Welcome and Introductions

WE'RE MEETING TO TALK ABOUT COL-

WHAT'S "COL"?

IT LOOKS LIKE HIS SCREEN FROZE.

SHOULD WE WAIT?

YEAH, LET'S WAIT.

I WAS ON MUTE ... I AGREE.

HI, SORRY I'M LATE. WHAT DID I MISS?

-LABORATION.

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Mission and Community

Associate Vice President for Research and Vice Dean for Scientific Integrity

- Advancing Scientific Integrity, Services and Training (ASIST)
  - Research Resources
  - Education & Training

- Conflict of Interest
  - Individual & Institutional COI Management

- Incident Response & Issue Resolution
  - Coordinated Issue Resolution
  - Risk Mitigation

- Research Misconduct
  - Investigate Allegations
  - Federal Reporting

- Clinical Quality Management Plan
  - Prospective Research Monitoring Program
  - QA/QC Measures

- Research Quality Management Plan
  - Facilitate Actionable Best Practices
  - Unit-level Prescription and Execution
Recap Year 1 Successes

**November 15, 2019**
Conducted unit-level self-assessment of Research Administration Operational Standards

**December 31, 2019**
Appointed RQT members
Provided org structure & relationship between with CRU, Vice Chair, Lead Research Administrator, and Business Manager to Chair or Director AND DOSI

**March 1, 2020**
Submitted first year operational plan to Dept Chair or Center/Institute Director AND DOSI

**June 30, 2020**
Ensured attestation to SCAP among primarily appointed faculty & staff engaged in research
General Housekeeping

• Use new “RQMP” project in REDCap instead of the old “Research Admin. Operational Standards Toolkit” project moving forward

• RQT directory posted to dosi.duke.edu

• Let us know prior to renaming an RQO or LRA
Go to dosi.duke.edu

Navigate to Research Quality Management page

Click on link for Team Directory
Year 2 Milestones

• RQMP Central Office spent July-Sept planning
• Today’s objective is to go over Group A milestones
  – In addition to today’s presentation, a detailed handout of expectations will be provided after the event
• Group B will be described in detail at start of 2021
RQMP Year 2 Milestones

Timeline

* SCAP attestation plan maintenance
  *Escalation Plan
* Sub-Unit Participant List

October 30, 2020

December 18, 2020
* Complete sub-unit data management profile

* Submit updated research quality operational plan
* Confirm inventory of “house staff” cohort
* SOURCE survey f/s completion

March 31, 2021

June 30, 2021
* Organize one internal RCR training
  * Attend Research Integrity training for RQO, LRA
* Organize one MRH/MRP demo

Group A Milestones

Ongoing ➔ Increase MRH / MRP usage, Maintain RCR training for faculty and staff, Maintain SCAP relevancy and attestations
RQMP Year 2 Milestones Timeline

* SCAP attestation plan maintenance
  *Escalation Plan
  *Sub-Unit Participant List
  October 30, 2020

*Submit updated research quality operational plan
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Group B Milestones

Ongoing → Increase MRH / MRP usage, Maintain RCR training for faculty and staff, Maintain SCAP relevancy and attestations
Update Operational Plan

- Plans developed in Year 1 are living documents that should be kept relevant.
- We have identified ways to help improve Plans in Year 2 (next slide).
- The final deadline tied to this milestone is 3/31/21…but don’t wait!
Update Operational Plan (cont.)

- Address unit-specific feedback
- Incorporate global feedback
- Enhance SCAP section
- Confirm RQT roster
- Upload current organizational chart
- Establish escalation path for research administrative issues
Why an Escalation Path?

Research administration is a complex system of policy, process, rules and regulations.
Why an Escalation Path?

- **Minimize delays**, especially when the timeline is critical (e.g., proposal deadlines)
- **Minimize distraction**, ensuring time and energy is spent on most important tasks
- **Preserve relationship between grant manager and investigators** by promoting compliance up the faculty and administrative hierarchies
- **Promote accountability and integrity** in the administrative process
When to Escalate?

• Will the issue cause an irreversible delay if not escalated? (e.g. a sponsor deadline will be missed)

• Is the issue causing inefficient or duplicative work?

• Have you tried different strategies to resolve the issue or contain the risk but to no avail?

• Have you tried to find a common solution with the other party but without success?
Effective Escalation

- **Effective Escalation** relies on:
  - **Communication:** Are stakeholders aware of the “who”, “how”, and “when” of your escalation process?
  - **Culture:** Is escalation embraced as an effective problem-solving tool?

Effective escalation is an art and a science.
Unit Escalation Plan

• Develop an escalation plan for grants and research administrative issues and upload a list of individuals within your unit involved in that escalation path in Section R of the RQMP REDCap project by 10/30/2020.

• Note: If you are having difficulty defining an escalation plan due to the structure of your unit or uncertainty of the details needed, contact us at rqmp@duke.edu for a consultation.
Sub-Unit Data Management Profile

Purpose

• RQMP provides an opportunity to increase transparency on current data practices within the sub-units

• Our goal at this stage is to take the temperature and understand baseline practices, not to impose changes
Sub-Unit Data Management Profile

• Determine if there is a logical way to “group” research within your unit into formal, administrative sub-units, e.g., research labs directed by a PI(s) or Director(s) where the responsibility for the research is under consistent leadership.
  – If **yes**, upload a list of the formal, administrative sub-units within your overall unit into the “RQMP” REDCap Section P. by **10/30/20**
  – If **no**, reach out to the RQMP central office by **10/30/20** so that we can meet to discuss further.
Sub-unit Data management survey

• The survey will be done out of a separate REDCap project called “Sub-Unit Data Management Survey”.

