USF MISCONDUCT IN RESEARCH PROCEDURES

These Misconduct in Research Procedures are to be used in conjunction with USF Policy 0-301, Misconduct in Research ("**the Policy**"). They apply when an allegation of research misconduct is made to an appropriate USF official in accordance with the Policy. Capitalized terms that are not defined have the same definitions as set forth in the Policy.

I. Conducting the Assessment and Inquiry

A. When an allegation of research misconduct is received

As soon as practicable after receiving an allegation of research misconduct, the Research Integrity Officer (RIO) will assess the allegation to determine whether:

1. It falls within the definition of research misconduct included in the Policy or applicable federal agency regulation; and
2. It is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

If both of these criteria are met, an inquiry must be conducted.

In conducting the assessment, the RIO need not interview the complainant, respondent, or other witnesses or gather information or data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

However, if the RIO elects to interview the complainant, respondent, or other witnesses who may have information related to the alleged misconduct, these interviews should be conducted as soon as practicable, and any ancillary evidence needed to facilitate the assessment should be requested and reviewed expeditiously. The RIO may seek advice as necessary, including that of the appropriate dean or department chair.

If the RIO determines the two criteria are met, the RIO will immediately consult with the IO to determine if there are other USF officials that need to be notified of the allegation and to identify an appropriate individual to serve as inquiry chair.

Upon conclusion of the assessment, the RIO or RIO's designee must retain all relevant documentation pertaining to the assessment in accordance with University and research sponsor requirements.

B. Alternative procedure for conducting the assessment

If the RIO is unavailable to expeditiously perform the assessment, is unable to discern whether an allegation warrants referral for inquiry, or has a potential conflict of interest that could undermine the integrity of the assessment, an ad hoc review committee will be appointed by the IO or the IO's designee to review and assess the allegation. If the ad hoc committee is not readily available to meet, then the allegations may be reviewed with other individuals as deemed appropriate by the IO.

C. Initiation and purpose of inquiry and sequestration of the research records

If the RIO determines that the criteria for an inquiry are met, s/he will immediately initiate the inquiry process. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether the allegation warrants an investigation. An inquiry does not require a full review of all the evidence related to the allegation.

On or before the date on which the respondent is notified in accordance with **I.D.**, below, of these Procedures (Notification of inquiry) or the inquiry begins, whichever is earlier, the RIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the inquiry, inventory the records and evidence, and sequester them in a secure manner. Records or equipment that are clearly identifiable as personal and not the property of USF will not be made a part of the inquiry record. Where feasible and appropriate, the RIO will work with the affected laboratories and researcher(s) to provide copies of records to the respondent and other research personnel to facilitate the continuation of the research pending completion of the inquiry. Where the research records or evidence encompass scientific instruments shared by multiple users, custody may be limited to copies of the data or evidence on the instruments, so long as those copies have evidentiary value substantially equivalent to that of the instruments themselves.

The affected school, college, or campus will assist with the sequestration to the extent possible by providing information prior to the sequestration regarding the nature of the potential material involved and making personnel with the necessary technical expertise available to assist during the sequestration. This assistance may include inventorying the research records and evidence and providing for the storage of materials that require special handling, such as biological or chemical materials.

D. Notification of inquiry

At the time of or before beginning an inquiry, the RIO or the inquiry chair must make a good faith effort to notify the respondent in writing that an inquiry is being initiated. The notification will include a summary of the allegation(s), a copy of the Policy and these Procedures, and will invite a response to the allegations. If the inquiry subsequently identifies additional respondents, the RIO or the inquiry chair must also notify the additional respondents in writing. The inquiry chair will notify the complainant (if known) that an inquiry has been initiated.

The RIO or the IO may also elect to inform the Provost of all research misconduct matters that have progressed to the inquiry stage. If the allegations involve one or more of the conditions specified in **I.A**. of these Procedures (When an allegation of research misconduct is received), the IO is responsible for notifying the Provost.

