

PROCEDURE NAME (R*)

Responding to Allegations of Research Misconduct

PROCEDURE NUMBER (O*)

RES 1.04a

EFFECTIVE DATE (R*)

October 21, 2002

PROCEDURE APPLICABILITY (R*)

This procedure is applicable to:

- Research proposed, conducted or reported at the University of Louisville (University) by University-related individuals, i.e., those with an appointment or official affiliation with the University of Louisville, including faculty, academic staff, students, postdoctoral scholars, visiting scholars who make significant use of University Research resources (including participation in any sponsored project awarded to the University or associated organizations), and those with any other University teaching and/or Research titles such as adjunct or clinical;
- Research proposed, conducted or reported elsewhere by such University-related individuals as part of their University-related duties or activities; and
- at the discretion of the University, to Research proposed, conducted, or reported where such Research is claimed, cited, or implied to have been done at the University, or where a University appointment or official affiliation is claimed, cited, or implied in connection with the Research.

REASON FOR PROCEDURE (O*)

This document establishes the procedures for the Research Misconduct Policy (RES 1.04). These procedures apply to Allegations of Research Misconduct when the Respondent is one of the following individuals:

- faculty, staff, students, other trainees, and all other members of UofL's Research community, regardless of pay or leave status; and
- former University students or employees, if the alleged Research Misconduct occurred during the period of attendance or employment at the University.

PROCEDURE STATEMENT (R*)

The Research Integrity Officer (RIO) will oversee the review process to ensure that these procedures are followed in a manner that is fair and unbiased. The RIO will consult with University Counsel and the Deciding Official (DO), as needed, throughout the Proceedings should any procedural or interpretation issues arise.

Access to Research Records

In accordance with University policies, during its review of an Allegation of Research Misconduct, the University may access and take custody of all Research Records, in all formats, that are generated during the Research or scholarship and that may be relevant to its review of the Allegation(s), regardless of where the records are stored. Initial Sequestration of Evidence may occur at any time after Allegations are received. The RIO will take all reasonable and practicable steps to obtain custody of relevant Research Records and Evidence, as soon as feasible, and store them in a secure manner in accordance with the University policy and procedure. All data and records that could be relevant to the University's review of the Allegation(s) will be sequestered by the RIO. Sufficiently detailed documentation will be kept permitting later assessment of the adequacy of the process by the RIO. The documentation will be kept in a secure manner.

If Research Records exist outside of the University, the RIO has authority, in consultation with the DO or University Counsel, to contact the appropriate officials to locate and secure all Research Records relevant to the Complaint.

Scope of Proceedings

The University will review any significant issues discovered throughout the three phases of the Research Misconduct Proceeding: the Preliminary Assessment, the Inquiry, and the Investigation, including any Evidence of additional Allegations of possible Research Misconduct.

During any phase of a Research Misconduct Proceeding, additional Allegations may arise that are related to an ongoing Inquiry or Investigation which justify expanding the scope beyond the initial Complaint.

If any new Allegations arise, the RIO will notify the Respondent, in writing, of the decision to review the new Allegation(s) with a description of the Allegation(s) and copies of all documentary Evidence regarding the new Allegation(s). If the Allegations involve a new Respondent, the RIO will inform the new Respondent, in writing, of the decision to review the Allegation(s) with a description of the Allegation(s) and copies of all documentary Evidence regarding the new Allegation(s).

Phases of Research Misconduct Proceedings

Preliminary Assessment

Receipt of Allegation. Allegations of Suspected Research Misconduct submitted in accordance with the Research Misconduct Policy (RES-1.04) will undergo a Preliminary Assessment to determine if the Complaint is specific, credible and meets the definition of Research Misconduct. Allegations not submitted in accordance with RES-1.04 will be dismissed from further consideration under RES-1.04 but may be referred to an appropriate Institutional Official for review under other applicable University policy.

Sequestration of Research Records. The RIO has authority to promptly locate and secure the originals of all Research Records and other relevant materials if it is believed that such records may become relevant during an Inquiry or an Investigation of alleged Research Misconduct. As soon as practicable upon the initiation of a Preliminary Assessment, the RIO shall inventory the records and Evidence and sequester them in a secure manner. Where appropriate, the RIO shall give the Respondent copies of, or reasonable, supervised access to the Research Records. When original research records cannot be obtained, copies of records that are substantially equivalent in evidentiary value will fulfill the sequestration requirement.

Analysis of Allegation(s). Every effort will be made to complete the Preliminary Assessment within thirty (30) Days, or as soon as practicable, depending on the complexity of the Complaint. If the Complaint does not name a specific Respondent, the RIO, in consultation with the others, as needed, will determine, to the extent possible, the roles and responsibilities of the individuals involved in the questioned Research to name one or more Respondents.

