MUSC
Medical University
of South Carolina

Department of Surgery
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RESEARCH/PRE-AWARD

Grant Preparation and Administration Handbook

Grants Administrator I: Raegan Whiteside
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Introduction

The primary purpose of the Department of Surgery's pre-award and post-award team is to foster responsible conduct of university research and scholarship in compliance with federal, state and university regulations and guidelines. We offer resources for Department of Surgery faculty, students and staff in their research-related activities through administrative and technical assistance.

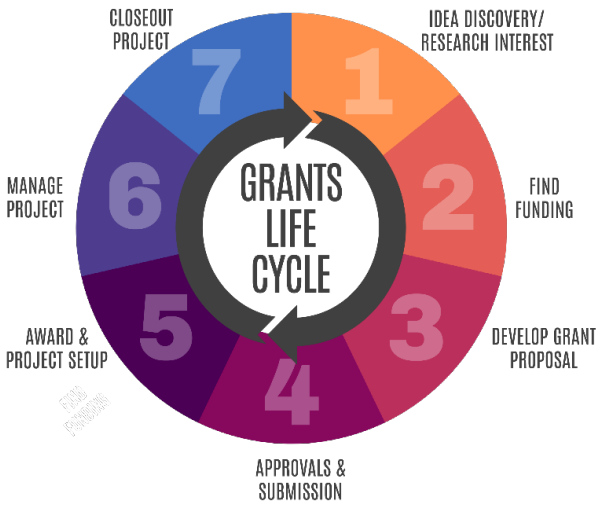
In such a complex research environment it can be easy for confusion to arise about the administrative policies and procedures that govern the research enterprise. This handbook is intended to give all new and current faculty a practical overview of the research policies and procedures at MUSC and the Department of Surgery.

Anyone contemplating applying for funds from an external source should contact the Department of Surgery's Grants Administrator. An application or preliminary proposal should NOT be sent by an individual faculty or staff member directly to an agency, foundation or to ORSP. Such proposals must be routed through the Office of Research & Sponsored Programs via the Cayuse SP IPF and must go through the Department of Surgery Grants Administrator first.

Grants Overview

Life Cycle

The Grant Life Cycle provides an overview of the entire research proposal submission and administration process.



1. Idea Discovery/ Research Interest
    a. Starts with an idea for a research project you'd like to pursue.
    b. Make sure you have completed all needed Onboarding items.
2. Find Funding
    a. Identify potential funding sources. Look at NIH, DOD, internal grants, and other funding institutions and organizations to find possible funding opportunities for your idea/interest.
3. Develop Grant Proposal
    a. Develop the proposal's concept including: identifying the human and capital resources necessary to carry out your project.
    b. Work with the department GA to develop your proposal.
        i. Common Submission Documents
4. Approvals & Submissions
    a. Important Deadlines
        i. The Department of Surgery GA needs all completed application documents to review 6 business days prior to the sponsor deadline
        ii. ORSP needs all completed, DOS reviewed applications documents to review 3 business days prior to the sponsor deadline. ORSP will receive the documents through the internal processing form (IPF) in Cayuse which the DOS GA will submit after they review for the Dept.
    b. Once ORSP reviews and approves the IPF in Cayuse, the GA will give the PI the go ahead to submit their application.
        i. If it is a federal grant, after ORSP reviews and approves, they will reach out to the GA and PI to ensure no further changes are needed. If all is okay, ORSP will submit the application through Cayuse 424.
5. Award & Project Setup
    a. If the proposal is funded, you will receive a Notice of Award. **All NOAs must go through ORSP in order to officially set up the award with GCA and in OurDay.**
    b. When an NOA is first received, the budget will need to be updated. Working with the DOS GA, the original budget is updated with any changes needed (personnel changes, dates, amount awarded, etc). The NOA also may ask for other compliance documents needed (IRB, IACUC, etc).
    c. This is when the Project Setup will begin and the Post Award Team becomes active in the process.
        i. Project Numbers assigned
        ii. Accounts established

iii. Sub agreements created (if applicable)

6. Manage Project
    a. Activities that are part of the Award Management phase and continue throughout the life of the grant include:
        i. Monthly budget reviewing
        ii. Progress reporting
        iii. Time and effort reporting
        iv. Sponsor invoicing
        v. RPPR
        vi. NCEs
        vii. Etc.
7. Closeout Project
    a. When the award has ended (the project period is complete), the Award Close-out begins. The project budgets are reconciled and closed, and a final performance report is sent to the sponsor.

Contents

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Research Administration

Pre-Award Administration:

Raegan Whiteside – Grants Administrator (GA)

Please reach out to your GA for helpful checklists, templates and timelines for submitting grants. She has access to many helpful resources and is your go-to resource for submissions and pre-award questions.

- Assist with the preparation and submission of funding requests to federal agencies, state agencies and institutes, foundations, and other funding sources.
- Edit grant applications for adherences to guidelines, formatting requirements, errors, and inconsistencies in referencing, typos and stylistic conventions, providing detailed feedback regarding any changes.
- Liaison between the University research offices (ORSP, GCA, etc), funding agencies, and contract entities.
- Assist with the development of proposals, budgets, budget justifications, letters of support, scope of work and management plans for research grants and contracts. Also assist with biosketches, Other Support, VA MOUs, etc. Ensure final documents are approved by the appropriate officials prior to submission, securing appropriate institutional signatures for grants and contracts.
- Assist with establishing sub-awards.
- Clarify submission requirements and guidelines from potential funding agencies.
- Prepare IPF, Cayuse 424 applications and RPPRs in eRA Commons for routing. Assist with the electronic grant application package submission.
- Available to identify and explore research funding opportunities based on faculty research interest.
- Intellectual property or technology transfer.
- Provide leadership and strategic development of the key operational and administrative components of the Division of Research. Also, provide institutional information regarding the grant regulatory process.
- Able to assist with IBC and IACUC, eIRB.
- Provide research compliance oversight, to ensure that grantees follow grant regulations and policies.
- Collection and submission of Just in Time (JIT) Information.
- Pre-award process for non-competing and competing continuation awards.
- Provides divisional oversight for compliance with academic research and other regulatory, federal regulatory and institutional policies.
- Maintain overall department submission report for tracking and analysis.

