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 resolution that avoid premature or unnecessary escalation of issues to central research administration support offices, when often the issues can be resolved compliantly at the unit 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.

The Research Quality Escalation Plan consists of four parts:

- Part A: General Research Administration Issues
- Part B: Overlap (Scientific, Budgetary, Commitment)
- Part C: RCR Training Compliance
- Part D: Research Noncompliance

Parts A and C of this Escalation Plan were completed as part of the Year 4 milestones. Part B has been modified and expanded to further outline the pathway for identifying and resolving issues of scientific, budgetary, and commitment overlap. Part D describes the unit's current pathway used to manage research noncompliance. Please note that Part D may follow the pathway the unit articulated in Part A.

THIS ESCALATION PLAN IS DESIGNED FOR:

Department of Orthopeadic Surgery

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** 1st Level POC	*Ashley Jones (copy Carrie Killelea)*
ALTERNATE	**ADMINISTRATIVE** 1st Level POC	*Dr. Carrie Killelea*
PRIMARY	**SCIENTIFIC** 1st Level POC	*Dr. Adam Goode (copy Ashley Jones)*
ALTERNATE	**SCIENTIFIC** 1st Level POC	*Dr. Sean Ryan*

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** 2nd Level POC	Dara Purvis
ALTERNATE	**ADMINISTRATIVE** 2nd Level POC	Jason Remoff
PRIMARY	**SCIENTIFIC** 2nd Level POC	Dr. Shyni Varghese
ALTERNATE	**SCIENTIFIC** 2nd Level POC	Dr. Adam Goode

UNIT LEADER	Dr. Ben Alman

3. If the 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 – ESCALATION PATHWAY FOR SITUATIONS OF SCIENTIFIC, BUDGETARY, AND COMMITMENT OVERLAP

Before a sponsor releases an award and/or as part of 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, and/or 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.

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

At pre-award, this is accomplished via:

- The **Duke Intent to Submit (I2S) form,** if the application has potential similarities/overlap with other submitted or awarded research projects. If actual or perceived overlap exists, the following question must be answered "Yes" at the Intent to Submit stage: *Does the application have potential similarities/overlap with other submitted or awarded research projects? Yes/No*

  When this question is answered "Yes", a drop down appears where the submitter can explain the nature of the overlap. A team member in the Duke Office of Scientific Integrity (DOSI) reviews and determines if any further action is needed.

- For applications to Federal sponsors: When applying to two federal sponsors simultaneously, it is necessary to disclose this by marking "Yes" to the following question on the SF424 form: *Is this application being submitted to other agencies? What Other Agencies? Yes/No*

At Just-in-Time and/or during the course of the award, this is accomplished via:

- **Other Support/Current & Pending** at either Just-in-Time or in the Research Performance Progress Report (RPPR).

More information about overlap and ways to identify and address it is in myRESEARCHhome (requires NetID login).

The following table may be useful for the RQT to determine the roles and responsibilities for managing instances of scientific, budgetary or commitment overlap:

	Principal Investigator (PI)	Unit Leadership (Chair / Director, Chief Administrative Officer)	Vice Chair for Research (VCR) or Research Quality Officer (RQO)	Lead Research Administrator (LRA)	Office of Research Administration / Management Center Leadership	Duke Office of Scientific Integrity
Communicate overlap disclosure requirements to ensure that all faculty and staff are aware of and adhere to this procedure		P	P	S	C	C
Identify potential issues of overlap and request review	P			S	C	C
Disclose and resolve issues of overlap	P			S	C	
Conduct initial review of potential overlap			P	S	C	C
Provide necessary information and cooperate with review	P				C	
Enforce consequences for failure to disclose overlap		P	P	S	C	

P = Primary (responsible for completing the task or accountable to ensure task is complete)
S = Support (provides support for primary (primary retains ultimate responsibility for proper completion)
C = Compliance (creates policies/procedures; monitors for compliance)

Below, please describe how the unit will help ensure proper identification, review, reporting, and management of scientific, budgetary, and/or commitment overlap.

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

The RQO and LRA will communicate with the research faculty using the following methods:
• LRA will send out pertinent information to all research faculty and research staff using a research faculty and research staff dedicated listserv.
• LRA and RQO will communicate changes in institutional policies and procedures during the monthly research faculty meeting and/or monthly department faculty meetings (as indicated)
• When new research focused faculty arrive within the department, the RQO and LRA have a leadership role in onboarding those individuals
The LRA and the Grant Manager, attend the Research Administration meetings and the Grant Manager communicates these requirements to the grant administrators

Who (name) within the unit is responsible for ongoing communication of overlap disclosure requirements to ensure all faculty and staff are aware of and adhere to this procedure?

Ashley Jones

2. When a research administrator is assisting the investigator and actual or perceived overlap is detected, the research administrator should discuss the disclosure requirement directly with the investigator and the investigator should work with the research administrator to ensure appropriate disclosure (if applicable).

   In addition to the responsibility that the investigator has for proactively disclosing potential or actual issues of overlap, the **research administrator should regularly review applications**, effort commitments, budgets, and progress reports to identify potential issues of overlap. When there is potential overlap discovered or actual overlap disclosed, the review and resolution steps must be documented and reported via the Overlap Review and Resolution Form.

