

Research Quality Plan Guidance

(A summary of RQMP Town Hall | Feb 11, 2020)

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Overview of the Research Quality Management Program (RQMP)

Each department, center, and institute in the School of Medicine is developing a research quality management program. The program for each unit is led by a Research Quality Officer (RQO) and Lead Research Administrator (LRA). The oversight responsibilities of the RQO and LRA are generally split between research and research administration respectively, however, the intent of bringing these responsibilities together under one program is to facilitate communication and understanding between these branches and to ensure that faculty and staff are working collectively toward common goals of improved research quality, scientific integrity and accountability.

The Research Quality Officer (RQO) and Lead Research Administrator (LRA) each have multiple responsibilities as described in their unit's Research Quality Management Program. Depending on the structure, size, and operations of the unit, RQOs and LRAs may want/need to delegate specific responsibilities to additional people in order to adequately fulfill each responsibility (the RQO, LRA, and these additional people (delegates) make up the Research Quality Team). The RQO or LRA still hold ultimate responsibility for RQMP facilitation, but coordinating the responsibilities amongst a team of leaders can support efficiency, creativity/energy levels, and implementation. There must be regular communication between the RQO, LRA, and the whole Research Quality Team in regards to progress, successes, and challenges of the unit's RQMP.

Use the following sections as guidance for writing your unit's Research Quality Plan, required to be completed and entered into REDCap by March 1, 2020.

Definitions/Acronyms:

Research Quality Management Program (RQMP): Each unit is developing an RQMP and collectively, the School of Medicine is calling this initiative the RQMP.

Research Quality Plan (RQ Plan): Each unit is developing a research quality plan that defines their program. Within each plan, the unit describes who will be accountable for each responsibility and how those responsibilities will be carried out.

REDCap Research Admin Operational Standards Toolkit (RAOST) database: A central database, RAOST, using the REDCap tool, was built to provide a central system where each unit is required to enter their research quality plans following a specific template. At least one person from each unit has access to upload information into the database by the appropriate milestone dates for FY19/20. However, the information within the database may be downloaded and shared with all members of the research quality team and unit leadership as needed.

Research Quality Officer (RQO): Each Department/Center/Institute's RQMP is led by two individuals, of which the Research Quality Officer is one. They are accountable for operationalizing several research quality responsibilities which may be carried out personally by the Research Quality Officer or by a delegate.

Lead Research Administrator (LRA): Each Department/Center/Institute's RQMP is led by two individuals, of which the Lead Administrative Administrator is one. They are accountable for operationalizing several research administrative quality responsibilities, which may be carried out personally by the Lead Research Administrator or by a delegate.

Research Quality Team (RQT): Together, the RQO and LRA work together as the research quality team, along with any additional delegates who are working to implement the responsibilities defined in the research quality plan.

Research Quality Management Program – RQO Responsibilities

Role of RQO

(REDCap Form J, Section 2: #1)

WHAT is the RQO?

The Research Quality Officer will/is:

- Ensure that everyone on the Research Quality Team is working together to effectively communicate and work toward the long and short-term goals as outlined in each unit's research quality plan;
- Serve as the primary liaison between Department/Center/Institute and DOSI for issues related to research integrity and research quality;
- Considered a leader in research integrity and research quality by their colleagues;
- Responsible for ensuring that operations are efficient, effective, compliant and meeting the established goals and objectives;
- Operationally and strategically-minded; willing and able to contribute productively to continuous improvement efforts;
- Responsible for serving as liaison between the School and the department/unit, which includes relaying critical and topical information bi-directionally

WHO holds the RQO accountable?

The Research Quality Officer is accountable to their department chair or institute/center director (if the RQO does not directly serve in that position), the scientific integrity initiatives as outlined by the Office of Scientific Integrity and the Office of Research Administration, the School of Medicine, and the research and administrative community within their unit.

WHY do we need an RQO?

- To drive strategy and direction of research integrity and research quality across the School of Medicine and Duke
- To provide focus and direct input as Duke addresses issues and identify opportunities for improvement
- To establish success measures (and other good institutional practices) that drive performance and compliance in research quality and research integrity
- To act as a role model in emphasizing the importance of research integrity and research quality to their department/institute/center, the School of Medicine and the larger research community

HOW TO OPERATIONALIZE

- Organize regular meetings with your unit's RQT where both the RQO and LRA leadership teams will be present
- Be an accountable partner of research compliance and integrity in your unit
- Speak up when something concerns you (see something, say something)
- Give feedback/share innovative ideas for good institutional practices that promote a culture of integrity and compliance

FAQs on role of RQO

1) How often is the RQO expected to organize meetings with the Office of Research Administration (ORA) and the Department of Scientific Integrity (DOSI)?

