NOTICE OF CHANGE IN PROPOSED REGULATION

Date: March 2, 2017

REGULATION TITLE:

REGULATION NO.:

1.0101

University of Florida; Policy for Dealing

With Conduct in Research

SUMMARY OF CHANGES: The following substantive changes have been made to the proposed amendments to this regulation:

- clarified the timing for disclosing a conflict of interest and included the designee as one of the participants in section 4(d);
- deleted the qualified description of the process and investigation in sections 4(c), 6(b), 6(c), and 6(d);
- revised the contact information in section 5(a);
- removed a provision updating the accused, without eliminating the ability of the accused to inquire and receive updates of the status of the process in section 5(d)1;
- clarified the accused's right to counsel in section 5(d)1;
- clarified the type of report being referred to in section 5(d)3;
- clarified the time period for the accused's opportunity to respond to the final inquiry report to 30 days in section 5(d)3;
- clarified the composition of the committee in section in section 6(a)2;
- removed a 10 day deadline that is not required in section 6(a)2;
- removed a notification that is not required in section 6(b);
- clarified who gets notified of the allegation of research misconduct in section 6(b); and
- clarified scope of the investigation and role of counsel for the accused during interview in section 6(e).

THE FULL TEXT OF THE PROPOSED REGULATION IS ATTACHED TO THIS NOTICE.

REGULATIONS OF THE

UNIVERSITY OF FLORIDA

6C1-1.0101 University of Florida; Policy for Dealing with Conduct in Research

- (1) University Policy -- It is the policy of the University that each individual faculty and staff member and student is expected to maintain high ethical standards in the <u>proposal</u> for, conduct and reporting of his/her research. Should alleged incidents of <u>Research</u> mMisconduct in research occur, reporting of such possible violations is a shared responsibility, and it is the duty of the faculty, staff members and students to respond in a fitting manner to resolve issues arising from such alleged misconduct.
- (2) Faculty, Staff, and Student Responsibilities -- Faculty members, staff, and students at the University of Florida are expected to maintain ethical standards in the conduct and reporting of scientific and scholarly research. Faculty, staff, and students have responsibilities for ethical conduct in research not only to the University, but also to the community at large, to the academic community, and to private and public institutions sponsoring the research activities.
- (3) Definition of Research Misconduct -- Research Misconduct is defined for the purposes of this regulation as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
- (a) 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.

- (b) Research Misconduct does not include honest error or differences of opinion. It does not include authorship disputes. In addition, failure to comply with federal requirements affecting specific aspects of conducting research, misappropriation of federal funds, failing to comply with the University's Institutional Review Board policies and procedures, or other inappropriate actions in research which do not fall within the definition of research mMisconduct as stated in this paragraph and which are in violation of existing University regulations or policies are addressed under such other regulations or policies.
 - (c) A finding of Research Misconduct requires:
- 1. There be a significant departure from accepted practices of the relevant research community;
 - 2. The misconduct be committed intentionally, knowingly, or recklessly; and
 - 3. The allegations be proven by a preponderance of the evidence.
- (4) Basic Principles Governing Investigations of Research Misconduct If allegations of Research Misconduct are made, the procedures implemented may vary depending on the type, seriousness, and technical nature of the alleged Research Misconduct. Faculty, staff, and students will be guided by the following principles:
- (a) The rights of all faculty members, staff, and students of the University must be protected to the extent possible, whether they be the accused or accusers, witnesses, or research subjects during the process of inquiry, investigation and fact finding, including protecting the privacy of the accused and of those who in good faith report alleged Research mMisconduct or serve as witnesses. There shall be no recrimination toward a person bringing an allegation in good faith, and retaliatory conduct against complainants, witnesses, committee members, and other persons involved in the Research Misconduct process who are

acting in good faith will be deemed misconduct subject to disciplinary action under University regulations or the applicable collective bargaining agreements.

If an allegation is found to have been brought maliciously or in bad faith, the filing of the complaint can be cause for a finding of misconduct and subsequent disciplinary action against the complainant in accordance with University regulations or the applicable collective bargaining agreement.

