Graduate Appointee Training Program

2025-2026 Research Discovery

Handbook



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Research at Western Michigan University

Research at WMU is overseen by the Office of Research and Innovation (ORI) (wmich.edu/research). In addition, the Research and Creative Scholarship Council a standing council of the Faculty Senate, is responsible for reviewing, developing, and recommending policies involved in the enhancement and implementation of research and creative activity at WMU.

ORI is essential to advancing WMU's research and innovation agenda. ORI supports faculty, students, and staff in securing external funding for research and creative activities, while fostering a culture of discovery and collaboration. By driving these initiatives, ORI strengthens the University's impact, reputation, and commitment to excellence in research and innovation. ORI assists researchers by offering information and services regarding:

- Identifying funding sources
- Grant proposal preparation and submission processes
- Developing partnerships with industry, government, and other institutions
- Coordinating multidisciplinary collaborations within the University
- Technology transfer, commercialization, and intellectual property support
- Oversight of research compliance, including human subjects, animal care and use, biosafety, radiation safety, export controls and other federal policy requirements

In addition, the University possesses a myriad of research facilities and equipment. Facilities and equipment represented here are shared resources with varied availability. Some exist in the laboratories of individual scientists where access needs to be coordinated on a case-by-case basis through the ORI.

- BSL-1 and BSL-2 laboratories equipped to handle radioactive material
- A 5,616-square-foot animal facility maintained under AAALAC standards and housing rodents, reptiles, birds, aquatics, and amphibians in 14 animal rooms and two procedural rooms
- A Nuclear Regulatory Commission broad scope material license
- A University Imaging Center offering comprehensive scientific/technical expertise for basic research and light microscopy equipment
- Greenhouse facilities and environmental chambers
- High performance liquid chromatography (HPLC) for protein purification and other applications
- Spectroscopic assay capabilities for UV, visible, and fluorescence assays
- DNA sequencing capabilities
- Major instrumentation for research in chemistry
- A noise and reverberation laboratory for evaluation of noise levels and sound absorption capacity
- A wind tunnel for research in aviation and wind loading on structures
- Large load frames for mechanical testing
- High performance and large-scale computing facilities
- Papermaking, coating, recycling, and printing facilities for production and testing of printed media
- Technology transfer support available through the ORI.

External research funding provides many opportunities for graduate students to work as graduate research assistants. While conducting research can provide exciting opportunities to contribute to advancing knowledge, it is fraught with the potential for serious problems. Although it is the responsibility of faculty research supervisors to train graduate student researchers in the art of research, student researchers need to make themselves aware of the principles of good research, such as regulations for working with human and animal subjects and potentially hazardous materials (e.g., viruses, radiation) and understanding the principles of research ethics. Other issues that must be considered are research misconduct and conflict of interest.

Research Ethics

The Office of Research and Innovation has compiled a number of research ethics resources. There are nine core areas comprising the Responsible Conduct of Research, and ORI provides resources for each area at wmich.edu/research/compliance. These include:

- 1. **Animal research:** There are materials that address issues important to conducting research involving animals, including definition of research involving animals, ethical principles for conducting research on animals, federal regulations governing animal research, institutional animal care and use committees, and treatment of animals.
- 2. **Authorship and publication practices:** The focus of these materials includes the purpose and importance of scientific publication, and the responsibilities of the authors. They cover topics such as collaborative work and assigning appropriate credit, acknowledgments, appropriate citations, repetitive publications, fragmentary publication, sufficient description of methods, corrections and retractions, conventions for deciding upon authors, author responsibilities, and the pressure to publish.
- **3. Collaborative science:** These materials feature research collaborations and issues that may arise from such collaborations. Topics include setting ground rules early in the collaboration, avoiding authorship disputes, and the sharing of materials and information with internal and external collaborating scientists.
- **4. Conflict of interest and commitment:** The definition of conflicts of interest and how to handle conflicts of interest are specified. Types of conflicts encountered by researchers and institutions are addressed, including topics such as conflicts associated with collaborators, publication, financial conflicts, obligations to other constituencies, and other types of conflicts.
- **5. Data acquisition, management, sharing and ownership:** These resources focus on accepted practices for acquiring and maintaining research data and proper methods for record keeping and electronic data collection and storage in scientific research. Topics include defining what constitutes data; keeping data notebooks or electronic files; data privacy and confidentiality; data selection, retention, sharing, ownership, and analysis; data as legal documents and intellectual property, including copyright laws.
- **6. Human subjects:** Issues important in conducting research involving human subjects are addressed, including topics such as the definition of human subjects research, ethical principles for conducting human subjects research, informed consent, confidentiality and privacy of data and patient records, risks and benefits, preparation of a research protocol,

