



## Guidance for the response to allegations of research non-compliance in the Campus schools

Revised 12/5/2019

### **Purpose:**

To define institutional best practices for organizing and initiating an investigation after a report of research noncompliance. Noncompliance is defined as the failure to follow federal, state, or local regulations governing research, institutional policies related to research, or the requirements or determinations of the IRB, IACUC, or other similar research-related review board. This may pertain to the principal investigator, research staff, or any member or component of a research program.

### **Procedure:**

#### *Initial communication*

- 1) Upon receipt of an allegation of research noncompliance, the person who received the allegation must reach out to school/center/institute leadership (e.g., Associate/Divisional Deans for Faculty Affairs, Research, Administration, etc.), hereinafter "School Leadership." School Leadership will immediately notify the dean/director and other University officials, including the Vice President for Research, the Associate Vice President for Research/Vice Dean for Scientific Integrity, University Counsel, and the Office of Audit, Risk and Compliance, as appropriate. Duke's Senior Response Committee, co-chaired by the Associate Vice President for Research/Vice Dean for Scientific Integrity and the School of Medicine (SoM) Executive Vice Dean for Administration, may be convened based on the nature of the allegation.
- 2) Upon receipt of an allegation of research misconduct,<sup>1</sup> the person who received the allegation **must** also contact the Misconduct Review Officer at 919-668-5115. Urgent action may be needed to preserve emails and/or electronic files from deletions/alterations. If employment has already been terminated or termination is pending, Office of Information Technology (OIT) assistance should be requested to ensure that email is appropriately preserved and no affiliate email accounts are created/approved for the terminated employee.
- 3) Depending on the nature of the report, School Leadership may contact other units or offices for assistance in conducting and supporting the investigation, such as the following:<sup>2</sup>
  - Office of Audit, Risk, and Compliance (OARC)
  - Duke Office of Scientific Integrity (DOSI)
  - University Counsel
  - Staff & Labor Relations
  - Campus Human Subjects Protection Program (Campus IRB)
  - DUHS Institutional Review Board (DUHS IRB)
  - Duke Animal Care and Use Program (IACUC)
  - Duke Office of Clinical Research (DOCR)
  - Duke Health Technology Solutions (DHTS)
  - Occupational and Environmental Safety Office (OESO)
  - Office of Information Technology (OIT)
  - Office of Research Contracts (ORC)
  - Office of Research Support (ORS)
  - School of Medicine Research Administration (SOM-RA)
  - Post Award Financial Management (PAFM)

The staff from the offices selected will be the investigation team.

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<sup>1</sup> <https://dosi.duke.edu/misconduct-research>

<sup>2</sup> See Appendix A for additional contacts related to research activity noncompliance

- 4) School Leadership will reach out to the department chair (or institute/center director) and business manager to help facilitate the investigation and any required document sequestration. Communications with the principal investigator and/or other research staff involved in the report may also require coordination with department chair, institute/center director, and/or business manager. In the event that the department chair, institute/center director, and/or business manager are implicated by the allegation, this step may be omitted.
- 5) As needed, based on the nature of the report and sponsor requirements, School Leadership or other appropriate institutional official(s) will notify the sponsor(s) of the ongoing investigation as well as facilitate future communication to the sponsor or federal agencies. Coordination with University Counsel is required for sponsor/agency notification.

#### *Initial meeting*

- 1) Upon receipt of an allegation of noncompliance, School Leadership will assess the allegation and reach out to the office(s) needed to assist in the investigation and schedule an urgent meeting/conference call. At this meeting, roles will be assigned based on the nature of the complaint (e.g., data issues, research billing concern, IRB complaint, etc.).
- 2) A secure Duke Box folder should be created as a secure repository for documents related to the investigation. Key information and a running list of actions and decisions made should be kept in the Box documentation that are easily identified and updated regularly for all parties to access.
- 3) Confirm which office and staff member(s) will take the lead in the investigation (“Investigation Lead”). If there are multiple allegations to the report spanning the expertise of multiple offices, ensure there is single point person for each office needing to be involved in the investigation. The overall Investigation Lead will keep all records and coordinate communication with the individuals involved. Potential conflicts of interest must be reviewed prior to determining which individuals should be involved in the investigation. Anyone with potential or perceived conflicts of interest must not participate in the investigation or meetings.
- 4) Create a contact list of office and cell phone numbers for everyone involved in investigating the allegation and upload that list to the Box folder.
- 5) If additional support is needed to conduct the investigation, sequester records, and/or review records, this assistance may be available from the Office of Research/Duke Office of Scientific Integrity.

