

WAYNE STATE UNIVERSITY HUMAN RESEARCH PROTECTION PROGRAM (HRPP)

Wayne State University's HRPP is a comprehensive university-wide program that ensures the safe and ethical conduct of human participant research by all faculty, staff, and students of Wayne State University and its affiliates. This program includes review of proposed research by relevant oversight committees; continuing oversight for compliance with applicable regulations and policy; education and training for investigators, staff, and committee members; quality assurance; and continuing process improvement. The realization of the University's commitment to the highest human participant protection standards requires the dedication of all members of the WSU research community and University administration.

Mission Statement

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. Our mission is to create an institutional culture that values integrity in the conduct of research as well as the pursuit of knowledge and innovation that provide human benefit.

In accordance with ethical principles, applicable laws and regulations and our Federal-wide Assurance, the Wayne State University's Institutional Review Board (IRB) **must approve all research involving human participants, both biomedical and social science/behavioral, before research commences.**

Authority

WSU has established a Federal-wide Assurance (FWA 00002460) through the Office of Human Research Protection (OHRP) to conduct human participant research. WSU's FWA covers all human participant research, both biomedical and behavioral, conducted at Wayne State and its affiliates, regardless of the source of funding. WSU's FWA covers faculty, employees of WSU and its affiliated institutions, students, trainees, and anyone conducting such research under the auspices of WSU or its affiliates. All research carried out at WSU or its affiliates' sites by individuals not otherwise associated with WSU (e.g., an investigator from an outside institution) needs review and approval from both institutions' IRBs. Local (WSU and its affiliates) investigators who wish to use an outside IRB as the IRB of record for a particular research study must apply to the IRB for authorization to do so.

All research that meets the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), or Department of Defense (DoD) definition of human participant research is subject to the policies and procedures of the HRPP and review by WSU's Institutional Review Board (IRB). See "What is Human Participant Research", available on the IRB website, for assistance in this determination. For further assistance, investigators are encouraged to contact the IRB Administration Office. Pre-review of submitted protocols is conducted by specified individuals within the IRB Administration Office for certain types of research.

The IRB has the authority to approve, require modification in (to secure approval), or disapprove human research activities at WSU and its affiliate institutions; to suspend or terminate approval of research not being conducted in accordance with pertinent laws, IRB requirements or University policy; and to observe, or have a third party observe, the consent process and other aspects of the conduct of the research.

Ethical Principles, Laws and Policies

In accordance with its dedication to the highest levels of research integrity, all research at Wayne State University is conducted in compliance with the principles of the Belmont Report and other ethical codes of conduct for research, such as the Declaration of Helsinki and the Nuremberg Code, and is consistent with Good Clinical Practice (GCP) guidelines. Wayne State has made a commitment to conduct *all* research, regardless of sponsorship, under these principles and all relevant local, state, federal and international regulations in order to provide the same high level of protection for all human participants.

The determination of whether research meets the definition of “human participant research” is based on the following definitions established by the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), and the Department of Defense (DoD):

Human Participant

DHHS: A living individual about whom an investigator (whether professional or student) (1) conducting research obtains data through intervention or interaction with the individual, or (2) identifiable private information. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

DoD: Research supported by the Department of Defense and “involving a human being as an experimental subject” is subject to the Federal Policy for the protection of human subjects in research, i.e., the Common Rule. However, because of the DoD culture, organizational structure, and population, DoD Directive 3216.02 lays out additional requirements that apply as well. In the case of human research sponsored by the Department of the Navy, Secretary of the Navy Instructions (SECNAVINST 3900.39D) apply. These requirements are designed to cover risks unique to DoD employees that differ from civilians both in the conduct of research and in participation in research (e.g., deployability, personal conduct standards, and duty to report certain personnel actions).

FDA: In addition to the above, FDA related research must also comply with the following definition: an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human (individual) or a patient. For research involving medical devices, a human subject is also an individual on whose specimen an investigational device is used.

Research

DHHS: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

FDA: Research also includes clinical investigation which is defined as “any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration (FDA) or is not subject to requirement for prior submission to the FDA as part of an application for a research or marketing permit.