Although there is no set minimum requirement for contact the expectation is that you would meet with ORA at least every six months. There is no expectation to organize meetings with DOSI on any more than an ad hoc basis, excepting those requested by DOSI itself (for example [COI/OA issued management plans](#) for unit members)

Training and Science Culture and Accountability

(REDCap, Form J, Section 2: #2, 4, 5)

WHAT are the goals for these RQO responsibilities?

As defined in the Research Quality Plan instructions:

- Ensure that research faculty and supporting scientific staff are aware of institutional policies and procedures related to conduct of research (e.g., code of conduct, faculty handbook, staff handbook, new information from leadership)
- Ensure faculty and staff engaged in research are aware of and in compliance with faculty/staff RCR training
- Ensure that faculty and staff engaged in research attest to the Science Culture & Accountability Plan (SCAP)

WHO is the target audience for implementation?

Faculty and staff engaged in research (as identified in the Responsible Conduct of Research -RCR training tracker)

WHY are training and accountability important?

Dedicating time to thoughtful discussion, workshops, and online assessment at the unit-wide level ensures that the unit's research community establishes common priorities and language for discussing them, defines transparent expectations for behavior and research practices, and ensures inclusivity for the entire department (i.e., training and accountability are not just relegated to students or faculty- they're important for the entire research community).

HOW TO OPERATIONALIZE

RCR

- Ensure the RCR training requirement is communicated to all faculty and research staff in your unit: <https://dosi.duke.edu/RCR>.
- Routinely login to the RCR training tracker app (<https://radapps.duke.edu/rcr>) to check RCR compliance and manually add or exempt unit members as needed.

SCAP

- Update your unit's SCAP on a regular basis.
- To meet the SCAP June 30 attestation milestone, add the URL (web address) for your unit's SCAP to the RAOST REDCap database.
- Communicate with your unit's faculty and staff about your unit's SCAP- explaining why this document is an important departmental code of conduct, and include the DOSI-provided SCAP attestation survey link.

Overall communication of Duke policies

- Coordinate specific training opportunities within your unit for discussing research integrity challenges and guidance on how to approach/resolve these challenges.
- Communicate (by email, departmental meetings, special workshops, seminars, newsletters, - in as many ways as fits the nature, scope, and relative urgency of the new policy) with faculty and research staff to ensure they are aware of the institutional policies and procedures communicated

to you by funding agencies, Office of Scientific Integrity, Office of Research Administration, and the School of Medicine.

FAQs on SCAP attestation and training

1) Where can I find guidance on what should be in a SCAP?

There is a SCAP guidance document available for download at: <https://dosi.duke.edu/advancing-scientific-integrity-services-and-training/accountability-research/science-culture>. Additionally, all School of Medicine departments, centers, and institutes have posted their SCAPs on their websites, if you want to read additional examples.

2) Why doesn't the School of Medicine have a central SCAP that all unit's members can attest to?

School of Medicine Departments, Centers, and Institutes each have their own unique environments and discipline-specific perspectives on best practices in research. While some portions of unit SCAPs may be similar, it is important that the unit SCAP reflect the unit's expectations, actual practices, and resources.

3) What is the future requirement for SCAP attestation, beyond the June 30, 2020 milestone?

The School of Medicine FY 20/21 milestones have not yet been determined, and will in part be informed by the RQMP development ongoing in FY19/20. It is recommended that all faculty, staff, and students are aware of and read their unit's SCAP as a part of new-person on boarding when they start in the unit.

4) How will the centralized SCAP attestation handle new people that start in the unit between March 1 and June 30?

All new people hired into the unit after March 1 should still be sent the link for attestation to their unit's SCAP, but if these newer people are not able to attest to their departmental SCAP by June 30 due to the shortened timeline, their attestations will not be counted in the June 30, 2020 requirement (i.e., the goal is for all faculty and staff engaged in research to attest, but assessment of milestone completion will only evaluate the SCAP attestations for those who have started in the unit before March 1, 2020).

5) Several faculty and staff have recently signed/attested to our unit's SCAP. Do these people need to sign and attest again?

If the unit has already tracked SCAP attestations for several faculty and staff, the unit may write to rgmp@duke.edu and describe their attestation process and then send rgmp@duke.edu a list of unique IDs, net IDs, and the date of the attestation in an electronic spreadsheet.

8) Why aren't students and postdocs, important members of our unit's research community, required to attest to the SCAP?

It is recommended that units send the SCAP attestation link to everyone, including faculty, staff, students, and postdocs, however, the central tracking system used for SCAP attestation can currently only track faculty and staff attestations to their primary units. Consequently, assessment of the June 30th milestone completion will only evaluate attestations for faculty and staff engaged in research (the same population that is required to complete RCR training).

9) What about faculty and staff with multiple appointments -- which unit's SCAP should they attest to?

