Research Misconduct Policy

January, 2016

MARQUETTE UNIVERSITY
RESEARCH MISCONDUCT POLICY AND PROCEDURES

Preamble

Marquette University has a duty to ensure the integrity of research and will respond to each allegation of research misconduct in a thorough, competent, timely, objective, and fair manner. This policy applies to all disciplines of research including the applied and natural sciences, social sciences, and humanities. Its reach covers all institutional members of Marquette University and any individual who is employed by, is an agent of, or is affiliated by contract or agreement with the institution: institutional officials, tenured and untenured faculty, staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees. This policy applies not only to recipients of federal grants but also to individuals engaging in non-federally funded research. Students who are accused of research misconduct are subjected to the guidelines within this policy. However, students who are accused of academic dishonesty not relating to sponsored research will be under the jurisdiction of other existing university policies.

1.0 General policy (93.100)

Research misconduct is contrary to the integrity of research and to the interests of the university and those entities that sponsor the university's research. The institution has a duty to ensure the integrity of research and primary responsibility for responding to and reporting allegations of research misconduct. The institution will respond to each allegation of research misconduct in a thorough, competent, timely, objective, and fair manner.

Marquette University's policy is consistent with the requirements of federal agencies from which the institution requests and receives funding for research and research training, including 42 CFR part 93, "Public Health Service Policies on Research Misconduct."

1.1 Purpose (93.101)

The purpose of this document is to establish the responsibilities of Marquette University (the institution) and its members in responding to misconduct issues; define what constitutes misconduct in research; and describe the policies and procedures for reporting and responding to allegations of research misconduct covered by the policy.

1.2 Applicability (93.102)

The effective date of this policy is March 20, 2006.
This policy and the associated procedures apply to institutional members of Marquette University and includes any individual who is employed by, is an agent of, or is affiliated by contract or agreement with the institution. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and sub awardees, and their employees.

This policy and its associated procedures apply to allegations of research misconduct involving all forms of research as defined herein.

For the purpose of compliance with the PHS regulation at 42 CFR part 93, this policy and its associated procedures shall particularly apply to allegations of research misconduct involving:

- Applications or proposals for PHS support for biomedical or behavioral extramural or intramural research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information;
- PHS supported biomedical or behavioral extramural or intramural research;
- PHS supported biomedical or behavioral extramural or intramural research training programs;
- PHS supported extramural or intramural activities that are related to biomedical or behavioral research or research training, such as the operation of tissue and data banks or the dissemination of research information; and
- Plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training.

This policy and its related procedures apply as well to allegations of research misconduct involving any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for PHS or other federal funds resulted in a grant, contract, cooperative agreement, or other form of PHS or other federal support.

This policy and its associated procedures do not supersede or establish an alternative to any existing policies, regulations, or procedures for handling fiscal improprieties, the ethical treatment of human or animal subjects, criminal matters, personnel actions, or actions taken under federal debarment and suspension regulations, including those pertaining to HHS at 45 CFR part 76 and 48 CFR subparts 9.4 and 309.4.

This policy and its associated procedures shall normally be followed when an allegation of possible research misconduct is received by an employee of Marquette University. Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interests of Marquette University and the federal agency with oversight in the particular case. Any change from normal procedures also must ensure fair treatment to the respondent. Any variation will occur only in rare situations and should be approved in advance by the Research Integrity Officer (RIO).

1.3 Rule of interpretation (93.107)

Any interpretation of this policy must further the policy and purpose of the HHS or other federal agency as may be applicable and the federal government to protect the health and safety of the public, to promote the integrity of research, and to conserve public funds.

2.0 Research misconduct (93.103)

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- Fabrication is making up data or results and recording or reporting them.
- Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research misconduct does not include honest error or differences of opinion.

2.1 Requirements for findings of research misconduct (93.104)

A finding of research misconduct requires that:

- There be a significant departure from accepted practices of the relevant research community; and
- The misconduct be committed intentionally, knowingly, or recklessly; and
- The allegation be proven by a preponderance of the evidence.

2.2 Time limitations (93.105)

Six-year limitation. This policy applies only to research misconduct occurring within six years of the institution receiving an allegation of research misconduct.

Exceptions to the six-year limitation. The six year limitation does not apply in the following instances:

- Subsequent use exception. The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized.
- Health or safety of the public exception. If the institution or a federal sponsor determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.
- ``Grandfather" exception. If the institution received the allegation of research misconduct before the effective date of this policy.

2.3 Standard and Burden of Proof (93.106)

Standard of proof

A finding of research misconduct must be proved by a preponderance of the evidence.

Burden of proof

The institution has the burden of proof for making a finding of research misconduct. The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where the institution establishes by a preponderance of the evidence that the respondent intentionally,

knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.

The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised. In determining whether the institution has carried the burden of proof imposed by this part, the finder of fact shall give due consideration to credible evidence of honest error or difference of opinion presented by the respondent. The respondent has the burden of going forward with and proving by a preponderance of the evidence any mitigating factors that are relevant to a decision to impose administrative actions following a research misconduct proceeding.

