

Research Quality Management Program Implementation Plan Overview

Purpose

To better support a culture of Research Quality, Scientific Integrity and Accountability that integrates both the Research and the Research Administration arm, all School of Medicine departments, centers and institutes will develop and implement a Research Quality Management Program (RQMP).

Scope

The effort to organize and implement each unit's RQMP will be led by a unit-level Research Quality Team (RQT), comprised of a Research Quality Officer (RQO) and a Lead Research Administrator. The RQT will be responsible to their respective unit's research/administration leadership, as well as the Duke Office of Scientific Integrity (DOSI), and Office of Research Administration (ORA).

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/ORA and department/center/institute leadership, with regard to the team's activities.

RQO Responsibilities:

1. Describe how Dr. Ornit Chiba-Falek will serve as the Research Quality Officer

The RQO will assemble a team that includes the current attendees of the regular 'Neurology Research Ethics Plans & Progress' meeting and in addition the lead grant admin (Whitney Baker) and maintain the monthly meetings to review activities and compliance with DOSI policies. In addition, a report, on an as needed basis, from the Div. Research Ethic delegate (Dr. Gottschalk) on his bi-monthly meetings with DOSI and a report from lead grant admin (Whitney Baker) on her bi-monthly meeting with ORA will be presented and discussed.

2. Ensure that research faculty and supporting scientific staff are aware of institutional policies and procedures.

Information regarding institutional policies and procedure will be disseminated in several ways: (1) for primary research faculty via our standing monthly division faculty meetings; (2) for lab managers via monthly meetings directed by the Div. Research Ethic delegate (Dr. Gottschalk) the Div. lab manager (Mr. Mace); (3) for supporting scientific staff in the individual labs via communication (lab meeting or email) initiate by each lab manager; (4) for all affiliated research faculty and supporting scientific staff via emails distribution to the Div. listserv 'Neuro-translational-all' sent by the Div admin assistant on behalf of the Div. RQO: i. new policies and announcement emails from DOSI will be forwarded. ii. Content published at <https://dosi.duke.edu/quality-management-programs/research-quality-management> will be disseminated quarterly in a newsletter format.

3. Serve as the primary liason with conflicted faculty within unit and DOSI-COI/OA.

Using tools available and distribution lists of non-compliant tasks, the RQO will communicate with faculty and elevate issues to Chair and Business Manager as required.

4. Ensure faculty and scientific staff engaged in research are in compliance with RCR training.

Using tools available and distribution lists of non-compliant tasks (RCR tracker), the Research Ethic Delegate, Dr. Gottschalk, with the supervision of the RQO, will review the RCR tracker periodically and communicate with faculty and staff concerning RCR training non-compliance. The RQO will communicate resources available for training, email & orally communicate urgent alerts and changes to departmental wide SCAP plan. The Div. Research Ethic delegate (Dr. Gottschalk) will follow up and report to the RQO the compliance status of RCR training of all faculty and scientific staff engaged in research for Neurology.

5. Ensure that faculty and staff engaged in research attest to Scientific Culture & Accountability Plan.

SCAP will be disseminated with the attestation link to all affiliated research faculty and supporting scientific staff via (1) listserv email distribution, (2) a new link in the Div. website page, and (3) link in the Dept weekly newsletters two weeks following the initial website posting. The Div. Research Ethic delegate (Dr. Gottschalk) will track and ensure (on a monthly basis) that all faculty and staff engaged in research will sign the attestation.

6. Facilitate Clinical Quality Management Planning.

RQO will facilitate communication via departmental wide emails, discussion at faculty meetings and communication at Department specific research focused meetings.

In addition, the Department will do the following:

- Regularly communicate with the CRU Director and Research Practice Manager (RPM) to discuss CQMP-related activities including discussions around if experienced and well-qualified reviewers being designated in the department.
- Review the quarterly summary reports sent by the CQMP to evaluate trends.
- 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.

