

# Wheeling Jesuit University Institutional Review Board

## Policies and Procedures

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### 1.0 Introduction

#### 1.1 Overview

The primary purpose of the Wheeling Jesuit University Institutional Review Board is the protection of research participants. The Institutional Review Board does not endorse the quality of the research and approval does not absolve researchers from the responsibility to monitor and maintain the project within their professional guidelines. The ultimate responsibility for the ethical conduct of research remains with the researchers.

It is the policy of Wheeling Jesuit University to respect and protect the rights and welfare of individuals. In the conduct of research, the actions of this institution are guided by the principles set forth in *The Belmont Report* (1979) and the practices detailed in the United States Code of Federal Regulations “Protection of Human Subjects” (*Title 45 CFR Part 46*) promulgated by the Department of Health and Human Services. This document is also referred to as the Common Rule because 14 Federal agencies that conduct research involving human participants have agreed to follow these regulations.

The Wheeling Jesuit University Institutional Review Board is a standing committee, constituted according to Federal regulations, that is responsible for ensuring that the rights and welfare of human research participants are protected. The Institutional Review Board is an independent Board, not under any direct supervision or direction of Wheeling Jesuit University administration. The Institutional Review Board has the authority to approve, to require modification as a condition of approval, and to disapprove proposed activities that are within the scope of its authority. In addition, the Institutional Review Board has the authority to verify that ongoing research studies involving human participants comply with its regulations and may suspend or terminate approval for ongoing studies under its jurisdiction. Furthermore, the Institutional Review Board has the authority to determine whether or not any activity is covered by these policies and procedures and whether it requires review by the Institutional Review Board.

***No research involving human subjects may be undertaken at Wheeling Jesuit University without prior review by the Institutional Review Board. Failure to observe the policies and procedures described herein will be considered serious misconduct, subject to sanctions, including possible recommendations for termination of faculty appointment, student enrollment, or other affiliation with Wheeling Jesuit University.***

## **2.0 Institutional Review Board**

### **2.1 *The Role of the Institutional Review Board***

The primary responsibility of the Institutional Review Board is to protect the rights and welfare of the human participants in research investigations conducted by Wheeling Jesuit University, by agents of the University, and by agencies or individuals seeking to do research in which members of the University community participate. This protective role of the Institutional Review Board has three primary components: to assure institutional compliance with state and federal policy on research investigations involving human participants, to review proposed research investigations involving human participants conducted under the auspices of the institution or by agents of the institution, and to conduct ongoing reviews of approved research investigations.

2.1.1 First, the Institutional Review Board has an ongoing responsibility to understand, interpret, and promote compliance with the most current State and Federal policies pertaining to research involving human participants. These policies originate from the Federal Department of Health and Human Services, the National Institutes of Health, and the Office for Human Research Protections, as well as relevant State policies. To assure compliance with these policies, the Institutional Review Board designs and implements educational programs and training for Institutional Review Board members, department representatives, investigators, institutional officials, and members of the University Community.

In addition to these educational activities, the Institutional Review Board is also responsible for developing the written procedures for submitting research applications, for conducting initial review of the research protocols, for conducting continuing reviews of approved research, and for ensuring prompt reporting to the Institutional Review Board of changes in the approved research or unanticipated problems involving risk to the participants or noncompliance with Institutional Review Board policy.

2.1.2 The second component of the Institutional Review Board's role is the review of research protocols involving human participants. The research protocol must provide information regarding:

- The purpose and rationale of the research

- The research participants used in the study (e.g. volunteers, students, sampling method)
- The location of the research
- Any agents (e.g., drugs) used
- The procedures (observations, techniques, instruments, devices) used
- The research design or the research questions used
- The potential benefit to the research participants or general knowledge acquired from the study
- Any risks or hazards from participation in the research and precautions taken to reduce the risks and hazards
- Plans for remedial action that will be taken if any physical, psychological, or emotional injury occurs
- A description of how confidentiality will be assured
- A consent form or consent procedure for participation

The major points of this review and the approval process are described in the Investigators Manual.