#### *Sequestration logistics*

In the event that study or laboratory files or other documents or evidence must be sequestered, the following procedure should be followed:

- 1) Sequestration should be conducted before or at the time the faculty or staff are notified of the allegation to ensure that all records are preserved.
- 2) Identify one investigation team member to provide support and assistance to the team in executing the sequestration (the “Logistics Lead”). Tasks should include (appropriate tasks may be delegated to administrative personnel):
  - a. Obtain a fund code, if needed, through the school finance office and determine who will manage the code
  - b. Arrange for moving boxes to be available at the site of sequestration (must not arrive before sequestration)
  - c. Schedule appropriate vendor to move boxes and/or secure carts or personnel to assist in moving boxes from sequestration site to secure storage site
  - d. Ensure OIT or school-based IT resources has sufficient electronic storage available and is available to participate on sequestration team
  - e. Determine secure location to store boxes, if not already identified, and ensure controlled access to location (i.e., limit number of keys)
  - f. Identify a backup contact person to assist Logistics Lead when receiving boxes coming from long-term storage
  - g. Arrange for use of a copier and copy code, if needed

- h. Assist in scheduling meetings and/or conference calls for staff involved in conducting investigation
- 3) Confirm with Logistics Lead that the supplies and personnel will be available by the requested date and time of sequestration prior to alerting department/division leadership of the date/time of sequestration.
- 4) Based on the nature of the complaint, alert department or institute/center leadership to the sequestration when the timing is known or shortly after sequestration occurs. The respondent of the allegation must **not** be notified in advance of the sequestration.
- 5) At least two personnel assisting with the investigation should be present to observe the entire sequestration process.
- 6) Keep a record of the number of boxes per study or other general description of contents of each box collected from the research site. Have the study coordinator, lab manager, or other study or lab team member sign this document confirming that the boxes will be sequestered.
- 7) In the event that additional resources or supplies are needed, the staff member conducting the sequestration should reach out to the Logistics Lead to request assistance.

*Communication logistics*

- 1) The Logistics Lead should schedule regular meetings with the Investigation Lead(s) and school and Provost's Office leadership. Frequency can be determined at start of investigation. Each lead should state a summary of activities, decisions, and upcoming events at the meeting.
- 2) Any changes to the scope or plan for the investigation should be communicated to all personnel involved (e.g., adding/removing studies from review, changing percentage of review, etc.). The point person should notify all leads/contacts when a change is made and update associated documents.
- 3) Files should be uploaded in Box for group review, when possible.
- 4) At the conclusion of the investigation, the Investigation Lead or other designated person, with input from School Leadership and others involved in the investigation, should provide a summary of findings and recommendations to the investigation group, Provost's Office leadership, OARC, University Counsel, and to the department/center/institute leadership of the matter being investigated. This report should include necessary corrective action measures, a timeline for completion, and the person/office responsible for ensuring completion. Additionally, institutional processes should be reviewed to determine whether new policies/ procedures are required or existing policies/procedures need to be updated.