   How will the unit ensure research administrators and investigators are aware of these expectations 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.*

The RASR Grant Administrator will discuss possible overlap issues with the PI. If the issue is not resolved the grant administrator will request the assistance of the Grant Manager and LRA to determine if there is an actual overlap and determine next steps. If additional

steps are identified the LRA will escalate to the RQO to resolve the issues related to overlap. On the RASR side, the Grant Administrator will escalate to the RASR Zone Director if there are continued questions and/or disputes about the overlap.
The RQO and LRA will communicate this expectation to the PIs during the research faculty meeting and the RASR Grant Manager for Federal and Foundation grants, will communicate this expectation to the Research Administrators.

Who (name) within the unit is responsible for ensuring research administrators and investigators are aware of the expectation to identify, report and escalate potential or actual issues of overlap?

Adam Goode

3. As part of year 5 implementation of the escalation path, the Research Quality Team (RQT) is no longer expected to operationalize the process for properly addressing overlap. The process outlined below should be followed.

   If potential **scientific** overlap is disclosed via I2S, the Duke Office of Scientific Integrity (DOSI) will send a direct communication to the investigator, RQT, and research administrator (if already assigned) that outlines how to properly address the overlap. For more information, refer to the myRESEARCHpath page dedicated to this topic here.

   Upon receiving a report of potential overlap at any point prior to submission of the proposal to ORA, the Department Chair, Vice Chair for Research, Research Quality Officer (RQO) and/or designee should initiate a 3rd party review. An alternative reviewer should be identified 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.

   The review will involve reviewing relevant documents, inquiring with the investigator(s), and consulting with other experts as necessary. The review will aim to determine conclusively whether overlap exists, the extent of the overlap, the impact on the research project(s) involved, and a plan for resolving the overlap.

   The plan to resolve overlap will include at least one of the following courses of action:
   1. Delay submission of the application
   2. Revise the scope of work
   3. Revise the effort commitment
   4. Revise the budget
   5. Decline or terminate the affected award(s)

Who (name) in the unit is responsible for determining conclusively whether overlap exists – and if so, the extent of the overlap and impact on the research project(s) involved?

Adam Goode (Clinical) & Shyni Varghese (Basic)

If the review confirms the existence of overlap, who (name) in the unit is responsible for communicating the outcome of the review with the investigator(s) and work with the investigator(s) to develop a plan to resolve the overlap?

Ashley Jones

Who (name) in the unit is responsible for approving the plan for resolving the overlap before submission to the Office of Research Administration?

Adam Goode (Clinical) Shyni Varghese (Basic)

4. If the unit receives an inquiry about overlap from the sponsor and/or the Office of Research Administration, it is the unit's responsibility to address it and ensure an adequate and timely response is developed and approved by the investigator and relevant unit research leaders.

   Who (name) within the unit is responsible for addressing the inquiries about overlap from the sponsor and/or the Office of Research Administration?

Adam Goode (Clinical) Shyni Varghese (Basic)

PART C – ESCALATION PATHWAY FOR NONCOMPLIANCE WITH AND REPERCUSSSIONS 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*.

The LRA meets at least bi-weekly with the RQO and discusses individuals who are out of compliance for RCR training and all other requirements (e.g. SCAP attestation). We then have a step-wise process for those that remain noncompliant from the automated email reminders. First, the LRA directly communicates with these individuals about the

requirement to complete the training and communicates the repercussions. This communication is done by email and/or phone and often includes the faculty's administrative support to help with the effectiveness. Second, the RQO then directly communicates with these individuals, in the RQMP role. This communication is done by email and/or phone and again involves a reiteration of the requirements and the potential repercussions if not completed (i.e. research activities may be limited). Third, the RQO then requests that the Department Chair follow up individually if non-compliance persists. This escalation only occurs in rare situations as we have found the process to be effective for the vast majority of our faculty, but it does remain the final part of our RCR training pathway.

PART D – ESCALATION PATHWAY FOR ISSUES OF RESEARCH NONCOMPLIANCE

Research noncompliance can be described as a failure (either intentional or unintentional) to follow rules, regulations, and institutional policies governing research or research administration. At Duke, the Research Policy Manual states "All individuals in the Duke University community share a responsibility to apply and uphold the highest standards of scholarly integrity; as well as compliance with the principles and requirements as outlined [in the Duke Research Policy Manual – Chapter 3: Research Integrity]."

There are several areas where scientific or administrative research noncompliance may manifest. These include, but are not limited to, disclosure of conflicts of interest, failure to seek prior approval, animal care and use noncompliance, change in scope of the science, human subjects' research/IRB noncompliance, violations of federal sponsor requirements, poor data management practices, and authorship disputes. Each of these may lead to a violation of laws or regulations governing the conduct of research.

If your unit has a pathway for managing scientific or administrative research noncompliance, please describe it below.

Currently, the department manages scientific and administrative non-compliance through both the RQMP team and the CRU. Human subject non-compliance, IRB non-compliance, authorship conflicts, and poor data management are typically managed at the CRU and will escalate major or any unresolved issue to the RQMP team and involve the department chair as needed. Non-compliance concerns regarding the failure to seek prior approval or conflict of interest are typically managed with the PI and the RQMP team.