E. Appointment of the inquiry committee

The RIO, in consultation with other University officials as appropriate, is responsible for appointing an inquiry committee to conduct the inquiry. The committee will typically consist of at least three individuals, two of whom should have appropriate backgrounds or expertise to assess the allegation(s). Inquiry committee members must not have an unresolved conflict of interest—personal, professional, or financial—in relation to the inquiry. As necessary, the RIO may select inquiry committee members from outside the University if expertise is needed or to avoid a conflict of interest. The inquiry committee may consult with outside experts as necessary to appropriately perform the inquiry. Outside experts, if utilized, are strictly advisory to the inquiry committee and must be promptly informed of the requirement to maintain strict confidentiality regarding the inquiry.

F. Charge to the inquiry committee and initial meeting

The RIO will hold an initial meeting with the inquiry committee during which the RIO will present the inquiry committee with a written charge that:

- describes the allegations and any related issues identified during the allegation assessment that are germane to the committee's work;
- explains that the purpose of the inquiry is to conduct an initial review of the evidence–including any testimony given by the respondent, complainant, and key witnesses–to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;
- sets out the criteria for determining whether an investigation is warranted;
- informs them of their responsibility for preparing or directing the preparation of a written report of the inquiry that meets the requirements of the Policy and **I.J.** of these Procedures (The inquiry report), below;
- emphasizes that all matters related to the inquiry must be kept confidential; and
- sets forth the timeline for completion of the inquiry.

At this first meeting of the inquiry committee, the RIO will review the charge with the committee, discuss the allegations and any related issues, explain the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The RIO or designee will be present or available throughout the inquiry to advise the committee as needed.

G. Inquiry process

The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether an investigation is warranted. An investigation is warranted if:

1. there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct in the Policy, and

2. preliminary information-gathering and fact-finding from the inquiry indicate that the allegation may have sufficient substance to warrant an investigation, or the available research record is inadequate to make such a determination so that a more detailed analysis is required.

As part of the inquiry, the inquiry committee may interview the respondent, the complainant, and key witnesses as it deems necessary, and will examine relevant research records and materials. However, the committee is not obligated to conduct witness interviews or to perform an exhaustive review of all the evidence as part of the inquiry process.

After evaluation of the evidence, the inquiry committee will prepare an inquiry report with its recommendation to the IO regarding whether an investigation is warranted. The report must comply with the requirements of any applicable funding agency and generally will include the name and position of the respondent, the specific allegations of research misconduct that were considered; the identity of any federal support for the research at issue; the identity of University and any federal policies and procedures under which the inquiry was conducted; a determination of whether the alleged research misconduct warrants an investigation; and the basis for that determination.

If the respondent makes a legally sufficient admission of research misconduct, research misconduct may be determined at or before the inquiry stage if all relevant issues are resolved. In these instances, the inquiry committee must consult with the RIO, who may consult with other University officials and research sponsors as necessary to determine the next steps that should be taken.

H. Time for completion

The inquiry should normally be concluded within 60 days of its initiation. Exceptions to this 60-day limit require approval of the IO. Any extension granted must include documentation of the reasons for the extension beyond 60 days. Notification of extensions will be provided to research sponsors as required by law, regulation, or award terms.

I. The inquiry report

At the conclusion of the inquiry, the inquiry committee must prepare a written inquiry report. The inquiry report must include the following elements, as applicable:

- the name and position of the respondent;
- a description of the allegation or allegations of research misconduct that were considered;
- the funding support, as applicable, including, for example, award numbers, applications, contracts, and publications listing the research sponsor;
- the basis for recommending or not recommending that the allegation or allegations warrant an investigation;
- any written comments on the draft report by the respondent or complainant, as addressed in **I.J.** (Comments on the inquiry report), below;
- the names and titles of the committee members who conducted the inquiry and the experts (if any) who were consulted;
- a summary of the inquiry process used;
- a list of the research records reviewed;
- summaries of any interviews; and,
- whether any other actions should be taken if an investigation is not recommended.