2.1.3 The third component of the Institutional Review Board's responsibility is the continuing review of approved research investigations. The Institutional Review Board conducts continuing reviews to ensure compliance with the approved protocols. This review process does not negate the investigator's responsibility to inform the Institutional Review Board promptly of any changes or deviation from the approved protocol or any unanticipated problems that might produce or increase risk to the research participants. In addition, the Institutional Review Board may suspend or terminate research approval for noncompliance with Institutional Review Board policy and procedures.

#### 2.1.4 Board Membership

Federal regulations impose very specific requirements on the composition of Institutional Review Boards (§46.107). Members of the university and community are selected to serve on the Institutional Review Board based on their expertise and experience in both scientific and non-scientific areas. Board composition will be diverse and its members vary on the dimensions of profession, cultural background, race, and gender. The Wheeling Jesuit University Institutional Review Board will have at least one community representative and IRXU faculty members.

### 2.2.1 Membership

Members will be openly solicited from the University. Members will be expected to attend all regularly scheduled meetings. Members will be expected to review research proposals that come before the Board, participate in the development of Institutional Review Board administrative procedures, review ongoing research, and assist in efforts to inform and train Wheeling Jesuit University faculty, students, staff, and administration.

Members will be expected to recuse themselves from discussion and votes on research proposals in which there is a conflict of interest or a perceived potential conflict of interest.

The term of membership will be a two-year renewable term so that 1/3 of the committee is replaced or reappointed each year.

### 2.2.2 Chairperson

The Chairperson is a faculty member appointed by the university president. The term for the Chair will be a three-year renewable term. While the Institutional Review Board is an independent Board, not under any direct supervision or direction of Wheeling Jesuit University administration, for administrative purposes, the Chairperson of the Institutional Review Board reports to the Vice President of Academic Affairs and Dean of Faculty.

## 2.3 *Board Meetings*

The full membership of the Institutional Review Board of Wheeling Jesuit University has regularly scheduled meetings. The Board conducts its business yearlong and will schedule special meetings during the summer months -- if the need arises. The day and location of the meetings are subject to change depending upon the university calendar.

Special meetings will be held with at least one-week notice to all members.

A quorum of more than fifty-percent of the voting membership will be required to hold an official meeting.

## **3.0 Terminology and Definitions**

### 3.1 *What is Research?*

The term "Research" is defined by the Federal Government, Department of Health and Human Services, as "a systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (§46.102(d)). Activities that meet this definition are considered to be research, whether or not they are supported or funded by a Federal program.

1. *What is Human Research?*

At Wheeling Jesuit University, any research that meets the definition set forth in 3.1 involving human participants conducted by faculty, staff, administrators, or students will be considered to be Human Research. Any outside agent who proposes to collect data from members of the Wheeling Jesuit University community will require a Wheeling Jesuit University Institutional Review Board review as well as any other relevant Institutional Review Board.

Research studies may include various invasive or non-invasive procedures. Invasive procedures could be the removal of body tissues or fluids, administration of drugs, exposure to various forms of radiation, or alteration of diet or environment. Non-invasive procedures could be interviews, surveys, simple observation, administration of questionnaires, or review of records.

2. *Who is a Research Participant?*

The Wheeling Jesuit University Institutional Review Board will review research that involves human research participants. A human research participant is a living individual about whom an investigator (whether faculty, staff, administrator, student or outside agency) is conducting research. Researchers may obtain data through intervention or interaction with the individual, or identify private information from the individual. Intervention in research may include physical procedures by which data are gathered or manipulations of the research participant's environment that are performed for research purposes. Some examples of human research participants are individuals involved in clinical trials, psychological experiments, groups that are being studied, or surveys in which questionnaires are administered.

3.3.1 *What is a vulnerable population?*

A vulnerable population consists of the following

Prisoners	Mentally disabled people
Pregnant women	Economically disadvantaged people
Physically handicapped people	Educationally disadvantaged people
Children under 18	Fetuses of fetal material
Neonates	

3.4 *What is Student Research?*

Student research is research that is conducted as part of a class requirement in which students systematically collect data from human participants. To qualify as student, research the activity must be documented in an approved course syllabus.