Post Award Administration:

Katie Castello, Nick Brettingen, John Byrne

- Post-Award/Financial Management and Monitoring
- Review departmental cost-sharing commitments in award.
- Establish and monitor sponsored research projects within the grant financial systems (i.e. OurDay, Cayuse, etc.).
- Process daily transaction paperwork associated with sponsored research projects (i.e. approving ISDs, internal charges, lab billing and study participant visit payments).
- Invoice clinical trial sponsors according to billing guidelines in contract.
- Build and manage study trackers to ensure sponsors are paying appropriately and accurately.
- Process account reconciliation of grant expenditures; processing department submitted cost transfers as required.
- Ensures that all Faculty, Staff, and Students traveling under a grant follows the University policies and procedures for travel expenditures.
- Work with The Office of Grants & Contract Accounting (GCA) to file all federal grant financial reports and most other financial reports.
- Ensures compliance with requested grant audits.
- Ensures expenditures are allowable under grant.
- Ensures funds are being expended in a timely manner.
- Ensures cost overruns or severe under-spending are not developing in specific budget categories.
- Manage Discretionary accounts.
- Provide PI with monthly and/or quarterly budget reports and MTD expenditures.

Centralized Clinical Research Infrastructure

Morgan Overstreet – Leady Study Coordinator

- Clinical trial feasibility study start-up coordination
    - Corporate Trials Feasibility Review
    - Protocol Review
    - Budget review and negotiation
    - Liaison for contract negotiation through ORSP
    - Trial activation coordination
- IRB coordination and submissions
    - New IRB applications
    - Annual renewals
    - Amendments
    - Informed Consent Revisions
    - Final reports
    - Safety reports
    - Protocol deviations
    - Serious adverse event reports
    - Advertising/ recruitment materials
- Regulatory maintenance
    - CV's and licenses for the Principal Investigator and all Sub-Investigators Local laboratory pricing
    - Creation and maintenance of all federally required regulatory forms

        - Other sponsor specific regulatory requests
        - SPARC request submissions and maintenance
        - Office of Clinical Research Liaison
- Study Patient coordination
    - Recruit, evaluate, consent and determine eligibility of patients for clinical trial participation
    - Ensures compliance and adverse event monitoring for clinical trial patients
    - Oversight of all patient care pertaining to a patient enrolled in a clinical trial Site monitoring

Onboarding: Getting into Research

Requirements:

- NetID
- Mandatory Compliance
- Conflict of Interest Disclosure
- CITI Training
- eRA Commons
- ORCID
- Cayuse Account
- Other Research Trainings

Have a VA Appointment?

Laboratory Set Up

Activate NETID

- Why do I need to activate my NETID?
  - To have access to your MUSC email account and other systems
- When do I need to activate my NETID?
  - Immediately.

Steps:

- Navigate to http://netid.musc.edu
- Login with your NETID and temporary password (received at sign-up/orientation)
  - You will be prompted to update your password every 180 days
- Accept the User Agreement
- Create password recovery questions
- Create new password
- Problems? Contact the Help Desk (843-792-9700)

eRA Commons

The eRA Commons site is a web-based system that supports the full life cycle of grants administration functions for the NIH as well as the Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control (CDC), Food and Drug Administration (FDA), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Veterans Health Administration (VHA).

Use of an eRA Commons Account

- Submit federal grant proposals
- Track the status of grant applications through the submission process, view errors and/or warnings and check the assembled grant image.
- View summary statements and score letters following the initial review of applications.
- View notice of award and other key documents.
- Submit Just-in-Time information (SO only) requested by the grantor agency prior to a final award decision.
- Submit the required documentation, including the Financial Status
- Report/Federal Financial Report and final progress report, to close out the grant.
- Submit a No-Cost Extension notification (SO only) that the grantee has exercised its one-time authority to extend the final budget period of a project period of a grant without funds.
- Post-Submission Material
- Submit an annual progress report electronically for SNAP and Fellowship awards using the Research Performance Progress Report (RPPR).
- Look for the Non-Competing Grant Progress Report (PHS 2590) Instructions on the NIH Forms & Applications page

Who needs an account?

- Principal Investigators (PIs) submitting a grant application.
- Trainees on NIH training grants.
- Post-Docs paid from NIH grants.
- Graduate and undergraduate students who participate in NIH-funded projects for at least one person month or more (NIH-OD-13-097)
- Administrative staff who wish to assist PIs.
- An eRA Commons ID is required for all federal grant submissions.

Commons user name?

The user name identifies you in Commons and, along with your password, allows access and provides functionality according to your assigned role

Request an eRA Commons Account

- Why do I need an eRA Commons account?
    - To submit federal grant applications or act as a Co-Investigator on another PI's submission. Required for all federal grant submissions.
- When do I need an eRA Commons account?
    - Request an account within two weeks of your hire date.

Steps:

- Send an email to orsp@musc.edu with a subject line of "Request NIH Commons Account."

- In the body of the email, include your full name, email address and the role you are requesting. This will determine your access and rights within the system.

Delegate Rights to Grants Administrator (GA) in eRA Commons

Steps:

- Go to Status
- Go to Admin (at the top)
- Delegations
- Search or Add Delegate (on the right side)
- Find Credentials: WHITESIR
- Choose “Asst Role”

Open Researcher and Contributor Identifiers (ORCID) IDs

https://orcid.org/

Individuals supported by research training, fellowship, research education, and career development awards will be required to have Open Researcher and Contributor Identifiers (ORCID) IDs beginning in FY 2020. Please note any applications found to be non-compliant with this new requirement will NOT be accepted for agency review, so please plan accordingly.

Background

ORCID IDs are unique, persistent digital identifiers that distinguish individual investigators and can be used to connect researchers with their contributions to science over time and across changes of name, location, and institutional affiliation. These free identifiers are assigned and maintained by the non-profit organization ORCID. In addition, many Foundation submissions now require the application to have an ORCID ID.

The requirement for ORCID identifiers will be **incorporated into the appointment process** for trainees, scholars, and participants supported by institutional research training, career development, and research education awards that require appointments through the xTrain system, including the following: T03, T15, T32, T34, T35, T37, T42, T90/R90, TL1, TL4, TU2, K12/KL2, R25, R38, RL5, RL9

At the time of appointment, the xTrain system will check whether appointees have ORCID IDs and appointments will be not be accepted for agency review unless an ORCID ID is linked to the individual's eRA Commons Personal Profile.