J. Comments on the inquiry report

The RIO or inquiry chair must notify the respondent whether the inquiry committee found an investigation to be warranted, provide a copy of the draft inquiry report for review and comment, and include a copy of the Policy and these Procedures. If the respondent wishes to provide comments, they must be in writing and submitted within 10 days of receipt of the draft inquiry report. The University may, at the RIO's discretion, inform the complainant of the results of the inquiry–whether the inquiry found an investigation to be warranted–and provide relevant portions of the draft inquiry report to the complainant for comment. If the complainant has or wishes to provide any comments, they must be submitted in writing within 10 days of receipt of relevant portions of the draft inquiry report. Based on the comments received, the inquiry panel may, but is not required to, revise the inquiry report. However, any comments received from the respondent or the complainant will be attached to the final inquiry report, which must be delivered by the RIO to the IO within 10 days of receipt.

K. University decision and notifications

1. Decision by the Institutional Official

   The RIO will transmit the final inquiry report, all supporting documents, and any written comments to the IO, who will make the final determination, in writing, as to whether an investigation is warranted. The IO, in consultation with appropriate USF officials, including the highest-ranking research administrator at the college or school where the respondent is employed, will determine whether the findings as stated in the inquiry report indicate possible research misconduct and thus warrant an investigation. If the

findings in the inquiry report are not supported by the information presented, the IO may remand the inquiry report to the inquiry committee chair and request that additional support be provided for the findings, or the IO may designate this function to the RIO.

The outcome of the inquiry will be one of the following:

a. A determination of insufficient evidence to warrant investigation. If there is not sufficient information presented indicating research misconduct to warrant proceeding with an investigation, the IO will notify the respondent of the dismissal of the matter, with a copy to the complainant.

b. A determination of sufficient evidence to warrant investigation. If there is sufficient information presented indicating research misconduct to warrant proceeding with an investigation, the IO will refer the inquiry report and all supporting documentation to the Standing Committee on Research Misconduct, along with the charge to initiate an investigation.

The inquiry is complete when the IO makes this determination. There is no appeal.

2. Notifications

The RIO or inquiry chair must notify the respondent in writing whether the inquiry found that an investigation is warranted. The notice must include a copy of the inquiry report, along with a copy of the Policy and these Procedures, as well as any applicable research sponsor research misconduct policy or award terms.

The University must provide research sponsors, as required by award terms, with the IO's written decision and a copy of the inquiry report. Notification to research sponsors must occur no later than 30 days after the IO's decision that an investigation is warranted or shorter period as may be required by the award terms.

At the IO's discretion, the RIO will notify the Dean of the School or College where the respondent is assigned, as well as the appropriate department chair. The IO may also elect to inform the Provost of the IO's determination. Other University officials will be informed on a need-to-know basis.

3. Documentation of decision not to investigate

If the IO determines that an investigation is not warranted, the RIO must secure and require to be maintained, for seven years after the termination of the inquiry, sufficiently detailed documentation of the inquiry to permit a later assessment by research sponsors, as warranted, of the reasons why an investigation was not conducted. These documents must be provided to research sponsors as required by law, regulation, or award terms.

In addition, when the IO determines that an investigation is not warranted, any reference to the allegation in the personnel file of the respondent must be removed promptly.

II. The Investigation

The purpose of the investigation is to develop a factual record by exploring the allegation(s) in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegation(s). This is particularly important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or it if affects research that forms the basis for public policy, clinical practice, or public health practice.

A. Initiation and notification

If the IO determines that an allegation warrants an investigation, the investigation must begin within 30 days of the determination. The IO, in consultation with other appropriate University officials, may suspend the respondent from further participation in the research project at issue or other institutional responsibilities, but only if the IO determines that serious harm to the respondent or others would be threatened by the respondent's continuance of the respondent's duties. Any such suspension is not alone grounds to interrupt payment of salary.