- (b) University regulations and/or applicable collective bargaining agreement provisions shall govern any formal disciplinary proceedings initiated in response to a finding by the investigating authority of Research Misconduct.
- (c) Confidentiality shall be maintained throughout an inquiry or investigation of alleged Research Misconduct to the greatest extent possible and consistent with the laws of the State of Florida and federal law. Inappropriate dissemination of information relating to a Research Misconduct allegation can form the basis for a finding of misconduct and subsequent disciplinary action against faculty, staff, or students.
- (d) The University will take reasonable and practicable steps to provide that persons who review an allegation of Research Misconduct, including such persons participating in the inquiry and investigation, do not have personal, professional, or financial conflicts of interest with regard to the accused, the complainant or others involved in the inquiry or investigation process. It is the duty of those participating in the inquiry and any investigation to be free of such conflicts of interest and to bring any question of any such conflict to the attention of the Director of Research Compliance in the Office of Research or designee, or in the Director or designee's case, the Vice President for Research, prior to participating and at any time thereafter when a conflict arises.

- (e) Notwithstanding other provisions of this regulation, if federally-sponsored research is involved, the time limits set forth in the applicable federal regulations will govern the process and be substituted for the time limits set forth in this regulation if the federally-established time limits differ from those in this regulation.
 - (5) Receipt and Processing of an Allegation of Research Misconduct
- (a) Filing the Allegation of Research Misconduct. Allegations of Research Misconduct may be brought by anyone who has reason to believe that such misconduct has occurred. Any such allegation must be brought to the Director of Research Compliance in the Office of Research, at-whose contact information is located at eompliance@research.ufl.edu, 352 294 1632 office, 352 273-1988 fax or website at http://research.ufl.edu/faculty-and-staff/research-compliance/research-ufl.edu/research/compliance.html. Such allegation normally should be made in __writing and signed; however, an allegation may be made anonymously. The specific grounds for the allegation of Research Misconduct should be stated. Any relevant
- (b) Time limitations. This policy applies only to #Research mMisconduct
 occurring within six6 years of the date an allegation of #Research mMisconduct is received
 (limitation period), subject to the following exceptions:

documentation supporting the allegation should be included with the complaint.

- 1. Subsequent use exception. The respondent continues or renews any incident of alleged rResearch mMisconduct 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.
 - 2. Health or safety of the public exception. If the University, following

General, etc.) of the sponsoring agency or agencies supporting the research (federal designated office), if applicable, or if that federal designated office determines that the alleged Research mMisconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

3. Grandfather exception. If the federal research is involved and the agency's regulations impose a different limitation period, that limitation period shall apply. If the allegation is received by the University, or any applicable federal agency if federal research is involved, before the effective date of this regulation's, or the federal agency regulation's, imposition of a limitation period, the limitation period that became effective after receipt of the allegation shall not apply. Department of Health and Human Services (HHS) or the University received the allegation of research misconduct before the effective date of this regulation.

(b)(c) Processing the Allegation of Research Misconduct - Pre-Inquiry Review. The Director of Research Compliance or designee is charged with reviewing the allegation to determine if an inquiry is warranted. An inquiry is warranted if the allegation falls within the definition of Research Misconduct and is sufficiently credible and specific so that potential evidence of Research Misconduct may be identified. Regardless of whether an inquiry is—warranted, a record of the allegation, the steps taken to review the allegation, and the basis for—proceeding or not proceeding to the inquiry shall be maintained by the Vice President for—Research or designee in accordance with section (8) of this regulation.

(e)(d) Inquiry Process

1. Upon determining that an inquiry is warranted, the Director of Research

Compliance or designee shall proceed with an inquiry into the allegation. The Director of Research Compliance or designee reviewing the allegation shall be responsible for making a good faith effort to notify the accused in writing of the allegation, and advising the accused of the procedures to be followed by the University, affording the accused an opportunity to respond to the allegation, and keeping the accused informed of the progress of the inquiry process. The accused shall be provided with a copy of this regulation or web-link to the regulation, describing the procedures to be followed. The accused has the right to retain legal counsel or be advised by a faculty union representative, if appropriate.

