

WAYNE STATE UNIVERSITY HUMAN RESEARCH PROTECTION PROGRAM

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 our affiliates. WSU's Human Research Participant 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 behavioral and biomedical, before research commences.*

AUTHORITY

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

THE HUMAN RESEARCH PROTECTION PROGRAM

The HRPP is a comprehensive university-wide system that includes research review, education, and quality assurance and compliance oversight. The realization of the University's commitment to the human participant protection standards requires the dedication of all members of the WSU research community. The HRPP programs of education and outreach and its policies and procedures ensure the safe and ethical conduct of human participant research by all faculty, staff, and students of Wayne State University and its affiliates.

ETHICAL PRINCIPLES

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. Wayne State has made a commitment to conduct *all*

research, regardless of sponsorship, under these principles and all relevant regulations in order to provide the same high level of protection for all human participants.

LAWS AND POLICIES

Wayne State University's human participant policies and procedures apply to all research activities, behavioral or biomedical, by WSU employees, faculty, and students or by individuals who are members of affiliate institutions. The determination of whether research meets the definition of "human participant research is a two step process: (1) does the research meet the definition of research required by the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) (2) does it involve human participants as defined by the DHHS or FDA. All research that meets the DHHS or the FDA definition of human participant research is subject to the policies and procedures of the HRPP and review by the IRB.

REGULATORY DEFINITIONS:

Human Participant Research: An activity that either: (1) Meets DHHS definition of "research" and involves "human subjects" as defined in DHHS regulations; OR (2) Meets the FDA definition of "research" and involves "human subjects" as defined by FDA regulations.

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.

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:

The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of this policy.

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.

LAWS, REGULATIONS AND UNIVERSITY POLICIES**Federal Regulations**

Wayne State University complies with the Code of Federal Regulations (CFR), the Common Code, as it applies to human participant research such as the Department of Health and Human Services regulations [45 CFR 46] and its subparts, the Food and Drug Administration regulations [21 CFR 50 and 56], the Veterans Administration regulations [38 CFR 46] including subparts, and all other relevant federal regulations.

Health Insurance Portability Privacy Act (HIPAA) [45 CFR 46, Parts 160, 162, and 164; 38 CFR 46, Parts 160, 162, and 164]

Wayne State’s Human Investigation Committee (HIC) serves as the HIPAA Privacy Board for all human participant research at WSU and its affiliates. It must assure that HIPAA and all other privacy and confidentiality regulations are met for all research conducted at Wayne State University and its affiliates: the hospitals of the Detroit Medical Center, and the John D. Dingell Veterans Medical Center.

Wayne State University Federal Wide Assurance (FWA)

The Wayne State University Federal Wide Assurance (A00002460) extends university policies and procedures to all human participants, in medical and behavioral research, conducted at Wayne State or its medical affiliates, regardless of the source of funding. This includes all schools, colleges and institutes. All research carried out at WSU facilities by individuals not otherwise associated with WSU (e.g., a colleague at another university using students, employees or patients from WSU as research subjects) will need approval from both university IRBs. The Wayne State FWA covers faculty, employees of WSU, employees of its affiliated medical institutions, student and trainees

and post-docs, fellows and residents. An individual who is eligible to accept responsibility for the conduct of research at Wayne State must be included as a co-investigator or faculty sponsor whenever someone from outside WSU wishes to conduct research at WSU.

State and Local Law: [45 CFR 46.116; 45 CFR 46.102; 38 CFR 46.116; 38 CFR 46.102]

As required by the Common Code, Wayne State University is committed to assuring that human participant research complies with all applicable state and local law. Prior to initial approval and yearly thereafter, all Human Investigation Committee policies are reviewed by the Office of General Counsel (OGC) to ensure their compliance with state and local law. The OGC keeps up to date with all relevant changes in state and local law. Laws that require the immediate attention of the Human Investigation Committee are reported to the Compliance Officer and the HIC chair immediately and the information is reported at the next scheduled HIC meetings. Relevant information will also be disseminated to the research community by the Educational Coordinator.

WAYNE STATE UNIVERSITY STATUTES AND POLICY

University Research Statutes

- (Section 2.41.01.150) 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.
- (Section 2.41.01.140) 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.

Wayne State University Policy

- (3-1) **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 sub delegate in writing to associate vice presidents, assistant vice presidents, deans and directors the approval of appointments within their respective division.
- (89-3) **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.

- (96-2) **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.

Wayne State University Policies and Procedures Manual

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

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, Human Investigation Committee (HIC) and Institutional Review Board are included as are all of the HIC policies and procedures. 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 widely available to the research community on the Office of the Vice President for Research website and is also available at the Human Investigation Committee offices and the Office of Research Compliance and Regulatory Affairs.