On or before the date on which the investigation begins, but no more than 30 days after the IO determines that an investigation is warranted, the RIO must notify research sponsors, as required under applicable federal regulations or award terms, of the decision to begin the investigation and, if required, provide them with a copy of the inquiry report. Within a reasonable time after determining that an investigation is warranted, but before the investigation begins, the RIO or chair of the Standing Committee on Research Misconduct, must notify the respondent in writing of the allegations to be investigated.

Additional allegations of research misconduct related to the respondent that are raised during the investigation may be addressed by the investigation panel without necessarily having to go through the inquiry process outlined in these Procedures. If additional allegations are raised, the respondent must be provided with timely notice of the additional allegations.

B. Sequestration of the research records

Before or at the time the respondent is notified of the investigation, the RIO must take all reasonable and practical steps to obtain custody of and secure any additional research records and evidence needed to conduct the investigation that were not previously sequestered. The sequestration must be consistent with the process set forth in these Procedures. If additional items become known or relevant during the investigation, the RIO must take custody of those records if possible.

C. Referral to Standing Committee and appointment of investigation panel

After making the determination of sufficient evidence to warrant investigation, the IO must forward the inquiry report and all supporting documentation to the chair of the Standing Committee , along with a written charge to initiate an investigation. The Standing Committee will meet within 14 days of the chair's receiving the charge or as soon thereafter as is practical.

The Standing Committee will appoint an investigation panel comprised of individuals as set forth in the Policy to conduct the investigation. No member of the Standing Committee may serve as an investigation panel member. Outside experts may be included on the investigation panel, where warranted, to secure the necessary expertise or avoid conflicts of interest.

The chair of the Standing Committee will notify the respondent of the proposed investigation panel membership, and the respondent will have three business days to object to the proposed membership of the investigation panel based on grounds of bias or conflict of interest. The Standing Committee chair will consider any objections and make the final determination whether to replace or retain the objected to panel member. If the Standing Committee chair determines it is appropriate to select a different member-for the investigation panel, the respondent must be notified of the new selection and provided with the same opportunity to object as was provided with the investigation panel members who were proposed initially.

D. Charge to the investigation panel and the first meeting

Within 10 days of appointing an investigation panel, the chair of the Standing Committee will hold an initial meeting with the investigation panel during which the Standing Committee chair will present the written charge to conduct an investigation that:

1. describes the allegation or allegations and any related issues identified during the inquiry;
2. identifies the respondent by name and title;
3. informs the panel that it must conduct the investigation as prescribed in the Policy and these Procedures (**II.E**.);
4. defines research misconduct;
5. informs the investigation panel of:
    a. the standard for making a finding of research misconduct, including the preponderance of the evidence standard;
    b. the investigation panel's obligation to evaluate the evidence and testimony to determine whether research misconduct occurred, and if so, the type and extent and who was responsible;
    c. the requirement to prepare or direct the preparation of a written report of the investigation that meets the requirements of these Procedures (**II.H.**);
    d. the requirement to maintain confidentiality throughout the course of the investigation; and

e. the timeline for completion of the investigation.

The RIO, chair of the Standing Committee, or other designee will meet with the investigation panel at its initial meeting when it receives the charge from the chair of the Standing Committee (or designee) to explain the Policy, the role of the investigation panel in the process, the conduct of the investigation, and the importance of confidentiality. The RIO will offer staff and other resources to support the Standing Committee and investigation panel as needed. Examples of support that may be made available are assistance with scheduling, copying, and courier services.

Also at its initial meeting, the investigation panel will select a panel chair who will be responsible for coordinating investigation panel meetings and witness interviews, assigning tasks to investigation panel members, ensuring that the investigation is completed within the designated time frame, and preparing the investigation panel's investigation report. Alternatively, the Standing Committee may appoint the panel chair from among the investigation panel members.