- 2. Sequestration of Research Data
- a. All original research data and/or other records involved in the allegation must be secured by the Director of Research Compliance or designee on On or before the date the accused is notified of the allegation or the inquiry begins, whichever is earlier, the Director of Research Compliance or designee must promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the #Research mMisconduct proceeding, inventory the records and evidence, and sequester them in a secure manner. If the data are contained on a shared piece of equipment, a copy of the data may be made and secured if the copy has substantially equivalent evidentiary value.
- b. Sequestration of research data and/or other records shall not constitute disciplinary action, but is meant to preserve the data and other records. Upon request, the accused shall be provided a reasonable means of access to the data and other records or to legible reproductions.
 - c. An inventory shall be made of the sequestered research data and/or other records.
 - 3. The Director of Research Compliance or designee shall conduct the inquiry, which

may include the use of one or more additional reviewers and/or scientific consultants. Any formal interviews conducted as part of the inquiry process shall be recorded. The inquiry shall be concluded by the Director for Research Compliance or designee within fifty (50) calendardays, and a final decision shall be made by the Vice President for Research or designee whether an investigation is warranted within sixty (60) calendar days, of the commencement of the inquiry unless circumstances clearly warrant a longer period. If the inquiry and the final determination as to whether an investigation is warranted under paragraph (6)(a)1- of this regulation together take longer than sixty (60) calendar days from the commencement of the inquiry to complete, the record of the inquiry shall include documentation of the reasons for exceeding the sixty (60) day period. In addition the Director of Research Compliance or designee shall submit to the designated agency official, if and when required under applicable federal regulations when federally-sponsored research is involved, a written request for an extension of time to complete the inquiry. Prior to forwarding the final inquiry report to the Vice President for Research or designee, the committee shall provide the final inquiry report to the accused who shall have the right to review and comment in writing within a specified periodof timethirty (30) days of the date on which the accused received the report. Any comments received are to be attached to the final inquiry report and be made part of the record.

4. Upon conclusion of the inquiry, the Director of Research Compliance or designee responsible for conducting the inquiry shall submit a written report of the findings to the Vice President for Research or designee and to the accused indicating whether an investigation is warranted. An investigation is warranted if there is a reasonable basis for concluding that the allegation falls within the definition of Research Misconduct and preliminary fact finding from the inquiry indicates the allegation may have substance.

In addition to the conclusion reached, the written report shall state what evidence was reviewed. The accused shall be provided with a copy of the report and the accused's comments—on the report, if any, will be made part of the record. Documentation of the inquiry shall be maintained in accordance with section (8) of this regulation and shall, upon request, be provided to authorized sponsoring agency personnel.

- (6) Post-Inquiry Procedures
- (a) Upon receipt of the report, the Vice President for Research or designee shall review the report and proceed in the following manner:
- 1. In cases where the Director of Research Compliance or designee determines that an investigation is not warranted, the Research Misconduct process shall be terminated unless the Vice President for Research or designee determines within ten (10) days after receiving the report (and 60 days after the commencement of the inquiry) that an investigation is warranted. Such a determination by the Vice President for Research or designee must be in writing, give specific reasons why the investigation is warranted, and made a part of the inquiry report. If a determination that an investigation is not warranted is made, the accused shall be notified and detailed documentation of the inquiry shall be maintained in accordance with section (8) of this regulation.
- 2. In cases where the determination has been made that an investigation is warranted, the Director of Research Compliance or designee shall initiate an investigation,- including by constituting an ad hoc investigation committee to conduct the investigation, within thirty (30) calendar days from the finding that an investigation is necessary. The ad hoc investigation committee will <u>include persons with</u> consist of three or more <u>faculty</u>-members, <u>including</u> faculty, other employees, and/or other persons —(not connected with the University) who have

do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry or investigation. Where the accused is a faculty member, the committee shall consist of a majority of University faculty members. The committee shall be given the authority and assistance necessary to conduct a thorough investigation of the matter. The committee shall pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible #Research mMisconduct and continue the investigation to completion. Any such evidence shall be handled in accordance with paragraph (5)(c)27 of this regulation. Such investigation shall commence no later than ten (10) calendar days after the committee's appointment. The accused shall upon request be given access to all relevant documents records reviewed by the committee in a manner that will not compromise the security of the records or the conduct of the investigation.