- institutional review boards, adherence to study protocol, proper conduct of the study, and special protections for targeted populations, (e.g., children, minorities, and the elderly).
- 7. **Mentor-trainee relationship responsibilities:** The responsibilities of mentors and trainees in pre-doctoral and postdoctoral research programs are addressed. Topics include the role of a mentor, responsibilities of a mentor, conflicts between mentor and trainee, collaboration and competition, selection of a mentor, and abuse of the mentor/trainee relationship.
- 8. **Peer review:** The purpose of peer review in determining merit for research funding and publications is addressed. Topics include the definition of peer review, impartiality, how peer review works, editorial boards and ad hoc reviewers, responsibilities of the reviewers, privileged information and confidentiality.
- 9. Research misconduct: The definition of research misconduct and the WMU Research Misconduct Policy and Procedures are available at wmich.edu/research/compliance/ethicscenter/misconduct. Topics include fabrication, falsification, and plagiarism; error vs. intentional misconduct; institutional misconduct policies; identifying misconduct; procedures for reporting misconduct; protection of whistleblowers; and outcomes of investigations, including institutional and Federal actions.

Data Acquisition, Management, Sharing, and Ownership

[The material in this section was selected from the online course "Guidelines for Responsible Data Management in Scientific Research" (ori.hhs.gov/data-management-0), developed by Clinical Tools, Inc. and funded by the Office of Research Integrity, U.S. Dept. of Health and Human Services.]

Data Collection

Data collection refers not only to what information is recorded and how it is recorded, but also to how a particular research project is designed. Although data collection methodology varies by project, the aim of successful data collection should always be to uphold the integrity of the project, the institution, and the researchers involved.

Data collection may seem tedious or repetitive, but the data produced in research ultimately prove or disprove hypotheses and justify or counter a body of research. In addition, thorough data collection accomplishes the following:

- Enables those involved in the research to more accurately analyze and assess their work
- Allows independent researchers to replicate the process and evaluate results
- Impresses upon research team members the importance of data management
- Details the rationale behind a research project
- Provides justification to sponsors for expenditures and project decisions
- Yields reliable and valid results, and hypothesis testing

Collecting Reliable Data

Data collection guidelines and methodologies should be carefully developed before the research begins. The researchers must determine what sort of data will be collected and how this data will be analyzed. For data to be considered reliable, data collection should occur consistently and systematically throughout the course of the project.

The Importance of Planning for Data Collection

Team members who will collect data should be thoroughly trained to ensure consistency in data collection. By collecting data in a well-planned, systematic manner, team members will be able to answer any question about a project, including the following:

- The purpose behind the research
- The particular methodologies chosen
- The implementation of these methodologies
- How data were collected and analyzed
- If unexpected results or significant errors were encountered
- The implications of the research and future directions

A clear and comprehensive account of a project and its purpose and direction make it much easier for research to be disseminated, understood, and evaluated by other members of the scientific community.

Collecting Valid Data

Collecting valid data ensures that when research is evaluated it will be deemed good science—meaning that the research is both precise and honest. Thorough data collection should thus include a continuous system for rigorously evaluating effective or deficient elements in the project protocol or the research team's techniques.

Record Keeping

When data are actually collected, the records should attempt to accurately represent the progress of a project and answer such questions as what, how, and why data were collected or amended. Records should be durable and accessible but safe from tampering or falsification. For smaller projects, bound notebooks provide a convenient way for all research team members to keep track of data and daily activities of a project. When keeping written records, errors should be marked and dated but never erased. This way, they can provide a quick visual account of any changes or errors that have occurred.

A downside of written records is that searching for a specific fact or trying to compare observations from several sources can be difficult. Also, maintaining handwritten records is not possible for larger projects such as clinical trials or epidemiological surveys.

Electronic Records

Electronic records allow researchers to efficiently access and compare information from different sources and across similar projects. There are numerous electronic data capture programs that allow researchers to enter, store, and audit research data. However, security of electronic records is a significant concern, although there are methods for protecting electronic records. In addition, it may be time-consuming and may not be cost-effective for large ongoing projects to migrate their data records to electronic files. Therefore, most projects employ a combination of written and electronic record keeping to balance the risks and benefits.

Attention to Policy and Procedure

In addition to record keeping, the validity of the data collected can also be affected by whether or not proper policies and procedures for research are followed on a project and an individual level. One should be constantly aware of all the guidelines that might apply to the project's implementation and dissemination, including special regulations that involve human and animal subjects, hazardous materials, or other controlled biological agents. Every research team member should be aware of project guidelines and standards for collecting valid data, to ensure consistency throughout the project.