3.0 Definitions

Administrative action means an institutional action in response to a research misconduct proceeding taken to protect the health and safety of the public, to promote the integrity of research, research training, or activities related to that research or research training and to conserve public funds; or an institutional action in response either to a breach of a material provision of a settlement agreement in a research misconduct proceeding or to a breach of any federal debarment or suspension.

Allegation means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an institutional official.

Complainant means a person who in good faith makes an allegation of research misconduct.

Conflict of interest means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.

Day, for the avoidance of any misunderstanding, shall mean one calendar day. Where the policy or federal regulation requires action by the institution to take place within a specified number of days, weekends and holidays shall be included in the count. Where a time extension is required, the policy explains when and how an extension may be requested. The RIO has the authority to request extensions from cognizant federal agencies as appropriate.

Deciding Official means the Provost of the University or his or her designee.

Evidence means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact.

Extramural support means funding from an outside entity, or applications or proposals therefore, for research, research training, or activities related to that research or training, that

may be provided through: grants, cooperative agreements, or contracts or subgrants or subcontracts; or salary or other payments under grants, cooperative agreements or contracts.

Federal Support means extramural support involving a federal agency.

Finding means a statement from the RIO stating the action the institution intends to take based on a recommendation of the inquiry or investigation committee.

Good faith as applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have based on the information known to the complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to a committee member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping an institution meet its responsibilities under this policy. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures described in this policy and its associated procedures. The aim of an inquiry is to determine whether an allegation or apparent instance of research misconduct warrants an investigation.

Institution means Marquette University.

Institutional member or members means a person who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees.

Investigation means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions.

NSF regulation means the National Science Foundation requirements for grantees related to research misconduct, as stated in the NSF Grants Policy Manual.

OIG means the Office of the Inspector General, the office within the National Science Foundation that is responsible for the agency's research misconduct activities.

ORI means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the research misconduct and research integrity activities of the U.S. Public Health Service.

PHS means the U.S. Public Health Service, an operating component of the DHHS.

PHS regulation means the Public Health Service regulations establishing standards for institutional inquiries and investigations into allegations of research misconduct, which is set forth at 42 CFR Part 93, "Public Health Service Policies on Research Misconduct."

Preponderance of the evidence means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

Research means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research). Research at Marquette University includes all forms of scholarship from the various disciplines. For the purpose of compliance with the PHS regulation, research is further defined as *relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.*

Research Integrity Officer (RIO) means the institutional official responsible for assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations. At Marquette University, the Vice President for Research and Innovation is the RIO.

Research misconduct proceeding means any actions related to alleged research misconduct taken under this part, including but not limited to, allegation assessments, inquiries, investigations, ORI or other federal agency oversight reviews, hearings, and administrative appeals.

Research record means the record of data or results that embody the facts resulting from scientific or other scholarly inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, books, proceedings, edited anthologies, visual and auditory media and any documents and materials that the respondent provides to the RIO or other institutional official or federal agency in the course of the research misconduct proceeding.

The purpose of including documents provided by respondent in the research record is to hold the respondent responsible for the integrity of those research documents regardless of when they were prepared or furnished to the institution or the cognizant federal agency. Because the complainant is not being held responsible for the record of data or results that embodies the facts resulting from the research at issue, comments provided by the complainant during the research misconduct proceeding are not included in the definition of

the term "research record." Those comments may be considered by the institution and/or the federal agency and they may be admitted as evidence in any hearing, but they are not part of the research record. If the complainant possesses documents that embody the facts resulting from the research that is the subject of the research misconduct proceeding, those documents are research records and the institution is responsible for maintaining and securing those documents in the same manner as other research records. Those documents are distinct from analyses of research records or results that a complainant may prepare prior to or in the course of a research misconduct proceeding to support his or her allegation of misconduct. Any such documents may be considered evidence pertinent to the allegation, but they are not part of the research record.

Respondent means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

Retaliation for the purpose of this policy means an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to a good faith allegation of research misconduct or good faith cooperation with a research misconduct proceeding.

4.0 Rights and responsibilities

4.1 Marquette University

Marquette University has an obligation to:

- Have a written policy and procedures for addressing allegations of research misconduct;
- Ensure that its members are aware of the policy and their obligations under the policy.
- Respond to each allegation of research misconduct for which the institution is responsible under this policy in a thorough, competent, timely, objective and fair manner, including precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional or financial conflicts of interest with the complainant, respondent or witnesses;
- Foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct;
- Take all reasonable and practical steps to protect the positions and reputations of good faith complainants, witnesses and committee members and protect them from retaliation by respondents and other institutional members;
- Provide confidentiality to the extent required by this policy to all respondents, complainants, and research subjects identifiable from research records or evidence;
- Take all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to, their providing information, research records, and evidence;

- Cooperate with federal sponsor agencies, including HHS, during any research misconduct proceeding or compliance review;
- Assist in administering and enforcing any administrative actions imposed by a federal sponsor agency, including HHS, on its institutional members; and
- Have an active assurance of compliance with each federal sponsor agency as required.

4.2 Institutional members

Institutional members share responsibility for maintaining sound research practices. Institutional members have a duty to report to the RIO observed, suspected, or apparent research misconduct. Institutional members who receive or learn of an allegation of research misconduct have a duty to immediately report the allegation to the RIO. Institutional members have a duty to cooperate with research misconduct proceedings, including but not limited to providing information, research records, and evidence.