If the RIO determines that any Allegation within a Complaint fits within the definition of Research Misconduct in this policy and is sufficiently credible and specific so that potential Evidence of Research Misconduct may be identified, the RIO will condense the Complaint to specific written Allegation(s). Any specific Allegation within a Complaint that does not fit within the definition of Research Misconduct in this policy or is not sufficiently credible or specific so that potential Evidence of Research Misconduct may be identified, will be dismissed under the Research Misconduct Policy.

Any issue within the Complaint that constitutes a valid issue under other University policies or rules, the RIO will recommend the relevant portions of the Complaint be referred to the appropriate University authority or direct the Complainant(s) to the appropriate University authority.

Assessment Report. Based upon the analysis of the Allegations, the RIO will issue an Assessment Report and submit it to the DO for review. Recommendations for dismissal of submitted Allegations by the RIO require the approval of the DO. Any Allegations found to be specific, credible and within the scope of Research Misconduct and within the jurisdiction of 42 CFR 93.102 will be referred for Inquiry¹. The Complainant, if known, will be notified of any Allegations that were dismissed and informed of alternate reporting pathways, if applicable.

Appeals. The Complainant may appeal the decision to dismiss the submitted Allegation to the DO within seven (7) Days of receiving the dismissal notification. An appeal of the dismissal of the Complaint must be based on new information provided by the Complainant(s) that was not already considered during the Preliminary Assessment, or on Evidence from the Complainant(s) that there was a substantial procedural irregularity during the Preliminary Assessment. The DO will decide as soon as possible after receipt of appeal whether to affirm the dismissal or to refer the Complaint, or any Allegations within the Complaint, to an Inquiry. The decision of the DO is final.

Inquiry

If the DO determines that the criteria for an Inquiry are met, the Inquiry will be initiated. The purpose of the Inquiry is to determine whether there is sufficient credible Evidence of possible Research Misconduct to warrant investigating. An Inquiry does not require a full review of all the Evidence related to the Allegation.

Initiation and Purpose of the Inquiry. As soon as practicable, the RIO shall conduct the Inquiry directly, designate an appropriate individual to conduct the Inquiry or appoint an Inquiry Panel from Members of the Standing Research Integrity Panel. The RIO will act promptly but will also be engaging in Sequestration activities at this time (see below). The purpose of the Inquiry is information-gathering and initial fact-finding to determine whether the Allegation or apparent instance of Misconduct has substance and warrants a formal Investigation. It is intended to separate serious Allegations deserving further formal Investigation through this process from trivial, frivolous, unjustified, or clearly mistaken Allegations.

Sequestration of Research Records. As soon as practicable upon the initiation of an Inquiry, the RIO shall take all reasonable and practical steps to obtain custody of all the Research Records and Evidence needed to conduct the Research Misconduct Proceeding, that were not previously sequestered during the Preliminary Assessment. When original research records cannot be obtained, copies of records

¹ If the Assessment Report indicates that the Allegation is specific, credible and within the scope of Research Misconduct, but falls outside the jurisdiction of 42 CFR 93.102, the matter may be referred for Questionable Research Practices Review.

that are substantially equivalent in evidentiary value will fulfill the sequestration requirement. Institutions may also sequester research records and evidence whenever additional items become known or relevant to the inquiry. Wherever possible, the RIO shall give the Respondent copies of the data or Evidence sequestered or reasonable, supervised access to the sequestered Research Records. If new Allegations arise during the Inquiry or new information comes to light, additional Sequestration activities may occur to ensure a complete representation of the Research Record has been secured.

Selection. The RIO will carefully review the DO determination and identify the most appropriate path for the Inquiry: RIO directed, Designee directed or Inquiry Panel. If a Panel will be seated, at a minimum, the Inquiry Panel will contain three (3) members. The appointed members must have the necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant Evidence. The Panel members must not have any personal, professional, or financial Conflicts of Interest with either the Respondent, the Complainant, or witnesses. The Inquiry Panel should include at least one faculty member who is an expert in the field of Research that gave rise to the Allegation and may, if necessary, include one or more such experts from outside the University. The RIO will consult with University Counsel prior to consulting with an external expert.

Notification to Respondent. The RIO will inform the Respondent of the initiation of the Inquiry, the identity of the RIO, Designee or Panel members assigned to the Inquiry, and provide written notice of the Allegations, a summary of the Inquiry process and applicable University policy. The Respondent will also be provided the opportunity to provide a written response to the Allegations. If the Inquiry process identifies additional Respondents, the same notification process will be utilized for the new Respondents, but the process will not begin anew.

The RIO will notify the DO, the Dean/VP of the unit in which a Respondent holds primary appointment and University Counsel of the initiation of any Inquiry.