Best Practice Tips - Record Keeping

Diligent record keeping is essential to ensuring the integrity of research data. To help maintain data validity and reliability, consider these tips when planning or completing data collection:

- Include notes: Your records should allow you not only to account for what occurred during the course of research but also to reconstruct and justify your findings. It is important that records include notes about what methods did or did not work, observations, and commentary on the project's progress. Keep notes according to the research team's predetermined communication plan.
- **Personal notebooks:** For smaller projects using handwritten data, each team member should have his or her own personal notebook for recording project data, observations, etc. Entries should be made in a chronological and consistent manner—for instance, each new workday should begin on a new page. Try not to leave blank lines between entries.
- **Noting errors:** Use a consistent system for noting errors or adjustments. In written records, make entries in indelible pen so that records cannot be altered or damaged. If information needs to be changed or amended, mark through the entry with one solid line and initial and date the change. The records can thus reflect what has occurred during the course of a project.
- **Recording information:** Record anything that seems relevant to the project, its data, and the standards of the project. At a minimum, records should include the following information:
 - date and time
 - names and roles of any team members who worked with the data
 - materials, instruments, and software used
 - identification number(s) to indicate the subject and/or session
 - data from the experiment and any pertinent observations from the data's collection
 - it may also be helpful to include a summary of the day's data collection activities and a task list for the next day.
- Transferring information: When transferring records from written to electronic format, use a double entry system to reduce rates of incorrectly entered electronic data. To implement such a system, have two different Research Assistants enter all of the raw data into the software program, then cross-check the data to identify and remedy inconsistencies at the time of data entry.

Data Management: Research Team Responsibilities

Responsible data management is important in all phases of a project, from planning and data collection to data analysis and dissemination. Consequently, each research team member should know what role he or she plays in data management and his or her specific responsibilities. By clearly defining what is expected of each member and to whom each person reports, a PI can structure a project for success.

Research Team Members

Although titles, roles, and responsibilities vary by organization or institution, most research teams are made up of at least five key members:

- 1. **Principal Investigator**: The Principal Investigator (PI) is the individual who is ultimately responsible for a project and its research. The PI **enables** other team members to conduct research, and is the final authority on all scientific and medical issues related to the project. By obtaining funding and seeing that a project has the right team members, proper resources, and guidance, a PI ensures the success of the project. A project may have more than one PI, in which case they are Co-Principal Investigators.
- 2. **Research Director (Project Director)**: The Research Director **controls** the project. By directing the protocol for how the research and data collection are carried out, the Research Director often knows more about the day-to-day operations of the project than the PI. The Research Director works closely with the PI to both report on and redirect research. Sometimes, the Research Director is the PI.
- 3. **Research Associate (Project Coordinator)**: Under the guidance of the Research Director and the PI, the Research Associate **coordinates** the project. This individual carries out the research itself, collecting data and assessing the effectiveness of project protocol, suggesting changes to the methodology as needed.
- 4. **Research Assistant**: A Research Assistant, although normally the least experienced member of a research team, **carries out** the project work. A Research Assistant performs the day-to-day tasks of a project, including collecting and processing the data and maintaining equipment.
- 5. **Statistician**: The Statistician **analyzes** the data that are collected during the project. In some projects, the statistician may simply analyze and report on the data (under the guidance of another team member) after data collection has been completed. In other projects, a statistician is involved in the construction and analysis of research throughout the entire course of a study.

Other Team Members

Additional team members may be involved in research studies, including clinical research specialists, laboratory technicians, interns or student researchers, grant administrators, and others. Their roles should be defined by the PI at the outset of the project.

The Research Team's General Responsibilities

It is important to note that the research team members' positions may be flexible—one person might serve in several positions or one role might involve the efforts of several individuals. Additionally, keep in mind that many organizations and/or research teams have limited funding, so team members may have to fill more than one role.

The table below provides further examples of each member's role and responsibilities, how these positions differ, and where there is overlap in team members' roles.

Team Member	Primary Responsibilities	Accountable To
Principal Investigator	 Writes grant requests and proposals for a project Initiates a research project and aids in the design and implementation of protocols Selects the research team members Provides team members with the necessary technical and equipment training Creates a structured and effective work environment Writes and publishes research articles to disseminate project findings Responsible for ensuring compliance with regulations and university policies and securing approval from appropriate oversight committees (e.g., IRB, IACUC, etc.) Responsible for ensuring all required training is completed and certification is current (e.g., IRB, RCR, Research Security, etc.) 	 Funding agency Sponsor institutions Professional associations Employer and/or contractor Legal and academic regulations
Research Director (aka Project Director)	 Designs guidelines for project methodology, including data collection procedures Works with PI to redefine and redirect protocol as needed Manages team members' time and project budgetary issues Evaluates and documents project progress and compliance with protocols Ensures that a project complies with federal and Institutional Review Board guidelines Assists with writing research articles to disseminate findings 	Principal Investigator

Research Associate	Follows and implements research	Principal Investigator
(aka Project	guidelines	Research Director
Coordinator)	 Coordinates and conducts experiments and data collection 	• Statistician (at times)
	• Provides basic analysis for data	
	 Monitors experiments and their compliance with the protocols 	
	• Aids in reporting project research	
Research Assistant	Performs experiments and collects data	Principal Investigator
	• Maintains research supplies and/or	 Research Director
	equipment	• Research Associate
	Performs general background and clerical	• Statistician (at times)
	work (e.g., literature review, transcription,	
	etc.)	
Statistician	• Ensures project design will produce	• Principal Investigator
	reliable and valid data	 Research Director
	• Ensures research will create significant data	
	(e.g., via sample size or analysis methods)	
	• Monitors data collection and analysis	
	• Analyzes and prepares data for reporting	

Data Management Responsibilities of the PI and Research Director

Most of the specific tasks of data management fall to the PI and Research Director. For instance, these individuals are usually responsible for the following:

- 1. Ensuring that every person who is involved in the project knows his or her rights regarding data ownership.
- 2. Ensuring that the protocol is meticulously planned and that staff is thoroughly trained to maintain the integrity of the data collected.
- 3. Determining how to best store, protect, analyze, and disseminate the data.
- 4. Developing a plan for addressing research misconduct and data mismanagement.