Several faculty and staff have appointments or research collaborations across multiple units. While faculty and staff are encouraged to read and be aware of the SCAPs from all of the units where they are affiliated, the June 30, 2020 milestone will require tracking of required faculty and staff attestation to the SCAP of their unit of primary affiliation (i.e. on the attestation form, required faculty/staff members will select their Department/Institute/Center unit of primary affiliation from a drop-down menu and will read and attest to that unit's SCAP, and then that person will be marked as "complete" on SCAP attestation reports).

10) What is the SCAP attestation requirement?

By June 30, 2020, all faculty and staff engaged in research are required to attest to the Science Culture and Accountability Plan (SCAP) for the Dept/Cen/Inst. of their primary affiliation. This milestone requires a close partnership between DOSI and RQTs:

1. By March 1, 2020: RQTs are to provide a web address where your unit's SCAP is posted (please use the dedicated text box in Section J, #5b in the REDCap RAOST to enter the URL (web address) for your unit's SCAP. Entering this information is a required part of your research quality plan).
2. By March 15, 2020: DOSI will send RQTs an email that includes:
 - a) List of required faculty and staff for each unit
 - b) Template email text that RQTs may use to communicate SCAP attestation requirement with unit list of required faculty and staff (template will include a link to the SCAP attestation survey).
2. By April 15, 2020: RQTs should start communications with unit list of required faculty and staff about the SCAP attestation requirement and share the SCAP attestation survey link.

DOSI will provide monthly SCAP attestation reports to RQTs starting in April.

11) When will I be expected to contact relevant faculty and staff about RCR training non-compliance?

How and when you communicate with relevant faculty and staff about the RCR training program and non-compliance is up to each unit. The important point is that all of the unit's faculty and staff engaged in research are aware of the RCR requirement and are in compliance with the requirement.

Faculty and staff receive automatically generated email notices of upcoming deadlines and non-compliance of RCR training. Currently all units have designated RCR admins that have access to the RCR training tracker app (<https://radapps.duke.edu/rcr>) that tracks unit members' RCR training progress. RQOs and LRAs should develop a strategy such that there is at least one RCR admin in the unit checking the RCR-training tracker at least once a month to check on RCR compliance, to ensure that new persons are correctly added as engaged in research, and to exclude persons who are not engaged in research. It should be noted that ultimately the responsibility for regularly checking the RCR training tracker rests with the RQO, though they may delegate this responsibility. In addition to ensuring someone is consulting the RCR training tracker regularly, a strategy should be formulated on how to communicate with non-compliant persons and new persons (to guide them through the RCR requirement), and about new RCR training opportunities.

Clinical Quality Management Planning

(REDCap, Form J, Section 2: #6)

WHAT are the goals for this RQO responsibility?

Ensure that findings from the Clinical Quality Management Program (CQMP) Quality Management (QM) reviews are being internally evaluated for significant issues and trends and that appropriate corrective and preventive actions (CAPA) are being assigned to address the findings if applicable.

WHO is the target audience for implementation?

Faculty and staff within Duke Clinical Research Units (CRU)/Oversight Organizations (OO) engaged in clinical research.

WHY does the department need to internally review findings?

Individual QM reviews may identify issues and lead to corrections on the study level. Evaluating QM review findings across studies will allow CRU/OO leadership to identify trends for Key Quality Indicators (KQI) governing the conduct of clinical research on the department and School of Medicine (SOM) level.

HOW TO OPERATIONALIZE

- Regularly communicate with the CRU Director and Research Practice Manager (RPM) to discuss CQMP-related activities. For example, are experienced and well-qualified reviewers being designated in the department, are QM reviews being conducted well and on-time?
- Review the quarterly summary reports sent by the CQMP to evaluate trends. For example, did QM reviews identify issues in a particular KQI or in a certain type of study, were there any unreported reportable protocol deviations, were there any significant or reoccurring findings that did not have a corresponding CAPA?
- Request additional information from the CQMP for trend analysis if needed.
- Talk to faculty and staff to better understand significant and reoccurring issues across studies and evaluate the need for future CAPAs. Champion department-wide and SOM-wide CAPAs when indicated.
- Respond to requests from DOSI to support CQMP efforts as needed.

FAQs on CQMP

1) My unit doesn't deal with clinical research/CQMP, what should I put for this section?

If your unit doesn't deal with clinical research or doesn't have a CQMP you may put "Not Applicable" for this section of your research quality plan. Please feel free to email cqmp@duke.edu if you are unsure if this section applies to you.

2) For CQMP requirements, what types of studies are exempted?

Low risk internally funded studies are exempted. All external studies will need to have a CQMP plan even if low risk.

Best Practices in Data Management

(REDCap, Form J, Section 2: #7 & (if applicable) Section N)

WHAT are the goals for this RQO responsibility?