7. Ensure best practices related to Data Management

Raw data files are being deposited directly to the password protected departmental server. All files should be marked by the researcher name/initials, date and experiment such that they can be traced back in the lab notebook to the original description of the generation of the data included in the file. The Div. Research Ethic delegate (Dr. Gottschalk) keeps a log sheet of data depositing activities for each research team.

We are considering transition to electronic notebooks system. We first introduced LabArchives platform to our faculty in the Jan 2020 meeting and are scheduled for a demo directed to all affiliated supporting scientific staff and trainees for Feb 17th, 2020. The plan is to gradually implement an electronic option (contingent feedbacks from faculty and staff) while still maintaining the traditional hard copy notebook in the interim period of evaluation. A data management plan will be implemented and maintained for the The Kathleen Price Bryan Brain Bank and Biorepository.

8. Ensure faculty and staff successfully complete required corrective actions.

Using tools available and distribution lists of non-compliant tasks, the RQO will communicate with faculty and elevate issues to Chair and Business Manager as required.

LRA Responsibilities:

1. Describe how Whitney Baker will serve as the Lead Research Administrator.

LRA will meet with grants administration team regularly and will attend research related departmental meetings such as monthly Neurology RA meetings, quarterly Neurology/RASR/RQO update meetings and quarterly projection meetings with research faculty and GCA. LRA will ensure that GCAs send and/or meet with research faculty on a monthly basis to go over projections, proposals, effort, etc. LRA will meet with central offices as needed to troubleshoot issues and implement new processes. LRA attend Research Admin Leaders meeting and serve as the overall liaison between the department research team and central offices.

2. Ensure that research faculty and supporting scientific staff are aware of institutional policies and procedures.

LRA will send out pertinent information to all research faculty in Neurology using a research faculty dedicated listserv. That information will then be uploaded and available to faculty via Neurology's intranet, if applicable direct links to the policy will be provided as well. When new faculty with a research interest arrive within the department, LRA will have a role in onboarding those individuals. Other examples: Newsletter, divisional director meetings.

3. Ensure administrative staff compliance with RCR-A training.

Using institutionally available tools, LRA will identify non-compliant staff, including CRU group, who need to complete RCR-A and will facilitate its completion.

4. Promote use of the Intent to Submit tool and attendance at proposal / award kick-off meetings.

Faculty who express an interest in submitting a grant are directed to the Intent to Submit tool as the first step in the process that they need to complete. LRA will meet with research administrators when a new

award is received and help them identify all the areas of importance for the award kick-off meeting. LRA will attend proposal/award kick-off meetings for complex awards or at staff request.

5. Review Request for Rush Service (formerly "Proposal Waiver Requests") and Return for Changes data

LRA will be the primary contact for review of Rush service requests and RFC data and will use data to facilitate conversations within the department. LRA will meet with the RQO on a quarterly basis to discuss faculty submissions of Rush service requests and RFC data. Other examples: delegate to GCAs for review.

6. Facilitate implementation of the 5-day internal deadline for proposals, including waiver requests.

LRA will promote use of SAS meetings for proposal submissions to ensure agreed upon deadlines to meet the 5-day deadline. For proposals outside of SAS services, LRA will work with staff to identify a timeline of appropriate deadlines to be met in order to help facilitate an on-time submission. LRA will continually remind faculty of the importance of the deadlines during the faculty monthly projection meeting.

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

LRA will attend research navigator's meetings for new faculty and will continue to direct faculty to MRH to submit intents to submit, to review/approval proposal and award attestations and, COI, and to view effort. NOTE: Blake can give you data on usage stats for your department.

8. Oversee DOSI-issued COI/Outside Activities (OA) management plans within the unit.

Using institutionally available tools, LRA will add management plan to an internal tracking spreadsheet which will be available to all staff and research quality team.

9. Ensure all staff performing research administration duties have a reporting relationship to an administrator.

This requirement is part of RASR's operational standards. All RASR staff and CRU group, who has a RACI classified position, will have a reporting relationship to an administrator.