Responsibilities of the Other Team Members

The primary data management responsibilities of the Research Associates and Research Assistants are usually in data collection: ensuring the reliable and valid collection of the data and protecting the data that they have collected. Statisticians are primarily responsible for ensuring comprehensive and accurate data analysis. All research team members are responsible for letting the PI or Research Director know if they suspect data fraud, manipulation, or other misconduct.

Data Storage

Once data have been collected and recorded, the next concern is data storage. Data storage is crucial to a research project for the following reasons:

- Properly storing data is a way to safeguard your research investment.
- Data may need to be accessed in the future to explain or augment subsequent research.
- Other researchers might wish to evaluate or use the results of your research.
- Stored data can establish precedence in the event that similar research is published.
- Storing data can protect research subjects and researchers in the event of legal

allegations.

Type and Amount of Data to Retain

Generally speaking, enough data should be retained so that the findings of a project can be reconstructed with ease. While this does not mean that a project needs to retain all the raw data that were collected, relevant statistics and analyses from this data should be saved, along with any notes or observations. Furthermore, if research involves the use of biological specimens, care should be taken to retain them until their quality degrades.notes or observations. Furthermore, if research involves the use of biological specimens, care should be taken to retain them until their quality degrades.

Electronic Data

The key issues for electronic data storage are thorough documentation to allow data to be appropriately used in the future and storage format that is easily adaptable to evolving computer hardware and software. There are some additional considerations that are unique to electronic data storage, including the following:

- Rapid access to the data
- Fast read/write rates
- Low cost
- Ability to archive the data
- Removability
- A backup system, such as storing data on data storage drives

Data Protection

Data protection should be a part of every project's plan for data storage. The best way to protect data, whether in written or electronic form, is by limiting access to the data.

In order to maintain the integrity of stored data, project data should be protected from physical damage as well as from tampering, loss, or theft. This is best done by limiting access to it. PIs should decide which project members are authorized to access and manage the stored data.

Notebooks or questionnaires should be kept together in a safe, secure location away from public access, e.g., a locked file cabinet. Privacy and anonymity can be assured by replacing names and other information with encoded identifiers, with the encoding key kept in a different secure location. Ultimately, the best way to protect data may be to fully educate all members of the research team about data protection procedures.

How Can Data Be Protected?

Theft and hacking are particular concerns with electronic data. Many research projects involve the collection and maintenance of human subjects data and other confidential records that could become the target of hackers. For example, thousands of personal information and identification records were jeopardized when hackers infiltrated systems at the University of California twice in 2005. The costs of reproducing, restoring, or replacing stolen data and the length of recovery time in the event of a theft highlight the need for protecting the computer system and the integrity of the data (Kramer et al., 2004).

Electronic data can be protected by taking the following precautions:

Protecting access to data

- o Use unique user IDs and passwords that cannot be easily guessed.
- Change passwords often to ensure that only current project members can access data.
- o Provide access to data files through a centralized process.
- o Evaluate and limit administrator access rights.
- o Ensure that outside wireless devices cannot access your system's network.

Protecting your system

- o Keep updated anti-virus protection on every computer.
- o Maintain up-to-date versions of all software and media storage devices.
- o If your system is connected to the Internet, use a firewall.
- o If your system is connected to the Internet, use intrusion detection software to monitor access.

• Protecting data integrity

- o Record the original creation date and time for files on your systems.
- Use encryption, electronic signatures, or watermarking to keep track of authorship and changes made to data files.
- Regularly back up electronic data files (both on- and offsite) and create both hard and soft copies.
- o Ensure that data are properly destroyed.

Third-Party Data Protection

Many research institutions have offices for information technology that work with the PI to assess the project's needs and develop a data protection protocol. For PIs without such an office, contracting with an outside information technology firm or hiring a project member to specifically focus on data protection and maintenance may be necessary.

Finally, database software programs often include features that help with data protection.

Data Sharing and Reporting

Data sharing is the way in which research is accurately represented to the scientific community and the general public. As part of the scientific process, data are expected to be shared and reported. This serves several purposes, including the following:

- Acknowledging a study's implications
- Contributing to a field of study
- Stimulating new ideas

By sharing research results, a project may advance new techniques and theories and benefit other research. It encourages collaboration between researchers in the same field or across disciplines. Additionally, reporting of clinical research data can have a direct impact on the quality of health care provided to patients.