Promote the use of best practices in data management, including management, provenance, security, and storage of data.

WHO is the target audience for implementation?

Institutionally-Designated Shared Resources that are accountable to your unit as the owning organization will need to create data management plans and have them uploaded to REDCap by the June 30th 2020 deadline.

While individual PI's are strongly encouraged to have data management plans, the current milestones will not require assessment of individual PI's data management plans.

WHY does a department need to set and support data management standards?

It is important that shared resources and research teams develop a good working plan for how to manage their data workflows and how to communicate and implement that plan, to ensure that the data and analyses remain intact, accessible, and understandable.

At the department level there are specific tools, resources, and discipline specific considerations that must be evaluated and discussed to ensure that the department's research programs, and the underlying data sets and documentation are securely and properly managed.

HOW TO OPERATIONALIZE

- Familiarize yourself with [Duke's Data Management Plan Guidance](#).
- Learn more about the data management resources available at Duke (e.g. [Duke Data Management Resources](#)).
- Host workshops for the department, advertise existing Duke workshops, consider how to implement and advocate for self-assessment of current practices and provide space to reflect and adopt new practices.
- Consider requiring Data Management Plans of all PIs in your unit, discuss best practices at regular meetings (i.e. faculty meetings, lab meetings, and/or retreats).
- If your unit is the owning organizational unit for one or more institutionally-designated shared resource, then your RQT will be responsible for collecting their data management plan(s) and uploading them into the RAOSt REDCap database by June 30, 2020.

FAQs on data management

1) What is the Duke policy on data management plans?

All Duke research units are encouraged to develop a Data Management Plan (DMP) that describes the data governance policies within each group (i.e. how data are documented, organized, stored, and shared). The only groups currently required to submit their DMPs to their Research Quality Team are institutionally-designated shared resources (sometimes called “Cores”). If you are unsure if your unit has an institutionally-designated shared resource or whether a core is identified as such, please contact rqmp@duke.edu.

2) How do data management plans benefit researchers in my unit?

Developing a detailed, accurate, and holistic data management plan is a useful research practice: 1) writing down your group’s actual management practices from data collection to archival aids internal review of your group’s workflow, highlighting potential gaps where data integrity may be vulnerable (e.g., data entry errors, data loss, lack of traceability), 2) generating a written plan to be shared and read by everyone in your research group promotes transparency, shared expectations, and standardized practices. Having researchers develop data management plans also helps ensure researchers are better prepared for current and upcoming funder requirements around data management practices (funding agencies like the NSF already require data management plans and the NIH will require data management plans within the next 2 years).

3) Where can I get help creating a data management plan?

Help is available in a few places:

1. Access the Duke Data Management Plan Guidance document: <https://duke.box.com/v/DMPGD-fullPDF>
2. Use the online DMPTool to tailor your DMP to either our Duke standard or to adhere to a funder’s standard: <https://dmptool.org>
3. Visit the Duke Office of Scientific Integrity’s website to learn more about data management plans: <https://dosi.duke.edu/advancing-scientific-integrity-services-and-training/accountability-research/data-management-plan>
4. Visit the Duke Libraries Research Data Management resource pages (navigate many topics from the left side of the page): <https://guides.library.duke.edu/c.php?g=633433&p=4428949>
5. Email ASIST with questions on your DMP at asist@duke.edu or email the library experts at datamanagment@duke.edu

4) Can our department get an orientation/training that outlines data management best practices?

We do not currently have data management seminars scheduled, but the Duke Office of Scientific Integrity’s ASIST team and the Duke Libraries Center for Data and Visualization Sciences are available to consult with your research group or department/center/institute about data management best practices. If you would like to set up a training for your group, please contact rqmp@duke.edu and we will work to schedule an appropriate workshop with your group.

5) Should our department have a data management expert on hand to help researchers adhere to best practices?

If your research unit has the resources to hire a data manager, that may be a helpful resource for people. Data managers can be very helpful in setting up databases or other IT resources. Individual researchers are

still encouraged to create their own data management plans to evaluate their own practices throughout the lifecycle of the data.

6) Are there training materials available for teaching researchers about good data management practices?

Yes, we house an online RCR learning module on data management in Duke LMS. To access this learning tool, please click on the button labeled “Access RCR Data Management and Quality Course” on this site: <https://dosi.duke.edu/advancing-scientific-integrity-services-and-training/facultystaff-responsible-conduct-research-rcr-1>

There are also good tips available on the Duke Libraries Research Data Management resource pages (navigate many topics from the left side of the page):

<https://guides.library.duke.edu/c.php?g=633433&p=4428949>

7) Our unit’s institutionally-designated shared resource/core only provides a service and does not create or analyze data, is it still required to have a data management plan?

