

Duke

RESEARCH QUALITY ESCALATION PLAN

The role of research administration is an important one at Duke. Research administrators are responsible for facilitating the scholarly work of Duke investigators while also ensuring Duke's compliance with applicable sponsor and University regulations pertaining to research, including policies that govern human research subjects protection, animal care and use, conflicts of interest and/or commitment and grants/contracts administration.

Efficient, effective and compliant research administration relies on strong partnership and communication among unit level administrators, central research administration support offices, and the investigators they support.

The purpose of an escalation plan is to establish clear pathways to avoid premature or unnecessary escalation of issues to ORA, when often the issues can be resolved compliantly at the local level. Having a clear escalation path helps minimize delays, preserve intra-unit relationships between investigators and administrators, and improve efficiency, accountability, and integrity of all activities within the unit.

As part of the Year 7 activities of the Research Quality Management Program (RQMP), the Escalation Plan includes a pathway to be used for situations of scientific, budgetary, and commitment overlap (when disclosed via the Intent to Submit (I2S) process, proposal, Research Performance Progress Report (RPPR), Just in Time (JIT), or at sponsor or institution's request) as well as a pathway for managing compliance with and repercussions related to Responsible Conduct of Research (RCR) requirements.

PART A of this Escalation Plan outlines the steps that will be taken when resolution of a general research administration issue requires hierarchical intervention within the unit. Issues are typically communicated between the Office of Research Administration (ORA) to the grants manager in the unit. The grants manager should resolve the issue within the unit (escalating if necessary). If the issue is not resolved at that level, the escalation plan described in Part 1 will be followed.

PART B outlines the steps that will be taken to manage situations of scientific, budgetary and commitment overlap.

PART C outlines the steps that will be taken to manage noncompliance with and repercussions related to RCR trainings.

THIS ESCALATION PLAN IS DESIGNED FOR:

Medicine

PART A – ESCALATION PATHWAY FOR GENERAL RESEARCH ADMINISTRATION ISSUES:

1. ORA will communicate the problem in writing directly to the 1st Level point(s) of contact (POC) and will include the following details in the communication:
 - High level summary of the issue
 - Applicable governance (e.g., award terms/conditions, sponsor or Duke policy, etc.)
 - Action or decision needed to resolve
 - Deadline for resolution
 - Instructions for next level escalation (if applicable)

PRIMARY	ADMINISTRATIVE 1 st Level POC	<i>Deborah Martin, RASR, Zone 2 Lead</i>
ALTERNATE	ADMINISTRATIVE 1 st Level POC	<i>Darcy Lewis</i>
PRIMARY	SCIENTIFIC 1 st Level POC	<i>Gow Arepally</i>
ALTERNATE	SCIENTIFIC 1 st Level POC	<i>Laurie Snyder</i>

2. 1st Level POC will resolve the issue, if possible. If requested by ORA (or other central research administration support office) to escalate beyond the 1st Level POC and/or if the 1st Level POC is unable to resolve the issue, the 1st Level POC will involve the 2nd Level POC and/or Unit Leadership for ultimate decision on resolution.

In units where the escalation path directly goes from the first level POC to the Unit Leadership, due to the lack of a 2nd Level POC, put "N/A" in the spaces for the 2nd Level POCs.

PRIMARY	ADMINISTRATIVE 2 nd Level POC	<i>Amy Porter-Tacoronte</i>
ALTERNATE	ADMINISTRATIVE 2 nd Level POC	<i>Ellen Steinhour</i>
PRIMARY	SCIENTIFIC 2 nd Level POC	<i>Scott Palmer</i>
ALTERNATE	SCIENTIFIC 2 nd Level POC	<i>Christopher Holley & Christina Wyatt</i>

UNIT LEADER	<i>Kathleen Cooney</i>
--------------------	------------------------

3. If issue is not resolved by the stated deadline, ORA (or other central research administration support office) may escalate the issue to Duke's Incident Response and Issue Resolution (IR2) Committee. Note: the IR2 committee works to resolve issues that could hinder research progress or that could create an institutional risk, but that do not generally require a formal institutional response. **Only central research support offices are authorized to escalate to and communicate with the IR2 Committee.**

ADDITIONAL NOTES:

- Some issues require both administrative and scientific escalation. In these cases, communication will go to both POCs with instructions regarding the action or decision needed to resolve the issue.
- Issues with a short deadline when a quick response is necessary (e.g., proposal deadline), the 2nd Level POC and/or Unit Leadership may be included in the initial escalation communication to ensure the deadline is met.