Data sharing usually occurs once a study has been completed. Data reporting includes discussion of the data, the data analysis, and the authorship of a project, especially in the context of a particular scientific field. Data sharing and reporting are typically accomplished by publishing results in a scientific journal or establishing a patent on a product.

Sharing Data Prior to Publication

Before publication, there is often no obligation to share any preliminary data that have been collected. In fact, sharing at this stage is sometimes discouraged because of the following reasons:

- The implications for a set of data may not be understood while a project is still in progress. By waiting until a project is ready for publication, researchers ensure that what they share has been carefully reviewed and considered.
- There is fear that less scrupulous researchers will use shared research results for their own gain. This apprehension causes some researchers to refrain from disseminating their findings (Helly et al., 2002).

However, in some cases preliminary data should be shared immediately with the public and/or other researchers since it would be of immediate benefit (e.g., if a research project found that a new drug placed subjects at grave risk or greater benefit) (Steneck, 2004). In addition, many researchers find it worthwhile to present preliminary findings in a conference setting before the study is complete to inform peers about their forthcoming research.

Sharing Data After Publication

After a project's research has been published or patented, any information related to the project should be considered open data. Other researchers may request raw data or miscellaneous information related to the project in order to verify the published data or to further their own research project. However, each project should evaluate its ability to share raw data in terms of specific needs and budget constraints.

Obligation to Report

PIs should be aware of the various guidelines and restrictions that may apply to the dissemination of their research. There are usually stipulations, specific to the funding agency or sponsor institution, describing when and how results should be shared. For instance, SBIR research may be subject to certain data reporting requirements, depending upon project phase. In addition, government-sponsored research or research related to biological agents may be subject to federal legislation such as the Patriot Act or the Freedom of Information Act.

Data Ownership

Data ownership refers to the control and rights over the data as well as data management and use. Understanding data ownership, who can possess data, and who can publish books or articles about it are often complicated issues, related to questions of project funding, affiliations, and the sources and forms of the research itself. For federally funded research, ownership of data involves at least three different entities: the sponsoring institution, the funding agency, and the principal investigator (PI). In many cases, the institution/organization owns the project data, but the PI and the funding agency have "rights" to access and use the data. Usually, the PI has physical custody of the data on behalf of the organization. However, these rules vary by institution and funding source. Some general guidelines are presented below:

1. **The Sponsoring Institution**, e.g., a university or a research firm:

Most often, the sponsoring institution/organization maintains ownership of a project's data as long as the PI is employed by that institution. The institution often controls all funding or the disbursement of government funding; consequently, it is also responsible for ensuring that funded research is conducted responsibly and ethically. Within the sponsoring

- institution, a PI is granted stewardship over the project data; the PI may control the course, publication, and copyright of any research, subject to institutional review.
- 2. **The Funding Agency**, e.g., The National Institutes of Health (NIH), the National Science Foundation (NSF), or the Centers for Disease Control and Prevention (CDC): Many research projects are funded by federal government agencies, philanthropic organizations, or private industries. These agencies often have specific stipulations for how

data will be retained and disseminated: for example, they—rather than the PI—decide whether to publish the project's results or market a resulting product. The PI and institution should understand his or her funding agency's regulations regarding a research project and the data it produces. Note that requirements for federal grants may be different than government contracts.

3. The Principal Investigator:

In addition to being the steward of a project's data, a PI may retain some ownership of the data. In small businesses, it is assumed that rights and ownership of data remain with the business itself or with the funding agency, unless otherwise stipulated. In academic institutions, however, PIs are sometimes allowed to take their research and its data with them if they change research institutions. Many universities have offices and policies in place to ensure that such a transfer of data respects both the rights of the researcher and those of the institution(s). (USDHHS, 1990)

Subjects' Rights to Ownership

It is also important to consider data ownership from the perspective of individuals who suggest research ideas and/or participate in the research (see article suggested below for additional reading). Some research subjects are expressing a desire for partial ownership or control of research in which they have participated. For instance, in two recent court cases, the defense contended that research institutions had improperly benefited in extending their study's implications beyond any consent that the participating subjects had given. Since human subjects are often sources for data that may be otherwise unavailable to researchers, it is important to consider study participants' beneficence and dignity in relation to the project's progress and goals.

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Guidelines for Human Subjects Research at WMU

Much research at the university level involves the use of human research subjects. The primary role of the Western Michigan University Institutional Review Board (WMU IRB) is to protect the rights and welfare of human research participants.

Federal regulations define "research" as "a systematic empirical investigation designed to develop or contribute to generalizable knowledge." Federal regulations define "human subject" as "a living individual about whom an investigator...conducting research obtains: 1) data through intervention or interaction ..., or 2) identifiable private information."

The three basic ethical principles that guide the WMU IRB are derived from the Belmont Report of 1979 (https://hrs.gov/ohrp/regulations-and-policy/belmont-report). These three principles are:

- 1. **Respect for persons:** This principle involves protecting the autonomy of all people, treating them with courtesy and respect, and allowing for informed consent.
- 2. Beneficence: This is the concept that researchers should act for the benefit of others and have the welfare of the participant as a goal of any study. The rules of this principle are (1) do not harm and (2) maximize possible benefits and minimize possible harms.
- 3. **Justice:** This principle ensures that equals are treated equally and the costs and benefits to potential research participants are administered fairly and equally. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.