E. Investigation process

The investigation panel, with the assistance of chair of the Standing Committee or the RIO, as appropriate, must:

- use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;
- take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable;
- pursue diligently all significant issues and leads discovered that are determined to be relevant to the investigation, including any evidence of additional instances of possible research misconduct that were not part of the original allegation or allegations but have come to the attention of the investigation panel during the course of the investigation, and continue the investigation to completion; and,
- interview the respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent investigation panel. The interviews must be recorded or transcribed, and each individual questioned by the investigation panel must be provided with a copy of their responses and given the opportunity to submit corrections. Witnesses should make themselves available according to the schedule established by the investigation panel chair. If a witness chooses not to make themselves available, the investigation panel may proceed in their absence.

After information gathering is completed, the investigation panel must deliberate to determine whether the information reviewed supports a finding of research misconduct. In reaching its conclusions, the panel will use a preponderance of the evidence standard. The investigation panel may also provide recommendations for corrective action; however, the

panel's recommendations are not binding on the Standing Committee or individuals responsible for implementing disciplinary or corrective action.

During the investigation, as with all of the research misconduct proceedings, all documents related to the investigation are treated as limited-access records which are confidential and exempt from disclosure under section 119.07(1), Florida Statutes; they may be released only as provided in section 1012.91(1)(b), Florida Statutes, and University Regulation USF10.017, Limited-Access Personnel Records.

F. Time for completion of investigation

The time for completion of an investigation, from start to finish, is 120 days. This period includes all aspects of the investigation: information gathering, deliberations, preparation of a draft investigation report, consideration of any comments received from the respondent and complainant, preparation of the final investigation report and submission of the report to the chair of the Standing Committee for review by the Standing Committee, consideration of the report and deliberations by the Standing Committee; decision of the Standing Committee and preparation and submission of the Standing Committee report to the IO for review; referral to the appropriate University officials of proposed administrative actions to be taken against the respondent, subject to the final approval of the IO, and sending the final report to research sponsors when required. If the investigation panel determines that the investigation will not be completed within the 120-day period, it must request an extension, which is subject to the approval of the IO or designee. In instances where the allegation of research misconduct relates to an externally-supported project, the RIO must submit a written request for an extension to the research sponsor or ORI as required by applicable law, regulation, or award terms.

G. Standard for making a finding of research misconduct

1. A finding of research misconduct requires all of the following:

    - that the misconduct alleged meets the definition of research misconduct as set forth in the Policy or applicable federal agency or research sponsor policy;
    - that the alleged misconduct is a significant departure from accepted practices of the relevant research community; and
    - that the misconduct was committed intentionally, knowingly, or recklessly.

2. A finding of research misconduct must be proven by a preponderance of the evidence. If the respondent raises any affirmative defenses to an allegation of research misconduct, the respondent has the burden of going forward with and proving the affirmative defenses by a preponderance of the evidence.

H. The investigation report

1. The investigation panel is responsible for preparing a written draft investigation report that complies with the requirements outlined in the U.S. Public Health Service (PHS) regulations at 42 C.F.R. Part 93, except when special factors may suggest a different approach is necessary. These requirements apply to both draft and final investigation reports, which must:

    - Describe the type of research misconduct alleged (fabrication, falsification, or plagiarism) and identify the respondent;
    - Describe the specific allegations of research misconduct considered in the investigation;
    - Describe and document any federal or other external support for the research at issue, including, for example, grant, grant application, and contract numbers and publications listing the support;
    - Identify and summarize the research records and evidence reviewed and identify any evidence taken into custody but not reviewed; and,
    - Include a copy of the Policy and these Procedures as well as any other applicable University policies and procedures under which the investigation was conducted.

2. The statement of findings specific to each allegation, must provide a decision as to whether research misconduct did or did not occur and, if it did, must:

    - Identify whether the research misconduct was:
        - falsification, fabrication, or plagiarism;
        - a significant departure from accepted practices of the relevant research community; and
        - committed intentionally, knowingly, or recklessly;
    - Summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any effort by the respondent to establish by a preponderance of the evidence that the respondent did not engage in research misconduct because of honest error or a difference of opinion;
    - Identify specifically any external funding;
    - Identify whether any publication known at the time of preparation of the investigation report needs correction or retraction;
    - Identify the person(s) responsible for the misconduct; and,

- List any current support or known applications or proposals for support that the respondent has pending with any federal or other research sponsors.