(b) In the case of federally-sponsored research, the decision to proceed with an investigation shall be reported in writing (with a copy of the inquiry report providing the basis of the recommendation to investigate, and any comments on the report by the accused) to the designated office (Office of Research Integrity, Inspector General, etc.) of the sponsoring agency or agencies supporting the research on or before the date of the initiation of such an investigation and by the applicable federal agency regulations' deadline. The notification to the sponsoring agency shall, at a minimum, include the name of the person(s) against whom the allegations have been made, the general nature of the allegation, and the application or grant number(s) involved. A copy of the notification shall be furnished to the accused and accused and the accused's dean or director appropriate supervisor. If the results of the inquiry contain

any reasonable indication of possible criminal law violations, the Director of Research Compliance or designee shall notify the official as designated by the agency's regulations within twenty four (24) hours of obtaining such an indicationimmediately. The Director of Research Compliance or designee shall keep the designated agency official apprised of any development during the course of the investigation which discloses facts that may affect current or potential agency funding for the individual(s) under investigation or that the agency needs to know to ensure appropriate use of federal funds and otherwise protect the public interest. The Vice President for Research or designee shall take interim administrative actions, as appropriate, to protect federal funds and insure that the purposes of the federal financial assistance are carried out. The Director of Research Compliance or designee is responsible for notifying the designated agency official immediately at any stage in the inquiry or investigation if: (i) the health or safety of the public is at risk, including an immediate need to protect human or animal subjects; (ii) federal resources or interests are threatened; (iii) research activities should be suspended; (iv) there is reasonable indication of possible violations of civil or criminal law; (v) federal action is required to protect the interests of those involved in the Research Misconduct proceeding; (vi) there is a reasonable probability that the Research Misconduct proceeding may be made public prematurely; or (vii) the research community or public should be informed.

The Vice President or designee normally will wait until the outcome of the investigation to notify others, such as corporate sponsors, journal editors, co-authors or affiliated institutions, of the allegation of Research mM is conduct, unless there exists compelling reasons in the judgment of the Vice President for Research or designee, such as a danger to human health, welfare, or safety, the need for information or cooperation of the other part(ies)-to-

conduct a fair and complete investigation or to otherwise respond as required or appropriate, or the indication of ongoing \mathbf{r} Research \mathbf{m} Misconduct that warrants another institution conducting its own inquiry.

Throughout the notification process outlined above, all communications to sponsoring agencies, institutions, organizations, and representatives thereof shall emphasize that nofinding of guilt has been made at that time.

(c) An thorough investigation of the allegation shall be completed within one hundred twenty (120) calendar days of the initiation of the investigation. If the investigation will exceed one hundred twenty (120) calendar days, the record of the investigation shall include documentation of the reasons for exceeding the one hundred twenty (120) day period. In addition, if the investigation will not be completed within one hundred twenty (120) calendar days, the Director of Research Compliance or designee shall submit to the designated agency official, if and when required under applicable federal regulations when federally-sponsored research is involved, a written request for an extension-and anexplanation for the delay that includes an interim report on the progress to date and an estimate for the date of completion of the final report. The 120 calendar day time limitation shall include conducting the investigation, preparing the report of findings, making that report available for comment by the subjects of the investigation, and submitting the report to the designated agency official. If the Vice President for Research or designee plans to terminate an inquiry or investigation for any reason without completing all relevant requirements under federal law with regard to federally-sponsored research, a report of such planned termination, including a description of the reasons of such termination shall be made to the designated agency official who will then decide whether further investigation should

be undertaken.