### 3.5 *What is the role of course instructors?*

Instructors are responsible for introducing Institutional Review Board concepts to human research related courses. They are responsible for screening individual research projects and making an initial determination as to whether the project may fall into the category of “human research.” If the research falls into the category of human research, then the Institutional Review Board must review it.

#### *What is meant by risk?*

A participant is considered to be at risk if there is any potential physical, emotional, or psychological harm caused as a result of participation in the study. It is the responsibility of all researchers to both anticipate the potential risks a study may cause and to act to minimize it. It is also the responsibility of the researcher(s) to both identify and establish procedures to ameliorate any unanticipated harm that may occur as part of a research project in which they have a role.

### 3.7 *Levels of Review*

There are three review levels: Exempt, Expedited, and Full Board. The Institutional Review Board will determine the review level. The requirements for each level are described more fully in this section.

#### 3.7.1 **Exempt Status**

Exemptions do not apply to research involving any of the following defined as vulnerable populations:

Prisoners	Mentally disabled people
Pregnant women	Economically disadvantaged people
Physically handicapped people	Educationally disadvantaged people
Children under 18	Fetuses of fetal material
Neonates	

Research studies that involve humans are subject to review to ensure protection of the participants. If a research protocol meets one or more of the conditions listed below, it may be classified as an *exempt project*.

The following exempt conditions have been developed and described within the Federal Common Rule (45CFR 46).

### 3.7.1.1 *Exempt Conditions*

**Type 1.** Research conducted in established or commonly accepted educational settings, involving normal educational practices such as

- research on regular and special education instructional strategies or
- research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. This research may involve minors.

**Type 2.** Research that involves only the recording and analyzing of public or usual behavior. Research design and instruments include:

- Educational tests. Educational tests include cognitive, diagnostic, aptitude, or achievement tests. This research MAY involve minors.
- Survey procedure. This research may NOT involve minors. Wheeling Jesuit University Institutional Review Board does not consider the collection of demographics (e.g., age, gender, and race) that accompany data collection with educational tests or within established or commonly accepted educational settings to be a survey procedure.
- Interviews. This research is NOT exempt if minors are subjects.
- Observation of public behavior. This is NOT exempt if minors are subjects and the investigators participate in the activity being observed. In this case, “participation” means obtaining data through intervention or interaction with the subject. Exempt Type 2 research may involve other designs and instruments. These must be considered on an individual basis.

**Type 3.** Research that involves only the collection or study of existing data, documents, or pathological specimens. This type of research MAY involve minors. There are two categories of Type 3 research:

- Data is publicly available. One example might be schools’ report cards or demographic data, available through school, state, or federal education websites.
- Data is not publicly available, but it is recorded in such a manner that subjects cannot be identified.

**Type 4.** Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

- Public benefit or service programs.
- Procedures for obtaining benefits or services under those programs.
- Possible changes in or alternatives to these programs or procedures
- Possible changes in methods or levels of payment for benefits or services under those programs. This research MAY involve minors.

**Type 5.** Taste and food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed. This research MAY involve minors.

Protocols for exempt review may be submitted at any time. The Chairperson or designee performs review unless the project is referred to a higher review level. The original copy of the application form and protocol narrative should be submitted to the Institutional Review Board office.

### 3.7.2 *Expedited Review*

The Institutional Review Board will use expedited review procedures for research that involves no more than minimal risk to the participants and to review minor changes in previously approved research during the period the approval is valid. The Chairperson or designee will perform review.

Research activities that may be reviewed through the expedited research process are those involving no more than minimal risk and in which the only involvement of human participants will be in one or more of the following categories (carried out through standard methods):

1. Collection of hair and nail clippings in a non-disfiguring manner, deciduous teeth, and permanent teeth if patient care indicates a need for extraction.
2. Collection of excreta and external secretions including sweat, uncannulated saliva, or placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
3. Recording of data for subjects 18 or older using non-invasive procedures routinely employed in clinical practice. Non-invasive procedures involve the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. They also include such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography.

It does not include exposure to electromagnetic radiation outside the visible range (for example, X-rays or microwaves).