At any time, any institutional member may have confidential discussions and consultations about concerns of possible misconduct with the RIO and be counseled about appropriate procedures for reporting allegations. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may contact the RIO to discuss the matter. The RIO will counsel the individual regarding appropriate procedures for reporting allegations. If this policy does not pertain to the circumstances described by the individual, the RIO may refer the matter to other offices as appropriate.

4.3 Research Integrity Officer

The Vice President for Research and Innovation shall serve as the institution's Research Integrity Officer (RIO) with primary responsibility for policy oversight and implementation, including dissemination and education. The RIO is responsible for implementing the procedures associated with the policy. The RIO shall:

- appoint the inquiry and investigation committees and ensure that they include the necessary and appropriate expertise to conduct a thorough and authoritative evaluation of the evidence in an inquiry or investigation.
- assist inquiry and investigation committees and all institutional members in complying with these procedures and with the applicable standards imposed by the government or other external sponsors.
- secure and maintain the institution's files and records pertaining to inquiries and investigations, including research records.
- monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto and those who cooperate in inquiries or investigations. The RIO shall also ensure that these persons shall not be retaliated against in the terms and conditions of their employment or other status at the institution and will review instances of alleged retaliation for appropriate action. Institutional members should report any alleged or apparent retaliation to the RIO.
- ensure timely compliance with all notification requirements of PHS and other federal agencies. For the purpose of complying with the PHS regulation, this

includes filing an annual report with ORI which contains information specified by ORI on the institution's compliance with the PHS regulation. Along with its assurance or annual report, an institution will send ORI such other aggregated information as ORI may request on the institution's research misconduct proceedings covered by the PHS regulation and the institution's compliance with these regulations.

The RIO has the sole authority to determine the need for and to request any appropriate and well justified time extensions from cognizant federal agencies.

The RIO shall report to the Deciding Official.

4.4 Complainant

The complainant has the responsibility for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry or investigation.

The complainant has the right to be informed of the results of the inquiry and investigation and the right to be protected from retaliation. The institution is required to make diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

4.5 Respondent

The respondent shall be informed of the allegations when an inquiry is opened and shall be notified in writing of the final determinations and resulting actions. The respondent shall have the right to be interviewed by and present evidence to the investigation committee, and to review and comment on the inquiry report and draft investigation report. The respondent has the right to have the advice of counsel.

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of the inquiry and investigation. If the respondent is not found guilty of research misconduct, he or she has the right to receive institutional assistance in restoring his/her reputation.

5.0 Research misconduct proceedings

5.1 Confidentiality (93.108)

To the extent allowed by law, the institution shall maintain the identity of respondents and complainants securely and confidentially and shall not disclose any identifying information, except to:

- those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and
- ORI or other authorized federal agency as it conducts its review of the research misconduct proceeding and any subsequent proceedings.

To the extent allowed by law, any information obtained during the research misconduct proceeding that might identify the subjects of research (i.e., Human Subjects) shall be maintained securely and confidentially and shall not be disclosed, except to those who need to know in order to carry out the research misconduct proceeding.

In order to serve on the inquiry or investigation committee, prospective members must agree to observe the confidentiality of the proceedings and any information or documents reviewed as part of the inquiry. Outside of the official proceedings of the committee, they may not discuss the proceedings with the respondent, complainant, witnesses, or anyone not authorized by the RIO to have knowledge of the inquiry.

Others involved in the misconduct proceedings, including any experts or witnesses, will also be advised of the confidentiality requirements and must agree in order to participate.

5.2 Conflict of interest (93.300(b) and 93.304(b))

The RIO will take reasonable steps to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses. The RIO will consider whether the individual or any members of his or her immediate family:

- has any financial involvement with the respondent or complainant;
- has been a coauthor on a publication with the respondent or complainant;
- has been a collaborator or co-investigator with the respondent or complainant;
- has been a party to a scientific controversy with the respondent or complainant;
- has a supervisory or mentor relationship with the respondent or complainant;
- has a special relationship, such as a close personal friendship, kinship, or physician/patient relationship with the respondent or complainant; or
- falls within any other circumstances that might appear to compromise the individual's objectivity in reviewing the allegations.

Prospective members of the inquiry or investigation committees must disclose to the RIO any potential conflicts of interest and agree to promptly disclose to the RIO any new conflicts of interest they may acquire during the course of the proceedings.

Any experts participating in the misconduct proceedings will also be screened by the RIO for any unresolved personal, professional, or financial conflicts of interest.

5.3 Interim Protective Actions (93.318)

At any time during a research misconduct proceeding, the institution shall take appropriate interim actions to protect public health, federal funds and equipment, and the integrity of the PHS or other federally supported research process. The necessary actions will vary according to the circumstances of each case, but examples of actions that may be necessary include delaying the publication of research results, providing for closer supervision of one or more researchers, requiring approvals for actions relating to the research that did not previously

require approval, auditing pertinent records, or taking steps to contact other institutions that may be affected by an allegation of research misconduct.