Charge. At the first convened meeting, the RIO will review the Allegation(s) with the Designee or Panel; discuss the appropriate procedures for conducting the Inquiry; and provide guidance on organization of efforts. The RIO will also provide copies of relevant University policies and federal regulations. During the Inquiry, additional new Allegations may arise that justify broadening the scope of the Inquiry. The RIO will determine whether a new Allegation relates to an ongoing Inquiry. The RIO, in consultation with the Designee or Inquiry Panel, will determine whether the new Allegation is specific and credible so that potential Evidence of Research Misconduct may be identified and whether the Allegation has substance to warrant an Investigation. If the new Allegation is not specific and credible, the Allegation will be dismissed.

Responsibilities. The RIO, Designee or Inquiry Panel will use diligent efforts to ensure that the Inquiry is thorough, impartial, fair, and appropriately documented. The Inquiry will be completed within 90 Days of the initial meeting unless additional time is required. The RIO, Designee or Inquiry Panel will:

- Maintain confidentiality of the proceedings;
- Make a Good Faith effort to interview the Complainant, the Respondent, and key witnesses and provide recordings or transcripts for correction;
- Examine relevant Research Records and materials;
- Evaluate the Evidence, including the testimony obtained during the Inquiry;
- Consider whether potential evidence of honest error or difference of opinion exists; and
- Decide whether an Investigation is warranted based upon whether the reviewed Allegations are credible, specific, and fall within the definitions of Research Misconduct.

The RIO, Designee or Inquiry Panel is not expected to determine whether Research Misconduct occurred or the role of the Respondent in any Research Misconduct.

Review of the Inquiry Report and Actions. The RIO, Designee or Inquiry Panel will prepare a draft written report that includes identification of the Respondent, statement of the Allegation(s) and relevant PHS support; a timeline and procedural history, an inventory of sequestered research records, a description of the Evidence reviewed and analyses conducted; summaries of the relevant interviews or transcripts of any interviews that were transcribed; and the conclusions of the Inquiry regarding the basis for recommending whether the allegations warrant or do not warrant an investigation and any institutional actions implemented.

The RIO shall provide the Respondent with a draft copy of the draft report, together with a written notice that the Respondent may submit written comments within ten (10) Days. The DO may extend this time for good cause. Any comments submitted by the Respondent will be attached to the final Inquiry report.

The RIO, Designee or Inquiry Panel will finalize the report after reviewing the Respondent's comments. The final report (including comments on the inquiry report from the respondent), along with all supporting materials, will be sent to the DO.

DO decision and documentation of decision. The DO will review the final Inquiry report and provide a final determination, within seven (7) Days of receiving the report, as to whether an Investigation is warranted. In the event the DO disagrees with any of the RIO, Designee or Inquiry Panel's recommendations, the DO will document the basis for the decision in writing. The Inquiry is completed when the DO makes this determination.

University of Louisville

Official University Administrative Procedure

The RIO (or, in the case of federal agencies required to be notified, the DO), will notify the Respondent(s); the Complainant (if approved by the DO); the relevant Dean(s)/VP(s); the Provost; University Counsel; the Designee or members of the Inquiry Panel; and any government officials required to be notified of the DO's decision.

If an Investigation is warranted, the RIO will inform any cognizant oversight agency or funding entity of the Allegations, as required by contract or law, and will keep the oversight agency or funding entity informed as required.

If an Investigation is not warranted, the RIO will inform any persons involved in the Inquiry to whom the University disclosed the identity of the Respondent that the Inquiry did not produce sufficient Evidence to warrant formal Investigation. In these instances, the RIO will secure and maintain for seven (7) years after the termination of the Inquiry sufficiently detailed documentation of the Inquiry to permit a later Assessment of the reasons why an Investigation was not conducted. These documents shall be provided to Federal ORI or other authorized government personnel upon request.

If the entire Complaint is dismissed but recommendations for Corrective Actions for other concerns were identified during the Inquiry, such action will be referred to the appropriate University authority.

Investigation

If the RIO, Designee or Inquiry Panel indicates an Investigation is warranted and the DO agrees, the University will initiate the Investigative phase of the Research Misconduct Proceedings.

Initiation and Purpose of the Investigation. Within 30 Days of any determination by the DO that an Investigation is warranted, the RIO shall appoint an Investigation Panel. The RIO may extend this time for good cause. The purpose of the Investigation is to develop a factual record by exploring the Allegations 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, and steps to be taken to correct the Research Record. The Investigation will also determine whether there are additional instances of possible Research Misconduct that would justify broadening the scope beyond the initial Allegations.