4. Collection of blood samples by venipuncture in amounts not exceeding 450 milliliters in an eight-week period and not to exceed two times per week from subjects 18 or older who are in good health and not pregnant.
5. Collection of both supra-and sub-gingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.



6. Voice recordings made for research purposes, such as investigations of speech defects.
7. Moderate exercise by healthy volunteers.
8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory or test development, in which the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption are not required.
11. The original copy of the application form and protocol narrative should be submitted to the Institutional Review Board Office.

### 3.7.3 *Formal Review*

Research protocols not meeting the eligibility criteria of the exempt or expedited categories are subject to full Institutional Review Board review.

When it is determined that a full Institutional Review Board review is required, the original copy of the application form, protocol narrative, informed consent, or assent forms must be submitted in the required format to the Institutional Review Board office ten (14) working days prior to the published Institutional Review Board meeting date.

A Protocol Summary Checklist for Investigators has been developed to ensure that all steps in the application process have been successfully met. This form is for the investigator's use only. It does not need to be submitted to the Institutional Review Board. The checklist can be found in the Investigator's Manual.

## **4.0 Principal Investigator Responsibilities**

The Principal Investigator (PI) or Investigators (PIs) are the faculty members, staff members, students, or administrators at Wheeling Jesuit University or elsewhere who are primarily responsible for the research study being conducted involving human participants. According to the Office for Human Research Protections (OHRP) under the Department of Health and Human Services, beginning in October, 2001, every investigator applying to the Institutional Review Board for research involving human research participants must document that they

have completed the OHRP or similar education and training program regarding human research protections. An Institutional Review Board protocol application will not be approved until the investigators submit a certificate of completion from the approved training program at the time of submission. The OHRP homepage for this training program may be accessed through the Wheeling Jesuit University Institutional Review Board web site: [http://www.wju.edu/academics/irb/Institutional Review BoardTraining.asp](http://www.wju.edu/academics/irb/Institutional%20Review%20BoardTraining.asp).

In the case of multiple investigators at multiple sites, the applicants at Wheeling Jesuit University should contact the Chair of the Institutional Review Board office for specific guidance.

In addition, it is the responsibility of the PI to:

- Manage the development of the project in accordance with accepted scientific standards;
- Ensure the integrity and safeguarding of all collected data;
- Ensure project review of all human participant research by the University Institutional Review Board, before initiating the study;
- Ensure that participants in research be informed of all risks and benefits so that their decision to participate is based on pertinent information;
- Assure project adherence to approved research protocols and policies;
- Notify the Institutional Review Board of any changes made to the protocol or participant consent process or document;
- Report any potential changes in the risk-benefit ratio that are manifested or discovered during the research process;
- Meet the continuing review requirements established by the Institutional Review Board;
- Report all serious and adverse effects encountered during the investigation to the Institutional Review Board;
- Immediately notify the Institutional Review Board if a protocol is withdrawn.
- Remain aware of and comply with the policies of the Institutional Review Board at Wheeling Jesuit University.

All other personnel assisting with the design or conduct of an investigation including students, faculty, staff, or non-institutional members shall be considered co-investigators. Co-investigators are expected to report to the PI any deviation from approved protocol, increased participant risk, or serious or adverse effects to research participants.

## 5.0 Additional Approvals

In addition to approval from the Institutional Review Board, the PI is also responsible for seeking approval from external facilities where data collection will occur and from animal research committees, as appropriate. These approvals should accompany the Institutional Review Board protocol submission and be signed on the organization's letterhead. An email from an official organizational Web site from the approving authority is acceptable.

**If approval cannot be obtained before submission, contingent approval may be provided with the agreement that written approval from the cooperating institution will be submitted to the IRB Chair prior to research beginning. This will be assessed and decided on a case by case manner.**

## 6.0 Special Protections for Vulnerable Populations

*Who is a member of a Vulnerable Population?* Vulnerable populations in research consist of groups or classes of individuals who may be at a higher risk than normal for coercion, deception, or undue influence in their decision to participate in research protocols. They include children, prisoners, pregnant women, people with mental or emotional disorders, and people who are educationally or economically disadvantaged. A complete list is found in Section 3.1.1.