By submitting a protocol to WMU IRB:

- Investigators comply with university policy and federal regulations.
- Investigators promote the protection of the rights and welfare of research participants.
- Faculty set an example for student researchers.
- Students learn about the ethical conduct of human research.

University policy requires that <u>all research</u> involving <u>human subjects</u> be submitted to WMU RB. Any fulltime faculty or staff employee of WMU may serve as a Principal Investigator. Students (including graduate students) may serve as Student Investigators but <u>not</u> as Principal Investigators. Adjunct or part-time faculty may serve as Co-Principal Investigators, at the discretion of the Principal Investigator.

Before a protocol can be approved, all investigators must have completed the appropriate on-line training modules at <u>citiprogram.org</u>. Please note that this is separate and distinct from the Responsible Conduct of Research online course that is required for new graduate students. In taking the CITI on-line training modules, researchers will learn about the history of ethical concerns in human subjects research and important documents that govern such research, as well as be thoroughly informed about such principles as confidentiality of data, recruitment of subjects, informed consent/assent, etc.

Federal regulations divide human subjects research into categories based on the level of risk to which subjects will be exposed by participating in the research. University policy uses two categories—expedited review and full board review:

1. Research that can be reviewed by an exempt or expedited process poses no more than minimal risk to the subject and falls into at least one of the federally defined categories. Examples include: research in educational settings; anonymous surveys; surveys collecting information that is not sensitive; analysis of voice recordings; studies involving moderate

- exercise; studies of existing data; and research on individual or group characteristics or behavior.
- 2. **Research that requires full board review** may expose the subjects to greater than minimal risks or involves protected research populations (e.g., children, pregnant women, incarcerated individuals, persons unable to give consent due to diminished mental capacity). These research protocols will be reviewed by the full board at a convened meeting.

Information and application forms are available online at

https://wmich.edu/research/compliance/wmuirbThere are no deadlines for expedited submissions. They are reviewed on a continuous basis.

Applications submitted for <u>full board</u> review must be submitted on or before the first Wednesday of the month and will be reviewed at a full board meeting on the third Wednesday of that month.

No research or subject recruitment may begin until WMU IRB has given your research protocol full approval with no revisions. This includes research conducted by graduate students writing a thesis or dissertation which involves research with human subjects.

All changes in a research protocol must be approved before the change is incorporated into the protocol.

Other Institutional Review Boards and Safety Committees

Institutional Animal Care and Use Committee (IACUC)

A local review board charged with the protection of the welfare of animals in research conducted at WMU. WMU policies adhere to federal requirements contained in the Animal Welfare Act, *The Public Health Service Policy on Humane Care and Use of Laboratory Animals*, the U.S. Department of Agriculture's *Guide for the Care and Use of Agricultural Animals in Research*, and the National Research Council's *Guide for the Care and Use of Laboratory Animals*.

The IACUC reviews **all** research and teaching protocols involving **vertebrate animals**. The use of animals in research involves responsibility for the stewardship of the animals and accountability to the scientific community and society. Stewardship goes beyond the immediate research needs to include acquisition, care, and disposition of the animals, while responsibility to the scientific community and society requires an appropriate understanding of, and sensitivity to, scientific needs and community attitudes toward the use of animals in research.

Three basic principles are particularly relevant to the ethics of research using animals:

- **Respect for Life:** Living creatures deserve respect. Animals used in research should be of an appropriate species and health status, and should involve the minimum number required to obtain valid scientific results. Methods such as mathematical models, computer simulation, and *in vitro* systems should be used whenever possible.
- Societal Benefit: The advancement of biological knowledge and improvements in the protection of the health and well-being of both humans and other animals provide strong justification for animal research. The assessment of the overall ethical value of animal use should include consideration of the full range of societal goods, the populations affected, and the burdens expected to be borne by the research animals.

• Non-malfeasance: Vertebrate animals are sentient. Minimizing distress, pain, and suffering is a moral imperative. Unless the contrary is established, consider that procedures that cause pain or distress in humans also cause pain or distress in other sentient animals.

Before a researcher can order animals for research projects, he/she must have an IACUC approved protocol. The IACUC meets monthly to consider animal protocols.

Before a protocol can be approved, all investigators must have completed the appropriate on-line training modules at <u>citiprogram.org</u>. Please note that this is separate and distinct from the Responsible Conduct of Research online course that is required for new graduate students.

Biosafety Committee

The Biosafety Committee was formed to ensure that all teaching, research, and clinical activities involving the use of potentially hazardous microbial agents and/or their products are conducted in a safe and secure environment. All research involving recombinant DNA molecules conducted under the aegis of Western Michigan University is reviewed by this committee. Recombinant DNA molecules are defined as either (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) DNA molecules that result from the replication of those described in (i).