Allegations subject to the PHS regulation

At any time during a research misconduct proceeding that involves PHS funding or applications for funding, the RIO shall notify ORI immediately if he or she has reason to believe any of the following special circumstances exist:

- health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- HHS resources or interests are threatened;
- research activities should be suspended;
- there is a reasonable indication of possible violation of civil or criminal law;
- federal action is required to protect the interests of those involved in the research misconduct proceeding;
- the research misconduct proceeding may be made public prematurely; and/or
- the research community or public should be informed.

Allegations subject to NSF regulation

At any time during a research misconduct proceeding that involves NSF funding or applications for funding, the institution shall notify NSF Office of the Inspector General immediately if it has reason to believe any of the following special circumstances exist:

- there is reasonable indication of possible violations of civil or criminal law;
- public health or safety are at risk;
- NSF's resources, reputation, or other interests need protecting;
- federal action may be needed to protect the interests of a subject of the investigation or of others potentially affected;
- the research community or the public should be informed; and/or
- research activities should be suspended.

5.4 Referral of non-research misconduct issues

If the research misconduct proceeding identifies non-research misconduct issues, the RIO should refer these matters to the proper institutional or federal office for action. Issues requiring referral are described below.

Criminal violations. Potential violation of criminal law under federal grants and contracts should be referred to the Office of the Inspector General at the relevant agency. If the possible criminal violation is identical to the alleged research misconduct (e.g., alleged false statements in a PHS grant application), the institutional official should report the criminal charge to the relevant federal agency with oversight responsibility for research integrity (in the case of PHS, OIG) and request guidance for further reporting from that office. See also **Interim Protective Actions.**

Violations of Human and Animal Subject Regulations. Potential violations of human subject or animal care and use regulations should be referred to the Office of Research Compliance for further action as appropriate.

Violation of FDA regulations. Potential violations of Food and Drug Administration regulated research requirements should be referred to the FDA Office of Regulatory Affairs.

Fiscal irregularities. Potential violations of cost principles or other fiscal irregularities should be referred to the Office of Research and Sponsored Programs and the Office of the Comptroller for further action.

5.5 Custody and maintenance of research records and evidence (93.305)

Before or at the time the RIO notifies the respondent of the allegation, inquiry, or investigation, the RIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner.

Thereafter, the RIO will undertake all reasonable and practical efforts to take custody of additional research records or evidence discovered during the course of a research misconduct proceeding. The RIO should obtain the assistance of the respondent's supervisor and institutional counsel in this process as necessary.

Taking custody of research records from the respondent

The RIO should notify the respondent that an inquiry is being initiated simultaneously with the sequestration so that the respondent can assist with the location and identification of the research records. If the respondent is not available, sequestration may begin in the respondent's absence. The respondent should not be notified in advance of the sequestration of research records to prevent questions being raised later regarding missing documents or materials and to prevent accusations against the respondent of tampering with or fabricating data or materials after notification.

Taking custody of research records from others

In addition to securing records under the control of the respondent, the RIO may need to sequester records from other individuals, such as coauthors, collaborators, or complainants.

If requested, a copy of each sequestered record will be provided to the individual from whom the record is taken as soon as practical.

Taking custody of shared instruments

Where scientific instruments shared by a number of users are involved, custody may be limited to copies of the data or evidence from such instruments, so long as those copies serve the same evidentiary purpose as the instruments. Questions about such copies should be referred to the institutional counsel and/or the relevant federal agency.

Inventory and dated receipts

A dated receipt should be signed by the sequestering official and the person from whom an item is taken. If it is not possible to prepare a complete inventory list at the time of collection, one should be prepared as soon as possible, and then a copy of the inventory should be given to the person from whom the items were collected.

Maintaining custody and providing copies or access

The RIO will lock records and materials in a secure place. The person from whom items are collected may be provided with a copy of the items. Where feasible and at the RIO's discretion, that person will have access to his or her own original items under the direct and continuous supervision of an institutional official. This will ensure that a proper chain of custody is maintained and that the originals are kept intact and unmodified. Questions about maintaining the chain of custody of records should be referred to the institutional counsel.

5.6 Retention and custody of the research misconduct proceeding record (93.317)

Research misconduct proceeding records include the following:

1. The records that the institution secures for the proceeding pursuant to this policy and pertinent to the inquiry and/or investigation, except to the extent the institution subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained;
2. The documentation of the determination of irrelevant or duplicate records;
3. The inquiry report and final documents produced in the course of preparing that report, including the documentation of any decision not to investigate (i.e., the RIO's determination letter);
4. The investigation report and all records (other than drafts of the report) in support of that report, including the recordings or transcriptions of each interview.

Unless custody has been transferred to HHS or other federal agency, or ORI or other appropriate federal authority has advised the institution in writing that it no longer needs to retain the records, the institution will maintain records of research misconduct proceedings in a secure manner for 7 years after completion of the proceeding or the completion of any PHS or other federal proceeding involving the research misconduct allegation, whichever is later.

On request, the institution shall transfer custody or provide copies to HHS or other federal authority of any institutional record relevant to a research misconduct allegation covered by this policy and subject to federal regulation, including the research records and evidence, to perform forensic or other analyses or as otherwise needed to conduct an HHS or other authorized federal inquiry or investigation or for ORI or other authorized federal agency to conduct its review or to present evidence in any subsequent proceeding.