Two divergent and seemingly conflicting issues have been discussed regarding people who have vulnerable conditions. The first is that extra protections and care must be taken so that these individuals are not taken advantage of by aggressive investigators. The second issue is that people with these conditions must not be discriminated against in the design of research protocols so that these individuals may assume the benefits as well as the risks.

Specific Federal regulations have been promulgated to protect research participants in studies involving fetuses, pregnant women, and human tissues from In Vitro Fertilization processes (Subpart B, Sections 46.201-211). Subpart C (46.301-306) has also been passed to protect prisoners who may serve as research participants. Recently, Subpart D (46.401-409) has also been passed which addresses children as research participants.

Officials at the National Institutes of Health (NIH) suggest that researchers who plan to involve research participants with mental or emotional disorders have little guidance and no formal regulations from the government to follow and that some direction is needed for ethical, health, and safety reasons (NIH, 1998). Federal regulations, however, do suggest that when vulnerable populations are included as research participants, Institutional Review Boards should have members with knowledge of those disorders on the Board to provide expertise in the evaluation process. The regulations also indicate that specialists may be recruited on an as-needed basis to consult in situations when the Institutional Review Board is in such a need.

## 7.0 Modifications to Protocol

A modification is defined as any change to an Institutional Review Board approved research protocol initiated by any investigator associated with a research protocol. Investigators are required to report in writing any proposed changes whatsoever to the Chairperson of the Institutional Review Board for review and approval *prior* to the initiation of the change.

Modifications are defined in two ways:

*Minor* - A minor modification is one of minimal change in risk to the subjects. Examples of minor modifications include title or principal investigator changes, the addition of co-

investigators, additions or changes to advertisements, a decrease in the frequency of a test or procedure, or extending the period for participant recruitment. Minor amendments may be treated as expedited review at the discretion of the Institutional Review Board Chairperson.

*Major* – A major modification is one that is, at the discretion of the Institutional Review Board Chairperson, substantive in nature and potentially alters the risk to the subjects. Examples of major modifications may include an increase in the frequency of a test or procedure, safety issues, multiple changes in study design, adding additional participants, extending the duration of the study, changing the recording medium of the study, or any other such circumstance. The Institutional Review Board reviews major modifications in the same manner as the original application.

A study previously reviewed and approved under the expedited protocol may be subject to a full review if modifications have increased the risk of participation. It should be noted that the above-mentioned examples are presented as general guidelines only. For further clarification, specific questions related to modifications should be directed to the Institutional Review Board Chairperson. Each modification will be reviewed on a case-by-case basis.

Modifications to research protocols will be handled consistent with the time frames related to those of expedited and full reviews of originally submitted research protocols.

## **8.0 Continuing Review & Other Reporting**

According to Federal regulations, the Institutional Review Board must conduct continuing review of previously approved protocols for studies, at intervals appropriate to the degree of risk posed to subjects, but not less than once per year. **For studies exceeding one year's duration, the Wheeling Jesuit University Institutional Review Board will require an annual progress report.**

Investigators are required to submit the resubmission Institutional Review Board application and required supporting documentation to the Institutional Review Board as described in the Institutional Review Board Handbook and the Institutional Review Board Investigators Manual. This will include any material facts related to the protocol including, but not limited to, the stage of the protocol, the number of participants to date, unexpected difficulties or findings, and an estimated timeframe for completion of the protocol.

If a protocol passes its expiration date without a continuation approval, it will be considered closed and no subject recruitment or data analysis may be conducted until a new application is submitted and approved by the Board.

*Other Reporting.* The Institutional Review Board may at any time, with cause, require an immediate status report. An immediate status report must be responded to in writing within seven (7) days of receipt. A request for an immediate status report will be sent via certified

mail to the PI. Failure to respond to a request for an immediate status report will result in the suspension of any protocol in which the PI is involved.

An immediate status report will be requested if the Institutional Review Board suspects that there has been an unreported modification to the research protocol, an unreported adverse event (Section 12) or non-compliance with any Institutional Review Board or Federal regulation governing the protection of human participants.

*Request to Change the Principal Investigator or to Add or to Remove an Investigator from a Study.* In the event that an investigator needs to be removed or added to a protocol, the investigator must indicate this change to the Institutional Review Board.

