Topics Covered

• DOD Seminar and PEERS Workshop – Wanda Hutto Pierce, ORD
• Revised Matrix Tool – Jackie Carter, Human Resources
• PRA Updates – Cullen McWhite, OCR
• Notices/Updates/Reminders – ORSP
DOD Seminar

The Military Operational Medicine Research Program manages research aimed at developing effective countermeasures against stressors to maximize health.

DATE
September 24, 2018

RESEARCH AREAS
Injury Prevention and Reduction
Psychological Health and Resilience
Physiological Health
Environmental Health and Protection

SEMINAR SPEAKER
CDR Christopher Steele, PhD
Military Operational Medicine Research Program
US Army Medical Research & Materiel Command
"Introductions are Everything!"
NIH Resubmission DO's & DON'Ts

Date: Wednesday, August 8, 2018
Time: 10:00 am-11:00 am
Location: Bioengineering Building Room 112

Given today's competitive funding environment it is important that investigators be familiar with the NIH resubmission process should their initial grant application be rejected for funding. The MUSC ORD is therefore hosting an open informational session reviewing best practices for NIH resubmission and responding to reviewer comments. Senior faculty members with NIH study section experience from the MUSC Colleges of Health Professions, Medicine, and Nursing will be available for questions.

REGISTER

Additionally, if you are an early career faculty member who would like to apply for participation in the linked PEERS 2018 Specific Aims Workshop, please visit our website for more information.

For questions, contact Alexis Nagel, Ph.D. (nagle@musc.edu)
The MUSC Office of Research Development (ORD) is pleased to offer its annual...

**PEERS 2018 Specific Aims Workshop**
(Providing Education & Enrichment for Research Success)

**APPLICATION DEADLINE:**
Tuesday, July 24, 2018

MUSC early career faculty members may apply to participate in the PEERS 2018 Specific Aims workshop to receive feedback on their working NIH aims pages from junior faculty peers, senior faculty mentors, and ORD staff to enhance the written quality of this critical application document.

Eligible applicants will be within 10 years of completing their terminal research degree or clinical training, and submitting an NIH career development or independent research grant application in Fall 2018 or Spring 2019.

The workshop will take place between July 31, 2018 and August 28, 2018 and will encompass two group critique sessions as well as the informational seminar, "Introductions are Everything: NIH Resubmission DOs & DON'Ts.

Click here to access the PEERS 2018 Specific Aims Workshop application.

For questions, please contact Dr. Alexis Nagel (njage@musc.edu)
MUSC Clinical Research Staff Job Classification Project
Revised Matrix Tool for New Hires
Jackie Carter, SHRM-CP
Human Resources

Clare Tyson, MA, CCRA
SCTR Research Coordination & Management

Sarah Brewer, MA, CCRA
Office of Clinical Research
Phase I

Primary Goals:

1. Address recruitment and retention issues
2. Establish a career development track
Phase II – New Hires

Primary Goals:

1. Enhance and address challenges from Phase I

2. Greater inclusivity of clinical research

3. Align the Matrix with the Joint Task Force for Clinical Trials Competency Framework (domains) & CTSA supplemental grant (competency statements)
What does this mean?

NO MORE EXCEL SPREADSHEET!

“Matrix Survey” = new REDCap tool
The Revised Matrix Survey
Revisions

New Tool Format

- User-Friendly
- Concrete Competency Statements
- Real-time Updates
- Centrally Managed
- Professional Development
- Job Descriptions

Domain: Research Operations

**Research Operations: Recruitment**
- Must provide value
  - Provides administrative support of recruitment strategies: prepares mailings, distributes flyers, phone marketing, etc.
  - Creates or adapts advertising and recruitment materials for the research study. Tracks recruitment and generates basic recruitment reports for the research team.
  - Develops recruitment strategies, plans, and tools. Engages the community, physicians, and identifies barriers to recruitment.
  - Synthesizes and interprets recruitment reports to assess effectiveness of recruitment strategies and implements innovative solutions to maximize recruitment strategies by allocating resources appropriately.
  - Not part of the job.

**Research Operations: Screening**
- Must provide value
  - Provides administrative pre-screening support to study team, may maintain logs and data entry related to screening.
  - Screens potential subjects via telephone interviews or conducts a basic medical chart review for inclusion criteria for minimal risk studies. May screen for greater than minimal risk studies under supervision.
  - Screens participants for all studies independently (i.e., screening for eligibility criteria).
  - Screens participants independently and provides oversight and training to study team members who screen participants.
  - Provides oversight and training to entire unit or department with regards to subject screening. Establishes department/unit-wide systems and policies related to subject screening.
  - Not part of the job.