INSTITUTIONAL AFFILIATIONS AND AGREEMENTS

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

This affiliated relationship not only allows the faculty to submit one research protocol to the Wayne State University IRB regardless of where it is being conducted, it also allows faculty to have access to patients and clinical data that they might not otherwise have.

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
 - 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

HUMAN RESEARCH PROTECTION RESPONSIBILITY

Wayne State University bears full responsibility for the conduct of all human subject research covered by its Federal Wide Assurance (FWA). However, many units within the University share in this responsibility. In addition to the Office of the Vice President for Research (OVPR) and Office of Research Compliance and Regulatory Affairs (ORCRA), they are: deans of schools, chairs of departments, directors of institutes, the Sponsored Program Administration Office, Technology Commercialization, the Administrative Office of the Human Investigation Committee, the Institutional Review Boards (IRBs), principal investigators, other key personnel, and the research participants. Each has a crucial, yet distinct, role to play in protecting human participants in research.

The President of the University

The President of Wayne State University is elected by the eight member Board of Governors and then appoints his Executive Administration, including the Vice President for Research. The President of the University has the authority to delegate responsibility for research activities to the Vice President for Research. The President creates a University environment that promotes the highest standards of research integrity in human participant research.

The Vice President for Research (VPR)

On behalf of Wayne State University, the Vice President for Research assumes the obligations of the institution's Federal Wide Assurance including signing the FWA documents. He or she 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 participants' research.

The Vice President for Research is also responsible for the appointment of Institutional Review Board members, IRB chairs and the Chair of the Human Investigation Committee. In addition, the VPR must ensure that there are sufficient resources, space, and staff to support the IRB's review and record keeping obligations. The VPR supports the authority of the IRB and their decisions and ensures that the IRB is free from inappropriate influence. The Vice President for Research has delegated research compliance responsibility to the Assistant Vice President for Research.

The Assistant Vice President Research (AVPR)

The Assistant Vice President for Research 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 Assistant Vice President has the authority and responsibility to support, supervise and manage selected units within the division that concern human participant research. These include the Human Investigation Committee, the Institutional Review Boards, the Office of Environmental Health and Safety and the Financial Conflict of Interest Committee.

Critical to the Wayne State University education mission, the AVPR also oversees the development and presentation of University-wide educational programs and on-line training in 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 Assistant Vice President for Research serves as a liaison between the University community and the public at large on issues related to protecting human participants in research.

DEPARTMENTS UNDER THE OVERSIGHT OF THE OFFICE OF RESEARCH COMPLIANCE AND REGULATORY AFFAIRS

The Human Investigation Committee (HIC)

The HIC is given the responsibility to oversee the approximately 2500 active research protocols from Wayne State and their health care affiliates. The HIC is comprised of five IRBs that meet monthly:

- four specialized IRBs that review Medical and Social/Behavioral protocols
- a Steering Committee which consists of the chairs and vice chairs of the other four IRBs, at least one elected member from each IRB, several appointed members, a representative from the Detroit Medical Center and John Dingell Veterans Administration Hospital and the Assistant Vice President for Research
- support staff that is composed, in part, of:
 - Office Manager
 - Research Compliance Administrators
 - Office Clerk
 - Pre-reviewer
 - Process Improvement/Research Compliance Officer
 - Education Coordinator
 - Community Liaison
 - Adverse Events Coordinator/Administrative Assistant

HIC Oversight

The Assistant Vice President provides oversight to the Human Investigation Committee 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
- oversight of the educational instruction and training for IRB members, investigators, and research and administrative personnel in coordination with the Education Coordinator.
- 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 sitting on university wide and affiliate committees and sharing minutes between the HIC and affiliate institutions.

The Human Investigation Committee Chair

The Chair of the Human Investigation Committee is charged to review and approve new protocols and amendments to existing protocols that meet criteria for expedited review, and grant exemptions for research submissions. The HIC Chair is required to manage activities associated with applications for Single Time Use of a Test Article (“compassionate use”). The HIC Chair also serves as the Steering Committee chair, and generally sets the agenda for the monthly meetings. The telephone number of the office of the HIC Chair is listed on all Wayne State University and affiliate consent forms, as the contact person for research questions that may arise from study participants.

The Institutional Review Boards (IRB)

Wayne State University has five (5) Institutional Review Boards that have oversight over all human participant research at WSU and its affiliates registered under the Wayne State

FWA. There are three IRBs that review medical protocols involving adult participants (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.

The Steering Committee is registered as a fifth stand alone committee. It was created to ensure consistency between the four IRBs, to develop human participant policies and procedures for the University, to review all exceptions to policies, and to suspend or terminate individual protocols that may be out of compliance. In addition, the Steering Committee is charged with adjudicating issues referred by individual IRBs, approving HIC policy, and approving procedures for the operation of the HIC, and any appeals of IRB decisions.