5.7 Completing the research misconduct process (93.316)

The institution will carry inquiries and investigations through to completion and pursue diligently all significant issues.

Admission of misconduct or proposed settlement

The institution shall notify the relevant federal agency and, in the case of allegations subject to PHS regulation, notify ORI, in advance if the institution plans to close a case at the inquiry or investigation stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except the closing of a case at the

inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage, which will be reported as stated elsewhere in this policy.

The federal agency may conduct an oversight review and may approve or conditionally approve closing the case, direct the institution to complete its process, refer the matter for further investigation to HHS or other federal authority, or take a compliance action. The institution shall cooperate fully with the federal agency in these matters.

Termination of employment or resignation prior to completing the inquiry or investigation

The termination of the respondent's employment, by resignation or otherwise, before or after an allegation of research misconduct has been reported, shall not preclude or terminate the research misconduct proceedings. If the respondent, without admitting to the misconduct, elects to resign his or her position prior to the initiation of the inquiry, but after an allegation has been reported, or during an inquiry or investigation, the inquiry or investigation shall proceed. If the respondent refuses to participate in the research misconduct proceedings after resignation, the committee shall use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's refusal to cooperate and its effect on the committee's review of all the evidence.

6.0 Allegation assessment (93.307)

Upon receiving an allegation of research misconduct, the RIO shall promptly assess the allegation to determine whether an inquiry is warranted.

6.1 Criteria warranting an inquiry (93.307(a))

An inquiry is warranted if the allegation:

- falls within the definition of research misconduct;
- falls within this policy as set forth under the sections entitled **Applicability** and **Time limitations**.
- is sufficiently credible and specific so that potential evidence of misconduct may be identified.

Applicable federal regulation. If there is any doubt about whether an allegation may be subject to federal regulation, the RIO may consult with institutional counsel and the federal agency or agencies.

Sufficiently credible and specific. There is not always sufficient information to permit further inquiry into an allegation. For example, an allegation that a researcher's work should be subjected to general examination for possible misconduct is not sufficiently credible or specific to initiate an inquiry. In the case of such a vague allegation, the RIO should make an effort to obtain more information before initiating an inquiry, This information may be sought from any reasonable source, including the person making the allegation.

At the same time, it is important to recognize that the complainant is not the equivalent of a "party" in a dispute. Once the complainant has made an allegation of research misconduct, that person does not participate in the research misconduct proceeding except as a witness. The institution has an obligation to pursue allegations of research misconduct independent of the complainant's role.

6.2 Referral of other issues

Regardless of whether the RIO determines that a research misconduct inquiry is warranted, if the allegation involves federal support or applications for funding and concerns possible failure to protect human or animal subjects, financial irregularities, or criminal activity, the allegations should be referred to the appropriate institutional or federal office as prescribed in the section entitled **Referral of non-research misconduct issues**.

7.0 Institutional inquiry (93.307)

7.1 Custody of research records and evidence (93.307(b))

To the extent he or she has not already done so at the allegation stage and before or at the time of notifying the respondent, the RIO shall follow the steps described in section 5.5 entitled **Custody and maintenance of research records and evidence (93.305)**

7.2 Notice to respondent (93.307(b))

At the time of or before beginning an inquiry, the RIO shall make a good faith effort to notify in writing the presumed respondent, if any. If the inquiry subsequently identifies additional respondents, the RIO shall notify them as soon as possible.

The notification should:

- identify the research project in question and the specific allegations,
- define research misconduct,
- identify the PHS or other extramural funding involved,
- explain the respondent's right to review and comment on the inquiry report;
- address the respondent's obligation as an employee of the institution to cooperate;
- describe the institution's policy on protecting the complainant against retaliation and the need to maintain the complainant's confidentiality during the inquiry and any subsequent proceedings;
- provide a copy of this policy.

If no specific respondent has been identified at this stage of the process, the RIO will notify each potential respondent that an inquiry will be undertaken (e.g., each coauthor on a questioned article or each investigator on a questioned grant application). The RIO should consult with institutional counsel on proper notification under the circumstances.

7.3 Appointing the inquiry committee

The RIO, in consultation with other institutional officials as appropriate, shall appoint an inquiry committee and committee chair. The size and constitution of the committee shall be determined by the RIO. The committee shall include at least three Marquette faculty members. The inquiry committee should consist of individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside of the institution.

The RIO shall notify the respondent of the proposed committee membership, and the respondent will have the opportunity to submit a written objection to any appointed member of the committee based on bias or conflict.

7.4 Inquiry time limits (93.307(g))

The inquiry shall be said to begin when the inquiry committee receives the instructions at the first meeting.

For the purpose of complying with the PHS regulation, the inquiry committee will complete the inquiry within 60 days of its initiation unless circumstances clearly warrant a longer period. This 60 day period includes preparing the inquiry report and giving the respondent a reasonable opportunity of no less than seven days to comment on it.

If the inquiry takes longer than 60 days to complete, the RIO may approve an extension for good cause. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-day period. Where an extension is likely to be necessary, the RIO is advised to notify ORI in advance.