- (c) Whenever possible, interviews should be conducted of all individuals involved either in making the allegation or against whom the allegation is made, as well as other available individuals who have been reasonably identified as having relevant information regarding relevant aspects of the investigation, including witnesses identified by the accused. All such interviews shall be recorded or transcribed and the recordings made a part of the investigative file. However, recording failures that occur notwithstanding good faith attempts shall not require a delay or affect the validity of the proceedings, but in such event the Committee chair or designee will prepare a written summary of the interview hearing. A copy of the recorded or transcribed interview, or summary, shall be made available to the person interviewed upon request or as required under applicable federal regulations. Throughout the investigation, confidentiality shall be maintained to the extent possible, consistent with the laws of the State of Florida and federal law, and recognizing that individuals with a need to know or to participate for the conduct of a thorough, fair and compliant process will be involved. All individuals involved in the investigation should be informed of the confidentiality requirements. The investigation committee shall prepare and maintain the documentation to substantiate the investigation's findings. This documentation is to be made available to the designated agency official in the case of federally-sponsored research.
 - (d)
- (e) (i)—At the interviews conducted by the committee, the accused shall be permitted to be present with counsel, whose role shall be limited to advising the accused.

(d)(f) The purpose of an iInvestigation is to conduct a scientific review to determine if

an allegation is valid or not, therefore, counsel for the accused may advise the accused rRespondent during interviews but shall not speak for the accused on matters of science or the scientific process for or otherwise participate directly in the interview to avoid hindering or delaying the review of the science or scientific process in question by the Committee. The accused's Counsel may, at times designated by the Committee, raise procedural issues for the record and for the Committee's consideration, but shall not attempt to intervene at other times or on matters of science or the scientific process. If the accused or his or her counsel knows, or has reason to know, of any potential procedural infirmity prior to the initiation of an interview or relevant aspect of the process, the concern should be raised promptly upon having knowledge or reason to know of it and in advance of the relevant interview or other relevant aspect of the process, so that the concern may be considered and decided by the Committee without delay or interruption of the process. The Committee is not required to allow the counsel of the accused to speak on such concern at the interview if not timely raised. Conduct that disrupts in the an interview is grounds for the counsel being required to leave. In such event, the interview will continue without the counsel present, and the counsel's absence shall not require a delay or affect the validity of the proceedings. Counsel for the accused is expected to adjust his or her schedule to attend the interview if the accused desires such attendance, unless, in the good faith judgment of the Committee chair, there is an extraordinary justification for inability to attend. Subject to the counsel's satisfaction of that expectation, reasonable efforts will be made to schedule the interview of the accused at a time that will not delay the Committee's investigation when his or her counsel can attend. Failure of counsel to attend the scheduled interview, without such extraordinary justification, also shall not require a delay or affect the validity of the interview. After completing its

investigation, the investigation committee shall submit its findings and recommendations, in writing, to the Vice President for Research or designee. If a federally-sponsored project is involved, the final report submitted to the designated agency official must include the allegation, a description of the policies and the procedure under which the investigation was conducted, how and from whom information was obtained, the findings, and the basis for the findings, and include the actual text or an accurate summary of the views of the accused. The investigation committee shall attach to the report a list of documents or other information it considered in its investigation of the allegation. Prior to forwarding the final report to the Vice President for Research or designee, the investigation committee shall provide a draft report to the accused who shall have the right review and comment to respond to the committee in person or in writing within a specified period of time. Similarly, the investigation committee may provide a draft report, or portions of the draft, to the person(s) who raised the allegations who shall have the right to review and comment in writing or in person within a specific period of time which shall comply with the requirements of applicable federal regulations when federal research is involved. The committee shall include and consider such response the comments in finalizing its report and shall include them in the final report. The accused shall, upon request, be given a copy of or supervised access to the evidence on which the report is based. The person(s) who raised the allegations should be provided with those portions of the report that address their role and opinions in the investigation. (e)(g) The Vice President for Research or designee shall review the investigation committee's report and determine in writing whether the university accepts the report and findings. If the Vice President for Research or designee determines to modify or reject any findings and/or recommendations of the committee, the Vice President for Research or

designee shall provide written justification for such a decision to the committee and the accused.

Alternatively, the Vice President or designee may return the report to the committee with a request for further fact finding or analysis.