Each medical committee that reviews Dingell Veterans Administration Hospital protocols and the behavioral committee, maintain two (2) representatives from the VA hospital. The Detroit Medical Center has a representative that sits on both the Steering Committee and a medical committee. Each committee will also include members as required by federal regulations:

- at least one member whose discipline is nonscientific
- one community member
- in protocols involving vulnerable participants, a member who has knowledge of, and experience with members of that vulnerable category.

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 will 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 Assistant Vice President for Research and the HIC Chair, 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 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 Institutional Review Board (IRB) shall act independently of university officials. No university official shall attempt to influence the IRB inappropriately on any matter before the IRB, or within the IRB's jurisdiction. The Assistant Vice President for Research 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. Any violation of this policy should be reported to either the Vice President or Assistant Vice President for Research who shall have the authority to take such action as required to bring the university into compliance.

Conflict of Interest Committee (COIC)

The Conflict of Interest Committee and Subcommittee have review and oversight responsibility over financial, nonfinancial, and institutional conflict of interest concerning Wayne State University faculty, staff and students and the University affiliates, in the conduct of research. Conflict of interest is identified with required disclosure at submission of each protocol, yearly and within 30 days of any significant change. The Conflict of Interest (COI) Committee is a twelve member committee who serve in various roles and disciplines from across the University and includes the Assistant Vice President for Research. The COI Committee meets at least twice yearly, or as necessary, and addresses major conflicts of interest. For situations involving minimal to moderate conflicts of interest, a subcommittee which consists of the Assistant Vice President for Research and the Conflict of Interest Coordinator, meets as often as necessary to review these in a timely manner.

Institutional Biosafety Committee (IBC)

The Director of Environmental Health Safety and Health Physics reports to the Assistant Vice President for Research and serves the University in the area of bio-safety, the control of hazardous materials, and compliance with public health codes and regulations. The Biosafety Committee has review and oversight of research involving recombinant DNA, radiation and the use of biological agents. A representative from the Bio-safety office reviews all protocol summary forms prior to the assigned IRB meeting to determine if it is necessary to conduct an additional bio-safety review. If a review is required, the protocol must contain an approval from the bio-safety committee prior to IRB approval. The membership includes: the Assistant Vice President for Research, the Director of Environmental Health and Safety and representatives of John Dingell Veterans Hospital and Henry Ford Hospital.

Radiation Safety Committee

The Wayne State University Radiation Safety Committee establishes rules and policies for the safe and lawful use of ionizing radiation. The Committee provides oversight for the use of ionizing radiation and grants use authorization to qualified research faculty members. The Committee consists of the Associate Vice President for Research, Assistant Vice President for Research, Radiation Safety Officer, and authorized users of ionizing radiation as appointed by the Vice President for Research. All work involving

the use of ionizing radiation must first be reviewed and approved by the Radiation Committee.

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. 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.

Sponsored Program Administration

The Sponsored Program Administration (SPA) serves as an interface between the HIC, 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 HIC 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, an IRB letter of approval is required before an account is established.

At the time of the award, SPA provides the sponsor with documentation of 1) final HIC 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 Assistant 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) has 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 HIC policies for compliance with federal, state and local law and university policy prior to their being

submitted to the steering committee for final approval and yearly thereafter. The OGC will keep up to date with all relevant changes in state and local law. Laws that require the immediate attention of the Human Investigation Committee are reported to the Compliance Officer and the HIC chair immediately and the information will be reported at the next HIC meetings and disseminated to the research community by the Educational Coordinator. A representative of Office of General Counsel is a member of an IRB medical committee and also the Steering Committee.

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 Human Investigation Committee.

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 HIC review. All protocols from the Dingell Veterans Medical Hospital must have an approval letter from CIC at submission. The WSU Human Investigation Committee 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 and Monitoring Committee (PRMC)

The Karmanos Review and Monitoring Committee pre-reviews the scientific merit of cancer research protocols, ensures prioritization of therapeutic cancer protocols according

to the Institutes scientific priorities and 3) monitors scientific progress. The function of the PRMS is complementary to that of the Institutional Review Board. All protocols from Karmanos must have an approval letter form PRMC at submission.

Perinatal Clinical and Research Board (PCRB)

The PCRB pre-reviews some Obstetrics and Gynecology protocols to provide guidelines and input into the conduct of innovative care that is not research. The Assistant Vice President for Research Compliance is a voting member of this committee.

UNIVERSITY COMMITTEES WITH AN HRPP COMPONENT

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 subject research.