The requirement for ORCID identifiers will be **enforced at the time of application** for individual fellowship and career development awards, including the following: F05, F30, F31, F32, F33, F37, F38, F99/K00, FI2, K01, K02, K05, K07, K08, K18, K22, K23, K24, K25, K26, K38, K43, K76, K99/R00

Complete Mandatory Compliance

- Why do I need to take compliance training?
    - To satisfy federal law by ensuring that all MUSC employees are familiar with the Code of Conduct, Health Insurance Portability and Accountability Act (HIPAA), Information Security Policy, trained in anti-discrimination and anti-harassment, and disclosure any conflicts of interest
- When do I need to complete compliance training?
    - Must be completed within two weeks of hire date.

Conflict of Interest Disclosure Survey

Steps:

- Navigate to http://www.musc.edu/coi
- Click the "COI Disclosure" button
- Login with your NETID and the password created during your NETID Onboarding step.
- Click "Start Survey" and complete.
- Questions?
    - Kellean Van Morris, MPH
      MUSC Conflicts of Interest Coordinator
      vanmorris@musc.edu
      843-792-0158

MUSC Conflict of Interest FAQs

The public looks to university research as an independent, unbiased source of information. Because some university researchers also conduct research for private entities or have personal interests in private entities that contribute to research, the federal government, the State of South Carolina,
and MUSC requires disclosure of financial interests.

MUSC requires disclosure of interests that *appear to be related to your institutional responsibilities.*

MUSC Conflict of Interest FAQs

1. I have an external investigator who is affiliated with an institution that is listed in the FDP Clearinghouse. Do they need to fill out the external investigator FCOI certification and disclosure forms?

It depends on how the external investigator is participating in the project. It doesn't matter for FCOI purposes if the external investigator is paid or unpaid. The key to being covered by their institution's policy or MUSC's is whether they are performing the activity as part of their institutional responsibilities or as an individual.

- **Scenario 1 –** An external investigator is affiliated with an institution that is listed in the FDP Clearinghouse of Compliant Institutions and Entities AND is working within their institutional responsibilities (i.e. IF any money changed hands, it would go to the institution) then the External Investigator Financial Conflict of Interest Certification Form is not needed.

  However, if the external investigator's institution is not listed in the FDP Clearinghouse, then the form will need to be completed and forwarded to ORSP prior to proposal submission.

If Option # 1 is selected, it may be necessary for MUSC's COI Officer to review the other institution's FCOI policy to make sure it is FCOI compliant. If so, then the other institution will be asked for a copy of or a link to their FCOI policy.

If Option # 2 is selected, then an External Investigator Conflict of Interest Disclosure Form will be needed for each individual contributor from that institution.

- **Scenario 2 –** If the external investigator is NOT working within their institutional responsibilities (i.e. IF any money changed hands, it would go to the individual), then the contributor will need to complete the External investigator Financial Conflict of Interest Certification Form to show that they will be following MUSC's FCOI policy (unless they can document they have a PHS-compliant FCOI Policy) AND the External investigator Conflict of Interest Disclosure Form.

  NOTE: MUSC cannot assume the individual is performing the activities as part of their institutional responsibilities solely based on a support letter printed onto institutional letterhead.

2. I have an external investigator who is a federal employee (e.g. NIH scientist). Do they need to fill out the external investigator FCOI certification and disclosure forms?
NO – federal agencies are exempted from the definition of "Institution" in the PHS FCOI regulations and federal employees acting in their official roles* must disclose any SFI per the federal ethics policies and procedures. So, the federal employee's FCOI status will be "N/A" for the proposal and no written agreement would be necessary at the award stage to ensure proper SFI/FCOI reporting.

*Note: If acting as an individual, separate from their federal employment responsibilities, then they would disclose as individuals/consultants (as shown in Scenario 2 of Question 1 above).

3. I am submitting a grant during the MUSC annual FCOI disclosure period (annually in April). How will I know if ALL contributors to the project have current FCOI disclosures so the application may be submitted in compliance with the University and PHS FCOI guidelines?
During MUSC's annual FCOI disclosure period (annually, April 1 – April 30), the ERMA system will continue to automatically review each listed contributor's FCOI disclosure record to ensure each individual's FCOI disclosure is current based on the most recent disclosure date. Those without a current FCOI disclosure on file will be contacted by ORSP and asked to complete the online disclosure process so the application may be submitted in compliance with University and PHS FCOI guidelines.

Other FCOI FAQs:

- MUSC Conflict of Interest Office FCOI FAQs: https://web.musc.edu/about/coi/faq
- Conflict of Interest Forms: https://horseshoe.musc.edu/research/orsp/forms
- NIH FCOI FAQs: http://grants.nih.gov/grants/policy/coi/coi_faqs.htm

Cayuse

Request a Cayuse Account

- To obtain a Cayuse account, please send an email with your name and email address to **cayusesupport@musc.edu**

Other Cayuse Resources

User Manual, Tutorial, Examples, Guides, Etc.

Other Research Training

Research involving Human Subjects (IRB)?

Institutional Review Board (IRB): The Office for Human Research Protections provides Human Subject Regulations Decision Charts to guide Institutional Review Boards (IRB), investigators and others to decide if an activity is research involving human subjects that must be reviewed by an IRB.

Collaborative Institutional Training Initiative (CITI)

- All MUSC investigators and key personnel involved in the design, conduct, or reporting of human subjects research (including exempt research) are required to take and pass the Collaborative Institutional Training Initiative (CITI) web-based course on human research subject protection. www.musc.edu/citi (Log in with your NetID and password)
- The CITI Refresher course training is required every 3 years after the initial Basic course is successfully completed.

Transferring CITI Completion from another Institution

While some researchers may have taken CITI modules at a previous institution, MUSC requires that anyone transferring to MUSC must complete the MUSC Basic Biomedical or Social and Behavioral modules, as well as the Basic GCP modules. As of January 1, 2019, a researcher transferring to MUSC may not affiliate prior completed CITI modules to meet the MUSC training requirements.