- (7) Action Following Investigation.
- (a) If the University finds that the evidence indicates that the accused has not engaged in Research Misconduct, the Vice President for Research or designee shall promptly notify all appropriate individuals of the University's findings, including the accused. In the event that notification of the allegations has been sent to sponsoring agencies or others, the Vice President for Research or designee shall promptly notify all such agencies and others of the outcome of the investigation.
- (b) If the University finds that the evidence indicates that the accused has engaged in Research Misconduct, the Vice President for Research or designee and the Dean or Director responsible for the appointment and assignment of the accused shall review the investigation committee's report and the Vice President's or designee's determination as described in subsection (6)(f) of this regulation, and shall, within fifteen (15) calendar days of receipt of the committee's report or as soon thereafter as possible (which period shall be within the 120-day period provided for completion of the investigation unless an extension is authorized), make a preliminary determination as to the action to be taken by the University. The accused shall be promptly informed of such action to be taken and the reasons therefor. If a federally-sponsored project is involved, the Vice President for Research or designee shall provide the designated agency official with a copy of the investigation committee's report and the Vice President's or designee's determination and shall inform the designated agency

official of the action taken by the University as well as a description of any sanction(s) taken. Formal action will be taken in accordance with the appropriate provisions of University of Florida regulations or the applicable collective bargaining agreements as University procedures require. Examples of such action include, but are not limited to, the following: removal from a research project, monitoring and reporting of future research, reprimand, salary reduction, rank reduction, suspension, or termination.

- 1. If grievance proceedings are timely initiated by the accused and the outcome of the proceedings does not uphold the finding of Research Misconduct, the appropriate Vice Presidents, Dean or Director shall make every <u>reasonable and practical</u> effort to clear the record of the accused with sponsoring agencies and other appropriate individuals or institutions, and to <u>undertake diligent</u> efforts to protect the positions and reputations of those persons who in good faith made allegations, and shall notify the agencies, individuals or institutions of the outcome of the proceedings.
- 2. If grievance proceedings are timely initiated by the accused and the outcome of the proceedings uphold a finding of Research Misconduct, or if the accused does not timely file a grievance pursuant to an appropriate grievance procedure under an applicable University regulation or collective bargaining agreement, the designated official of the sponsoring agency and other appropriate individuals or institutions, including editors of relevant journals, shall immediately be notified. All findings of the proceeding shall be incorporated into the personnel file of the accused.
- 3. If a grievance proceeding is not completed within 120 days of the filing of the grievance, the Director of Research Compliance or designee is responsible for requesting from the designated federal official any extensions of time required under federal regulations

that are needed to accommodate the University's disciplinary and grievance processes.

- (8) Records. Research Misconduct Records under this regulation shall be maintained in a secure manner by the Vice President for Research or designee for a minimum of seven years after the research mMisconduct process is closed or seven years after the termination of any grievance proceedings concerning any discipline imposed as a result of any finding of Research Misconduct, whichever is later, and shall, upon request, be provided to authorized funding agency personnel. If a federally-sponsored project is involved, the records shall be maintained to at least meet requirements of federal regulations. If the applicable retention period under state law is longer than the applicable federal retention period, the records shall be retained for such longer period. Research Misconduct Records for purposes of this regulation shall be defined as:
 - (a) Records documenting the determination to proceed or not proceed to an inquiry;
- (b) Records secured pursuant to subparagraph (5)(b)1.a. of this regulation except to the extent the University subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained;
 - (c) Documentation of the determination of irrelevant or duplicate records;
- (d) The inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate;
- (e) The investigation report and all records (other than drafts of the report) in support of that report, including the recordings of each interview conducted;
- (f) Documentation of the Vice President's determination as described in subsection (6)(f) of this regulation and the actions taken under subsection (7)(b) of this

regulation; and

(g) Records of any grievance proceedings concerning a finding of Research Misconduct.

Specific Authority BOG Resolution dated -January 7, 2003.

History--New 5-23-96, Amended 3-30-07, 3-22-13, 3-[]-17-