PART B – PATHWAY FOR SITUATIONS OF SCIENTIFIC, BUDGETARY, AND COMMITMENT OVERLAP

Before a sponsor releases an award and/or as part of their progress reporting requirements, many sponsors require key personnel to disclose all other support (OS), current and pending support (CP), and other outside activities. This requirement is in place primarily to:

- Ensure transparency: All resources available in support of the investigator's work are being reported, including resources received through the institution as well as those received personally by the investigator;
- Assess potential scientific, budgetary, commitment overlap: The sponsor is not funding work that is already supported by another source and/or the investigator has sufficient time and resources available to conduct the proposed work as planned; and/or
- Evaluate the capacity of the individual to carry out the research as proposed.

The expectation at Duke is that any overlap (scientific, budgetary and/or commitment) is identified early and disclosed/mitigated to facilitate a smooth proposal submission/award acceptance process.

This is accomplished at pre-award via:

- The **Duke Intent to Submit (I2S) form**, if the application has potential similarities/overlap with other submitted or awarded research projects;
- A **cover letter**, if one or more of the specific aims being submitted in the federal application is also contained in a similar, identical, or essentially identical application submitted to another federal agency; or
- **Other Support** as part of the application, if submitting to the Department of Defense (DOD).

This is accomplished during the course of the award via:

- The Research Performance Progress Report (RPPR), which requires annual updates to Other Support.

The following information describes how the unit will help ensure proper identification, review, reporting, and management of overlap for research studies in the unit.

1. How will the unit ensure ongoing communication to faculty and grants administrators related to overlap disclosure requirements?

The RQMP team will be available for additional questions and review for faculty with overlap. Currently the RQT receives emails from DOMRA/RASR identifying the scientific overlap. The RQMP team holds quarterly townhalls to disseminate important information where faculty and DOMRA staff attend.

2. When a grants manager is assisting the Principal Investigator (PI) and actual or perceived overlap is detected, the grants manager should discuss the disclosure requirement directly with the PI and the PI should work with the grants manager to ensure appropriate disclosure (if applicable).

How will the unit ensure the grants manager and the PI are aware of this expectation and in compliance? Include a description of how disputes will be escalated and resolved within the unit. *If the unit has a RASR Zone Director, that individual must be included in the dispute resolution process.*

DOMRA (where grants are primarily managed in the DOM) will have ongoing education and reminders of overlap concerns. If there is a dispute between the GCA and PI, the GCA would engage their GCM and discuss further with the RQOs to resolve matters.

3. If potential **scientific** overlap is disclosed via I2S, the Duke Office of Scientific Integrity (DOSI) will send a direct communication to the PI, Research Quality Team (RQT), and grants manager (if already assigned) that outlines how to properly address the overlap. For more information, refer to the myRESEARCHpath page dedicated to this topic [here](#).

What is the process within the unit to ensure overlap disclosed via I2S is addressed appropriately?

For scientific overlap is identified, the GCA and GCM will directly involve the RQOs for assistance and resolution.

4. If potential **scientific or commitment** overlap is disclosed by the PI in the application for funding or Other Support, what is the process within the unit for conducting a third-party review of potential overlap prior to submission to the Duke Office of Research Administration (ORA)? *At a minimum, include the following aspects: how and by whom is the disclosed overlap routed to the reviewer; who are the typical point person(s) for review of overlap; what is the alternative review pathway when the typical point person has a conflict of interest, potential bias due to reporting relationship or other professional dynamics, or does not have the appropriate scientific training*

and background to perform a thorough review; if the unit has a RASR Zone Director, what is their role in the escalation pathway?

In our unit, the GCA would notify the GCM with escalation to the director of DOMRA (who is the LRA for the RQT). The LRA would engage the LROs depending if clinical or basic science for a third party review. If the LRO is not available, then the VC for research can be engaged. RQT meets monthly to review these issues with more urgent issues handled by email. If COI identified, then the COI team is engaged.