Core Clinical Research Training (CCRT)

OPTIONAL

https://research.musc.edu/resources/sctr/education/ccrt

The purpose of the Core Clinical Research Training is to prepare research team members to coordinate cost-effective healthcare research while at the same time, promote the rights and safety of human subjects, achieve recruitment and retention outcomes and contribute to the science of health care in compliance with the Good Clinical Practice Guidelines and federal regulations.

Research involving Laboratory Animal Subjects (IACUC)?

Institutional Animal Care and Use Committee (IACUC): The Institutional Animal Care & Use Committee (IACUC) oversees all animal research and instruction at MUSC in order to ensure that ethical regulatory and policy mandates governing the use of animals in research and instruction are met.

- MUSC has a mandatory minimum training program, Collaborative Institution Training Initiative (CITI) animal modules, for all personnel involved in the care and use of laboratory animals.
- All PIs and all protocol personnel needing access to the animal facilities must complete the MUSC Barrier Training offered through the Division of Lab Animal Resources (DLAR).
- All PIs describing survival or non-survival surgical procedures in their protocol and all protocol personnel who will perform or participate in surgical procedures as part of their described duties must complete the MUSC Surgical Training Course available through DLAR**.**

Have a VA Appointment?

Ralph H. Johnson VA Health Care System

Working with the VA

IRB information for those performing research at the VA

MUSC/VA MOU Requirements:

A University/VA MOU is required when submitting NIH-sponsored grant or contract applications for all MUSC faculty with a joint MUSC and VAMC appointment

- Why do I need one?
  - MUSC certifies to NIH that a PI is applying as part of a joint appointment by having an MOU on file
- When will the MOU be used?
  - A copy of the MOU is submitted with a Just in Time (JIT) and/or Progress Report for federal grants
- Where can I get a copy of my MOU?
  - The DOS GA has all VA MOUs on hand and updates them yearly so they do not expire.
- When does my VA MOU expire?
  - The VA MOU is valid for 1 year. The DOS GA is responsible for updating the MOU, getting the appropriate signatures and having on file an up to date and valid MOU.
- Can I use MUSC Personnel on my VA project?
  - Yes. You will need a MUSC VA Personnel Services Agreement (VA PSA) set up in order to use MUSC personnel on a VA project.
- What is a VA PSA?
  - The MUSC/VA Personnel Services Request contains a statement of work and position description of the MUSC personnel requested. This sets up an agreement that allows the work as well as sets up an account for the personnel to be funded with VA funds
- How do I set up a VA PSA?
  - Talk to the DOS GA. The GA will work with you to fill out the needed forms. The GA is required to submit an IPF to ORSP to begin the process between MUSC and the VA.

VA PSA Deadline Dates:

PSA Start Date	Due to VA	Route IPF by
Monday, January 1, 2024	Friday, December 1, 2023	Tuesday, November 28, 2023
Thursday, February 1, 2024	Monday, January 1, 2024	Wednesday, December 27, 2023
Friday, March 1, 2024	Thursday, February 1, 2024	Monday, January 29, 2024
Monday, April 1, 2024	Friday, March 1, 2024	Tuesday, February 27, 2024
Wednesday, May 1, 2024	Monday, April 1, 2024	Wednesday, March 27, 2024
Saturday, June 1, 2024	Wednesday, May 1, 2024	Friday, April 26, 2024
Monday, July 1, 2024 Thursday, August 1, 2024 Sunday, September 1, 2024	Monday, June 3, 2024	Wednesday, May 29, 2024
Tuesday, October 1, 2024	Friday, August 30, 2024	Tuesday, August 27, 2024
Friday, November 1, 2024	Tuesday, October 1, 2024	Thursday, September 26, 2024
Sunday, December 1, 2024	Friday, November 1, 2024	Tuesday, October 29, 2024

*The VA requests 6 weeks of lead time for processing.

Contact:

- Sarah Jackson, VA Grants Management Officer
  843-252-3755
  Sarah.jackson@va.gov

Laboratory Setup Policy

Due to the variety and amount of hazardous materials (biological, chemical, and radioactive) routinely present in biomedical laboratories, the laboratory environment has the potential to negatively impact the safety of staff, the community and the environment as well as the violation of federal, state and local regulations. The following guidelines are intended to assist laboratory personnel in setting up their laboratories.

Overview

All Principal Investigators shall assume primary responsibility for the proper set up of their laboratories as well as the handling, storage and disposal of all hazardous substances in their laboratories in order to protect students, faculty, staff, the community and the environment, and ensure compliance with all applicable institutional, local, state and federal regulations. The procedures detailed herein shall be utilized when setting up a laboratory at MUSC.

Responsibilities

- **Principal Investigators:**
  The responsibilities of the Principal Investigator shall include the following:

a) Training laboratory staff pertaining to laboratory hazards as well as the safety practices and techniques required to ensure a safe work environment in their laboratory. Such training includes identification of hazards, storage and containment of hazardous materials, proper laboratory practices, and emergency response and notification procedures in the event of an accident, injury, exposure or potential exposure.
b) Supervising the laboratory staff's safety performance to ensure that the required safety practices and techniques are continuously employed;
c) Informing the laboratory staff of the reasons for any precautionary medical practices advised or requested;
d) Selecting and providing personal protective equipment to all laboratory staff members based on the procedures used in the laboratory and the individual requirements of the staff members;
e) Maintaining written documentation for all training activities, which includes instruction in laboratory safety procedures, for all laboratory staff/personnel;
f) Investigating and reporting in writing to MUSC's Occupational Safety and Health Programs (OSHP) any significant problems affecting health and safety in their laboratory;
g) Complying with all applicable institutional, local, state and federal regulatory requirements.
h) MUSC's occupational and health manual is available on the horseshoe: https://horseshoe.musc.edu/university/risk-management/services/occupational-safety

Occupational Safety and Health Programs (OSHP)

Provides proper guidance for laboratory setup.