Federal Regulations

WSU complies with the Code of Federal Regulations (CFR), the Common Rule, as it applies to human participant research. These include the regulations from DHHS [45 CFR 46] and its subparts, the FDA regulations [21 CFR 50 and 56], the Veterans Administration regulations [38 CFR 46] including subparts, and all other relevant federal regulations.

The Common Rule and FDA regulations do not preempt other state and federal laws relating to the conduct of human research or to other aspects of the research itself. This guidance document describes related federal and state laws which may have bearing on the conduct of human research at WSU. The descriptions provided below are intended to assist investigators and the IRB in determining when such laws and regulations may apply and are not intended to provide the detailed information required to ensure compliance with these laws/regulations. Investigators and IRB staff should consult the applicable regulation for additional guidance.

45 CFR 46 Common Rule: Describes the requirements for IRB review and approval of research involving human subjects. Subpart A is known as the “common rule” as it has been adopted by the following federal agencies:

- Department of Health and Human Services (45 CFR 46)
- Department of Agriculture (7 CFR 1C)
- Department of Energy (10 CFR 745)
- Department of Housing and Urban Development (24 CFR 60)
- Department of Justice (28 CFR 46)
- Department of Education (34 CFR 97)
- Department of Veterans Affairs (38 CFR 16)
- Environmental Protection Agency (40 CFR 26)
- National Science Foundation (45 CFR 690)
- Department of Transportation (49 CFR 11)

(Note: Subparts B, C, and D have been adopted only by DHHS.)

Health Insurance Portability Privacy Act (HIPAA)

The IRB also serves as the HIPAA Privacy Board for all human participant research at WSU and its affiliates. It must assure that HIPAA rules and all other privacy and confidentiality regulations are met for all research conducted at WSU and its affiliates (45 CFR 46, Parts 160, 162, and 164; 38 CFR 46, Parts 160, 162, and 164).

State and Local Law

Wayne State University is committed to assuring that human participant research complies with all applicable state and local law. An attorney from WSU's Office of the General Counsel (OGC) is a full voting member of the IRB and therefore maintains updated knowledge of pertinent regulations and IRB policies. All IRB policies, and changes to policies, are reviewed by this attorney member to ensure their compliance with state and local law. New laws that require the immediate attention of the IRB are reported to the Compliance Officer and the IRB Chair, and the information is reported at the next scheduled IRB meeting. Relevant information is also disseminated to the research community by the Associate Director-IRB Administration. [45CFR 46.116; 45 CFR 46.102; 38 CFR 46.116; 38 CFR 46.102]

Wayne State University Statutes and Policy

University Research Policy

- Classified research, that is any research placed under restrictions that prevent it from being freely described and its results openly published in the traditional manner, shall be excluded. This provision may be waived in a national emergency, and then only in circumstances that require University participation. A sponsor, upon request, may have the privilege of reviewing a report of the results of an investigation prior to publication, but publication delays beyond 90 days are not acceptable (2.41.01.140).
- In all research programs accepted by the University, respect for the dignity of human beings and the humane treatment of research animals must be assured (2.41.01.150).

Wayne State University Policies (UP)

- **Delegation of Authority:** The Senior Vice Presidents, Vice Presidents and Chief of Staff are hereby delegated authority to appoint persons who serve in positions designated subject to the pleasure of the president in their respective divisions and are delegated authority to subdelegate in writing to associate vice presidents, assistant vice presidents, deans and directors the approval of appointments within their respective division. All subdelegation authority designations must be in writing with notification submitted to the Senior Vice President for Finance and Administration or his/her designee. (UP 99-4 §3-2)

- **Conflict of Interest Disclosure:** Wayne State University recognizes that conflicts of interest may exist because of relationships of management personnel and members of their immediate family with external parties with which Wayne State University conducts business, and seeks to minimize them. (UP 08-01§ 1.1)
- **Investigator Disclosure:** Wayne State University is required to have a policy for the disclosure of information by faculty and staff engaged in sponsored research and procedures for institutional review of the relevance of personal outside interests to the integrity of proposed sponsored research (UP 08-02 § 1.1).

Administrative Policies and Procedures Manual

- **Legal Services:** The Office of the General Counsel is responsible for all legal services required by the University and its faculty, staff, employees and students in the conduct of the University affairs (10.4).