• The Central RQMP Office will be responsible for survey distribution and collection.
Sub-Unit Data Management Profile

• Our goal is 100% completion of the surveys by the sub-units by 12/18/20.

• We plan to create a summary report of the results after the survey is completed to share with the RQTs.
SCAP Attestations Recap

• The Science Culture & Accountability Plan (SCAP) is a cornerstone for establishing a culture of quality, integrity and accountability.
• In Year 1, RQTs successfully ensured that all faculty and staff engaged in research attested to their unit-level SCAP by June 30, 2020.
SCAP Attestations moving forward

• Develop a strategy for keeping your unit-level SCAP relevant and obtaining ongoing attestations in the future.

Submit this information via REDCap (section J.5) by 10/30/20.
*Be sure to use the new “RQMP” REDCap project*. 
SCAP Plan Components to Include

– Who within the unit is expected to attest?
  • At a minimum, all primarily appointed faculty and staff (F/S) engaged in research.

– How will attestations continue to be obtained and tracked?

– How often will review/revision of the SCAP be required?
  • At a minimum, every three years

– Establish the plan for obtaining attestations from new F/S, and how often F/S need to re-attest.
  • At a minimum, within 90 days of hire
  • At a minimum, re-attestation every 3 years.
## Group A Milestones Recap

<table>
<thead>
<tr>
<th>Milestone/Sub-Milestone for Year 2 “Group A”</th>
<th>Due Date†</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. SCAP Maintenance Plan – Input into Section J.5</td>
<td>10/30/20</td>
</tr>
<tr>
<td>2. Describe Escalation Path – Input into Section R.</td>
<td>10/30/20</td>
</tr>
<tr>
<td>3a. Upload Survey Participant List into Section P. or Contact RQMP Central</td>
<td>10/30/20</td>
</tr>
<tr>
<td>3b. Ensure all Sub-units Respond to Data Management Survey</td>
<td>12/18/20</td>
</tr>
<tr>
<td>Submit Updated Operation Plan – Sections J-M*, Q for Org Chart</td>
<td>03/31/21</td>
</tr>
</tbody>
</table>

*If applicable, depending on needed updates and feedback from Central RQMP Office
†Please note that milestones are due at 11:59:59pm of the due date
Questions?

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<table>
<thead>
<tr>
<th>Question</th>
<th>Answer Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are the data management practices in your sub-unit documented in a Data Management Plan(s) or series of data management Standard Operating Procedures (SOPs)?</td>
<td>Yes or No</td>
</tr>
<tr>
<td>Does your data management plan(s) or data management Standard Operating Procedures (SOPs) cover all research activities in the sub-unit or are they project specific?</td>
<td></td>
</tr>
<tr>
<td>Are the data management plan(s) or SOP(s) accessible to all sub-unit personnel at any time?</td>
<td>Yes or No</td>
</tr>
<tr>
<td>Do personnel receive periodic training or education on the sub-unit's data management practices?</td>
<td>Yes or No</td>
</tr>
<tr>
<td>Is there documentation of the periodic training or education on the sub-unit's data management practices?</td>
<td>Yes or No</td>
</tr>
<tr>
<td>Would you describe the research/work in your sub-unit as primarily clinical or non-clinical?</td>
<td>Clinical or Non-clinical</td>
</tr>
<tr>
<td>Which types of data documentation solutions does your sub-unit utilize for non-clinical research? [select all that apply]</td>
<td>Paper Research/Lab Notebook, Electronic Research Notebook (ERN) (E.g. LabArchives, Open Science Framework, OneNote, GitHub, Jupyter, etc), Other paper or digital solutions (e.g., electronic files saved to a departmental server, REDCap, Box, paper printout from equipment etc)</td>
</tr>
<tr>
<td>Question</td>
<td>Options</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Why does your sub-unit use paper research/lab notebooks rather than ERNs or other digital documentation solutions? | ☐ More comfortable/mature organization process with paper notebooks  
☐ Don't have the ability to use ERNs or digital documentation at the bench or research location  
☐ Financial restraints  
☐ Other  
select all that apply |
| Please describe "Other" from your answer above.                          | * must provide value                                                    |
| Are the paper notebooks or paper documentation scanned/copied/transcribed digitally in order for the notebook or documentation to have a "digital surrogate"? | ☐ Yes  
☐ No  
If only for necessary documentation, please select yes |
| What are the major challenges you face in terms of data management?     | ☐ Finding specific data files  
☐ Running out of data storage space  
☐ Technical implementation solutions for building databases  
☐ De-identification (for blinding or for PHI)  
☐ Insufficient documentation attached to a data file (so you know how that file was produced)  
☐ Can't open a file, format obsolete  
☐ Can't open a file, media type obsolete or corrupted |
| What would help you to improve your sub-unit's data management practices? | * must provide value                                                    |