Finally, if a majority of the investigation panel makes a finding of research misconduct, the investigation panel may include in its investigation report recommendations for corrective action, including sanctions, to the IO. However, such recommendations are not binding on the Standing Committee, the IO, or the individuals responsible for implementing disciplinary or corrective action.

I. Comments on the draft investigation report and access to evidence

The chair of the Standing Committee, the RIO, or designee must provide the respondent with a copy of the draft investigation report for comment and, concurrently, with a copy of or supervised access to the evidence on which the report is based, and may provide the complainant with a copy of the draft report or relevant portions of the draft report for comment. Both the respondent and complainant will have 10 days from the date the draft investigation report or relevant portions of the draft report are received to submit written comments, if any, to the chair of the Standing Committee. Comments received from the respondent and complainant will be considered by the investigation panel when preparing the final investigation report. Whether included within the final report or not, comments must be attached to the final report.

In distributing the draft report to the respondent and the draft or portions of the draft report to the complainant, the chair of the Standing Committee will inform both the respondent and the complainant of the obligation of confidentiality and may establish reasonable conditions to ensure confidentiality.

J. Standing Committee review and action

Upon receipt of the investigation panel's report, the chair of the Standing Committee will distribute the report to the respondent and the members of the Standing Committee. The respondent will have five days from the date of receipt of the report to notify the Standing Committee that the respondent will respond to the investigation report either orally, at a meeting with the Standing Committee, or in writing. Should the respondent fail to provide notice within five days of receiving the report, the Standing Committee may meet at any time thereafter to discuss the investigation panel's report and prepare its response to the report.

If the respondent elects to comment on the report in person, the Standing Committee will meet with the respondent within 10 to 20 days after being provided notice that a meeting is requested. If the respondent chooses to submit a written response to the Standing Committee, the written response must be provided to the Standing Committee within 15 days of the respondent's notice; the Standing Committee is not required to meet prior to the expiration of the 15 days.

After review of the investigation report and the respondent's response, if any, the Standing Committee has the option to accept the report; reject the report and remand the case to the original investigation panel with instructions for further consideration or investigation; or,

nominate new investigation panel members for de novo review. If the case is remanded to the original investigation panel, the investigation panel must follow the Standing Committee's instructions for further consideration or investigation and must prepare a supplemental report to the Standing Committee within 20 days of receiving the Standing Committee's charge. If a new investigation panel is convened, the new investigation panel must follow the Procedures as set forth in **II** (The investigation).

Upon receipt of a supplemental report or a report from a newly convened investigation panel, the Standing Committee will proceed as set forth in **II.J.**, including providing the respondent with the supplemental report or new report and inviting a response for the consideration of the Standing Committee in its review of the matter.

K. Standing Committee report

The Standing Committee's report must be issued within 20 days after receipt of the respondent's final response or within 20 days of the expiration of the response period, if no response is received. The report must include:

- a summary of its review of the investigation report;
- An explanation of any rejection of findings or additional instructions to the investigation panel;
- a summary of the respondent's views;
- the Standing Committee's findings based on the information provided in the investigation report; and,
- any recommendations for corrective or administrative action (optional and non-binding).

Within 120 days of initiation of the investigation, after comments have been received and the necessary changes have been made to the draft Standing Committee report, the chair of the Standing Committee or designee will transmit the final Standing Committee and investigation reports with attachments, including the respondent's and complainant's comments, if any, to the RIO. The RIO must submit the final iteration of the Standing Committee and investigation reports to the IO within 10 days of the date the final reports are received.

L. Decision by the Institutional Official

The IO will review the investigation report and the Standing Committee's report and determine in writing:

1. whether the IO accepts the investigation panel's findings; and
2. the appropriate internal actions to be taken in response to the accepted findings of research misconduct.