Sequestration of Research Records. As soon as practicable upon initiating an Investigation, the RIO shall take all reasonable and practical steps to obtain custody of all the Research Records and Evidence needed to conduct the Research Misconduct Proceeding, that were not previously sequestered during the Inquiry or Preliminary Assessment. When original research records cannot be obtained, copies of records that are substantially equivalent in evidentiary value will fulfill the sequestration requirement. Institutions may also sequester research records and

evidence whenever additional items become known or relevant to the investigation. Wherever possible, the RIO shall give the Respondent copies of the data or Evidence sequestered or reasonable, supervised access to the sequestered Research Records.

Selection of the Investigation Panel. Upon determining that a formal Investigation is warranted, the RIO will appoint an Investigation Panel, the composition and size of which will be determined by the RIO. At a minimum, the Investigation Panel will have five (5) members. The appointed committee must have the necessary and appropriate expertise to conduct a thorough, formal Investigation and authoritative evaluation of the relevant Evidence. The Panel members must not have any personal, professional, or financial Conflicts of Interest with either the Respondent, the Complainant, or witnesses. The Investigation Panel should include at least one faculty member who is an expert in the field of Research that gave rise to the Allegation and may, if necessary, include one or more such experts from outside the University. The RIO will consult with University Counsel prior to consulting with an external expert.

Notification to Respondent. The RIO will inform the Respondent of the initiation of the formal Investigation, the composition of the Investigation Panel, and written notice of the Allegations to be investigated, including any new Allegations of Research Misconduct. The DO will notify the Dean/VP of the unit in which a Respondent holds primary appointment; the Provost; the Chief Compliance Officer and the University Counsel of the initiation of any Investigation.

Charge to the Investigation Panel. At the first convened meeting, the RIO will provide the charge to the Investigation Panel, which will include: (1) the purpose of the formal Investigation, (2) copies of the Allegations and the final Inquiry Report, (3) responsibilities of the Investigation Panel, as set forth below, (4) the requirements needed to support a finding of Research Misconduct, and (5) the expected timeframe for formal Investigation (consistent with applicable regulatory requirements, if any). The RIO will also provide copies of relevant University policies and federal regulations.

Responsibilities of the Investigation Panel. The Investigation Panel will use diligent efforts to ensure the Investigation is thorough, impartial, fair, and appropriately documented. The Investigation will be completed within 180 Days of the initial meeting of the panel unless additional time is required. The panel's determination of Research Misconduct may include recommended actions to correct the Research Record. In fulfilling its responsibilities, the Investigation Panel will:

- Maintain confidentiality of the proceedings;
- Examine all Research Records and other relevant Evidence relevant to reaching a decision on the merits of each Allegation;

- Interview each 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;
- Record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the Investigation; and
- Pursue diligently all significant issues and leads discovered that are determined relevant to the Investigation, including any Evidence of any additional instances of possible Research Misconduct, and
- Continue the Investigation to completion.

Review of the Investigation Report and Actions. The Investigation Panel will prepare a draft written report that summarizes its conclusions regarding whether Research Misconduct occurred and that may recommend corrective actions to address the Research Record, as appropriate. The report will include: the identity of the Respondent; the nature of the Allegation(s); the specific Allegations; funding source(s); sequestration details; methods used to examine the Evidence; a list of Evidence reviewed; interview transcripts; a statement of findings for each Allegation specifying whether Research Misconduct occurred and whether it was committed Intentionally, Knowingly, or Recklessly; the identity of the responsible individual for each finding of Research Misconduct; any publications that need correction or retraction; any federally funded projects that may have been impacted by the Research Misconduct; any sanctions or remediation that the Investigation Panel recommends.

The Respondent will be given a copy of the draft report to provide written comments on the report. Concurrently with the draft report, the Respondent will receive a copy of, or supervised access to the Evidence on which the report is based. The comments of the Respondent on the report, if any, must be submitted to the RIO within 30 Days of the date on which the Respondent received the draft. The RIO will distribute the Respondent's comments to the Investigation Panel and such comments will become part of the final report.

The Investigation Panel will finalize the report after reviewing the Respondent's comments. The final report, along with all supporting materials, will be sent to the DO.

DO decision and documentation of decision. The DO will review the final Investigation report and all investigatory materials. Within fourteen (14) Days of receiving the report, the DO will provide a written decision regarding Institutional finding of Research Misconduct. If the DO disagrees with any of the Investigation Panel's recommendations, the DO may return the matter to the Investigation Panel for further fact-finding or analysis or make an alternate determination. If the DO

elects the latter, the DO will document the basis for the differing decision in writing. The Investigation is completed when the DO makes this determination.

The RIO (or, in the case of federal agencies required to be notified, the DO), will notify the Respondent(s); the Complainant (if approved by the DO); the relevant Dean(s)/VP(s); the Provost; University Counsel; the members of the Investigation Panel; and any government officials required to be notified of the DO's decision.