Appendix A

**Research Activity Noncompliance / Internal Checklist**

<u>Question</u>	<u>Answer</u>		<u>Contact</u>
	Yes	No	
Is there a potential safety concern?			<p><b>IF IN IMMEDIATE DANGER, DIAL 911 TO CONTACT CAMPUS POLICE</b></p> <p><b><u>If it involves undergraduate students:</u></b> Mary Pat McMahon, Vice Provost/Vice President for Student Affairs 919-684-3737, <a href="mailto:studentaffairs@duke.edu">studentaffairs@duke.edu</a></p> <p><b><u>If it involves a postdoc:</u></b> Molly Starback, Administrative Manager, Office of Postdoctoral Services 919-681-7154, <a href="mailto:molly.starback@duke.edu">molly.starback@duke.edu</a></p> <p><b><u>If it involves graduate students:</u></b> Jacqueline Looney, Senior Associate Dean for Graduate Programs and Associate Vice Provost for Academic Diversity, The Graduate School 919-684-2056 <a href="mailto:jlooney@duke.edu">jlooney@duke.edu</a></p> <p>Beth Sullivan, Associate Dean for Research Training, School of Medicine 919-684-9038, <a href="mailto:beth.sullivan@duke.edu">beth.sullivan@duke.edu</a></p> <p><b><u>If human subjects are involved:</u></b> Holly Williams, Director, Campus IRB 919-684-3030, <a href="mailto:holly.williams.irb@duke.edu">holly.williams.irb@duke.edu</a></p> <p>Adrian Hernandez, Vice Dean for Clinical Research, School of Medicine 919-668-7515, <a href="mailto:adrian.hernandez@duke.edu">adrian.hernandez@duke.edu</a></p> <p>Jennifer Adams, DUHS Director of Clinical Risk Management 919-684-3277, <a href="mailto:jennifer.c.adams@duke.edu">jennifer.c.adams@duke.edu</a></p> <p><b><u>If it involves faculty or staff:</u></b> <i>Campus faculty or staff:</i> Larry Carin, Vice President for Research 919-681-6438 <a href="mailto:lcarin@duke.edu">lcarin@duke.edu</a></p> <p><i>SoM faculty:</i> Ann Brown, Vice Dean for Faculty 919-684-5002, <a href="mailto:ann.brown@duke.edu">ann.brown@duke.edu</a></p> <p><i>SoM staff:</i> Scott Gibson, Executive Vice Dean for Administration 919-684-3945, <a href="mailto:j.s.gibson@duke.edu">j.s.gibson@duke.edu</a></p> <p><i>SoN faculty:</i> Marilyn Hockenberry, Associate Dean for Research Affairs 919-684-9330 <a href="mailto:marilyn.hockenberry@duke.edu">marilyn.hockenberry@duke.edu</a></p>

<b>Question</b>	<b>Answer</b>		<b>Contact</b>
	Yes	No	
<b>Is there a potential Export Control or Foreign Corrupt Practices Act concern?</b>			Daniel Vick, Director, Office of Export Controls 919-668-2711, <a href="mailto:daniel.vick@duke.edu">daniel.vick@duke.edu</a>  Bill Nicholson, Office of Counsel 919-684-3955, <a href="mailto:bill.nicholson@duke.edu">bill.nicholson@duke.edu</a>
<b>Is there a potential biosafety, radiation, or lab safety concern?</b>			Wayne Thomann, Director, Occupational & Environmental Safety Office 919-684-6320, <a href="mailto:wayne.thomann@duke.edu">wayne.thomann@duke.edu</a>
<b>Does the matter present potential legal risk to the University?</b>			Ann Bradley Office of Counsel 919-613-4401, <a href="mailto:ann.bradley@duke.edu">ann.bradley@duke.edu</a>  Scott Elengold, Office of Counsel 919-684-3955, <a href="mailto:scott.elengold@duke.edu">scott.elengold@duke.edu</a>
<b>Is the matter something that could generate media attention/public interest?</b>			Michael Schoenfeld, VP, Public Affairs and Government Relations 919-681-3788, <a href="mailto:michael.schoenfeld@duke.edu">michael.schoenfeld@duke.edu</a>
<b>Does the matter involve sponsored research?</b>			Keith Hurka-Owen, Executive Director, Office of Research Support 919-681-8687, <a href="mailto:keith.hurka.owen@duke.edu">keith.hurka.owen@duke.edu</a>  Laurianne Torres, Associate Dean, Research Administration, SoM 919-613-7436, <a href="mailto:laurianne.torres@duke.edu">laurianne.torres@duke.edu</a>  Gavin Foltz, Associate Dean and Executive Director, Office of Research Contracts, SoM 919-681-0846, <a href="mailto:gavin.foltz@duke.edu">gavin.foltz@duke.edu</a>  Nate Martinez-Wayman, Director, Office of Sponsored Programs 919-668-5850, <a href="mailto:nate.martinez-wayman@duke.edu">nate.martinez-wayman@duke.edu</a>  James Luther, Associate VP Finance & Research Costing Compliance 919-684-5723, <a href="mailto:james.luther@duke.edu">james.luther@duke.edu</a>
<b>Does the matter involve human subjects research?</b>			Holly Williams, Director, Campus IRB 919-684-3030, <a href="mailto:holly.williams.irb@duke.edu">holly.williams.irb@duke.edu</a>  David Falcone, Director, Privacy, Ethics, and Compliance 919-684-0303, <a href="mailto:david.falcone@duke.edu">david.falcone@duke.edu</a>  Susanna Naggie, Associate Dean for Clinical Research Initiatives and Regulatory Affairs, DUHS IRB 919-681-5220, <a href="mailto:susanna.naggie@duke.edu">susanna.naggie@duke.edu</a>  Denise Snyder, Associate Dean for Clinical Research, School of Medicine, SoM 919-660-7580, <a href="mailto:denise.snyder@duke.edu">denise.snyder@duke.edu</a>