HUMAN RESEARCH PARTICIPANT PROTECTION PROGRAM MANUAL

The HRPP Manual describes the basic underlying principles and organizational structure of the Wayne State University Human Research Protection Program. Information concerning the Office of Research Compliance and Regulatory Affairs, the IRB, and the IRB policies and procedures are included. The manual contains all contact numbers and email addresses necessary to submit complaints, questions or comments, report issues of non-compliance or scientific misconduct or report undue influence on the IRB. The HRPP Manual is available to the research community on the websites of the Office of the Vice President for Research and the IRB, and hard copies are also available at the IRB Administrative Office and in the Office of Research Compliance and Regulatory Affairs.

IRB Oversight

The Vice President for Research has delegated authority to the Associate/Assistant Vice President for Research (AVPR) to provide oversight to the IRB by:

- Ensuring compliance with the FWA, federal regulations, state statutes, local law, IRB decisions, Institutional policies, and international ethical principles for protecting human participants in research.
- Oversight of the IRB review and approval process to ensure compliance with pertinent policies and regulations.
- Oversight of the educational instruction and training for IRB members, investigators, and research and administrative personnel in coordination with the Associate Director- IRB administration.
- 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 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 a liaison between the University and the community at large on issues related to protecting human participants in research;
- Oversight of the Financial Conflict of Interest (COI) Committee in coordination with the COI Coordinator;
- Oversight of biosafety and radiation safety programs through the Office of Environmental Health and Safety, which reports to the AVPR;
- Ensuring communication among all components of the human research community. This includes sitting on relevant university and affiliate committees and sharing minutes between the IRB and affiliate institutions.

INSTITUTIONAL AFFILIATIONS AND AGREEMENTS

Wayne State University has a unique relationship with the Detroit Medical Center, the John D. Dingell Veterans Affairs Medical Center, and the Oakwood Healthcare System. The affiliation agreements between these organizations specifically state that all human research activities will be conducted under the auspices of the WSU IRB, while clinical care will be conducted under the auspices of the specific health care institutions.

WSU MEDICAL AFFILIATES:

- Detroit Medical Center (Contract)
The hospitals of the Detroit Medical Center:
 - Children's Hospital of Michigan
 - Detroit Receiving Hospital/University Health Center
 - Harper University Hospital
 - Huron Valley-Sinai Hospital
 - Hutzel Women's Hospital
 - Kresge Eye Institute (operating rooms)
 - Michigan Orthopedic Specialty Hospital
 - Rehabilitation Institute of Michigan
 - Sinai Grace Hospital
- John D. Dingell Veterans Affairs Medical Center (Memo of Understanding)
- Metropolitan Detroit Research and Education Foundation
- Oakwood Healthcare System (Contract)

Overview of the IRB

Wayne State University has five (5) separate committees that are constituted as IRBs, and which have oversight over all human participant research at WSU and its affiliates registered under the Wayne State FWA. There are four IRBs that review medical protocols involving adult participants (PH1, M1, MP2, and MP4). Two of these IRB's (MP2 and MP4) are qualified to review research involving minors (individuals younger than 18 years of age). The Behavioral IRB (B3) is responsible for reviewing all behavioral and social science research in adults and minors.

Each committee that reviews John D. Dingell Veterans Administration Medical Center (VAMC) protocols maintains at least two (2) representatives from the VAMC. Each committee also includes members as required by federal regulations:

- at least one member whose discipline is nonscientific;
- at least one community (unaffiliated) member;
- appropriate scientific expertise.

The IRBs have the authority and responsibility to approve, require modifications to, or disapprove all human subject research before it is initiated in order to comply with ethical principles and federal, state and local regulations and institutional policy. With the exception of exempted research, the IRBs provide continuing oversight of all human participant research, at least yearly. The IRBs have the authority to assure, on an ongoing basis, that the risks of proposed research are justified by the potential benefits to the participants and to society, that the risks do not fall disproportionately on one group and that risks are minimized to the extent possible consistent with sound research design.

The IRBs are authorized to oversee the consenting process to ensure that agreement by an individual to participate in research is voluntary and knowing. Individuals who are particularly vulnerable (pregnant women, fetuses, children, prisoners, students, employees, or those whose capacity to consent may be in doubt) require additional protection during the consent process. In addition, there are designated members of the IRB committees to represent prisoners, handicapped and other vulnerable categories.