*Changes to the Protocol.* In order for a protocol to be changed in any way the Principal Investigator must inform the Institutional Review Board with a revised protocol to register those changes.

## **9.0 Adverse Event Reporting**

An adverse event is an unanticipated serious or unexpected negative physical, psychological, or emotional effect that is possibly related to an intervention associated with an Institutional Review Board approved research protocol. Investigators must report any adverse event associated with an Institutional Review Board approved protocol to the Institutional Review Board in writing within three (3) working days of the incident occurring.

For definition purposes an adverse event:

- is fatal
- is life threatening
- is permanently or significantly disabling
- requires medical treatment of any kind
- requires psychological counseling of any kind
- causes a congenital anomaly
- requires intervention to prevent permanent impairment or damage
- may result in future legal action against the University or Principal Investigator

Any adverse event is cause for a full Institutional Review Board review of the research protocol and the Institutional Review Board, at its discretion, may require changes to the existing protocol or suspend approval of the protocol because of the danger the protocol may represent to human subjects. Please refer to Appendix G – Adverse Event Report to document any of the above events that have occurred.

## **10.0 Protocol Deviations**

Principal Investigators are responsible for conducting research using human participants in compliance with Federal laws and regulations, the University's policies, and standards of professional conduct and practice. Failure to comply with regulations can result in the revocation of Institutional Review Board approval for a protocol and may jeopardize a researcher's ability to do future research at the University. Noncompliance by one investigator can affect the ability of all others at the University to conduct research involving human participants.

Examples of noncompliance include but are not limited to:

- failure to obtain approval before beginning the research
- failure to maintain approval for research
- failure to obtain informed consent when required
- failure to report adverse events
- failure to respond to a request for continuing review
- failure to respond to a request for an immediate status report
- failure to obtain approval of modifications to the approved protocol
- failure to adhere to the approved protocol
- performance of an unapproved study procedure
- performance of research at an unapproved site

These examples of noncompliance are referred to as protocol deviations. Investigators can almost always avoid protocol deviations by being aware of the Institutional Review Board requirements and following their approved protocol. Once a study is approved, the Institutional Review Board must approve any modification before the change is implemented in the protocol. If a protocol deviation does occur, the Principal Investigator must report it to the Institutional Review Board immediately upon discovery.

## **11.0 Research Misconduct Policy**

This policy is applicable to those who have allegedly committed research misconduct under the employment or relation to Wheeling Jesuit University.

11.1 Misconduct is defined as:

- Fabrication, falsification, plagiarism or other deviation from accepted research regulations established by Wheeling Jesuit University
- Misconduct committed intentionally, knowingly, recklessly
- This definition does not include honest error.

11.2 Reporting process:

All allegations of research misconduct (as defined above) will be reported to the Research Integrity Officer. Submission should be done in writing, signed by the complainant.

Once a misconduct allegation has been submitted it is forwarded to the Research Integrity Officer (RIO)

Within 10 days of receipt of the allegation, the RIO will notify the respondent of the allegations. This notification will include details about the allegation, although not necessarily the complainant's identity.

Within 3 days the RIO will assemble a review committee of three members (one designated as a chair) from a designated Research Integrity Review Committee (one of whom may be a subject matter expert appointed from the full-time faculty member from the university). The review committee will conduct a preliminary inquiry into the accusation to decide to whether the allegation alleges a misconduct in research and if it merits investigation. The respondent will be notified of the membership of the review committee. The complainant should be available to the committee.

During the inquiry stage the review committee may confer with persons other than the complainant and respondent as deemed appropriate. The committee may request for the supply of information, original copies of relevant records under the control of these persons. Anytime the respondent meets with the review committee the respondent may be advised with counsel or an advisor.

The Information Technology department will work with the RIO and Review Committee to help gather data and evidence as needed and with appropriate confidentiality.

Any interviews that are completed will be recorded or transcribed for an evidence entry to be reviewed by the Review Committee and Research Integrity Committee.

If the complainant requests anonymity, the request will be honored as much as possible.