Question	Answer		Contact
	Yes	No	
Are there subject billing implications?			<p>Colleen Shannon, Chief Compliance and Privacy Officer, DUHS Compliance 919-668-2573, <a href="mailto:colleen.shannon@duke.edu">colleen.shannon@duke.edu</a></p> <p>Denise Snyder, Associate Dean for Clinical Research, SoM 919-660-7580, <a href="mailto:denise.snyder@duke.edu">denise.snyder@duke.edu</a></p>
Does the matter involve animals involved in research?			<p>Anna Hampton, Director, Office of Animal Welfare Assurance 919-668-6721, <a href="mailto:anna.hampton@duke.edu">anna.hampton@duke.edu</a></p> <p>John Norton, Director, Division of Lab Animal Resources 919-684-4204, <a href="mailto:john.norton@duke.edu">john.norton@duke.edu</a></p>
Are there privacy breach considerations (i.e., HIPAA, NC privacy laws)?			<p>Colleen Shannon, Chief Compliance and Privacy Officer, DUHS Compliance 919-668-2573, <a href="mailto:colleen.shannon@duke.edu">colleen.shannon@duke.edu</a></p> <p>David Falcone, Director, Privacy, Ethics, and Compliance 919-684-0303, <a href="mailto:david.falcone@duke.edu">david.falcone@duke.edu</a></p>
Are there potential conflict of interest implications?			<p>Greg Samsa, Director, Duke Office of Scientific Integrity-COI 919-684-3121, <a href="mailto:greg.samsa@duke.edu">greg.samsa@duke.edu</a></p>
Does the matter involve external activities of an employee?			<p><i>Campus faculty or staff:</i> Larry Carin, Vice President for Research 919-681-6438 <a href="mailto:lcarin@duke.edu">lcarin@duke.edu</a></p> <p><i>SoM faculty:</i> Ann Brown, Vice Dean for Faculty, SoM 919-684-5002, <a href="mailto:ann.brown@duke.edu">ann.brown@duke.edu</a></p> <p><i>SoM staff:</i> Scott Gibson, Executive Vice Dean for Administration, SoM 919-684-3945, <a href="mailto:j.s.gibson@duke.edu">j.s.gibson@duke.edu</a></p>
Does the matter involve potential employee misconduct?			<p><b>Contact the employee's school dean's office/HR contact</b></p> <p><b>For sexual harassment, sexual misconduct, or discrimination (Faculty or Non-Faculty)</b> Kimberly Hewitt, VP of Institutional Equity and Chief Diversity Officer 919-684-8228, <a href="mailto:kimberly.hewitt@duke.edu">kimberly.hewitt@duke.edu</a></p> <p><i>Campus faculty or staff:</i> Larry Carin, Vice President for Research 919-681-6438 <a href="mailto:lcarin@duke.edu">lcarin@duke.edu</a></p> <p><i>SoM faculty:</i> Ann Brown, Vice Dean for Faculty, SoM 919-684-5002, <a href="mailto:ann.brown@duke.edu">ann.brown@duke.edu</a></p>