Yes; despite some shared resources/cores not producing/analyzing research data, information like equipment service logs, personnel training and customer billing information are still information that needs to be recorded, tracked and archived. Due to this, there would still be an expectation of at least a brief plan detailing the data management practices around that information.

8) Is there a requirement to use Lab Archives or another electronic research notebook (ERN) for the data management plan?

Duke has an institutional license with LabArchives, allowing everyone at Duke to use LabArchives for free (<https://dosi.duke.edu/labarchives>). However, there is no Duke requirement for researchers to use an ERN or LabArchives for research data and documentation.

Conflict of Interest (COI)/Outside Activities + Corrective Actions

(REDCap, Form J, Section 2: #3, #8)

WHAT are the goals for these RQO responsibilities?

Faculty and staff are individually accountable for their actions and, when indicated to, must 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.

In addition to individual accountability, there is also an important function of departmental accountability as an additional measure of collaboration and community. Identifying lead RQT members that can facilitate, coordinate, and motivate improved communication and awareness of individual requirements from these regulatory counterparts can be effective in ensuring understanding, fairness, and improved efficiency between central offices and individuals. Although most cases requiring this partnership will be infrequent and case-specific, there is one specific, and ongoing unit-level liaison responsibility: An RQO commitment to receiving DOSI-issued COI/OA- issued management plans for unit members and support in communicating the plans' restrictions and adherence to the affected unit's research team members.

WHO is the target audience for implementation?

All unit members who are engaged in research/data lifecycle/grants administration - faculty, research staff, trainees and administrative staff.

WHY does the department need to support centrally administered regulations?

Disclosure of outside interests is important to protect the institution in several ways:

- **Compliance:** The institution must be able to demonstrate that each member of the Duke research community adheres to applicable state and federal regulations designed to protect intellectual integrity, human/animal subjects, biosafety, etc.
- **Investigation:** Federal agencies employ inspectors to investigate reports of research misconduct or noncompliance
- **Credibility:** We must uphold high ethical standards and maintain public trust
- **Fines or loss of funding:** Failure to disclose can result in fines and funding can be suspended or revoked
- **Loss of employment:** Failure to disclose could result in disciplinary action (leading up to and including termination) and could make finding a new position difficult
- **Criminal penalties:** Violations of the False Claims Act could lead to criminal penalties
- **Inability to publish:** Researchers found to be in noncompliance may be barred from submitting work to research journals for a period of time

HOW TO OPERATIONALIZE

- Work with departmental leadership to review outside relationships of faculty to determine if a Conflict of Commitment (COC) exists – are they meeting expectations of the department? If not, conduct a COC review – DOSI-COI will assist in providing reported information or make searches

available to the LRA or RQO. The DOSI-COI office can be a part of the discussion but cannot determine COC alone

- Be able to find and direct colleagues to resources for institutional review committees, including IRB, IACUC, research misconduct review
- Work with the department chair for instances where a COI management plan is in place and ensure that:
 - any restrictions have been communicated to the faculty/research team AND
 - there is periodic review of the management plan and any necessary changes are communicated to DOSI-COI
- Ensure communication, including training and workshops, on COI; direct questions to DOSI-COI – dosicoi@duke.edu
- Periodically review DOSI-COI website for up-to-date guidance: <https://dosi.duke.edu/conflict-interest>

FAQs on COI and corrective actions

1) How do we track corrective actions that require future follow ups?

The protocol for tracking should be included as part of the corrective action, unless it is an internal corrective action process (as requested from say a CQMP review). If a corrective action is required of an institutional body (IRB, misconduct review etc), the follow-up frequency should be outlined there. If there is any uncertainty in the expected timeline or process, then the unit should consult with the institutional body leading the corrective action.

Research Quality Management Program – LRA Responsibilities

Role of LRA

(REDCap, Form L, Section 2: #1, #9)

WHAT is the LRA?

The Lead Research Administrator will/is:

- A Subject Matter Expert in Research Administration;
- The primary liaison between Department/Center/Institute and DOSI & ORA for administrative issues;
- Considered a leader in research administration by his/her colleagues (either in title or in function);
- Responsible for ensuring that operations are efficient, effective, compliant and meeting the established goals and objectives;
- Operationally and strategically minded; willing and able to contribute productively to continuous improvement efforts;
- Accountable for serving as liaison between the School and the department/unit, which includes relaying critical and topical information bi-directionally;
- Ensure all staff performing research administration duties have a reporting relationship to an administrator (i.e. in terms of organizational structure, a research administrator's position should not solely report to a faculty member if possible).

WHO chooses the LRA?

Lead Research Administrator is identified by the Chief Administrator of the unit

WHY do we need an LRA?