In addition to the AVPR and the IRB Chair, IRB committees have the authority to initiate random and for-cause audits to determine compliance with the research protocol and WSU policies and procedures. They inform the Associate/Assistant Vice President for Research of all suspensions, terminations and occurrences of noncompliance so that appropriate administrative action can be taken.

To prevent undue influence, the IRB acts independently of university officials or anyone who is not an official member of the IRB. No individual shall attempt to influence the IRB inappropriately on any matter before the IRB, or within the IRB's jurisdiction. The AVPR has the authority to oversee compliance issues and is charged with investigating allegations of undue influence upon the IRB and with taking corrective action if necessary.

The IRB Chair

The IRB Chair provides leadership for the IRB members of their individual committee, and serves as a liaison between the IRB and investigators when issues arise. He/she works closely with the Associate Director, IRB Administration; Sr. Director, Compliance; and the AVPR on regulatory issues. The IRB Chair

is also charged with reviewing and approving expeditable protocols, amendments, and continuations, as well as concurring with exemptions. The IRB Chair reviews applications for Single Time/Emergency Use of a Test Article and Humanitarian Use Device applications. He/she reviews deaths and other serious adverse events in consultation with other IRB Chairs and/or the Associate Director, IRB Administration or Sr. Director, Compliance. The telephone number of the office of the IRB Administration Office is listed on all Wayne State University and affiliate consent forms for the Chairs as the contact person for research participants who have questions or concerns.

Financial Conflict of Interest (FCOI) Committee

The FCOI Committee has review and oversight responsibility for financial conflicts of interest disclosed by researchers at WSU and its affiliates. Conflict of interest is identified through required disclosure at submission of each IRB protocol, yearly and within 30 days of any significant change. The committee members serve in various roles and disciplines from across the University and can include the AVPR. The FCOI Committee meets at least twice yearly, or as necessary, to develop management plans and update policies and procedures for compliance with federal regulations. For situations involving minimal to moderate conflicts of interest, a subcommittee meets as often as necessary to review these in a timely manner.

Institutional Biosafety Committee (IBC)

The IBC has review and oversight of research involving recombinant DNA and the use of biological agents. Research involving recombinant DNA and the use of biological agents must contain an approval from the biosafety committee prior to IRB approval.

Affiliate Hospital's Radiation Safety Committees

Each of Wayne State's affiliate hospitals' has their own radiation safety committee for the safe and lawful use of ionizing radiation. Each of the Radiation Safety Committees provides oversight, review and approval for the use of ionizing radiation in their institutions for research protocols over and above standard of care. This review and approval is required prior to submission to the IRB.

Additional HRPP Oversight Components

Deans and Chairs and Center and Institute Directors

The College Deans, Department Chairs and Center and Institute Directors, or their designees, 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. Deans and Chairs must also affirm that the research protocol is consistent with sound research design and is sound enough to yield the expected knowledge. An affirmation statement signed by the Dean or Chair is included in the Protocol Summary Form and certifies that the above criteria have been met. WSU's affiliates designate authorized signatories for their researchers' protocol submissions, and these signatories are on file in the IRB Administration Office.

Sponsored Program Administration

The Sponsored Program Administration (SPA) serves as an interface between the IRB, the PI and the granting agency. SPA reviews grant applications or contract proposals to ensure that research proposals involving human participants have or will have IRB review and approval before an account is established. The Sponsored Programs Form for External Support inquires if human subject research is a component of the research proposal. If so, the IRB letter of approval for a project is required before an account is established. Contracts for clinical trials are sent to the AVPR's office where they are reviewed for consistency with the IRB approved consent forms.

At the time of the award, SPA provides the sponsor with documentation of 1) final IRB approval and 2) verification that all "key personnel" have completed the mandatory WSU or other WSU approved human research participant training program. When a protocol has been closed, suspended or terminated SPA resolves the account based upon the contract/agreement. It is the responsibility of the SPA staff to ensure that all performance sites cooperating in the conduct of research maintain an FWA, the appropriate assurance of compliance, or both.