Prior to use of:	Contact:	Minimum amount of time
Chemicals	OSHP (Main Line)	1 week
Radioactive Materials	Radiation Safety (Main Line)	1 month
Recombinant DNA, microorganisms, biological toxins	Register with MUSC Institutional Biosafety Committee (IBC) Apply online: https://research.musc.edu/resources/ori/ibc/submission/inventory Biosafety Officer's Guidance Page: https://research.musc.edu/resources/ori/ibc/resources	1 month
Relocation Biosafety Cabinets	Biosafety Cabinet Service Program	
Animals	IACUC	
Human Subjects	IRB	

Procedure

The procedures detailed herein address the requirements for use of hazardous materials in the laboratory setting. Due to the various types of hazardous materials and regulatory requirements, these procedures have been subdivided into specific checklists for the pertinent safety offices. The appropriate checklist must be completed prior to use of the associated hazardous materials.

Submit a laboratory relocation notification to OSHP, Biosafety and Radiation Safety offices via the following online form: https://horseshoe.musc.edu/university/risk-management/forms

Office	Name	Phone #	Email Address
Occupational Safety and Health Programs (OSHP) Office	Main Line	843-792-3604	
Lab Safety/ Chemical Safety	General Questions	843-792-1260	oshp-vm@musc.edu
OSHP/ Hazardous Waste Manager	Main Line	843-792-3604	
Biosafety Officer	Dr. Christina Voelkel Johnson	843-792-3125	johnsocv@musc.edu
Radiation Safety Office	Dr. Sameer Tipnis	843-792-3833	tipnis@musc.edu
Asst. Radiation Safety Officer	Vladimir Henderson-Suite	843-792-3548	hendervl@musc.edu

	Chemical Safety Setup Checklist (Page 1 of 2)
	General Standards As you move in and unpack, do not keep chemicals that you know you will not need. Dispose of these chemicals (see Pick-Up Requests) or transfer them to a lab that can use them (see Chemical Reuse). Ensure all containers to be moved or disposed of are clearly marked (see Chemicals Awaiting Disposal) as to the contents and hazard. Containers must be in good condition and must close securely. Ensure the outside of the containers are clean and not contaminated with any hazardous materials.
	Unknown Containers Be sure all containers you unpack are clearly labeled. Make every effort to identify any unknown substances since disposal of true unknowns are associated with high cost. If the contents of a container can not be identified segregate it for identification during waste collection.
	Chemical Reuse Identify unopened chemicals that have not expired and will not be used. Such chemicals can be offered to neighboring labs. Donated chemicals must be removed from your chemical inventory and added to the receiving laboratory's chemical inventory.
	Pick-Up Requests To request a pick up for waste that has been properly labeled and containerized, go the site below, fill out the form completely and hit "Submit." https://horseshoe.musc.edu/university/risk-management/forms/chemical-waste-pickup-request-2 The hazardous waste disposal contractor picks up waste every Tuesday and Thursday. Most waste should be picked up within one week however at times situations arise that may not make this possible. If your waste has not been picked up within two weeks please call 792-3604 and let us know. However do not use this number to make the initial pick up request.
	Chemicals Awaiting Disposal When chemicals in your lab are used, have expired or are no longer needed they must be sent for proper disposal. Containers must be sealed and labeled with the MUSC hazardous waste or non-hazardous waste label as soon as any waste is placed in a container. If the chemical has expired or is no longer needed, it must be labeled as waste as soon as it is deemed to be a waste. This label should have the full noun name of the chemical. The chemical formula or structure can be on the label but can not be substituted for the full noun name. Do not use abbreviations. Hazardous and non-hazardous waste labels can be found online at: https://horseshoe.musc.edu/~/media/files/univ-files/risk-management-files/chemical-safety/all-waste-labels-musc.pdf?la=en You can print these labels out and tape them to the container. You may obtain stick on labels from OSHP by filling out a pick up request and noting that you need labels in the comments section. No chemicals should be put into the trash, poured into the sink or evaporated in a chemical fume hood. Designate a safe, conspicuous, well marked area to collect waste chemicals, keeping them properly segregated as prescribed in the ***Chemical Segregation*** section to facilitate collection by the disposal contractor.

For assistance with this section contact:
Alex Neeley **Tel.** 792-8386
Hazardous Waste Manager **email:** neeleyale@musc.edu

	Chemical Safety Setup Checklist (Page 2 of 2)
	Chemical Segregation As you unpack your chemicals please store them according to hazard class and ensure incompatible chemicals are segregated. Fisher, Baker and other chemical manufacturers use a color coded system for segregating chemicals. This may help you to separate them according to hazard class. Flammables and Combustibles (Red) Flammable Solids (Red) Corrosive Acids (White A) Corrosive Bases (White B) Poisons / Toxins (Blue T) Cyanides (Blue C) Oxidizers (Yellow OX) Peroxide Formers (Yellow PF) Water Reactives (Yellow WR) Organic Peroxides (Yellow OP)
	Chemical Inventory As you unpack your chemicals, take this time to update your written chemical inventory. You will be required to provide OSHP with an updated inventory after occupying the new laboratory location.
	Spill Clean-Up Have spill clean-up materials on hand before unpacking. Wear the proper personal protective equipment (gloves, lab coat, safety glasses or goggles). Ensure each chemical container is labeled and lids are on tightly and in good condition. **Contact OSHP (792-3604) if spills occur.**
	Transport Carts Use sturdy carts with raised edges on all sides to contain boxes when moving chemicals. Be especially careful when entering or exiting elevators as the wheels of some carts may get stuck and cause carts to tip over.