- To drive strategy and direction of research administration across the School of Medicine
- To provide focus and direct input as we address issues and identify opportunities for improvement
- To establish success measures (and other good institutional practices) that drive performance and compliance in research administration

HOW TO OPERATIONALIZE

- Directly participate or have a RQT delegate participate in monthly Research Administrative Leader (RAL) Meet-Up
- Be an accountable partner of research compliance and integrity in your unit
- Speak up when something concerns you (see something, say something)
- Give feedback/share innovative ideas for good institutional practices that promote a culture of integrity and compliance

Institutional Policies and Procedures (P&P) and Training Requirements

(REDCap, Form L, Section 2: #2, #3)

WHAT are the goals for these LRA responsibilities?

- Ensure staff performing research administration duties are compliant with, or are making adequate progress toward, all required training. This will expand to include RCR for Administrators (RCR-A) training once it has been instituted
- Ensure that research faculty and supporting scientific and administrative staff are aware of institutional policies and procedures related to research administration - (e.g., code of conduct, faculty handbook, staff handbook, new information from leadership)

WHO needs to be aware of institutional P&P and be trained?

All faculty and staff involved in research or the research lifecycle will need to be aware of institutional policies and procedures. In addition, staff involved in position-specific training (e.g. RCC training, etc.) will need to be adherent to those training requirements.

When RCR-A training is implemented, the training cohort will be identified and a list will be provided to the LRA for tracking.

WHY is awareness of and training on institutional P&P important?

Promoting awareness of institutional P&P and training ensures faculty and staff have the tools (knowledge, skills, ability) to perform work effectively and to guide others involved in the research process compliantly.

HOW TO OPERATIONALIZE

- Review their Department/Institute/Center's RAOST plan to see what assigned training select cohorts of research administrators are expected to complete.
- Check training status in the Duke Learning Management System (LMS), and the RCC Training Tracker. (Both can be accessed here: <https://finance.duke.edu/research/training/tracking>)
- Contact Monica Elam or ORA for help with data or questions about RCC training requirements
- Facilitate communication about institutional P&P and required trainings to relevant cohorts.

Suggested Communication strategies

- Monthly faculty meetings, research meetings, emails, newsletters, PI/BM/GM monthly meetings. Make sure to distribute minutes from meetings to attendees
- Communication by Chair and follow up in subsequent meetings/emails
- Division directors share information at division meetings
- SharePoint site for all communications/updates/processes
- Quarterly meetings for Research Quality Teams (RQTs)
- Include research administration requirements in clinical trial meetings
- Include lab managers in PI/BM/GM monthly meetings or a portion of the meetings (Important for lab managers to be aware of the research administration process)
- Repeat important topics via different communication mechanisms
- For RASR units, include Vice Chair for Research in BM/GM/RASR meetings

- Add research administration section/topics to department newsletters
- Include research staff, postdocs, fellows in communications
- Onboarding process for new faculty including review of faculty handbook
- Open communication between Chair, VC for Research and Research Admin Leaders
- If communication from central offices is distributed only to chairs or chief administrators, ensure there is a process in place to distribute to the LRA, RAL and GM, when necessary
- Extend communication and oversight to fellows and residents (e.g. at fellowship research retreat, have part of retreat cover research administration process, mock reviews, etc.)
- Cover research administration process during grand rounds for residents

Suggested Training implementation

- Once instituted, add RCR-A training requirement to assignment letters
- RAA training – monitor in LMS, discuss in RA meetings, monitor annual requirement

*An optional template “SoM Reporting Relationships Assignment Letter” in [Appendix A](#), is provided as a tool to help staff communicate reporting relationships and training requirements to the LRA

FAQs on Training

1) Can RASR staff be part of the RQT?

Yes; if a RASR staff member is responsible for the research administration operations in a unit, they can be on the RQT.

2) Will there be a similar training tracker for RCR-A training status as there is RCR training?

Yes, the goal is to build a training tracker app for RCR-A. Until that app is developed, DOSI will provide RCR-A tracking support for all units.

Pre-Award Processes

(REDCap, Form L, Section 2: #4, #5, #6)

WHAT are the responsibilities around Pre-Award Processes?

- Promote use of the Intent to Submit tool and attendance at proposal/award kick-off meetings
- Review Request for Rush Service (formerly “Proposal Waiver Requests”) and Return for Changes data
- Facilitate implementation of the 5-day internal deadline for proposals, including waiver requests

WHO needs to be aware of these processes?

- Faculty and unit grant administrators are responsible for following the established business processes
- Unit leadership is responsible for ensuring compliance

WHY is increased awareness around pre-award processes helpful?