Technology Commercialization

The Associate Vice President for Research and Technology Commercialization oversees the Technology Commercialization Office (TCO) which is responsible for the identification, protection, marketing and licensing of intellectual property (e.g., patents, unique biological or other materials, and copyrights) developed by Wayne State University faculty. TCO requires that all material transfers having to do with human participants (e.g. DNA, blood, serum, tissue) have been reviewed and approved by the IRB via an Affirmation Memo requesting the IRB approval letter. Faculty are referred to the Biosafety office for special handling procedures in the transfer of biological agents.

Office of General Counsel

A designated member of the Office of General Counsel (OGC) reviews all IRB policies for compliance with federal, state and local law and University policy prior to their being submitted for final approval by the AVPR, and yearly thereafter. The OGC keeps up to date with all relevant changes in state and local law. Laws that require the immediate attention of the IRB are reported to the IRB Compliance Officer and the IRB Chairs immediately and the information is reported at the next IRB meetings and disseminated to the research community by the Associate Director- IRB Administration. A representative of OGC is a member of at least one IRB board.

Graduate School

All graduate students are required to submit the Doctoral Dissertation Prospectus and Record of Approval Form which requires the student to submit an IRB approval letter if the research includes human participant

research. This form is then signed by the student, Dissertation Advisory Committee, the Departmental Graduate Advisor and the Dean of the Graduate School.

The Graduate School also provides additional information to students on university research compliance policies and procedures in the Internal Research Support Booklet available in the Graduate Office and website, Human Investigation Committee offices and the Office of the Vice President for Research and Research Compliance and Regulatory Affairs.

In addition, the initial graduate student packet includes a flyer on human participant research with the contact numbers of the Office of Research Compliance and Regulatory Affairs and the HIC.

Communication with Other Research Components

Department of Psychiatry Protocol Review Board (PPRB)

The ten member Psychiatry Protocol Review Board pre-reviews all Wayne State faculty Psychiatry and Behavioral Neuroscience proposals prior to being submitted to the HIC. All protocols from the Dept. of Psychiatry must have a letter of approval letter from the PPRB at submission.

John Dingell Veterans Medical Affairs Clinical Investigation Committee (CIC)

The CIC, a subcommittee of the JDVAMC Research and Development Committee, pre-reviews all VA projects involving human participants for scientific merit, ethics and compliance with federal VA regulations prior to submission for IRB review. All protocols from the John D. Dingell VA must have an approval letter from CIC at submission. The IRB maintains a representative as a non-voting member of the CIC committee to ensure consistency in human participant policies and procedures between the two institutions.

Barbara Ann Karmanos Protocol Review Committee (PRC)

The Karmanos PRC pre-reviews the scientific merit of cancer research protocols, ensures prioritization of therapeutic cancer protocols according to the Institute's scientific priorities and monitors scientific progress. All protocols from Karmanos must have an approval letter from the PRC at submission.

Perinatal Clinical and Research Board (PCARB)

The PCARB discusses Pediatric and Obstetrics/Gynecology protocols to provide guidelines and input into the conduct of innovative care and to help determine when it meets the definition of human subjects research. The AVPR is a voting member of this committee.

Detroit Medical Center (DMC) Research Review Process

The DMC Research Review Process requires investigators using DMC facilities to apply for authorization to perform research at DMC sites. The Research Review Process conducts a screening process that allows the DMC to review proposed studies, budgets and performance site agreements in order to ensure that they are appropriately structured to comply with State and Federal regulations and DMC policy. This review and approval are done prior to IRB review.

Oakwood Healthcare System Clinical Trials Office

The Oakwood Healthcare System requires investigators using Oakwood facilities to apply for preauthorization to perform research at a specified site(s). A screening process is conducted to ensure that

the research is appropriately structured to comply with State and Federal regulations as well as Oakwood policy and includes a review of the proposed study for scientific merit, the budget, and performance site(s) agreement. Administrative sign off on new projects is required prior to submission to the IRB. A Research Project Administrative Approval (RPAA) document must be included with all submissions to the IRB. Resident projects require a separate review from the Resident Research Review Committee and that approval must be included (in addition to the RPAA) with a protocol submission to the IRB.