For the purpose of complying with the NSF regulation and where the institution wishes to defer independent inquiry or investigation, the institution shall complete any inquiry and determine whether an investigation is warranted (i.e., the RIO shall write the determination letter) within 90 days of beginning the inquiry (i.e., within 90 days of delivering the instructions to the inquiry committee at its first meeting).

If completion of the inquiry is delayed but the institution wishes NSF deferral to continue, the RIO must contact NSF OIG and request an extension. This request and the NSF OIG reply will be entered into the records of the research misconduct proceeding.

7.5 Instructions to the inquiry committee and the first meeting

The RIO will prepare written instructions for the inquiry committee that describes the allegations and any related issues identified during the allegation assessment and states the purpose of the inquiry and the criteria warranting an investigation.

At the first meeting, the RIO will review the instructions with the inquiry committee, discuss the allegations, any related issues, and the appropriate procedures and time limits for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions. The RIO and institutional counsel will be available throughout the inquiry to advise as needed.

Provision of assistance

The RIO, in consultation with institutional counsel, will provide staff assistance and guidance to the inquiry committee and any experts on the procedures for conducting and completing the inquiry, including procedures for maintaining confidentiality, conducting interviews, analyzing data, and preparing the inquiry report.

Scope and purpose of inquiry (93.307(c))

The purpose of an inquiry is to conduct an initial review of the evidence to determine whether to conduct an investigation. Therefore, an inquiry does not require a full review of all the evidence related to the allegation.

The scope of inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses. The inquiry official or committee will evaluate the evidence and testimony only as far as necessary to determine the need for further investigation.

7.6 Criteria warranting an investigation (93.307(d))

An inquiry's purpose is to decide if an allegation warrants an investigation. An investigation is warranted if:

- there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct under this policy and involves federally supported research, or activities related to federally supported research or research training, subject to PHS or other federal regulation; and
- preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

7.7 Inquiry process

The inquiry committee will examine the relevant evidence, including research records and materials.

The inquiry committee may interview the complainant, the respondent, and experts or witnesses. Any interviews must be recorded and/or transcribed. Interviewees must be provided with a copy of the transcript to review and correct errors. Interviewees may add comments or information. Changes to the transcript will be made only to correct factual errors.

After consultation with the RIO and institutional counsel, the inquiry committee members will decide whether there is at this stage sufficient evidence of possible scientific misconduct to recommend further investigation.

7.8 The inquiry report (93.307(e), 93.309)

Elements of the inquiry report

The inquiry report shall be in the form of a recommendation to the RIO and be comprised of the following:

- the date the report is submitted to the RIO
- the name and position of the respondent;
- a description of the allegations of research misconduct;
- the PHS or other federal support pertinent to the allegation, including for example, grant numbers, grant applications, contracts, and publications listing the PHS or other federal support;

- the committee's recommendation to conduct an investigation or not; and
- the basis for the recommendation that the alleged actions require an investigation or not.

At the time the inquiry official or committee presents the inquiry report to the RIO, the committee shall also provide the RIO with the following:

- the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents.

Comments on the inquiry report by respondent (93.307(f))

The RIO shall provide the respondent with a copy of the inquiry report for review and an opportunity to provide the RIO with written comments. The RIO shall establish reasonable conditions for review to protect the confidentiality of the inquiry report.

The RIO will establish a reasonable deadline of no less than seven days for written comment that is consistent with the institution's obligations under this policy. The RIO shall inform the respondent of the deadline in writing. The respondent shall provide comments to the RIO within the allotted time or the opportunity for comment shall be deemed waived. Any comments that the respondent submits to the RIO within the allotted time must be attached to the inquiry report.

The RIO may approve an extension for good cause, and the reason for the extension will be included in the RIO's notification letter described below and, in this way, entered into the records of the research misconduct proceeding.

7.9 RIO determination (93.309)

The RIO, after carefully considering the inquiry report and any timely comments from the respondent, shall decide whether an investigation is warranted. The RIO's decision shall be written in the form of a determination letter and shall include the following, with attachments as appropriate:

- the date of the letter
- the institution's determination to conduct an investigation or not;
- the charges, if any, for the investigation to consider
- a description of the institutional policies and procedures under which the inquiry was conducted and a copy of the policies and procedures or reference to these;
- a detailed record of any time extensions granted, and any correspondence with the cognizant federal agency.
- the inquiry report with any timely comments received from the respondent:
    - the date the report is submitted to the RIO
    - the name and position of the respondent;
    - a description of the allegations of research misconduct;

- the PHS or other federal support pertinent to the allegation, including for example, grant numbers, grant applications, contracts, and publications listing the PHS or other federal support;
- the committee's recommendation to conduct an investigation or not;
- the basis for the recommendation that the alleged actions require an investigation or not;
- respondent's comments, if any, on the inquiry report.

The RIO will take possession of and provide to the appropriate federal agency upon request the following:

- the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents.

8.0 Notice of the results of the inquiry (93.308)

8.1 Notice to respondent and complainant (93.308(a), 93.310)

The RIO shall transmit the determination letter to the respondent within a reasonable amount of time after making the determination but before beginning the investigation (if warranted). (93.310)

The RIO shall notify the complainant of the outcome of the inquiry within a reasonable amount of time after making the determination.

