# IRB Policy & Procedure

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| **Wayne State University Institutional Review Board** | |
| **Subject** | **01-3 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, Administrative, General Counsel and IRB Approval 12/2019: Policy revisions combine 04-14 General Counsel: Roles and Responsibilities, Administrative Approval 3/22/2020, Administrative, General Counsel 07/2024, IRB Approval 08/2024, Administrative Approval 12/2024 |

**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, Nuremberg Code and the Belmont report. Our HRPP is compliant with

International Conference on Harmonization - Good Clinical Practice Guidelines (ICH-GCP) when required by a sponsor to the extent the guidelines are compatible with FDA regulations.

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 [For information about the components of the WSU HRPP, see WSU IRB Policy 01-2 Human Research Protection Program.

# 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; to 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 [04-02 Initial Protocol Submission](https://research.wayne.edu/irb/docs/document-005-policy-04-02-initial-protocol-submission-requirements.doc) [Requirements](https://research.wayne.edu/irb/docs/document-005-policy-04-02-initial-protocol-submission-requirements.doc) and our [Human Participant Research Determination Tool](https://research.wayne.edu/irb/docs/hpr_determination_tool_revised_for_cr.doc) and [Guidance Document.](https://research.wayne.edu/irb/docs/hpr_guidance-_activities_that_are_not_hpr_4_10_19.pdf)

**1.0 Definitions**

*Federalwide Assurance (FWA):* This is a confirmation of compliance with the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule) for the protection of human subjects in research, guided by the principles of the Belmont Report.

*Faculty Sponsor/Mentor:* The faculty member responsible for providing guidance and mentorship to student/resident Principal Investigators.

*Institutional Review Board (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.

*Principal Investigator (PI):* The person responsible for the conduct of research with human participants. This individual must have the experience, expertise, professional qualifications, research facilities, and resources necessary to ensure that the rights and welfare of the human participants are protected.

**2.0 Responsibilities of the Vice President for Research**

The VPR is 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 VPR is responsible for the evaluation of HRPP resources (personnel, technology, and office space) to support the HRPP components including the IRB, HRPP/IRB Education, Conflict of Interest, Sponsored Programs Administration, Community Outreach, Quality Improvement and Legal Counsel support. The evaluation is conducted at least annually, with adjustments made as necessary.

In addition, the VPR is responsible for the creation of the budget and resource allocation necessary to ensure that there are sufficient resources to support the IRB review process 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 allowed to function independently free from attempts to coerce or otherwise unduly influence the actions of the IRB (See section 5.1.2 of IRB policy 1-2 WSU HRPP). The VPR has delegated research compliance responsibility to the Associate/Assistant Vice President for Research [[WSU HR Policy 99-4 section 3.0;](https://policies.wayne.edu/hr/99-4-personnel-actions) 45 CFR46.107; 45 CFR 46.304; 21 CFR56.107].

# 3.0 Responsibilities of the Associate/Assistant Vice President for Research Compliance

The Associate/Assistant Vice President for Research (AVPR) serves as the Institutional Official and assumes the obligations of the Institution’s Federal Wide Assurance including signing the FWA documents. The AVPR oversees the Office of Research Integrity 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.
* Appoint IRB committee members and Chairs.
* Plan improvements based on the annual review of the Human Research Protection Program.
* Implement planned improvements.
* Ensure that the IRB is able to function independently without attempts to coerce or otherwise unduly influence the decisions of the IRB.
  + Promptly investigate all allegations of attempts to unduly influence IRB functions and/or IRB Members, or IRB Administration Office staff member.
  + Oversee the implementation of corrective actions to prevent coercion or undue influence of IRB functions and/or IRB members or IRB Administration Office staff members.

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 Director HRPP, IRB Training Coordinator and IRB Administration.
* 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 Sr. Research Compliance Specialist
* 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 IRB Training Coordinator acting as the Community Liaison.
* Overseeing the Conflict of Interest Committee in coordination with the Conflict of Interest Committee Manager.
* 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.