**Research Operations: Study Visit Preparation and Documentation**
- Must provide value
  - Schedules participants for study visits. May also assist with the preparation and gathering of study supplies, equipment, and documents as needed.
  - Schedules study visits and maintains subject level documentation for minimal risk studies or for other studies under direct supervision.
New Sections

- General Information Form
  - Automatically routed to Matrix upon completion
- Program Development/Management
- Percent Effort
- Special Comments Sections
- Completed by the supervisor
Certification, Education, Experience (CEE)

Relevant Experience = 50% Credit

- Non-research human specimen laboratory
- Medical billing
- Patient Care Tech
- Job experience that included documenting in EHR
- Data entry experience outside of the research setting
- Medical transcriptionist
- Experience working in a medical setting not listed above
The Matrix Support Team (MST)

• Working group of Investigators, Research Managers and HR Representatives

• Resource for supporting supervisors in completing Matrix
  • Assist with training
  • Assist with appropriate classification
  • Addressing questions/concerns proactively

• Ensure tool functionality
Revisions

- Integrated Workflow
Department Administrator Dashboard

Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Legend for status icons:
- Incomplete
- Unverified
- Partial Survey Response
- Completed Survey Response
- Many statuses (mixed)
- Many statuses (all same)

Dashboard displayed: [Default dashboard]

Displaying record Page 1 of 1: "5" through "14" of 5 records

Displaying Instrument status only | Lock status only | All status types

<table>
<thead>
<tr>
<th>Arm 1: Arm 1</th>
<th>Arm 2: User Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>Record ID</td>
<td>New Hires</td>
</tr>
<tr>
<td>5</td>
<td>✓</td>
</tr>
<tr>
<td>7</td>
<td>✓</td>
</tr>
<tr>
<td>10</td>
<td>✓</td>
</tr>
<tr>
<td>11</td>
<td>✓</td>
</tr>
<tr>
<td>14</td>
<td>✓</td>
</tr>
</tbody>
</table>
Roll Out

• July 27, 2018 – Send out User Survey
  • Create User Access (Dept. Administrators)

• August 1, 2018 – All New Hires
  • REDCap Matrix Survey Only
Take Away’s

• Important to attend trainings and disseminate and encourage attendance
  • July 20 9am-10:30am
  • July 26 11am-12:30pm

• Training and Resources Available
  • MyQuest
  • HR Website ([https://horseshoe.musc.edu](https://horseshoe.musc.edu))
  • REDCap Matrix Survey
  • Email MST researchmatrix@musc.edu

• All clinical research job postings must have a REDCap Matrix Survey
  • Must be completed by the supervisor
Thank you!

Matrix Support Team
researchmatrix@musc.edu
PRA Updates

Sarah Brewer, MA, CCRA
Prospective Reimbursement Analysis Manager
Office of Clinical Research

Cullen McWhite, BS, CCRC
Prospective Reimbursement Analysis Manager
Office of Clinical Research
OCR and HCC
Hollings Cancer Center – CTO Studies

• July 1, 2018 – HCC Corporate studies (IRB Board III)

• CTO Finance Staff submitting PRA requests
OCR and Revenue Integrity
Revenue Integrity

• Ensures research-related charges are billed to the appropriate payer

• Bills research study or third party payer (insurance/Medicare)

• Ensures required information is added to CMS claims for research-related services
  • NCT #
  • QCT Status
  • Z00.6 (ICD-10)
  • Q0/Q1 - investigational vs. routine services

• OCR & Revenue Integrity work together to resolve billing questions
PB Charges

- Studies with PRAs
  - PB Charges documented in SBP
  - “Billing by Effort” service added in SPARCRequest
  - Revenue will request confirmation from OCR

- Studies without PRAs (approved prior to 5/1/17)
  - Revenue will require study team to verify effort
  - “Billing by Effort” service added in SPARCRequest
    - Subsequent requests will not require additional documentation
Separating Research and SOC Charges

• Right Heart Cath for Research Only
  • During procedure, left heart cath is clinically indicated

• RHC/LHC were combined during coding

• OCR worked with Revenue to separate into 2 separate CPT Codes with RHC → Research and LHC → Third Party Payer/Patient
MRA/MRI Ordering and Billing

- Protocol specified an MRI
- MRA was ordered/performed and billed
- Services performed are services billed
  - Regardless of protocol/budget
  - Will be billed to correct payer
- Protocol departure should be submitted to IRB/Sponsor
THANK YOU

Office of Clinical Research (OCR)
Email Address: musc-ocr@musc.edu
Phone Number: (843) 792-7900
Address: Roper Medical Office Building,
         Suite 170

Web Address:  http://horseshoe.musc.edu/research/ocr
Clarification: Assignment Deadlines for Applications Submitted Under the NIH Continuous Submission Policy

**Submission is Continuous – Council Deadlines are not**

- Continuous submission is limited to R01, R21, and R34 applications that are eligible under the policy and would otherwise be due on the standard due dates listed in the table below.
- Eligible applications may be submitted at any time, but they will be assigned to Advisory Council rounds based on the schedule in the table below.
- The policy as described in NOT-OD-17-042, including the due dates and receipt deadlines described in the Notice, has not changed.
# Recent Notices