Biosafety Setup Checklist

	Biosafety Setup Checklist (Page 1 of 1)
	1. Investigators working with recombinant DNA, microorganisms or biological toxins must register these agents with MUSC's Institutional Biosafety Committee (IBC). Applications are submitted via the eProtocol system: https://eprotocol.musc.edu. Registrations must be amended if relocating to new facilities within MUSC or adding additional agents. Agents may be transferred to MUSC Investigators who have received prior IBC approval. IBC registrations and amendments adding new agents or locations require lab inspections. Contact the Biosafety Officer to schedule lab inspections. The following details what lab inspections entail: https://horseshoe.musc.edu/university/risk-management/services/biosafety/setting-up-a-biosafety-level-2-laboratory
	2. Transfer of CDC / USDA Select Agents (including toxins above regulatory limits) require the notification of the Biosafety Officer and IBC approval ***prior*** to arrival. See Listing of Select Agents- https://www.selectagents.gov/SelectAgentsandToxinsList.html
	3. Transport or shipment of biological materials, requires current shipping certification to ensure Department of Transportation (DOT) / IATA shipping regulations are followed. Individuals must have current training in order to package these items for shipment. The following link provides guidance for obtaining shipping training. https://horseshoe.musc.edu/university/risk-management/services/biosafety/shipping-issues-related-to-biomedical-research-labs
	4. Use of vertebrate animals must be registered with MUSC's Institutional Animal Care and Use Committee (IACUC). https://research.musc.edu/resources/ori/iacuc
	5. Human research studies must be approved by the Institutional Review Board (IRB). https://research.musc.edu/resources/ori/irb
	6. Biological Safety Cabinets must be certified upon installation, when moved, repaired or annually thereafter. The MUSC Biosafety Cabinet Service Program can arrange for the relocation, maintenance, repair and recertification of biosafety cabinets. https://horseshoe.musc.edu/university/risk-management/services/biosafety/the-musc-biosafety-cabinet-service-program
	7. Properly dispose of all biological waste. Dispose of all solid media, supplies and waste in biohazard / infectious waste bags. Live cells, cultures, frozen stocks, etc. must be autoclaved prior to disposal.
	8. Decontaminate all liquid biohazard waste by adding bleach to a final concentration of 10% by volume and allowing it 30 minutes of contact time before disposal down the drain with copious amounts of water.
	9. Place all disposable sharps (needles, syringes, blades, scalpels, etc.) in puncture resistant sharps boxes. Snap shut and deposit with biohazardous waste.
	10. All biological materials must be transported within MUSC utilizing primary and secondary containment. The primary and secondary containers must be sealed, leak proof and labeled with the biohazard symbol.

For assistance with this section contact:
Dr. Chris Voelkel-Johnson **Tel.** 792-3125
Biosafety Officer **email:** johnsocv@musc.edu

Radiation Safety Setup Checklist

Prior to working with Radioactive Materials at MUSC Investigators must be licensed By the Radiation Safety Office. To obtain an application for a license, go to pages 115 – 122 of appendix C of the Radiation Safety Manual and choose the one that best applies to you. You can find this at:

https://horseshoe.musc.edu/university/risk-management/policies

Please submit the application along with a drawing of your lab, a protocol and your CV. Allow at least 2 weeks for the approval. Applications and associated materials can be submitted to the Radiation Safety via Fax (792-5099) or via campus mail:

Radiation safety Office
19 Hagood Avenue, Suite 301
Charleston, SC
29425

Once the application is approved, a member of the RSO team will come by to assist you in setup.

This includes:

- Instructions on procurement of radioactive materials
- Instructions on how to fill out Radioactive Materials Inventory/Disposal sheets, Sewer Disposal sheets, Wipe Test logs, and Waste Disposal forms
- Instructions on spill cleanup
- Instructions on transferring of Radioactive Material
- Labeling of work areas
- Placement of Caution signs
- Examples and recommendations of different GM meters

If an individual is licensed and wishes to move from one licensed area to a new area he/she will have to follow the lab move procedure.

For assistance with this section contact:

John Hardee **Tel.** 792-4259
Radiation Safety Officer **email:** hardeejo@musc.edu

Pre-Award Process

Common Terms to know related to pre-award and grants

ORSP/ Pre-Award

Reporting to MUSC's Vice President for Research, the Office of Research and Sponsored Programs (ORSP) assists faculty and staff with the administrative processes involved in obtaining and conducting extramurally-funded programs.

What does ORSP do?

- ORSP reviews and approves grant and contract proposal submissions
- Reviews, negotiates, and officially accepts all sponsored program agreements/awards
- Provides post-award support services and guidance with the goal of maintaining regulatory, institutional, and sponsor compliance.
- Serves as the official point of contact for sponsored programs and is the authorized signatory for all sponsored project activities at MUSC.

For more information go here.

Proposal Submission Process

Three Day Policy & Due Dates

6 business days prior to sponsor deadline	All completed documents due to the DOS GA for review
3 business days prior to sponsor deadlines	All completed and DOS reviewed documents due to ORSP via Cayuse IPF routed by the DOS GA
Sponsor deadline	All completed and ORSP approved documents due to the sponsor

Grant submissions are due to ORSP three business days prior to the sponsor submission deadline. Grant submission materials are due to the DOS Grants Admin three business days prior to the ORSP deadline to ensure there is enough time for review and revisions prior to requesting ORSP approval.

The GA will **always** accept any materials prior to the due dates, especially when applying for federal grants as there are usually multiple submissions throughout the department around the NIH Standard Due Dates.

Please note the due dates given by the Dept GA may not follow the three-day policy exactly as adjustments may be made due to holidays, out of offices, subaward inclusion on the grant, etc.

NIH Standard Due Dates:
Also, deadlines may vary and change depending on type of submission, time of year, etc. Due to the NIH Standard Due dates, grant submission traffic through the department is higher around certain dates.

Internal Routing Requirements

Anyone contemplating applying for funds from an external source should contact the Department of Surgery's GA as soon as possible. An application or preliminary proposal should NOT be sent by an individual faculty or staff member directly to an agency, foundation or to ORSP. Such proposals must

be routed through the Office of Research & Sponsored Programs via the Cayuse SP IPF and must first go through the Department of Surgery GA.

MUSC Office of Research & Sponsored Programs **Internal Processing Form (IPF)** contains information required for institutional approval to perform the work proposed in the research contract or grant application. This information is used for reporting to the University, the Board of Trustees and the General Public. This form is web based and must be completed online through Cayuse SP.

Internal Processing Form (IPF)

- Completed online through Cayuse SP
- The Dept GA routes an IPF to ORSP for every grant application, RPPR, grant amendment, NCE, etc. ***prior*** to sending materials to the sponsor.
- An IPF contains information required for institutional approval to perform the work proposed in the research contract or grant application.
- This information is used for reporting to the University, the Board of Trustees and the General Public.

IPF FAQs

Who creates the IPF?

The Dept GA creates and routes the IPF.

When is an IPF routed?

An IPF is routed by the Dept GA to ORSP once all application materials are ready for review. The application materials should already be reviewed and approved by the PI and Dept GA with minimal to no edits needing to be made.

IPFs require approvals?