# 4.0 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 all applicable regulatory requirements.
* Assign protocol reviewers based upon expertise.
* Determine if an outside consultant is needed when the IRB roster lacks relevant expertise.
* Ensure that there is a permanent continuation reviewer on each committee.
* Serve as reviewer when he/she has appropriate expertise.
* Review Unanticipated Problems to determine if further committee action is necessary (see WSU IRB Policy 13-1 Unanticipated Problems and Event Reporting).
* Manage activities associated with applications for Single Patient Expanded Access requests.
* 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.

# 5.0 Responsibilities of the Principal Investigator (PI)

The PI is 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 described in [WSU IRB Policy 06-01: Principal](https://research.wayne.edu/irb/docs/document-024-policy-06-01-principal-investigator-roles-and-responsibilities.doc) [Investigator- Roles and Responsibilities](https://research.wayne.edu/irb/docs/document-024-policy-06-01-principal-investigator-roles-and-responsibilities.doc)

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# 6.0 Responsibilities of Study Coordinator/Research Staff/Research Nurse

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

**7.0 Responsibilities of the Deans and Department Chairs**

The College Deans and/or Department Chairs and other authorized signatories (“signatory officials”) are asked to certify that the Principal Investigator has the necessary expertise, facilities, resources, and staff to conduct the research as described in the protocol. The signatory official is also responsible for ensuring the following elements of the protocol’s scientific merit:

* 1. the research design is sound enough to yield the expected knowledge
  2. the aims/objectives are likely to be achievable within a given time period
  3. the rationale for the proposed number of participants is reasonable
  4. the scientific design described is adequately justified
  5. there is a clear differentiation between research procedures and standard care and evaluation

In signing the certification on the IRB forms, signatory officials certify that **(a)** appropriate support will be provided for the research project including adequate facilities and staff;**(b)** appropriate scientific and ethical oversight has been and will be provided; and **(c)** the research uses procedures consistent with sound research design; **(d)** the research design is sound enough to yield the expected knowledge.

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].

**8.0 Responsibilities of the Faculty Sponsor/Mentor:**

When the Principal Investigator (PI) of a research study is a resident, fellow, trainee, or student, then a faculty advisor/mentor/sponsor must be designated. Throughout this policy we refer to this role as faculty sponsor/mentor. The Wayne State University’s HRPP/IRB holds the faculty sponsor/mentor responsible for the overall management of all human participant research activities in conjunction with the PI. Management of the research encompasses the ethical, administrative, fiscal, and conduct of research involving human participants and/or their data. Faculty sponsor/mentors are required to:

* Guide and mentor the PI in a **culture of responsible research and ethical practice**, including the requirements of the IRB and the required [Responsible Conduct of Research course](https://gradschool.wayne.edu/students/professional-development/responsible-conduct) conducted by the graduate school.
* Collaborate with the PI during the preparation of a research protocol and IRB submission.
* Ensure the PI and faculty sponsor/mentor have adequate training and experience to conduct the research in accord with the protocol, including, but not limited to any cultural sensitivities, cultural norms, and/or dialect spoken.
* Fulfill the IRB’s human participant research training requirements (See the IRB [Mandatory Training website](https://research.wayne.edu/irb/mandatory-training) for more information about training requirements).
* Ensure the PI understands the responsibility of being a PI in human participant research and has reviewed and agrees to comply with IRB Policy [6-1 Principal Investigator: Roles and Responsibilities](https://research.wayne.edu/irb/docs/doc122_policy_06-01_principal-investigator-roles-and-responsibilities_11_2019.doc)
* Review the PI’s research plan to ensure the proposed research fulfills the following criteria:
  + Scientific and ethical aspects are appropriate for the study design,
  + Complies with the ethical principles outlined in the [Belmont Report](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/), all applicable human participant (subject) research federal regulations including [45 CFR 46](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html), university policies including [HRPP/IRB policies](https://research.wayne.edu/irb/policies-human-research) and other applicable federal or state laws,
  + Protects the rights and welfare of human research participants,
  + Confidentiality and security of all information obtained from and about human participants is maintained,
  + Privacy of human participants is maintained.
* Be familiar with the WSU IRB submission requirements, submission process, the IRB’s review process and IRB guidance and resources available to investigators.
* Report any real or potential conflicts of interest (COI) in compliance with the conflict of interest policies:
  + [Research Integrity COI website](https://research.wayne.edu/integrity/conflict-of-interest)
  + [IRB Policy 14-1 Conflict of Interest: Principal Investigator/Key Personnel](https://research.wayne.edu/irb/docs/doc150_policy_14-01_conflict-of-interest-pi-key-personnel_11_2019.doc)
* Review materials prepared by PI for IRB review and complete required actions before submitting them to the IRB. (Obligations & COI Statement)
* Consult with the PI on a regular basis to monitor research progress. Regular monitoring of the research process and maintaining IRB requirements. should include the following:
  + Ensure all required subsequent submissions such as amendments, unanticipated problems, and other reportable events, continuation/renewal/status updates and closure reports have been reviewed and approved by the IRB,
    - **Note:** A study closure/final report may be submitted by the faculty sponsor/mentor if the PI is no longer with the institution and cannot be successfully reached. The faculty sponsor/mentor must notify the Chair/Dean whenever a closure/final report must be submitted for the PI.
  + Ensure PI promptly reports any reportable events to the IRB in a timely manner according to the IRB Policy [13-1 Unanticipated Problems and Other Reportable Events](https://research.wayne.edu/irb/docs/13-01_unanticipated_problems_and_event_reporting_policy_8_1_2019.doc)

**9.0 Dean of Students:**

A representative from the Dean of Students Office grants researchers’ authorization to conduct research when the target population is WSU students. This applies only when recruiting or enrolling individuals from the WSU student general population. Authorization from the Dean of Students is not required when investigators are recruiting student participants from their own department/college.

The Dean of Students approves the recruiting and conduct of human participant research that is proposed to taking place at the WSU student center. The Dean of Students provides researchers with a letter of support to document authorization for the proposed research.

**10.0 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/SOPs and major revisions to policies/SOPs to determine if they comply with all federal, state, and local laws and University policy,
    - Reviews all research policies and SOPs
    - Reviews relevant changes in state and local laws on a regular basis
* Available for consultation on issues of non-compliance, scientific misconduct and export control.

For more information about the OGC policy review process, see WSU IRB Policy 05-03 Policy and Procedure Development and Approval

**11.0 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
* Receive any public allegations of non-compliance and complaints, document the allegation or

complaint on a participant intake form and forward to the Director HRPP or IRB Operations Manager

# 12.0 Responsibilities of the Veterans Affairs Medical Center (VAMC)

* Allow the University IRB to review all VA protocols (including exempt), conduct continuing reviews; adverse event reporting, amendments and to conduct quality assurance· reviews of all VA research activities,
* Assure that the Research &Development Committee considers the IRB review, and provides initial approval prior to the conduct of covered VA human subjects research. Provide information to the IRB about significant issues that come to light in the VA approval process that might affect the conduct of a protocol.
* Assure that no human research will be conducted without IRB approval or determination that the activity is exempt from review.
* Provide access to research subjects clinical records and/or case files to IRB as required for monitoring research activity. This includes any IRB member or designee.
* Provide access and training to IRB regarding VA policies and procedures that govern the VA Human Research Protection Program (HRPP) processes and determinations.
* Appoint two individuals to represent the VA Medical Center on each IRB that reviews VA research. At least one member will have scientific expertise. VA IRB representatives will have full voting membership of the IRB. At least one representative must be member of the R&D Committee. At least one VA representative will be present during full board review of VA research.
* Provide all necessary VA procedures and policies for inclusion in the University IRB SOP, so that the SOP can effectively be shared as one document.
* Assure that all key VA personnel engaged in research meet both VA and IRB training requirements and that there is a tracking system.
* Provide and facilitate the use of VA Forms 10-1086 by the University IRB.
* Adhere to requirements of University IRB regarding reporting of Conflict of Interest for IRB members.