8.2 If investigation is warranted (93.309; 93.310)

For the purpose of complying with the PHS regulation, the RIO must transmit the determination letter and the inquiry report with the respondent's comments (if any) to ORI within 30 days of finding that an investigation is warranted (typically within 90 days of delivering the instructions to the inquiry committee at its first meeting), and before initiating an investigation.

The RIO will be prepared to provide the following additional information to ORI on request:

- The research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents.

For allegations subject to NSF regulation, upon a finding of the inquiry that an allegation warrants an investigation, the RIO will immediately notify NSF OIG and shall keep NSF OIG informed as appropriate during the investigation.

8.3 If investigation is not warranted (93.309(c))

For allegations subject to the PHS regulation, the institution annually reports to ORI on allegations received, inquiries, and investigations. Where an inquiry finds that an investigation is not warranted, the inquiry and its outcome will be noted in the annual report to ORI.

For allegations subject to the NSF regulation, the institution will notify NSF as required by the agency. NSF does not, at present, require notification where an inquiry is completed within 90 days and finds no investigation is warranted. Where the RIO has requested an extension from NSF, the RIO shall follow NSF's instructions regarding subsequent reporting and notification.

Documentation of the decision not to investigate (93.309(c))

The Institution will keep sufficiently detailed documentation of inquiries to permit a later assessment by ORI or other federal agency of the reasons why the institution decided not to conduct an investigation. The institution shall keep these records in a secure manner for at least 7 years after the termination of the inquiry, and upon request, provide them to ORI or other authorized federal agency personnel. (93.309)

9.0 Institutional investigation (93.310)

9.1 Investigation time limits (93.310(a), 93.311(a))

The investigation will begin within 30 days after determining that an investigation is warranted. The investigation shall be said to begin at the first meeting of the investigation committee at which the committee receives its instructions.

For the purpose of complying with the PHS regulation, the institution will use its best efforts to complete all aspects of an investigation within 120 days of beginning it (i.e., within 120 days of the first meeting of the investigation committee). Completing the investigation includes conducting the investigation, preparing the draft report of findings, providing the draft report to the respondent and complainant and allowing 30 days for comment, submitting the report to the Deciding Official, preparing the institution's determination letter, and sending the final report and institutional determination to ORI. If unable to complete all aspects of an investigation within 120 days, the RIO may submit a written request for an extension to the relevant federal agency. This time limit does not apply to separate termination proceedings.

For the purpose of complying with the NSF regulation and where the institution wishes to defer independent inquiry or investigation, the institution shall complete any investigation, reach a disposition, and notify NSF within 180 days of beginning the inquiry. If completion of the investigation is delayed but the institution wishes NSF deferral to continue, the RIO must notify NSF OIG and request an extension in writing.

9.2 Notification requirements (93.310(b,c))

See the section entitled **Notice of the results of the inquiry (93.308)**.

The RIO will give the respondent written notice of any new allegation of research misconduct within a reasonable amount of time after deciding to pursue allegations not addressed during the inquiry or in the initial notice of investigation.

9.3 Custody of research records and evidence (93.310(d))

To the extent he or she has not already done so at the allegation or inquiry stages, the RIO shall follow the steps described in section 5.5 entitled **Custody and maintenance of research records and evidence (93.305)**

9.4 Appointing the investigation committee (93.310(e-f)

The RIO, in consultation with other institutional officials as appropriate, shall appoint an investigation committee and committee chair. The size and constitution of the committee shall be determined by the RIO. The committee shall include at least three Marquette faculty members. The investigation committee should consist of individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct a thorough investigation of all research records and evidence relevant to reaching a decision on the merits of the allegations. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside of the institution. They may be individuals who served on the inquiry committee.

The RIO shall notify the respondent of the proposed committee membership and the respondent will have the opportunity to submit a written objection to any appointed member of the committee based on bias or conflict.

9.5 Instructions to the investigation committee and the first meeting

Provision of assistance

The RIO, in consultation with institutional counsel, will provide staff assistance and guidance to the investigation committee and any experts on the procedures for conducting and completing the investigation, including procedures for maintaining confidentiality, conducting interviews, analyzing data, and preparing the investigation report.

Review of evidence (93.310(e))

The committee shall use diligent efforts to conduct a thorough examination of all research records and evidence relevant to reaching a decision on the merits of the allegations.

Interviews (93.310(g))

The committee shall interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation. The committee shall interview any available witnesses reasonably identified by the respondent as having information regarding any relevant aspects of the investigation.

Each interview will be recorded or transcribed. Each interviewee will be provided with his or her recording or transcript for correction. Interviewees may add comments or information. Changes to the transcript will be made only to correct factual errors. Each recording or

transcript and any additional comments or corrections will be included in the record of the investigation.

Pursue leads (93.310(h))

The committee shall pursue diligently all significant issues and leads discovered that it determines relevant to the investigation, including any evidence of additional instances of possible research misconduct, and shall continue the investigation to completion.