Radiation: Federal and State of Michigan rules and regulations require WMU to assure that exposure to radiation is ALARA (<u>as low as reasonably achievable</u>). The Radiation Safety/Biosafety Officer (<u>wmich.edu/research/compliance/radiation</u>) must approve research involving use of radiation and/or radioactive materials. The Radiation Safety Committee provides guidance and assistance in the development and implementation of policies and procedures used to ensure compliance with the rules and regulations governing radiation and radioactive material use.

Conduct in Research

Research and creative activities occur in a variety of settings at the University, including class papers, theses, dissertations, reports or projects, grant-funded projects, and service activities. Research and creative activities rest on a foundation of mutual trust. Misconduct in research and in creative activity destroys that trust and is prohibited. Students shall adhere to professional standards of integrity in both artistic and scientific research including appropriate representations of originality, authorship, and collaborative editing. More information is available at wmich.edu/research/compliance/ethicscenter/misconduct.

Definition: Misconduct in research is defined as serious deviation, such as fabrication or falsification of data, plagiarism, or scientific or creative misrepresentation, from accepted professional practices of the discipline or University in carrying out research and creative activities or in reporting or exhibiting/ performing the results of research and creative activities. It does not include honest error or honest differences in judgments or interpretations of data.

Clarification: Examples of misconduct in research include but are not limited to:

• **Fabrication of Data**: Deliberate invention or counterfeiting of information.

- Falsification of Data: Dishonesty in reporting results, ranging from unauthorized alteration of data, improper revision or correcting of data, gross negligence in collecting or analyzing data, to selective reporting or omission of conflicting data.
- Plagiarism and Other Misappropriation of the Work of Another: The representation of another's ideas or writing as one's own, in such ways as stealing others' results or methods, copying or presenting the writing or ideas of others without acknowledgment, or otherwise taking credit falsely. Representing another's artistic or technical work or creation as one's own. Just as there are standards to which one must adhere in the preparation and publication of written works, there are standards to which one must adhere in creative works in the tonal, temporal, visual, literary, and dramatic arts.
- **Abuse of Confidentiality**: Taking or releasing ideas or data of others which were given in the expectation of confidentiality, e.g., stealing ideas from grant proposals, award documents, or manuscripts intended for publication or exhibition/performance when one is a reviewer for granting agencies or journals or when one is a juror.
- **Dishonesty in Publication or Exhibition/Performance**: Knowingly publishing, exhibiting, or performing work that will mislead, e.g., misrepresenting material, particularly its originality, or adding or deleting the names of authors without permission.
- **Deliberate Violation of Requirements**: Failure to adhere to or receive the approval required for work under research regulations of federal, state, local, or university agencies, including guidelines for the protection of human subjects or animal subjects and the use of recombinant DNA, radioactive material, and chemical or biological hazards.
- **Failure to Report Fraud**: Concealing or otherwise failing to report known misconduct or breaches of research or artistic ethics.

Research Board Requirements: Misconduct in research includes failure to comply with requirements for the conduct of research and creative activities, e.g., the protection of human subjects, the welfare of laboratory animals, and biosafety. Allegations in these areas may be brought by the Human Subjects Institutional Review Board, the Institutional Animal Care and Use Committee, and the Institutional Biosafety Committee.

Intellectual Property Rights, Conflict of Interest

A substantial amount of research being conducted at Western Michigan University results in new findings, developments, and discoveries that can benefit society. Graduate research assistants sometimes contribute to research findings with commercial potential. The transfer of these discoveries to the commercial sector is coordinated through the Technology and Innovation Advancement ("technology transfer") function at WMU (wmich.edu/policies/intellectual-property) and the Western Michigan University Research Foundation. The Office of Research and Innovation is responsible for the management and commercialization of WMU's intellectual property through the research foundation.

The increasing involvement of academic researchers and educators with industry and private enterprise makes it easier for promising research observations to be translated into practical application in many different sectors. WMU encourages employees to: patent and license inventions arising from their research, develop partnerships with industry to market new

technology, apply for industry sponsored research funds, and serve as consultants for industry. Involvement in commercial activities comes with many benefits: practical application of new technology, royalty income for the employee and the University, the potential of external research funds, etc. The federal government, too, encourages universities to commercialize the results of federally supported research for the public good (Bayh-Dole Act). In some cases, graduate student researchers have been named as holders of patents and copyrights based on research conducted at universities.

Involvement with commercial ventures, however, could potentially divert university employees from their primary mission of education, research, and service. Conflicts of interest and commitment can arise when the interests of the commercial venture differ from the interests and primary obligations of the University and its employees, or when the commercial enterprise consumes an undue share of employee time.

Conflict of Commitment: Full-time faculty are expected to devote their primary professional time to teaching, research, and administrative responsibilities. Outside financial interests and activities should not interfere with these commitments.