Deadlines

Due to the sensitive and complex nature of Allegations of Research Misconduct, standard deadlines may be difficult to meet. If a procedural deadline cannot be met during the Research Misconduct Proceeding, the RIO will review and approve, where appropriate, requests for additional time. If a regulatory deadline cannot be met, the RIO will file a written notice with the oversight agency or funding entity and the DO, setting out the reasons why the deadline cannot be met and requesting an extension.

Additionally, the DO may grant deadline extensions to ensure a Respondent's right to due process or for other good cause.

The RIO shall document the reason for any extension, which shall be included in the Record of Research Misconduct Proceedings.

In cases where federal agency approval is involved, deadline extensions granted by federal agencies will take priority to the extent permitted by law. The RIO will ensure that periodic progress reports are filed with Federal ORI, if Federal ORI grants the request for an extension and directs the filing of such reports.

Findings of Research Misconduct

The University will consider, as appropriate and feasible, ways to restore the institutional reputations of individuals alleged to have engaged in Research Misconduct when such Allegations are not substantiated. Individuals seeking such relief should submit a written request to UofL ORI within 30 Days of the final disposition of the Research Misconduct Proceedings. Further, the University will consider, as appropriate and feasible, ways to protect the positions and reputations of those persons who made Good Faith Allegations.

If the University determines that Research Misconduct has occurred, the next step(s) depend upon the type of appointment the Respondent holds, the seriousness of the Research Misconduct, and the sanctions recommended. The finding of Research Misconduct itself will not, however, be subject to challenge.

Regardless of whether a finding of Research Misconduct is made; the University may impose Corrective Actions and Sanctions on the Respondent consistent with applicable policies and practices. The nature of Corrective Actions and Sanctions

388 shall correspond to the violation(s) of Research Integrity or finding(s) of Research
389 Misconduct.

390 If at any time a competent court or other government body determines that a
391 finding of Research Misconduct was erroneous, the DO shall promptly make all
392 reasonable and feasible/practical efforts to communicate this result to restore the
393 reputation of the Respondent(s).

394 **Mandatory Reporting to Funding Agencies and Regulatory Agencies**

395 The University is responsible for reporting to the appropriate federal funding and
396 regulatory agencies, as required throughout the duration of the Research
397 Misconduct Proceedings. In coordination with the UofL Office of Research Integrity,
398 the RIO and DO ensure the reporting milestones are met for each case. Following
399 the submission of the Institutional Record, the cognizant federal agency will review
400 the submission and make any additional information requests.

401 **Corrective Actions and Sanctions**

402 Following the final determination, the DO will decide on what actions to take in light
403 of any findings of Research Misconduct or other instances requiring Corrective
404 Action, approve the notification to the Respondent and the cognizant Dean/VP of
405 the decision, decide whether or not the Complainant will be notified, and decide if
406 and when external agencies or others, if any, are to be notified, what any such
407 notification will include, and to whom it should be directed. Nothing in this policy is
408 intended to inhibit Institutional Members from fulfilling mandated reporting
409 requirements or otherwise reporting unethical or improper activities to appropriate
410 authorities.

411 **Record Retention**

412 Upon resolution of the Proceeding and all ensuing related actions, the RIO shall
413 prepare a complete Institutional Record. The RIO shall secure the Institutional
414 Record and retain it for seven (7) years after the completion of the Proceeding, the
415 completion of the associated HHS proceeding, or for the period required by
416 applicable regulations or ensuing related actions, whichever is later. Access to the
417 materials in the file during the retention period shall be available only upon
418 authorization of the DO for good cause.

419 At the end of the retention period, the RIO shall return all original documents and
420 materials to the persons who furnished them. Following the retention interval, the
421 RIO will destroy the remaining portions of the file following established University
422 procedure unless the RIO makes a written finding that there is reason to retain it.
423 The finding will state explicitly the reasons why and the period during which the file
424 is to be maintained and will be entered in the file. The RIO shall provide the
425 Respondent either a notice that the file has been destroyed or a copy of the written
426 finding that the file will be retained.

Referrals

Other University Processes. A RIO, Inquiry or Investigative Panel may find that, while a Respondent's conduct does not constitute Misconduct, it nevertheless constitutes a Questionable Research Practice (QRP). Any such finding shall be referred to the DO for review. The DO may deem further action appropriate, including, applying Procedures for Responding to Allegations of Questionable Research Practices (RES 5.01a).

If the RIO or panel member receives a report of Retaliation during the Proceedings, that report will be referred to the appropriate University Official(s) for review and resolution.