- Ensures that there are clear roles and responsibilities for pre-award review and submission, and that related SOM and institutional policies are communicated and followed
- Ensures faculty are accountable for the overall administrative, financial and programmatic conduct of the project

HOW TO OPERATIONALIZE

- Communicate and enforce the 5 day internal deadline policy:
<https://medschool.duke.edu/research/research-support-offices/office-research-administration/grant-review-and-submission-process>
- Review Request for Rush Service (aka Proposal Waiver) and Return for Changes (RFC) data to understand your unit’s performance and address any negative trends. Data is available in Duke Box. If your unit does not have access, please contact Sherry Brown (sherry.k.brown@duke.edu)
- Promote the use of the Intent to Submit tool by organizing workshops, demos, and communications that highlight and explain the tool’s utility
- Hold regular meetings with faculty to learn about their plans.
- Record/standardize your process for reviewing/approving requests for rush service. Consider reasons of why you would deny requests.

FAQs on Pre-Award Process

1) When will the “request for rush service” fees start being enforced?

The implementation of “request for rush service” fees have not yet been determined, and will be informed, in part, by feedback from the RQTs ongoing in FY19/20.

myRESEARCHhome (MRH)

(REDCap, Form L, Section 2: #7)

WHAT are the responsibilities around myRESEARCHhome?

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

WHO needs to be aware of myRESEARCHhome?

Entire research community of the unit (faculty, research staff, grant administrators, business managers, faculty administrators)

WHY is myRESEARCHhome helpful?

myRESEARCHhome helps research faculty, scientific research staff, and the unit business/research administrators address the challenges of:

- Identifying and accessing research related information and resources
- Completing routine research related tasks quickly and effectively
- Managing their research portfolio/workload
- Coordinating across functions and departments on research-related tasks

HOW TO OPERATIONALIZE

- Take advantage of various ways to promote usage: onboarding offered via myRESEARCHnavigators (for faculty) and the Office of Research Administration (for administrators), redesigned training for research administrators, webinar series offered by OASIS, presentations by myRESEARCHhome team at departmental meetings
- Consider introducing MRH during new faculty onboarding (including intent to submit, proposal submission). During that onboarding:
 - Set MRH as default homepage in browser, must be kept through the first 90 days, so that individual gets used to using MRH from the very beginning.
 - Highlight MRH benefits – links, funding opportunities, balances, information regarding projects, recommended bookmarks/links
- Promote the use of myRESEARCHhome at key decision meetings (ex. Kickoff)

FAQs on MRH

1) Are there online demo resources for faculty?

Yes, visit: <https://www.youtube.com/watch?v=2C6LiB1EEcg&feature=youtu.be>

There is also help available through [myRESEARCHnavigators](#) and [Onboarding consultations](#).

2) Is there a set expectation for use of myRESEARCHhome?

Faculty and staff are encouraged to use MRH. The goal is for myRESEARCHhome to be sufficiently useful that faculty and staff use it by choice.

3) How often are we expected to update faculty members about myRESEARCHhome?

As often as needed to ensure that your unit's faculty and staff are aware of myRESEARCHhome and its utility, especially as new features come online that are particularly helpful for faculty and staff.

Conflict of Interest/Outside Activities

(REDCap, Form L, Section 2: #8)

WHAT are the goals for these LRA responsibilities?

Oversee DOSI-issued COI/OA management plans within the unit, confirming appropriate communication of restrictions and adherence to the plan by associated research team members

WHO is the target audience?

Anyone required to disclose conflicts of commitment/outside activities and their research teams and/or the administrative staff involved in the research process who are working with that individual

WHY does the department need to support centrally-administered regulations?

Disclosure of outside interests is important to protect the institution in several ways:

- **Compliance:** We must be able to demonstrate that we adhere to applicable state and federal regulations designed to protect intellectual integrity, human/animal subjects, biosafety, etc.
- **Investigation:** Federal agencies employ inspectors to investigate reports of research misconduct or noncompliance
- **Credibility:** We must uphold high ethical standards and maintain public trust
- **Fines or loss of funding:** Failure to disclose can result in fines and funding can be suspended or revoked
- **Loss of employment:** Failure to disclose could result in disciplinary action (leading up to and including termination) and could make finding a new position difficult
- **Criminal penalties:** Violations of the False Claims Act could lead to criminal penalties
- **Inability to publish:** Researchers found to be in noncompliance may be barred from submitting work to research journals for a period of time

HOW TO OPERATIONALIZE

- Communicate and work with the unit's primary "Liaison" for COI related matters (usually the RQO or delegate). For example, for annual COI forms, DOSI-COI issues a call and two reminders to the conflicted individual to provide completed copies. If the individual continues to be noncompliant DOSI-COI will provide lists of incomplete forms for the liaison to directly contact the conflicted individual to ask them to provide the completed forms or provide a reason for an extension or exemption request.
- Work with Vice Chair for Research and/or RQO to decide the best way for your department to collect/store/communicate the COI Management Plans and Cautionary Memos issued by DOSI-COI to research teams.
 - Decide how to track memos and plans. (DOSI-COI intends to roll out a central tracking system in the future)
 - Decide how to communicate the memos and plans to research teams like CRUs and be able to demonstrate process for auditing/monitoring purposes
 - Highlight if there are restrictions associated with the plan
 - Work with departmental leadership to review outside relationships of faculty to determine if a Conflict of Commitment (COC) exists – are they meeting expectations of the department?