If the IO's determination varies from the findings of the investigation panel, the IO will, as part of the IO's written determination, explain in detail the basis for rendering a decision different from the findings of the investigation panel.

Alternatively, the IO may return the report to the investigation panel with a request for further fact-finding or analysis.

The IO or IO's designee is responsible for ensuring compliance with all notification requirements of research sponsors. The IO or designee will, in consultation with other appropriate University officials, determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which fabricated, falsified, or plagiarized reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case.

At the IO's direction, the RIO will also notify the Dean of the School or College where the respondent is assigned, as well as the appropriate department chair. The IO or designee must report to the Provost and the Chief Compliance Officer in the USF Office of Compliance & Ethics on the full account of the research misconduct proceedings resulting in any formal finding of research misconduct that requires notification to external stakeholders, including, research sponsors, journals, and others, as appropriate, findings or any significant incidents of research-related non-compliance.

M. Notice of University findings and actions to research sponsors

The IO, RIO, or designee must notify research sponsors regarding the results of the investigation. Notifications must be consistent with law, regulations, and award terms. For example, for research misconduct allegations related to PHS funded awards, a notification must include:

1. a copy of the final investigation report with all attachments;
2. a statement of whether the University accepts the findings of the investigation report;
3. a statement of whether the University found research misconduct and, if so, who committed the research misconduct; and
4. a description of any pending or completed administrative actions against the respondent.

The RIO is also responsible for providing any information, documentation, research records, evidence, or clarification requested by a research sponsor to carry out its review of an allegation of research misconduct or of the University's handling of an allegation of research misconduct.

N. Maintaining records for review by research sponsors

The University must maintain and, upon request, provide to research sponsors, if required by law, regulation, or award terms, records of research misconduct proceedings, which include:

1. records secured by the University for the inquiry and investigation;
2. documentation of the determination of irrelevant or duplicate records;
3. the inquiry report and final documents produced in the course of preparing the inquiry report, including the documentation of any decision not to investigate; and
4. the investigation report and all records in support of the investigation report, including the recordings and transcriptions of each interview conducted in accordance with the Policy and these Procedures.

Records must be maintained in a secure manner for seven years after completion of a research misconduct proceeding or for such longer period as required by law, regulations, or award terms.

III. Completion of cases and reporting premature closures to research sponsors

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. As required by law, regulation, or award terms, the RIO must notify research sponsors in advance if there are plans to close a case at the inquiry or investigation stage on the basis that the respondent has admitted guilt or a reached a settlement with the University.

IV. Administrative and disciplinary action

If the IO determines that the respondent has engaged in research misconduct, the University may impose administrative or disciplinary sanctions, which may include, but are not limited to:

- Taking appropriate steps to correct the research record;
- Imposing special certification or assurance requirements to ensure compliance with applicable regulations or award terms;
- Removal of respondent from the research project in question;
- Termination or suspension of an active award;
- Issuance of a letter of reprimand;
- Special monitoring of future work;
- Salary reduction (consistent with applicable University policies and procedures); or
- Disciplinary measures allowed under applicable personnel or student policies, including suspension or termination of employment.

None of the foregoing sanctions limits the authority of a research sponsor to impose its own sanctions.

If the University believes that criminal or civil fraud violations may have occurred, the University must promptly refer the matter to the appropriate investigative office or entity

V. Other considerations

A. Termination or resignation prior to completion of the inquiry or investigation

Termination of the respondent's employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been made, will not preclude or terminate research misconduct proceedings.

If the respondent, without admitting to research misconduct, elects to resign their position after the University receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate, based on the outcome of the preceding steps. If the respondent refuses to participate in the process after resignation or termination, the University will use its best efforts to reach a conclusion concerning the allegations, noting in the report the respondent's failure to cooperate and its effect on the proceeding.

B. Protection of individuals involved in research misconduct proceedings

Throughout the research misconduct proceedings and after their conclusion, the University must make all reasonable and practical efforts 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, as well as any complainant, witness, and committee or panel member who cooperated in good faith with the research misconduct proceedings.