External Entities. On occasion, members of the University Research community submit Allegations of Research Misconduct to ULORI in which the Respondent's Home Institution is not UofL or where the actions in question did not take place at UofL. The RIO may consult with all pertinent Institutional Officials to determine whether the Research was conducted at the University. In these instances, if the Allegation never occurred at UofL, ULORI would coordinate referral of these matters to the appropriate institutional or federal office for action.

Proceedings Involving Special Circumstances

Administrative Actions During the Course of Proceedings. The RIO should be alerted promptly if any of the following circumstances detailed below are discovered during any stage of the proceedings:

- An immediate health hazard;
- An impact on fundamental fairness to the Respondent or other parties to the Research Misconduct Proceedings;
- Preserve the integrity of the Research;
- An immediate need to protect federal, state, local, or UofL interests, funds or equipment;
- An immediate need to protect the Complainant, the Respondent, their associates, or a witness;
- Likelihood that an alleged incident of Research Misconduct will be reported publicly;
- Allegation involves a public health-sensitive issue (e.g., clinical trial); or
- A reasonable indication of a possible civil or criminal violation.

If these above situations arise in connection with a scholarly activity that is externally sponsored, UofL may, and in some cases must, notify sponsoring agencies directly and immediately. Such administrative actions will not be deemed disciplinary in nature. The DO will determine the appropriate actions to take depending on the prevailing circumstances. The DO may consult with the Panel members, RIO, University Counsel, and other Institutional Officials in making these determinations.

Administrative actions can include: a temporary suspension of Research, additional monitoring of the Research process and the handling of federal funds and equipment, reassignment of personnel or the responsibility for the handling of federal funds and equipment, additional review of Research data and results, delaying publication, or informing the Research community or the public.

Allegations against Complainants. If at any point during a Research Misconduct Proceeding there is an Allegation or a reasonable basis for believing that a Complainant may bear any responsibility for the alleged Research Misconduct, the RIO shall inform the Complainant promptly of that Allegation or reasonable basis; and provide the Complainant all Respondent protections. Upon the request of any Complainant receiving such notification, the DO may approve a reasonable delay in any Proceeding necessary to protect the Complainant's interests, but the process shall not commence anew.

Allegations involving multiple Institutions. When Allegations involve research conducted at multiple Institutions, one Institution must be designated as the lead Institution **if** a joint Research Misconduct Proceeding is conducted. In a joint Research Misconduct Proceeding, the lead Institution should obtain Research Records and other Evidence pertinent to the proceeding, including witness testimony, from the other relevant Institutions. Under a formal Memorandum of Understanding, the joint Research Misconduct Proceeding may include panel members from the Institutions involved. The determination of whether further Inquiry and/or Investigation is warranted, whether Research Misconduct occurred, and the Institutional Actions to be taken may be made by the Institutions jointly or tasked to the lead Institution.

Reopened Complaints. Any Proceeding that has been closed without a finding of Research Misconduct may be reopened only if, in the opinion of the RIO in consultation with the DO, new and potentially significant information of Research Misconduct, not previously considered, has been presented.

Suspected Criminal Activity. During the Research Misconduct Proceedings, should suspected criminal activity be revealed, notification will be made to University Counsel, the Department of Public Safety and the Title IX Office, as appropriate. Every attempt will be made to keep the resulting activities separated. Should either office exert authority over an active proceeding, the RIO will suspend the active proceedings, make all appropriate notifications, and fully cooperate as needed.

Ceding Proceeding to Federal Agencies. In unique circumstances, the University may receive an Allegation from an external entity, such as a federal agency, in which portions of the Research Misconduct Proceedings have been completed. At the discretion of the DO, the external submission may be accepted as completing one or more phases and the University may proceed directly to the

next phase. In these instances, the University will clearly document the externally completed phases in the case file and the notifications to the Respondent(s). Likewise, should a federal oversight entity exert authority over an active proceeding, the University will cede all further action to the oversight body and fully cooperate as needed.

Admissions by Respondents. At any stage of the Proceedings under this procedure, and consistent with the requirements of the relevant oversight agency or funding entity, the RIO may attempt to resolve a Complaint. At the initiation of the resolution process, the University and the Respondent will agree to terminate the Research Misconduct Proceedings with a full written admission to all Allegations pending in the Research Misconduct Proceedings, or the Respondent will accept the University's findings and actions without an admission of Research Misconduct.

When entering a resolution, the University will take all actions it deems appropriate due to the Research Misconduct, including but not limited to referral to other University disciplinary processes, or correction or retraction of published papers.

The RIO will work with the Respondent and/or the supervisor of the Respondent to thoroughly review the Respondent's Research Record to identify any other potential Research Misconduct.

The RIO will provide the Respondent with a written document listing the full scope of Research Misconduct findings. A resolution with the Respondent may be reached only if the Respondent admits to, or accepts the findings of, the full scope of the Research Misconduct.