**NOT-OD-18-178** (continued)

For the Advisory Council Round:

<table>
<thead>
<tr>
<th>Non-AIDS Standard Application Due Dates</th>
<th>Continuous Submission Non-AIDS Application Receipt Deadline</th>
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</thead>
<tbody>
<tr>
<td><strong>R01</strong></td>
<td><strong>R21, R34</strong></td>
</tr>
<tr>
<td>May</td>
<td>Oct/Nov 5</td>
</tr>
<tr>
<td>October</td>
<td>Feb/Mar 5</td>
</tr>
<tr>
<td>January</td>
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<td>Jan 7</td>
</tr>
<tr>
<td>October</td>
<td>May 7</td>
</tr>
<tr>
<td>January</td>
<td>Sept 7</td>
</tr>
</tbody>
</table>
NOT-OD-18-179 (Update)
Transition from Inclusion Management System to New Human Subjects System (HSS) as of June 9, 2018

• Video tutorial for entering human subjects in ASSIST while preparing the RPPR:
  https://www.youtube.com/watch?v=RGCddTLPQ90&feature=youtu.be

• ASSIST User Guide Section 4.1 starting on page 92 (page 107 of the pdf):
NOT-OD-18-202
NIH Synchronizes Institutional Delegations and Now Allows Decimals in Effort Reporting Field in Research Performance Progress Reports (RPPR)

• Two recent enhancements within eRA Commons to streamline and improve the Research Performance Progress Report (RPPR) process for recipients.
  1) Allow PIs to delegate access/function to an assistant.
  2) Effort reporting fields will allow decimals rather than require rounding.

NOTE: Reporting effort of an individual of less than 1 CM on an RPPR will give an error.
Update

MUSC Service Contract – Task Orders for MUSC Personnel:

• Final submission date for personnel with a 9/1/18 start date is no later than Monday, July 30, 2018.
• Final submission date for personnel with 11/1/18 start date is no later than Monday, October 1, 2018.
• Going forward the lead time for personnel service contract orders is 6 weeks.
• NOTE: The VA will not process task orders for a 10/01/18 start date due to Federal FY18 closeout.
Update

ORSP Staff Backup Coverage Plan

Amy Boehm ↔ → Heather Ferguson
Eric Gevirtz → Ford Simmons
Ford Simmons → Caitlin Lecker
Caitlin Lecker → Eric Gevirtz
Becky Timpner ↔ → Liz Lawrence (sub-awards only)
or David Azbill (proposals/awards)

Contact Information:

http://academicdepartments.musc.edu/research/orsp/staff/
REMINDERS

Prior Approval Required by the Grants Management Official is required when a PI/PD is absent from the project during any continuous 3 month period or more (NIH Grants Policy Statement, 8.1.2.6).

- If you hear a PI/PD is leaving or has left MUSC, or
- If any uncertainty about an absence exists, please call ORSP asap!

MUSC’s COI (conflict of interest) Surveys **MUST be updated within 30 days** of discovering or acquiring a new Significant Financial Interest (SFI).

- Please periodically remind faculty about this requirement/expectation
- MUSC may be required to do some FCOI reporting to NIH, so time is of the essence with these updates
- Noncompliance can negatively affect funding; awards held-up, etc.
REMINDERS

Federal Award Final Close-out Requirements

• **Final Technical Reports** – responsibility of the MUSC PI/PD, must meet all the sponsor’s requirements and must provide ORSP with a copy of the final report submitted along with a time stamped proof of submission when the sponsor doesn’t have an ORSP accessible report tracking and retrieval system

• **Final Invention Reports** – responsibility of the MUSC PI/PD, must meet with the sponsor’s requirements, and submitted and accepted on-time (meeting the sponsor’s deadline); typically ORSP will need to review and certify these reports on behalf of MUSC

• **Final Financial Reports** – responsibility of MUSC’s Office of Grants and Contracts Accounting (GCA), however PI/PD and departmental staff must work with GCA to ensure ALL financials are in order so GCA has adequate time to compile, review and submit the report. Questions about Final Financial Reports should be directed to GCA.
Delinquent Non-Financial Reports

Given the risks posed by late or non-compliant final close-out reports, MUSC’s ORSP will notify via e-mail a non-compliant PI/PD, the chair of the PI/PD and MUSC’s Vice President for Research about any non-compliance in the area of final close-out reports. If for any reason the PI/PD cannot produce the required final reports, ORSP will contact the PI/PD’s department chair for a final resolution. As the PI/PD’s supervisor, the chair has the responsibility to ensure the PI/PD completes the final close-out report(s).

http://academicdepartments.musc.edu/research/orsp/policies_procedures/policy_extramural_award_closeout
Final Thoughts

• Any Announcements?

• Questions or Comments?

• PLEASE complete a survey & THANK YOU

• Next ORSP Information Session:
  August 15, 2018 @ 11:00 Location TBD