The Associate Research Deans Committee

The Associate Research Deans 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. The Vice President for Research, the Associate V.P. for Research and the Assistant V.P. for Research Compliance are committee members.

Research Coordinators Advisory Committee

The Research Coordinators Advisory Committee is a quality improvement committee for the HIC and is comprised of the Assistant Vice President for Research, Process Improvement/Compliance Coordinator, Education Coordinator and research coordinators from Wayne State University and its affiliate institutions. The purpose of this committee is to:

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

INTERNAL OVPR MEETINGS

Vice President for Research and the Assistant Vice President for Research Compliance

The V.P. for Research and Assistant V.P. for Research Compliance have a scheduled weekly meeting to discuss compliance issues. Additional meetings 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.

Managers Meetings

All administrators in the Division of Research meet weekly to discuss and exchange information concerning each department and any mutual concerns or issues. These meetings provide a venue to disseminate compliance information and identify any systemic human participant program deficiencies.

Members include: the V. P. for Research, Associate V.P. for Research, Assistant V.P. for Research Compliance, Assistant V.P. for Research and Technology Commercialization, and the Assistant V.P. for Research/Associate V.P. for Sponsored Programs Management.

EDUCATION AND TRAINING

Wayne State University Office of Research Compliance assumes the responsibility of providing education to the research community in ethical principles, laws, policies, regulations and university policy concerning human participant research. To facilitate this responsibility the Human Investigation Committee maintains an Educational Coordinator whose duties include the initial and ongoing training and education of IRB committee members, HIC administrators, research investigators, key personnel and appropriate staff.

Institutional Review Board Committee Members

Either the Education Coordinator or Process Improvement/Compliance Coordinator attend each IRB committee meeting to provide compliance expertise in the discussions, when needed, and also information on any recent developments in human participant compliance.

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 HIC policies and procedures including “Expectations of an IRB Member”. New committee members also observe a committee meeting prior to achieving voting rights.

In addition, IRB members and HIC staff receive ongoing training and updates at committee meetings, weekly staff meetings and a yearly educational seminar.

Information is also disseminated through a WSU online publication “Research @ Wayne”, the HIC website and instructional emails.

The HIC Chair, Education Coordinator and Process Improvement Compliance Coordinator are available when needed to answer any questions or concerns.

Principal Investigators and Staff

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

The Principal Investigator has the ultimate responsibility for the administration of the research protocol. The PI must ensure that all of the research staff have 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 Vice President for Research, the Education Coordinator and the Process Improvement and Compliance Coordinator.

The HIC 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 Education Coordinator and Process Improvement/Compliance Coordinator are available to take calls concerning community and participant questions and complaints. The Assistant Vice President serves as a liaison between the University and the community at large and is available for educational purposes.

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 Assistant Vice President for Research Compliance. The IRB members, investigators and staff, 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 ORCR oversight, and cross-membership between committees with an HRPP component.

Process Improvement and Compliance Coordinator

The Process Improvement and Compliance Coordinator 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 Process Improvement and Compliance Coordinator, in collaboration with other members of the HIC staff and the Office of Research Compliance, conduct an ongoing review of HIC policies and processes for process improvement purposes.

Audits and Protocol Reviews

The Process Improvement and Compliance Coordinator conducts for-cause audits and random protocol reviews. Results of the audits are reviewed with the Assistant Vice President for Research and the HIC Chair and the Steering Committee. 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 or reflected in internal HIC processes.

Steering Committee

The Steering Committee reviews and approves all HIC policies; discusses audit reports and remedial action plans evaluates problems within the medical/behavioral committees. As a part of their responsibility, the committee helps to identify problems in the HIC processes and policies and suggests solutions.

Budget Review

The Vice President for Research and Assistant Vice President for Research 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.

Annual IRB Review

The Assistant Vice President for Research and the HIC chair conduct an ongoing and formal annual review of the number and composition of the IRBs to ensure that they are adequate to ensure that reviews are accomplished in a thorough and timely manner.

Staff Evaluations

All ORC and HIC 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 Assistant V.P. for Research, HIC Chair, Process Improvement/Compliance Coordinator and IRB chairs to ensure that the committees maintain the required qualifications, expertise and experience. Also, the assessment of 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 Educational Coordinator and the HIC Chair is included on all Informed Consent forms, HIC website, Internal Research Support booklet and all outgoing correspondence. Both the Educational Coordinator and the Process Improvement/Compliance Coordinator keep a phone log of questions and comments that can be reviewed for consistent and ongoing issues.

Professional Conferences

University officials responsible for research compliance keep current in regulatory and policy developments through membership and participation in professional and trade associations. These include: The Council of University Research Administrators, the National Council of University Research Administrators, and the Council on Government Regulations etc.

Irvin Reid
President

Date