The RIO will inform the relevant oversight agency or funding entity, as required by law or contract, of the full scope of the Research Misconduct identified. A resolution with the Respondent may be reached only if the relevant oversight agency concurs with terminating the Research Misconduct Proceeding.

The RIO will prepare a written document including the admission or the resolution with the Respondent, the Research Misconduct findings, any known federal funding, the procedures that occurred up to the point of resolution, and any recommended Corrective Actions the University deems appropriate. The written document will be provided to the DO for concurrence.

In instances where the DO and/or the oversight agency does not approve the resolution, the Research Misconduct Proceedings will resume.

Proceedings Involving Special Populations

Institutional Officials. Allegations concerning an Institutional Official should be communicated to the Director, UofL ORI or the Executive Vice President, Research

and Innovation. The Executive Vice President, Research and Innovation, will assign responsibility for managing the Allegation to a RIO with no Conflicts of Interest and who does not directly or indirectly report to the Respondent. The Provost will serve as the DO for Allegations involving Institutional Officials. If the Allegation involves the Provost, then the President is the DO. The Board of Trustees will appoint a DO if the Allegation involves the President.

Statutory Affiliates. If the Research Misconduct Proceedings involve one or more of the University's Statutory Affiliates, UofL ORI will coordinate data collection and communications through a single point of contact to minimize the potential for violations of the confidentiality provisions. Following the completion of the proceedings, UofL ORI will collaborate with the DO to determine the appropriate final communication to provide back to the Statutory Affiliate point of contact.

Affiliated Research Organizations. If the Research Misconduct Proceedings involve one or more of the University's Affiliated Research Organizations, a Memorandum of Understanding (MOU) will be developed between the organizations. The MOU will outline the expectations for data Sequestration and preservation, panel composition (including cross population should both organizations seat panels) identification of the Deciding Official(s) and point of contact for each organization involved. Presence of the MOU will be communicated to the sponsoring agency, if required. If the Affiliated Research Organization(s) do not operate under a federal assurance or have a formal Research Misconduct policy, the MOU will be utilized to flow across regulatory provisions. In the specific instance of the Norton Children Research Institute, existing agreements have addressed these MOU requirements. In instances where the Affiliated Research Organization is also a federal agency (e.g. Veteran's Administration) this procedure does not preclude that agency from fulfilling its regulatory obligations.

Students. The RIO evaluates Allegations of Research Misconduct when a student's work has been published—such as a dissertation or article—or has been used in a grant proposal. However, student academic Misconduct involves work completed as part of a degree program—such as a master's thesis—or academic work published in a University academic platform or forum. If the RIO determines that the Allegation resides solely within the academic environment, the matter will be referred to the Dean of Students or Designee (undergraduate) or Graduate Dean or Designee (graduate or professional).

Modifications to Procedures

In appropriate cases, including those in which the Respondent admits responsibility, the DO in consultation with the appropriate Institutional Officials and, if needed, federal oversight agencies may consider whether to modify or eliminate any of the procedural stages of the procedures set forth below

The DO may approve departures from these procedures as required by law or as necessary to protect public health or safety, the integrity of Research, fundamental fairness to the Respondent or other parties, or an overriding interest of the University. The RIO shall document any approved significant departures in writing and include the documentation in the case file.

STANDARDS (O*)

Allegations Not Made in Good Faith. If the DO determines that the Complainant's Allegation of Research Misconduct was made with knowledge that the Allegation was false, or with reckless disregard for or willful ignorance of facts that would disprove the Allegation, or that any member of the University community acted in violation of the Research Misconduct Policy, the DO will determine whether any administrative action should be taken against such person.

Confidentiality. All persons involved in Proceedings under this procedure shall keep confidential, to the extent legal and practicable, the identities of Complainants, witnesses, and Respondents, limiting any disclosures to those who have a need to know and as allowed by applicable law or as provided in this procedure, including Respondent's right of consultation.

Except as may otherwise be prescribed by applicable law, confidentiality must be maintained for any records or Evidence from which Research subjects may be identified. Disclosure of any such records or Evidence from which these persons may be identified is limited to those who have a need to know to carry out a Research Misconduct Proceeding, Interim Actions, Sanctions, or Corrective Actions. The applicable laws and regulations may require the institution to disclose the identity of Respondents and Complainants to federal oversight agencies pursuant to the agency's review of institutional Research Misconduct Proceedings.

The RIO informs all parties of the confidentiality standard at the beginning of each phase of the case.

Despite the University's general commitment to preserving confidentiality noted above, there may be cases in which the University may need – at any stage of the process, including before the University's review has concluded – to notify and/or consult with external entities about the Allegation or aspects thereof. In any cases involving potential external notification, the Executive Vice President, Research and Innovation, in consultation with University Counsel, will decide when a notification should occur, what any such notification will include, and to whom it should be directed.