5. After the third-party review of **scientific or commitment** overlap has been performed (as described above), what is the process within the unit to ensure adequate information is conveyed to the necessary stakeholders (e.g., PI, grants manager, ORA) and that a plan is put into place to manage and document the overlap in compliance with the rules and regulations, when applicable? *Note that documentation regarding RQO review and approval should be submitted to ORA with any document containing overlap (e.g. Other Support with overlap statement).*

The LRO would discuss with the PI and document this discussion in writing to the rest of the RQT which would be conveyed to the GCA as appropriate. Any plan put in place would be communicated with ORA as well.

6. If there is an ad-hoc request (either by the sponsor or institution) to review or respond to a question of overlap, what is the process within the unit to address it and ensure an adequate and timely response is developed and approved by the necessary stakeholders?

The LRA would engage the LROs via email communication and then meet in real time, as needed, to resolve the issues.

7. If it is determined that overlap exists and resolution is necessary, what is the process within the unit to ensure overlap is resolved effectively and compliantly?

If the LRO identifies overlap, then the VC for Research is notified and a preliminary plan is put into place with PI engagement. The final plan is then reviewed by the DOM leadership team (VC for research, business manager, LRO and LRA as appropriate). We have monthly meetings in addition to the RQT meeting but can escalate quickly if needed with an ad hoc meeting.

PART C – ESCALATION PATH FOR NONCOMPLIANCE WITH AND REPERCUSSIONS RELATED TO RCR TRAINING

Since the inception of the RQMP at Duke, the Duke Office of Scientific Integrity (DOSI) has worked closely with the Research Quality Teams (RQT) to identify faculty and staff engaged in research who are required to complete Responsible Conduct of Research (RCR) training. RCR education strives to promote ongoing discussion and examination of research operating procedures (e.g., experimental design, data analysis, data management), academic and collegial relationships and collaborations, and the ethical considerations accompanying studies and the research culture itself. The RCR program at Duke follows similar initiatives started at the National Institutes of Health and the National Science Foundation to support a culture of scientific integrity in the research community.

All faculty and staff engaged in research must maintain compliance with RCR training by completing training by the required due date. Effective November 1, 2022, the requirement for faculty and staff to maintain RCR training compliance was enhanced by the addition of the following repercussions for non-compliance (any or all of the following consequences may be levied):

- No effort may be charged to externally-sponsored projects (iForm)
- Will not receive research incentives
- Lose PI status on any projects actively in award state
- Removal by department or team from IRB/IACUC protocols and may not continue work

The escalation process within DOSI begins at approximately 15 days after a due date has passed.

Below describes the RQT's role for monitoring RCR Training status and the escalation path that will be used within the unit when individuals do not comply.

1. Monitor RCR training status

- Research Quality Officer (RQO) delegate(s) currently identified in Section K of the RQMP REDCap database are responsible for tracking and ensuring that faculty or staff engaged in research are compliant with RCR training.
- The RQMP central office provides a weekly RCR Report on Box for Research Quality Teams to check researcher compliance. The RCR Report is filterable by unit and lists the training status for each researcher based on days before or after the due date for both RCR-100 and RCR-200 training. One time per month the RQMP team also sends the RCR report to RQTs as an attachment via email.
- Automated system email reminders are sent to individuals at 90, 60 and 30 days prior to training due dates. NOTE: at this time, reminders are also sent at 30, 60 and 90 days past the training due dates due to system limitations; however, the non-compliance thresholds for repercussions supersede the automated reminders.

2. Internally escalate instances of non-compliance

If the routine monitoring efforts by the RQO delegate(s) are unsuccessful, what is the pathway within the unit for non-compliance with and repercussions related to RCR training? *At a minimum, include the individual(s) in the escalation pathway who will reach out to the*

researcher to communicate the repercussions and any unit-specific processes that will be followed.

In addition to direct emails from the DOM to the faculty member, email communications are sent to the division chief and the divisional administrator. Noncompliance has been reviewed at the division chief meeting and action plans put into place for division with high non-compliance. The LRO have directly emailed and communicated with non-compliant faculty to complete requirements. Regarding the plan for communicating repercussions, we anticipate that the VC for Research would lead that communication with engagement of the division chief for that faculty member.

--