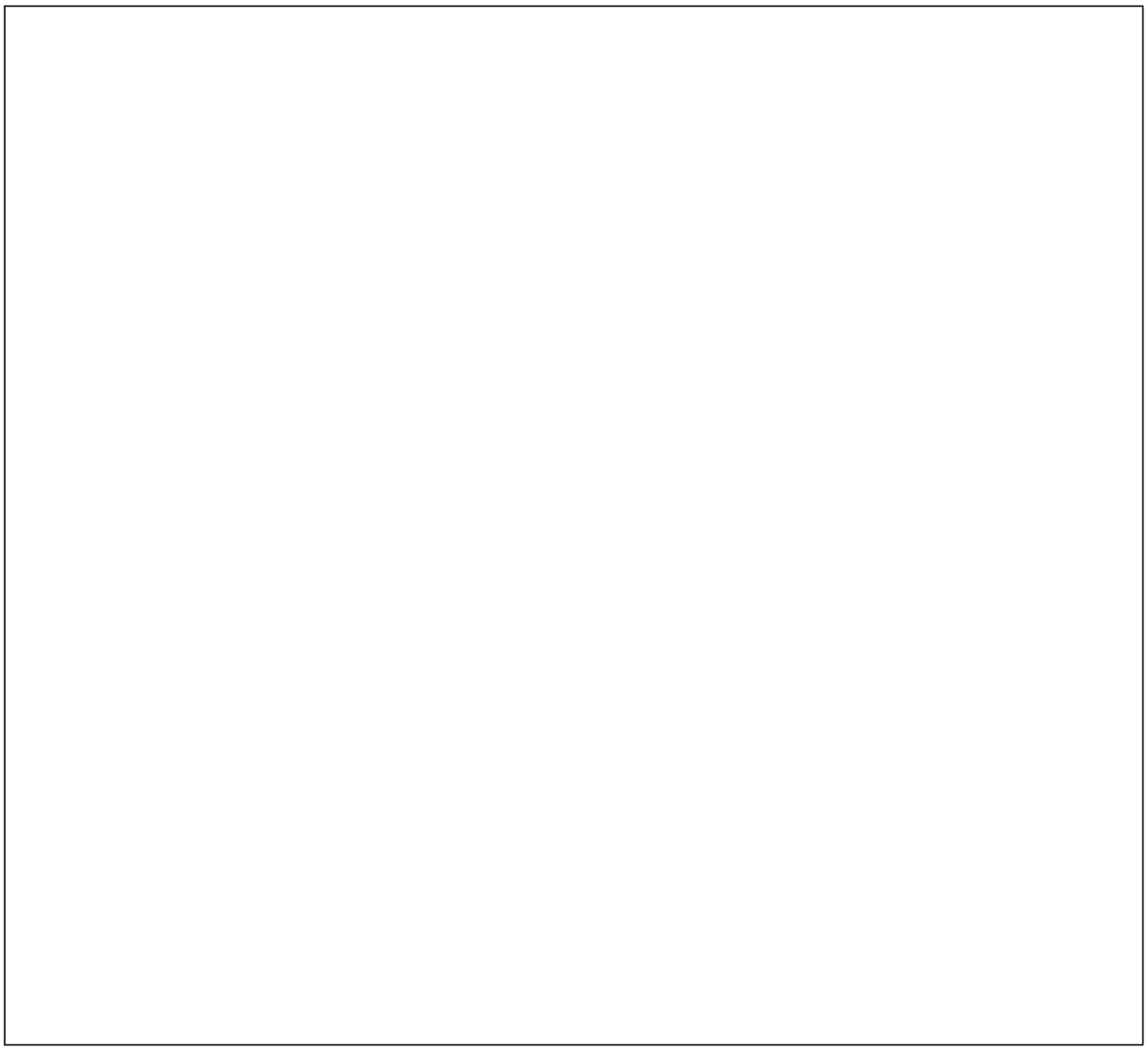

Preamble

Marquette University has a duty to ensure the integrity of research and will respond to each allegation of research mi

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 tiip3Oe nk-9(t.3 Tm[ )(a)M 177.0

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,

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 extram

- Cooperate with federal sponsor agencies, including HHS, during any research misconduct proceeding or compliance revi

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 advi BT1 0 0 1 275.81 695.5 72r[e)225 Tm[he)4( )-9(a)4(ll)-3(e)4(ga)4(t)]TJETBT

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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 all 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 er1 0 0 1 461.T[illegible]ETBT/F3 327DC29 450.67 Tm[h)]TJ/BT1 0 0 1 248.93 367.85 0 0r

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.

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 gm

7.4 Inquiry time limits (93.307(g))

The inquiry shall be said to begin when the inquiry committee receives the instructions at the fi

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 materia

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- 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.

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);
- rem