Conflicts of Interest. All parties involved in a Research Misconduct Proceeding must disclose potential or actual unresolved personal, professional, or financial Conflicts of Interest with a Complainant, Respondent, or witness to the RIO. If the RIO has such a conflict, the RIO will inform the DO. The DO will have the discretion to handle conflicts of interest identified under this policy, and the decision will be final. Should the DO have a conflict, the decision will rest with the Provost.

Conflicts of Interest in Research Misconduct Proceedings exist when the financial, personal, or professional relationships of an individual involved in the Proceedings may affect the Proceedings or the resolution of the Allegations. Perceived or actual Conflicts of Interest are treated identically under this policy. Possible Conflicts of Interest may include, but are not limited to, co-authorship of work with the Respondent or Complainant, or professional or personal relationship with the Respondent or Complainant beyond that of mere friends or colleagues (e.g., current or former student or mentor relationship, direct supervisory or subordinate job relationship, or marital/partner relationship). The subordinate relationship of a Respondent or Complainant to their dean or chair alone does not constitute a perceived or actual Conflict of Interest under this procedure.

Research Integrity Panel. The University will utilize a Research Integrity Panel (RIP) to ensure that the University's policy and procedures for dealing with Research Misconduct are consistent with federal regulations and emerging best practices. The RIP will consist of a pool of Institutional Members to serve as experts for the Inquiry and Investigation Panels, with expertise and training to participate in Research Misconduct proceedings. The membership will be drawn from all units and campuses within the University and will provide expertise in a variety of disciplines as well as linguistics, statistics, and institutional culture. The RIP will also include at least three members to represent the interests of the Graduate School. The RIP will fulfill the following functions:

- Serve as the pool from which members of Inquiry and Investigative Panels can be drawn;
- Assist the RIO in evaluating Allegations of Research Misconduct;
- Advise the RIO on appropriate members for Investigation Panels; and
- Advise the DO and the RIO on the implementing and revising of these Policy and Procedures.

Respondent's right to Consultation. At any stage of the Proceedings, a Respondent may consult with individuals of their choosing who do not otherwise have a role in the Proceedings. An advisor may, but need not, be an attorney. The advisor shall not present the case or otherwise directly participate in the

Proceeding. Seeking guidance from an individual outside the Proceedings does not alter the confidentiality provisions. Neither the Witnesses nor the Respondent may have legal counsel present at the meetings of the Inquiry and Investigation Panels, except at the express invitation of the Panels. Should legal counsel be invited, the invitation will be extended to all parties. When invited, legal counsel may observe but shall not participate in the Proceedings. With the prior approval of the Panels, the Respondent may be accompanied by a non-attorney colleague at meetings of the Panels. When invited, the non-attorney colleague may observe but shall not participate in the Proceedings. The Respondent(s) and advisors do not have the right to be present at interviews of witnesses or to question such witnesses at any stage of the Research Misconduct Proceeding.

Retaliation. The University will not tolerate Retaliation in any form against any individual who participates in a Research Misconduct Proceeding. Retaliation is a serious violation that can subject the offender to disciplinary action under appropriate University rules or policies. All parties to Research Misconduct Proceedings, including Respondents, Complainants, Witnesses, Panel Members, the RIO, DO, and staff, are entitled to be treated respectfully.

DEFINITIONS (O*)

Definitions for these procedures are located [here](#).

RESPONSIBILITIES (O*)

The \ Research Misconduct Roles and Responsibility Matrix is located [here](#).

FORMS/ONLINE PROCESSES (O*)

[to be completed]

RESPONSIBLE AUTHORITY (R*)

Executive Vice President, Research and Innovation

RESPONSIBLE UNIVERSITY DEPARTMENT/DIVISION (R*)

UofL Office of Research Integrity
300 E Market, Suite 300
502-852-2454
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HISTORY (R*)

This version of the procedure, effective **<ENTER EFFECTIVE DATE>**, governs all Research Misconduct Proceedings in matters submitted on or after January 1, 2026. The former version of this procedure will continue to govern matters in process prior to January 1, 2026, unless the University determines, in its sole discretion, that this revised procedure will apply.

Revision Date(s): Jan 2022, October 2023

Reviewed Date(s): Jan 2022, October 2023

The University Policy and Procedure Library is updated regularly. To ensure a printed copy of this document is current, please access it online at <http://louisville.edu/policies>.

ACKNOWLEDGEMENTS

In addition to regulatory resources, this document was modeled and referenced content from Stanford University, Indiana University, Ohio State University, University of Illinois, University of Michigan, University of New Hampshire, and Northwestern University.

R* = Required O* = Optional