If not, conduct a COC review and DOSI-COI will assist in providing reported information or make searches available to the LRA or RQO.

- Ensure communication, including training and workshops, on COI. Direct questions to DOSI-COI dosicoi@duke.edu.

FAQs on COI/Corrective Actions

1) Can SPS/iRIS assign a flag to a person or project when there is a COI management plan?

Not at this time.

2) Has there been any institutional guidance stating that the department is responsible for disseminating COI information?

The expectation is that the RQT would disseminate the relevant COI information about a conflicted individual to the research team members and/or administrative staff who are involved in research projects related to that conflicted individual.

3) How much detail should be disseminated about the nature of a conflicted individual's COI?

The expectation is that disclosure of a conflict by either the RQT or the conflicted individual themselves to their research teams and/or administrative staff involved with the research process would not need to include specific financial information, only that a conflict was present and with what organization(s).

4) How do I know what's going on if I'm in a center that has a conflicted individual as a secondary appointment since their primary appointment institutional unit/academic home receives the COI information?

The expectation is that the primary appointment institutional unit/academic home and the conflicted individual themselves would inform units of secondary appointments of conflicts those individuals may have. For future implementation, there is an aim to build a central system that departments/centers/institutes will be able to use for assistance with tracking conflicted individuals.

5) What is the responsibility of the conflicted faculty?

The expectation is that the conflicted faculty member would provide the information about their conflict to their research teams and/or administrative staff involved in research projects related to that conflicted faculty member.

Appendix A

SoM Reporting Relationships Assignment Letter

[date]

[name]

[title]

[department/unit]

[email address]

Re: Reporting lines & training requirements for staff performing research administration duties

Dear [name]:

As a Duke employee performing research administration duties, it is expected that you have appropriate training and reporting lines for this work. This letter serves to communicate those expectations.

Reporting Relationships. Effective [date], for that portion of your work that involves research administration, you will report to an administrative supervisor. If you have other duties that do not involve research administration, you will continue to report separately for that work.

Administrative Supervisor: [administrative leader name]

Other Supervisor (if applicable): [other supervisor name]

Training Requirements. By [date], you are expected to complete the training described in Attachment A of this letter, and complete any updated training as long as your assignment involves research administration duties.

Performance Evaluation. Effective [date], your performance evaluation will be completed by [administrative leader] using the Duke Performance Evaluation and Planning (PEP) form. If you have a dual reporting relationship with a faculty investigator, the faculty member may contribute to the staff PEP. The faculty investigator may not complete the PEP as the primary supervisor.

Reporting Concerns. Duke requires its staff, faculty and contractors to comply with all applicable federal, state and/or local laws and the related Duke policies and procedures. Any intentional violation of such laws, policies and procedures will result in corrective action. Duke also requires the prompt reporting of situations in which individuals suspect that violations of such laws, policies and procedures may have occurred. Duke wants you to speak up when words, behaviors or actions are not consistent with our values. Concerns that should be reported include, but are not limited to, criminal activity, harassment, suspected fraud, compliance violations, research misconduct or other violations of Duke's Statement on Values and Culture, the institutional Code of Conduct or Duke Health's statement on Integrity in Action. Retaliation for reporting your concerns is strictly prohibited.

Duke requires that you attest, once a year, that you have reported any personally-witnessed research compliance concerns (including financial and/or scientific misconduct) to an appropriate office.

To report a concern, you have a number of options.

- Contact 800-826-8109 to report your concern confidentially to a 3rd party administrator
- Duke’s Office of General Counsel, Duke Human Resources or the Office of Audit, Risk and Compliance. These resources are available during normal business hours for confidential advice and consultation.
- You may also consult Duke’s Human Resource website (www.hr.duke.edu) for information about this policy (Duke HR Compliance Policy – Number 04.13).

Please feel free to directly reach out to me at [administrative leader email] or [administrative leader phone] if you have questions about anything contained in this letter. I will be glad to answer any questions you may have.

_____	_____	_____	_____
Administrative Supervisor Signature	Date	Employee Signature	Date
<u>[administrative leader name]</u>		<u>[employee name]</u>	
Administrative Supervisor Name		Employee Name	
<u>[administrative leader title]</u>		<u>[employee title]</u>	
Administrative Supervisor Title		Employee Title	

Attachment A: Training Requirements

Course Name
RCC Certification
[TBD]
[TBD]
[TBD]
[TBD]