Yes! Once the Dept GA submits an IPF, it is routed for approvals before ORSP receives the Form. The IPF is routed automatically by the Dept GA.

Required Approvals for every IPF submitted:

Principal Investigator & Dept GA

If the proposal is being managed by a department or unit that is **NOT** the PI's home department…

Will need the managing unit Chair or Director approval

If key personnel on the budget are from a different department…

Will need the Key Personnel's Department Chair or Division Administrator(s) approval

What is Cayuse 424 and when would it be used?

All Federal applications are submitted via **Cayuse 424,** which is the industry standard for fast, accurate completion and submission of federal grant proposals.

Cayuse 424 Step by Step Instructions

Common Submission Documents

- Budget
- Budget Justification
- Biosketch
- Other Support
- Indirect Costs Waiver

Budget Preparation

When submitting a proposal to a sponsor the PI should assure that the financial figures represented in the budget are as accurate as possible.

PIs should keep the following in mind when preparing budgets:

- Allowability:
  - Budgets should not include items that the sponsor or MUSC has deemed unallowable. These should be mentioned on the FOA.
- Allocable:
  - Budgets should only include expenses directly related and necessary for the project performance.
- Commitment of Effort:
  - Proposal budgets should accurately represent the amount of time (effort) that all personnel are committing to the project. Other MUSC responsibilities should be taken into consideration when preparing a budget. Ensure there are no over commitments when looking at effort.
    - Over commitment: When the effort a PI has on grants totals more than their allotted Calendar Months or FTE
- Adequate personnel to achieve the research Aims.
- Reasonable:
  - Budgets should only include expenses anticipated in the prudent performance of the project.

Be Prepared to Answer: Budget Questions GA May Ask,

For PI
Title of project?
Find on FOA: - IDC Allowed? - Amount of grant per year? - Budget period?
Personnel: - Key Personnel? - Other Personnel? - Effort for personnel? - Will personnel effort be cost shared or funded on the grant?

Budget Items:
- Plan to fund an equipment purchase?
  o If so, what and how much is the estimated cost?
- Plan to fund a computer purchase?
  o If so, how much is the estimated cost?
  o How does this relate to the project specifically?
- Any other items?

Research Subjects:
- Are there animal subjects involved?
  o If yes, how much is the estimated costs of animal purchases AND animal per diem?
  o Have you submitted an IACUC approval?
- Are there human subjects involved?
  o If yes, how much is the estimated IRB costs?
  o Have you submitted an IRB approval?
Other:
- Will there be a subaward on this grant?
  o If yes, do you have a contact?

Budget Justification:

- A justification should accompany each budget in order to explain the relationship of the expense to the performance of the proposed work. The explanations should focus on how this budget item contributes to the aims of the project and how the estimated costs in the budget were calculated.
- All budget line items should be justified.
- Ask your GA for a budget justification template to get you started.

Biosketch

Documents an individual's qualifications and experience for a specific role in a project. NIH and other sponsors require submission of a biosketch for each proposed senior/key personnel and other significant contributors on a grant application.

- Please see instructions here.
- Please note:
    - Figures, tables, graphics and embedded or attached files are not allowed in the biosketch.
    - May not exceed five pages.
    - Must be a PDF file.
    - Use of hyperlinks and URLs to cite items is not allowed unless otherwise noted in the FOA. The only URL/hyperlink that is allowed is if you choose to input your full list of published work through "My Bibliography" (NIH recommends using this).
        - Instructions to include your My Bibliography link.
    - Quick Document Sections Overview:
        A. Personal Statement
            a. Cite up to 4 publications or research products that you would like to highlight
        B. Positions, Scientific Appointments and Honors
            a. List in reverse chronological order (most recent first)
        C. Contributions to Science
            a. Describe up to 5 of your most significant contributions to science (no longer than half a page)
            b. Each contribution can cite up to 4 publications or research products relevant to the contribution.
        D. Scholastic Performance
            a. Only completed by:
                i. applicants for predoctoral and postdoctoral fellowships
                ii. applicants to dissertation research grants (e.g., R36)
                iii. candidates for research supplements to promote diversity in health-related research from the undergraduate through postdoctoral levels

NIH Public Access Requirements – must be included on NIH biosketch and Reference pages for grant submissions.

Other Support

Provides information on active and pending support for personnel.
Most commonly requested for federal funded projects but sometimes requested by non-federal funded projects.
If Other Support is required for a submission, it will be in the FOA. Otherwise, Other Support is usually requested for the Just-in-Time (JIT).

**If requested, reach out to the Dept GA for help on putting the document together*

***NIH Other Support Instructions*

Please Note:

- **Other Support** includes all resources made available to researchers or senior key personnel in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant.
- Examples:
    - Other grants that personnel have effort on
    - Resources and/or financial support from foreign and domestic entities that are available to the researcher.
    - Financial support for laboratory personnel, and provision of high-value materials that are not freely available (e.g., biologics, chemicals, model systems, technology, etc.).
- Institutional resources, such as core facilities or shared equipment that are made broadly available, should not be included in Other Support, but rather listed under Facilities and Other Resources.
- In-kind contributions: office/laboratory space, equipment, supplies, or employees/students supported by an outside source. This also includes cost shares.
- Other support does not include training awards, prizes, gifts or start-up support provided to the individual by the applicant organization.

For information pertaining to the use of and policy for other support, see NIH Grants Policy Statement, Section 2.5.1: Just-in-Time Procedures.

Formatting:

- Devoted effort must be measured using "person months." NIH and other PHS agencies use the concept of "person months" as a metric for determining percent of effort. For more information about calculating person months, see NIH's Frequently Asked Questions on Person Months.
- The Other Support Document must be signed with a digital time stamped signature. Find instructions here.

Quick Document Sections Overview:

Project/Proposals Section:

- Provide Active and Pending Support of the senior/key personnel.
- Each PI/key personnel will have their own Other Support documentation.

