RESEARCH QUALITY MANAGEMENT PROGRAM
Duke University School of Medicine

OVERVIEW

As the Duke Office of Scientific Integrity (DOSI) continues to innovate and implement best practices for Research Quality, Scientific Integrity and Accountability, the School of Medicine aims to implement a Research Quality Management Program (RQMP) within each department, center and institute. Each unit-level Research Quality Team (RQT) will be comprised of a Research Quality Officer (RQO) and a Lead Research Administrator.

PROPOSAL

Each SOM department, center and institute will designate a Research Quality Team to (RQT) ensure implementation of best practices with regards to quality, integrity and accountability in research.

The specific makeup of the RQT within each department, center or institute will be at the discretion of the unit. However, all teams will have at minimum, a faculty Research Quality Officer (RQO) and a Lead Research Administrator. These two individuals will be responsible to the Duke Office of Scientific Integrity (DOSI), Office of Research Administration (ORA) as well as the research/administration leadership in their unit.

Milestones for the Research Quality Management Program (RQMP) are as follows:

- All units have performed a unit-level self-assessment of Research Administration Operational Standards by November 15, 2019
- All units have appointed a faculty RQO and a Lead Research Administrator. The organizational relationship between the RQO, Lead Research Administrator, CRU Director (if applicable), Vice Chair for Research (if applicable; if no VCR, then other scientific faculty lead and/or Division Chief(s), as applicable), Shared Resource Director(s), if applicable, and Business Manager will be defined and submitted to the Department Chair or Center/Institute Director and DOSI by December 31, 2019
- RQOs in all units have submitted a written first year operational plan to the Department Chair or Center/Institute Director and DOSI by March 1, 2020

Responsibilities

The RQT will have responsibility for research quality in 4 areas: Research Administration, Science Best Practices, Data Management and Accountability. The RQT will liaise with DOSI and department/center/institute leadership, with regard to the team’s activities. Roles and responsibilities for the RQT are as follows:

Research Quality Officer (or designee)

- Serve as the primary node of communication to foster a culture of integrity and accountability, unit-level training and development of best practices and/or resources for faculty and staff engaged in research
- Serve as the primary liason between institutionally-designated shared resources and core research facilities and your research unit, ensuring each shared resource and/or core facility generates and/or follows a data management plan
- Serve as the primary liason with conflicted faculty within unit and DOSI-COI/Outside Activities to generate a management strategy to mitigate bias and oversee restrictions of investigators within unit
- Ensure that research staff and faculty are aware of institutional policies and procedures related to the conduct of research
• Ensure compliance with Responsible Conduct of Research (RCR) training, and coordinating unit-specific training opportunities

• Ensure that research faculty and staff are aware of and attest to the Scientific Culture and Accountability Plan (SCAP)

• Facilitate Clinical Quality Management planning within the unit, if applicable

• Serve as the resource to ensure best practices related to Data Management, including management, provenance, security, and storage of data. May be unit’s primary reviewer of Data Storage Plans. May assist individual PIs or Shared Resource directors with Data Management Plan (DMP) development

• Ensure that faculty and staff are accountable for their actions and, when indicated, successfully complete required corrective actions. This includes action plans and/or follow-up from central research regulatory and administrative offices (i.e. COI/Outside Activities, IRB, IACUC, OARC, Senior Response Committee/Incident Response and Issue Resolution Committee) as well as from research misconduct reviews

**Lead Research Administrator**

• Serve as the primary node of communication to foster a culture of integrity and accountability, unit-level training and development of best practices and/or resources for research administrators

• Ensure that research staff and faculty are aware of institutional policies and procedures related to research administration

• Ensure compliance with Responsible Conduct of Research for Administrators (RCR-A) training

• Promote use of the Intent to Submit tool and attendance at proposal / award kick-off meetings, ensuring that grant administrators are well-trained to conduct the meetings (including use of tools to promote timely submission and thoughtful preparation of project)

• Partner with the Office of Research Administration to review Request for Rush Service (formerly “Proposal Waiver Requests”) and Return for Changes data and shift unit practices as needed

• Facilitate implementation of the 5-day internal deadline for proposals, including waiver requests. This includes empowering departmental grants staff to work with the research teams, elevating issues to ORA where necessary, and communicating directly with faculty to ensure a smooth submission

• Promote the use of myRESEARCHhome with faculty, research staff and grant administrators

• Oversee DOSI-issued COI/Outside Activity management plans within the unit, confirming appropriate communication of restrictions and adherence to the plan by affected research teams

• Ensure all staff performing research administration duties have a reporting relationship to an administrator and are adequately and appropriately trained to perform such duties

The RQT will be responsible for taking part in regular meetings with DOSI, ORA, and other groups as requested. They will be responsible for sharing relevant information from these meetings with their unit

**Structure**

At a minimum, each RQT will name a faculty RQO and a Lead Research Administrator.

The RQT will have defined organizational relationships within the department, including the following, where applicable: the faculty RQO, CRU Director, Vice Chair for Research (if no VCR, then other scientific faculty lead and/or Division Chief(s)), Shared Resource Director(s), Lead Research Administrator, and Business Manager(s). A description or flow chart of accountability is needed. These individuals may delegate activities of the RQMP to others in their unit; however, they remain the points of contact with DOSI.

Research Quality Teams who opt to delegate activities to those other than the Lead Research Administrator and faculty RQO should document the names and responsibilities of others in their unit within the organizational and operational plan.
Developing and maintaining an operational plan

Each department, center and institute shall develop an operational plan for their RQT. The plan should outline:

- The names of the faculty RQO and Lead Research Administrator. If tasks will be delegated across the department, those names/titles/responsibilities must be provided
- The reporting structure and planned communication within the department must be articulated
- Specifics related to each responsibility above (e.g., how the RQT will carry out the responsibility)

Operational plan and accompanying documents should be reviewed and updated annually and sent to rgmp@duke.edu.