other IRB staff, IRB members, and investigators in a timely manner.
* Maintain IRB study-related documentation in accordance with WSU policies, IRB policies, and federal regulations

**Policy Review**

The Associate/Assistant Vice President for Research at WSU, with advice from IRB Chairs; IRB members; Associate Director, IRB Administration; Sr. Director, Compliance; IRB staff and/or investigators determines when a new or revised policy or Standard Operating Procedure (SOP) needs to be established. In most cases, the Sr. Research Compliance Specialist and/or the Education Coordinator are responsible for writing policies and SOPs. However, any IRB 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:

o The Associate/Assistant Vice President for Research;

o IRB Chair;

o Associate Director, IRB Administration;

o Education Coordinator or Process Improvement/Compliance Coordinator;

o Research Compliance Administrator; and/or

o 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 reviewed policy/SOP has been reviewed by the administrative review personnel listed above, 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:

o IRB Committee Chairs;

o IRB Committee Vice-Chairs;

o Office of General Counsel representative;

o One alternate from each IRB committee; and

o The AVPR (as ex-officio).

• After review and discussion, the IRB sub-committee will vote (by majority) to:

o Approve the policy/SOP as written; or

o Approve the policy/SOP with proposed changes; or

o Disapprove the policy/SOP; or

o 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 IRB Chair or designee.

• All IRB 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 IRB 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 IRB administrative review and General Counsel to ensure that they reflect the best current practices and comply with all relevant University policies 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 IRB are promptly reported to the IRB Compliance Officer, the IRB Chair, or the AVPR. Further discussion and review of revisions to IRB policies are conducted with dissemination of the information to each of the committees. (See the IRB website for the General Counsel SOP.)