9.6 Opportunity to comment on draft investigation report (93.312)

Respondent. The institution shall give the respondent a copy of the draft investigation report and, concurrently, a copy of or supervised access to the evidence on which the report is based. The RIO will establish a deadline for written comment that is consistent with the institution's notification obligations under federal regulations, or in the absence of federal notification requirements, a reasonable amount of time determined at the RIO's sole discretion. The RIO shall inform the respondent of the deadline in writing. The deadline will not exceed 30 days from the time the RIO provides the investigation report for review and comment. The respondent shall provide comments to the RIO within the allotted time or the opportunity for comment shall be deemed waived. Any comments that the respondent submits to the RIO within the allotted time shall be attached to the investigation report.

The RIO may approve an extension for good cause, and the reason for the extension will be included in the records of the research misconduct proceeding.

9.7 Institutional investigation report (93.313)

The final institutional investigation report must include:

1. Allegations. Describe the nature of the allegations of research misconduct.
2. PHS support. Describe and document the PHS support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS support.
3. Institutional charge. Describe the specific allegations of research misconduct for consideration in the investigation.
4. Policies and procedures. If not already provided to ORI with the inquiry report, include the institutional policies and procedures under which the investigation was conducted.
5. Research records and evidence. Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed.
6. Statement of findings. For each separate allegation of research misconduct identified during the investigation, provide a finding as to whether research misconduct did or did not occur, and if so:
    a. Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard;
    b. Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent;
    c. Identify the specific PHS support;
    d. Identify whether any publications need correction or retraction;
    e. Identify the person(s) responsible for the misconduct; and

f. List any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies.

7. Comments. Include and consider any comments made by the respondent and complainant on the draft investigation report.

9.8 Maintain and provide records on request

The RIO will maintain and provide to ORI or other federal agency upon request all relevant research records and records of the institution's research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews. See section 5.6 entitled **Retention and custody of the research misconduct proceeding record.**

9.9 Institutional counsel

The investigation report shall be transmitted to the institutional counsel for review and comment.

9.10 Institutional review and decision

The RIO shall provide a Deciding Official with the investigation report. The Deciding Official shall consider the assembled record, including any comments provided by the respondent and/or complainant on the draft investigation report. Based on a preponderance of the evidence the Deciding Official shall decide whether the institution will accept the investigation report, its findings, and shall determine the appropriate institutional actions.

If this determination varies from that of the investigation committee, the Deciding Official shall provide a written statement explaining in detail the basis for rendering a decision different from that of the investigation committee; he or she shall also include this statement in the institution's letter transmitting the investigation report to ORI for cases subject to the PHS regulation or to the appropriate agency official for other funding agencies. The Deciding Official's explanation should be consistent with the PHS or other relevant federal definition of research misconduct, the institution's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The Deciding Official may also return the report to the investigation committee with a request for further fact-finding or analysis. The Deciding Official's determination, along with the investigation report, constitutes the final investigation report for purposes of ORI or other federal agency review.

When a final decision on the case has been reached by the institution, the RIO shall notify both the respondent and the complainant in writing. In addition, the RIO shall determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals, collaborators or the respondent in the work, or other relevant parties should be notified of the outcome of the case.

10.0 Institutional administrative actions (93.314)

The institution shall take appropriate administrative actions against individuals when an allegation of research misconduct has been substantiated.

If the Deciding Official determines that the alleged misconduct is substantiated by the findings, he or she will determine the appropriate actions to be taken after consultation with the RIO and others, including counsel, as appropriate. These actions may include:

- appropriate steps to correct the research record (e.g., withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found);
- removal of the responsible person from the particular project;
- special monitoring of future work;
- debarment from extramural grants; and/or
- initiation of steps leading to possible reprimand, probation, suspension, rank and/or salary reduction, or termination of employment.

For students, administrative actions may also include:

- loss of credit for the research; and/or
- initiation of steps leading to possible loss of assistantship, dismissal from the program, or dismissal from the university.

11.0 Institutional appeals (93.314)

The Deciding Official's decision with respect to the findings and corrective actions shall be final.

12.0 Notice to ORI of institutional findings and actions (93.315)

For allegations subject to the PHS regulation, the RIO will provide to ORI, upon completion of an investigation, the following:

- Investigation report and all attachments.
- Final institutional action. A statement whether the investigation found research misconduct and, if so, who committed the misconduct.
- Findings. A statement of whether the institution accepts the investigation's findings.
- Institutional administrative actions. A statement of any pending or completed administrative actions against the respondent.

For allegations subject to other federal agency regulation, the ORI will provide these materials to the appropriate agency

13.0 Cooperation with federal agencies

The institution shall cooperate fully and on a continuing basis with ORI or other federal agency during oversight reviews of the institution and its misconduct proceedings and during the process under which the respondent may contest findings of research misconduct by ORI or other federal agency and proposed administrative actions by the federal agency. This includes providing, as necessary to develop a complete record of relevant evidence, all witnesses, research records, and other evidence under institutional control or custody, or in the possession of, or accessible to, all persons that are subject to the institution's authority.

14.0 Protecting and restoring reputations (93.304(k))

The institution shall make all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made by the institution or cognizant federal agency, if any. The RIO shall consider appropriate measures in consultation with the Deciding Official and/or institutional counsel.

The RIO will undertake all reasonable and practical efforts to protect or restore the position and reputation of any complainant, witness, or committee member and to counter any potential or actual retaliation against these individuals.