Once the preliminary investigation is complete by the review committee, if deemed appropriate, the RIO ensures the appropriate steps are taken to safe keep the original copies of relevant research and data, and makes recommendations regarding respondent suspension (regarding pay and/or further work).

Within 30 days the review committee will report back to the RIO recommending one of the following:

- The matter be terminated due to the review committee agree unanimously that no violation was committed
- The full committee investigates the accusation of misconduct. If this is the recommendation, the RIO will initiate a full Research Integrity Review. Any sponsoring agency will be notified of the investigation.

This deadline can be extended by the RIO at the request of the review committee but cannot be extended beyond 60 days.

### 11.3 Research Integrity Officer

The Research Integrity Officer will be the Academic Vice President (AVP) or the AVP's appointee.

#### 11.4 Research Integrity Committee

When an accusation of misconduct is forwarded to the Research Integrity Committee for a formal investigation the RIO will present the respondent with a formal written statement of the allegations and evidence presented. The Research Integrity Committee can review and investigate any data related to the respondent's research. The committee can request further information from the respondent as deemed necessary.

Anytime the respondent appears before the committee counsel may accompany the respondent. The respondent has the right to present selected witness and evidence to the committee. The respondent or the respondent's counsel may cross-examine the presented witnesses.

Within 90 days of the referral of the case to the Research Integrity Committee, the chairperson will report the committee's findings to the RIO in writing. Findings will be categorized as one of the following:

- Finding of willful misconduct
- Finding that no willful misconduct was committed, but that serious error had occurred
- Finding that no misconduct or serious error was committed. If this is the finding then the case will be terminated.

If the respondent is found guilty of willful misconduct or serious error, the Research Integrity Committee will make recommendation of one of the following sanctions, in ascending order of severity:

- Letter of reprimand place in the respondent's employment file
- Special monitoring of future work
- Probation
- Removal from a particular project
- Termination of employment

Upon finalization of the investigation, the Research Integrity Committee's chairperson will submit the committee's findings, full committee report, and evidence to the RIO. The RIO will implement the selected sanctions after notifying the respondent of the findings, giving the respondent a period of time to request and argue for no/ a less/ or different sanction.

Sanctions recommended by the Research Integrity Committee are not eligible for Grievance Policy.

The Research Integrity Committee will be composed of 10 members and a Chairperson appointed by the President of the University. The membership shall be representative of the campus, including the humanities, sciences, undergraduate and graduate studies. Members shall be in place for three year terms, eligible for reappointment, except for the initial term of the committee which shall be staggered so that 1/3 of the members are replaced or reappointed each year. If a member's term ends during an investigation, the member may stay on the committee until the investigation is ended.



All investigation and proceedings completed by the Review Committee, Research Integrity Committee, and RIO are held confidential. Following the investigation, if misconduct is found, any sponsoring agency will be notified.

#### 11.6 Reporting

The RIO will report to the Office of Research Integrity any misconduct cases that are reported and the result of the investigation.

#### 11.7 Investigation Report

The Investigation Report shall include the following:

- Description of the nature of the allegations of research misconduct
- Description of the supporting agencies
- Description of the research charges presented
- Copy of the University's policies and procedures under which the investigation was conducted
- Research records and evidence
- Statement of findings with recommendations
  - Type of research misconduct committed
  - Supporting information for decision made
  - Identify any publications that would need to be retracted if applicable
  - Identify the person responsible for the misconduct
  - List any known support for the research

The following information is to be sent to the Office of Research Integrity:

- Full investigation report
- Final institution decision regarding the investigation
- Sanctions or actions following the decision made

#### 11. 8 Misconduct Report Maintenance

The university will maintain records of the misconduct investigations/proceedings in a secure manner for 7 years after completion

Information for the Research Misconduct Policy for Wheeling Jesuit University referenced information and writings in the Office of Research Integrity's Research Misconduct Checklist and the Georgetown University Research Misconduct Policy at [https://facultyhandbook.georgetown.edu/toc/section4#4&\\_ga=2.218675993.1499910565.1496841350-1851955642.1470841925j](https://facultyhandbook.georgetown.edu/toc/section4#4&_ga=2.218675993.1499910565.1496841350-1851955642.1470841925j).