Advisory Committees

The Faculty Research Advisory Committee

The Faculty Research Advisory committee meets quarterly to advise the Vice President for Research on matters related to research policies, procedures and direction at Wayne State University. The committee provides a forum for faculty to present input on the research environment of the university, including issues related to human participant research.

The Research Deans and Directors Committee

The Research Deans and Directors Committee meets bi-monthly to exchange information and discuss all aspects of research. The committee meetings provide an opportunity to discuss human subject compliance issues and gain input from individuals closely involved in the research endeavor from across the university.

Study Coordinators Advisory Committee

The Study Coordinators Advisory Committee is a quality improvement committee for research and the IRB and is comprised of self-nominated research coordinators from Wayne State University and its affiliate institutions. The purpose of this committee is to:

- suggest ways to improve communication between the IRB, Principal Investigators and their research coordinators
- discuss solutions to common problems encountered in managing research data, coordinating studies, and meeting the requirements of the IRB and federal regulators;
- identify necessary educational programs;
- identify improvements in the quality of the human research protection program.

Internal Meetings in the Office of the Vice President for Research

Vice President for Research and Executive Management

The VPR and the AVPR meet every week as part of an executive management meeting where each Associate/Assistant VP reports on the past week's activities. Additional meetings between the VP and AVPR occur as the need arises. These meetings involve issues concerning compliance and include a continual evaluation of the current resources and efficacy of the HRPP.

AVPR and Directors

The AVPR for Compliance oversees two Directors, who in turn oversee staff in their respective areas of compliance. The AVPR meets twice per month with the Directors to discuss compliance and regulatory issues.

Education and Training

WSU's Office of Research Compliance assumes the responsibility for providing education to the research community on ethical principles, laws, policies, regulations and university policy concerning human participant research. To facilitate this responsibility the IRB maintains an Educational Coordinator whose duties include the initial and ongoing training and education of IRB committee members, IRB administrators, research investigators, key personnel and appropriate staff. All IRB members, staff, and researchers must complete online training from the Collaborative Institutional Training Initiative (CITI). The Associate Director- IRB Administration and the Education Coordinator are responsible for notifying IRB members, IRB staff, and the research community at WSU and its affiliates of changes in IRB policy, federal regulations, as well as state or local laws or statutes. Notification is sent out promptly via e-mail (listserv), and is relayed at IRB meetings allowing discussion and clarification for IRB members. Revised policies, regulations, laws, or statutes are also posted on the IRB website with appropriate identification (i.e., "NEW") affixed to the link.

For research sponsored by the Department of Defense, initial and continuing research ethics education is required for all personnel who conduct, review, approve, oversee, support, or manage human participant research. Researchers, IRB staff, IRB members, and the research community at large will be notified of specific research requirements under a Department of Defense Addendum and educated about the requirements when appropriate.

Reappointment of IRB membership is evaluated on a regularly scheduled basis. Each individual is reviewed by the Assistant/Associate Vice President for Research, IRB Chair, the Associate Director- IRB Administration, and Director, Compliance. The evaluation consists of a review of an individual's attendance at meetings, active participation in discussion, adequacy of protocol review, and appropriate understanding of rules and regulations pertaining to research (including IRB policies and procedures, the federal code of regulations, local and state laws and statutes). Refresher CITI training courses must also be completed as a requirement for reappointment to the IRB.

IRB Committee Members

The Sr. Research Compliance Specialist attends each committee meeting to provide compliance expertise in the discussions, when needed, and also information on any recent developments in human participant regulations.

IRB members are initially required to attend an orientation session, with the Educational Coordinator, at which time they are presented with an IRB Member Manual that includes copies of Good Practices, ethical foundations and IRB policies and procedures including "Expectations of IRB Membership." New committee members must complete the online CITI training as a membership requirement. In addition, new members attend one or two committee meetings as an observer prior to achieving voting rights.

Committee members and IRB Administration Office staff receive ongoing training and updates at committee meetings, staff meetings and at the annual education seminar. Information is also disseminated through a WSU online publication "Research @ Wayne", the IRB website and instructional emails.

The IRB Chair, Associate Director-IRB Administration, and Education Coordinator are available when needed to answer any questions or concerns the IRB members may have.