Conflict of Interest: A conflict of interest encompasses personal, professional, commercial, or financial interests or activities outside of the University that may, either in actuality or in appearance: 1) compromise judgment; 2) bias the nature or direction of scholarly research; 3) influence decision or behavior with respect to teaching and student affairs, appointments and promotions, uses of University resources, contracting, or other matters of interest to the University; or 4) result in a personal or Family Member's gain or advancement arising out of University business.

Resources providing information on conflicts of interest are available on the ORI website (wmich.edu/research/compliance/ethicscenter/conflicts). An Institutional Official, or designee, will determine whether an individual's disclosure constitutes an actual conflict of interest that could affect the design, conduct, or reporting of the research or educational activities.

The University is responsible for maintaining objectivity in research by ensuring that the design, conduct, and reporting of research will not be biased by any conflicting financial interest of investigators responsible for the research. The rationale for establishing policies to manage conflict of interest in research is to protect employees and the University from potential accusations of misconduct.

Why Should You Care About Conflicts of Interest?

Researchers have a tradition of free inquiry and free exchange of ideas. Trust, the core ethical value in this issue, is essential in the scientific pursuit of the truth. A relationship based on trust is necessary with colleagues, the government, the study sponsors, and, of course, the public. Objectivity is fundamental to this trust.

Conflicts of interest are intrinsic to the researcher's enterprise. And that is why conflicts of interest are so serious. Not only can a conflict lead to injury or harm to particular study participants but, on a larger scale, a conflict of interest can damage an entire research enterprise by reducing the trust and confidence that people generally have in research.

Although graduate research assistants are not as likely as principal investigators to be vulnerable to a conflict of interest, they should be able to recognize potential conflicts that might occur.

Definition of a Conflict of Interest

A conflict of interest involves the abuse—actual, apparent, or potential—of the trust that people have in professionals. The simplest working definition states: A conflict of interest is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity. An apparent conflict of interest is one in which a reasonable person would think that the professional's judgment is likely to be compromised. A potential conflict of interest involves a situation that may develop into an actual conflict of interest. It is important to note that a conflict of interest exists whether or not decisions are affected by a personal interest; a conflict of interest implies only the potential—not a likelihood—for bias. It is also important to note that a conflict of interest is not considered misconduct in research, since the definition for misconduct is currently limited to fabrication, falsification, and plagiarism.

There are many varieties of conflicts of interest, and they appear in different settings and across all disciplines. All involve the use of a person's authority for personal and/or financial gain. Conflicts of interest may involve individuals as well as institutions. Furthermore, individuals, in certain circumstances, may have conflicts occurring on both an individual and an institutional level, as may be seen among members of an Institutional Review Board (IRB).

Laboratory Tips for the Research Assistant

Before the semester/school year begins:

Locate your research advisor's office and sit down and have a conversation, including these potential topics:

- Discuss what the advisor expects to learn from the research and his/her expectations for you over the following 3 to 6 months or longer.
- Ask questions!!! You are being paid to perform the service of assisting the faculty member in his/her research. The more knowledge and understanding of the project(s) you have, the easier this task becomes.
- Discuss your expectations in performing this duty. Recognize that this is an integral part of your professional development. Assisting on research projects outside of your thesis/dissertation offers you a chance to gain additional knowledge and insight into aspects of your field that may not be your specialty.
- Find and inspect your lab and storeroom areas. <u>Check</u>: the materials lists and inventory, the location of the first aid kit, eyewash station, fire extinguisher, outlets, switches, temperature controls, etc.
- Find out departmental procedure for ordering and obtaining supplies.
- Become familiar with safety rules and procedures, emergency procedures, evacuation
 plans, and the layout of your building. Not only is this useful in the event of emergencies
 like fires, etc., it is vital that you understand that this is "tornado country" and in the
 event of such an occurrence, you will have to shut down your lab quickly and get to
 shelter
- Set deadlines for submission of lab results or projects. Clarify rules and formats for reports.

During the semester/year:

Set a schedule and stick to it. A full-time assistantship requires 20 hours of work per week. In consultation with your research advisor, select a block of time (mornings, afternoons, or some

combination) and commit to that time of work. The set schedule makes you accessible to the faculty member and will aid you in budgeting your time.

Reminder: The assistantship is for 20 hours a week. You may work more or less than 20 hours in a given week, but your hours should average 20 per week. You should not be consistently working more than this. Your department should provide you with a timesheet on which to log your hours; the timesheet should be turned in every two weeks at the end of each pay period as a record of your hours worked.

Demonstrate the proper use and care of equipment. If you do not know how to use something, ask for help. It is better to ask for help and get trained than to try on your own and damage the equipment. If you do break something, report the damage immediately to someone of authority (your research advisor, the lab manager, or any faculty member) so that the damage can be repaired. Accidents and damaged equipment happen, but people get angry when others cover up their responsibility and equipment is not fixed when other researchers need to use it.

After the project/semester/year:

Sit down with your research advisor and evaluate the experience together by asking:

- What went especially well?
- What could have been done a bit differently?
- Were expectations met for you? For the faculty member?