Any use of the Policy or these Procedures to bring malicious allegations or allegations not otherwise made in good faith against any individual is a violation of the Policy and these Procedures. Any act of retaliation or reprisal against an individual for reporting in good faith a charge of research misconduct is a violation of the Policy and these Procedures. Such violations will be dealt with through regular administrative processes for violations of University policies.

C. Non-research misconduct issues

When issues of concern not related to research misconduct are discovered during the assessment, inquiry, or investigation of an allegation, the RIO will refer them to the Office of Compliance & Ethics, which is responsible for assessing reported activities that may involve improper conduct or violations of USF policies and referring these-matters in whole or in part to other offices or officials to address. Following are examples of issues requiring referral:

1. General misconduct. Inappropriate conduct, such as falsifying medical or billing records; false testimony; noncompliance with official procedures; failure to report or attempting to conceal research misconduct; or other misconduct that does not meet the definition

of research misconduct but may nonetheless affect the integrity of USF research and should be reported to Compliance & Ethics or the Office of Internal Audit.

2. Criminal violations. Potential theft or other criminal violations should be referred to Internal Audit. If the possible criminal violation is identical to the alleged research misconduct (*e.g.*, alleged false statements in a PHS grant application), the criminal charge should be reported to ORI. ORI will then refer it to the Office of the Inspector General (OIG) in the Department of Health and Human Services (DHHS).

3. Violation of human subject or animal subject regulations. Potential violations of human or animal subject regulations, including non-compliance with Food and Drug Administration (FDA)-regulated research requirements, should be referred to USF Research Integrity and Compliance (RIC) and reviewed by either the USF Institutional Review Board (IRB) or the Institutional Animal Care and Use Committee (IACUC).

4. Fiscal irregularities or misconduct. Potential violations of cost principles or other fiscal irregularities, such as mismanagement of research monies and personnel by contract or grant recipients, employees, or other related persons, should be reported to Internal Audit and Compliance & Ethics for appropriate review and follow-up with the IO, USF Controller's Office, federal agencies, and research sponsors, as appropriate.

5. Unacceptable or questionable research practices. The RIO, Internal Audit, Compliance & Ethics, the inquiry committee or investigation panel, or other individual(s) or entity(ies) involved in the research misconduct review process may find that while a respondent's conduct does not meet the definition of research misconduct, it may nonetheless constitute an unacceptable or questionable research practice. Any finding of unacceptable or questionable research practice(s) should be referred to the IO or RIO, who will communicate this information to the appropriate USF official(s), including the highest-ranking research administrator at the respective campus if the practice takes place at a campus, for review and further appropriate action.

VI. Related Requirements

A. External regulations and consequences

- US Code of Federal Regulations - **42 C.F.R. Part 93–Public Health Service Policies on Research Misconduct**

- US Code of Federal Regulations - **45 C.F.R. Part 689–Research Misconduct** [National Science Foundation (NSF)]

B. USF policies and regulations

1. Policies

   - 0-023, Internal Control

- 0-026, Compliance & Ethics Program
- 0-027, Florida Code of Ethics for Public Officers and Employees; Compliance and Disclosure
- 0-301, Misconduct in Research
- 0-309, Individual Conflicts of Interest in USF Research Projects and USF Financial Conflicts of Interest (FCOI)
- 0-317, Institutional Conflicts of Interest in Research
- 5-012, Records Retention and Disposition

2. Regulations
   - USF5.001, Fraud Prevention and Detection
   - USF10.017, Limited-Access Personnel Records
   - USF10.107, Ethical Obligations: Conflicts of Interest, Outside Employment, Employment of Relatives, and Public Office

C. Other relevant materials

- Significant Financial Interest Disclosure Review and Management Process for USF Research Projects Funded by Federal Agencies, for Certain Agencies, Foundations & Extramural Sponsors
- Florida BOG Regulation 4.001, University System Processes for Complaints of Waste, Fraud, or Financial Mismanagement