<u>Question</u>	<u>Answer</u>		<u>Contact</u>
	Yes	No	
			<p><i>SoM staff:</i>  Scott Gibson, Executive Vice Dean for Administration, SoM  919-684-3945, <a href="mailto:j.s.gibson@duke.edu">j.s.gibson@duke.edu</a></p>
Is there an allegation of Research Misconduct (i.e., falsification, fabrication, plagiarism)?			<p>Donna Kessler, Research Integrity Officer  919-668-5115, <a href="mailto:donna.kessler@duke.edu">donna.kessler@duke.edu</a></p>
Does the matter involve potential student misconduct?			<p><b><u>For sexual harassment, sexual misconduct, or discrimination</u></b>  Kimberly Hewitt, VP of Institutional Equity and Chief Diversity Officer  919-684-8228, <a href="mailto:kimberly.hewitt@duke.edu">kimberly.hewitt@duke.edu</a></p> <p><b><u>If it involves undergraduate students:</u></b>  Mary Pat McMahon, Vice Provost/Vice President for Student Affairs  919-684-3737, <a href="mailto:studentaffairs@duke.edu">studentaffairs@duke.edu</a></p> <p><b><u>If it involves graduate students:</u></b>  Jacqueline Looney, Senior Associate Dean for Graduate Programs and Associate Vice Provost for Academic Diversity, The Graduate School  919-684-2056 <a href="mailto:jlooney@duke.edu">jlooney@duke.edu</a></p> <p><b><u>If it involves Medical Students:</u></b>  Caroline Haynes, Advisory Dean and Director of Student Affairs,  919-684-0860, <a href="mailto:hayne001@mc.duke.edu">hayne001@mc.duke.edu</a></p>
Should the matter be referred to Internal Audit for a financial or compliance audit?			<p>Leigh Goller, Executive Director, Office of Audit, Risk, and Compliance  919-613-7639, <a href="mailto:leigh.goller@duke.edu">leigh.goller@duke.edu</a></p>
Should the matter be referred to the Research Compliance Assurance, i.e. a directed or for cause study review?			<p>David Falcone, Director, Privacy, Ethics, and Compliance  919-684-0303, <a href="mailto:david.falcone@duke.edu">david.falcone@duke.edu</a></p>
Does the matter involve the Duke Health System?			<p>Colleen Shannon, Chief Compliance and Privacy Officer, DUHS Compliance  919-668-2573, <a href="mailto:colleen.shannon@duke.edu">colleen.shannon@duke.edu</a></p> <p>Joseph Rogers, DUHS Chief Medical Officer  919-681-3422, <a href="mailto:j.pickett@duke.edu">j.pickett@duke.edu</a></p> <p>Jennifer Adams, DUHS Director of Clinical Risk Management  919-684-3277, <a href="mailto:jennifer.c.adams@duke.edu">jennifer.c.adams@duke.edu</a></p>

<p><b>Is there human subject information at issue that is subject to a Certificate of Confidentiality?</b></p>		<p>Ann Bradley Office of Counsel 919-613-4401, <a href="mailto:ann.bradley@duke.edu">ann.bradley@duke.edu</a></p> <p>Scott Elengold, Office of Counsel 919-684-3955, <a href="mailto:scott.elengold@duke.edu">scott.elengold@duke.edu</a></p>
<p><b>Is a response to the complainant needed?</b></p>		<p>Larry Carin, Vice President for Research 919-681-6438, <a href="mailto:lcarin@duke.edu">lcarin@duke.edu</a></p> <p>Adrian Hernandez, Vice Dean for Clinical Research, School of Medicine 919-668-7515, <a href="mailto:adrian.hernandez@duke.edu">adrian.hernandez@duke.edu</a></p> <p>Colin Duckett, Vice Dean for Basic Science, School of Medicine 919-668-3831, <a href="mailto:colin.duckett@duke.edu">colin.duckett@duke.edu</a></p> <p>Michael Schoenfeld, VP, Public Affairs and Government Relations 919-681-3788, <a href="mailto:michael.schoenfeld@duke.edu">michael.schoenfeld@duke.edu</a></p> <p>Ann Bradley Office of Counsel 919-613-4401, <a href="mailto:ann.bradley@duke.edu">ann.bradley@duke.edu</a></p> <p>Scott Elengold, Office of Counsel 919-684-3955, <a href="mailto:scott.elengold@duke.edu">scott.elengold@duke.edu</a></p>