Principal Investigators and Staff

All Investigators and their research staff are required to complete the CITI training modules prior to protocol approval. Successful completion of the modules is maintained in a database and is verified by IRB staff as a condition of IRB protocol approval. The Principal Investigator is also given individual training by the Education Coordinator, if requested. Individual or group training is available at any time through the Education Coordinator.

The Principal Investigator has the ultimate responsibility for administration of the research protocol. The PI must ensure that all his/her research staff has the knowledge, resources and ability to maintain the highest standards of compliance with all local, state and federal laws and regulations and University policy.

Principal Investigators and/or their staff may be required to have additional training if a compliance problem is identified.

Community

The responsibility for community outreach and education is shared between the Community Liaison, the Assistant/Associate Vice President for Research, The Associate Director-IRB Administration, and the Education Coordinator.

The IRB maintains a part time Community Liaison who speaks to interested community groups concerning the rights and responsibilities of research participants. As a part of the presentation, the liaison conducts a survey and the data are maintained for purposes of quality control.

The Associate Director-IRB Administration and the Education Coordinator and are available to take calls concerning community and participant questions and complaints. The AVPR serves as a liaison between the University and the community at large and is available for educational presentations.

PROGRAM EVALUATION PROCEDURES

Evaluation of the efficacy of the Wayne State University HRPP is the responsibility of the Vice President for Research in collaboration with the AVPR. The IRB members, staff, investigators, sponsors, administrators and participants also share in this responsibility with an obligation to report any concerns or suggestions for improvement of the HRPP. Program evaluation outside of the OVPR is actively encouraged by open access to the Office of Research Compliance and Regulatory Affairs and all departments within its oversight, and cross-membership between committees with an HRPP component.

Process Improvement and Compliance Coordinator

The Sr. Research Compliance Specialist is responsible for a continuing review of changes in all federal, state, and local laws and regulations concerning human participant research and assuring the HRPP policies and procedures are consistent with the current regulations.

The Sr. Research Compliance Specialist, in collaboration with other members of the IRB staff and the Office of Research Compliance, conduct an ongoing review of IRB policies and processes for process improvement purposes.

Audits and Protocol Reviews

The Sr. Research Compliance Specialist conducts for-cause audits and random protocol reviews. Results of the audits are reviewed with the AVPR and the IRB Chair. Serious issues are also reported to the Vice President for Research. Any systematic compliance deficiencies are discussed with the process improvement team and may result in new or revised policy, training and education programs are reflected in internal IRB processes.

Budget Review

The Vice President for Research and AVPR meet several times each year to discuss the HRPP budget needs to ensure that adequate resources are available to meet the highest standards of ethical conduct in research.

Review of HIC

The AVPR and the IRB Chair conduct an ongoing review of the number and composition of the committees to ensure that they are adequate for the numbers and types of protocols submitted to the IRB office. This evaluation occurs during regular meetings with the staff, and take into account any complaints or suggestions from researchers.

Staff Evaluations

All full-time IRB staff submit a yearly self assessment which includes job responsibilities, educational achievements, and additional training. The staff then meet with, and are evaluated by, their immediate supervisor for ongoing job efficacy.

IRB Member Evaluations

IRB members are evaluated by the AVPR, IRB Chair, Associate Director- IRB Administration, and Director- Responsible Conduct of Research to ensure that the committees maintain the required qualifications, expertise and experience. The assessment also includes the ongoing competence of each member, including expertise, meeting attendance, the number and types of reviews conducted, timeliness of reviews, ongoing training and professional development.

Yearly Risk Assessment

Each University department submits a yearly risk assessment to the Office of Internal Audit. The department self-evaluation also serves to identify potential problems that need to be addressed.

Questions and Complaints

Contact information for the IRB Chair is included on all Informed Consent forms. The IRB website and Internal Research Support booklet also contain contact information.

Professional Conferences

University officials responsible for research compliance keep current in regulatory and policy developments through membership and participation in professional associations, such as NCURA, NAILS, PRIM&R, COGR, AAHRPP, etc.

Summary

The WSU HRPP utilizes duly constituted IRBs for the oversight of all biomedical and behavioral research conducted by researchers at WSU and its affiliates. The program also encompasses a variety of University committees and University officials who are dedicated to ensuring compliance with federal state and local laws, and relevant institutional policies, in order to provide a comprehensive program for the protection for human participants in research.