- Enter your support entries so they are grouped together based on the "Status of Support" and are in the order of Active and Pending Support from top to bottom.
- VA vs MUSC
    - If an Investigator is VA-funded, VA support and MUSC support must be separated. The VA Section must be clearly labeled and broken out.
    - The following sample blurb is required at the top of the Other Support for anyone with less than 1 MUSC FTE:
        - *Dr. Smith holds a dual MUSC/VA appointment. His/her total professional responsibility (TPR) consists of 75% FTE for MUSC and a 6/8ths (6/8 = 0.75) VA appointment at the Ralph H. Johnson VA Medical Center. Dr. Smith may devote up to a total of 9 calendar months (0.75 x 12) each year to his/her non- VA projects. Dr. Smith may devote up to a total of 9 calendar months (0.75 x 12) to his/her VAMC projects.*
    - Behind the calendar months list in parenthesis (MUSC) or (VA) to denote which projects are being done on MUSC time, and which projects are on VA time.
    - Individuals with joint university and VA appointments may request the university's share of their salary in proportion to the effort devoted to the research project. The individual's salary with the university determines the base for computing that request. Signature by the Institutional Official on the application certifies that: (1) the individual is applying as part of a joint appointment specified by a formal Memorandum of Understanding between the university and the VA; and (2) there is no possibility of dual compensation for the same work, or of an actual or apparent conflict of interest regarding such work. Additional information may be requested by the awarding component(s).

In-Kind Contributions Section:

- Provide Active and Pending In-Kind contributions for all senior/key personnel.
- Enter your in-kind entries so they are grouped together based on the "Status of Support" and are in the order of Active and Pending Support from top to bottom
- Office/laboratory space, equipment, supplies, or employees/students supported by an outside source. This also includes cost shares

Overlap Section:

- After listing all support, summarize for each individual any potential overlap with the active or pending projects and activities, other positions, affiliations, and resources and this application in terms of the science, budget, or an individual's committed effort.

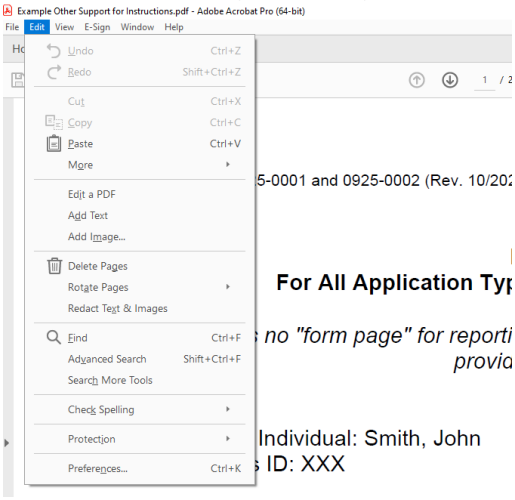
Other Information

PLEASE NOTE FOR CONSORTIUM/CONTRACTUAL ARRANGEMENTS OR MULTI-PROJECT AWARDS:
When providing Other Support under a consortium/contractual arrangement or that is part of a multi-project award: *Indicate the project number, Name of PD/PI, and source of Support for the overall project. Provide* ***all*** *other information (e.g. total award amount, person months) for the subproject only.*

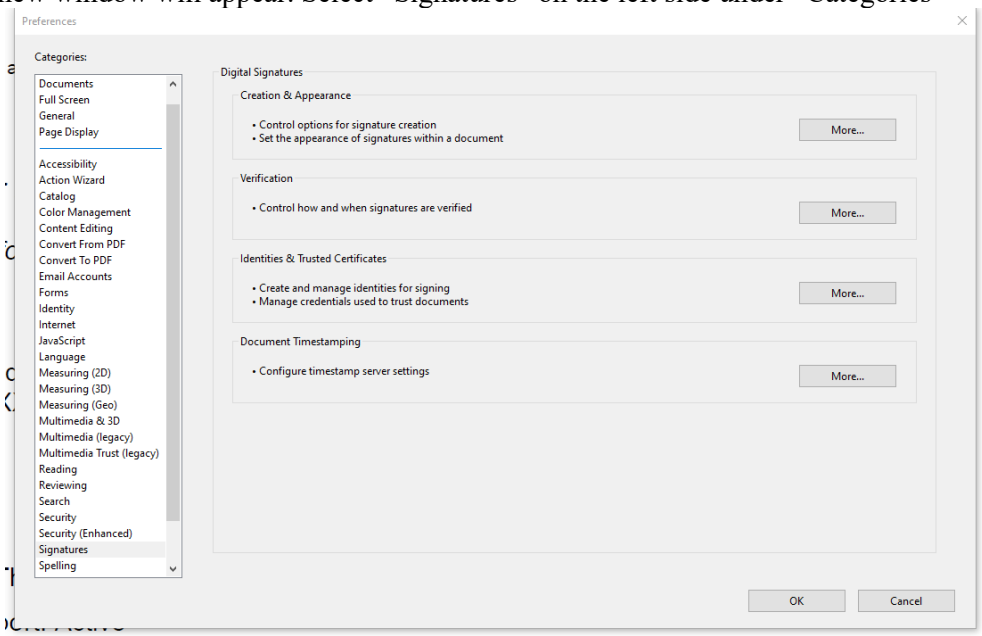
Digital Signature

NIH and many other organizations/institutions require a “digital signature” on Other Support documents and will not accept a typed or hand-signed signature (also known as a “wet signature”). Please follow the below instructions to include a digital signature on your Other Support.

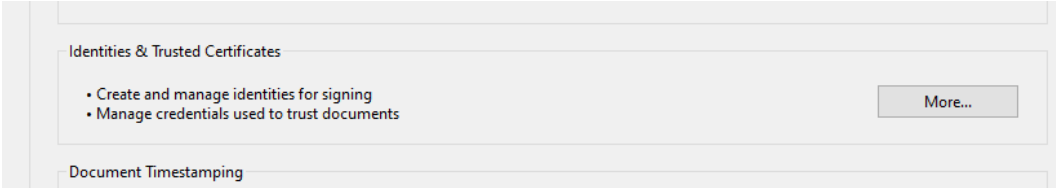
- Open the Other Support document in Adobe Acrobat.
- Click the Edit Tab and choose Preferences (at bottom).



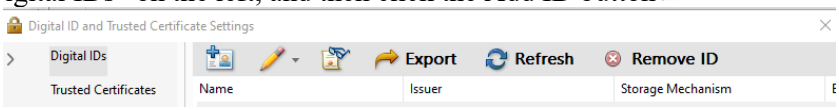
- A new window will appear. Select “Signatures” on the left side under “Categories”



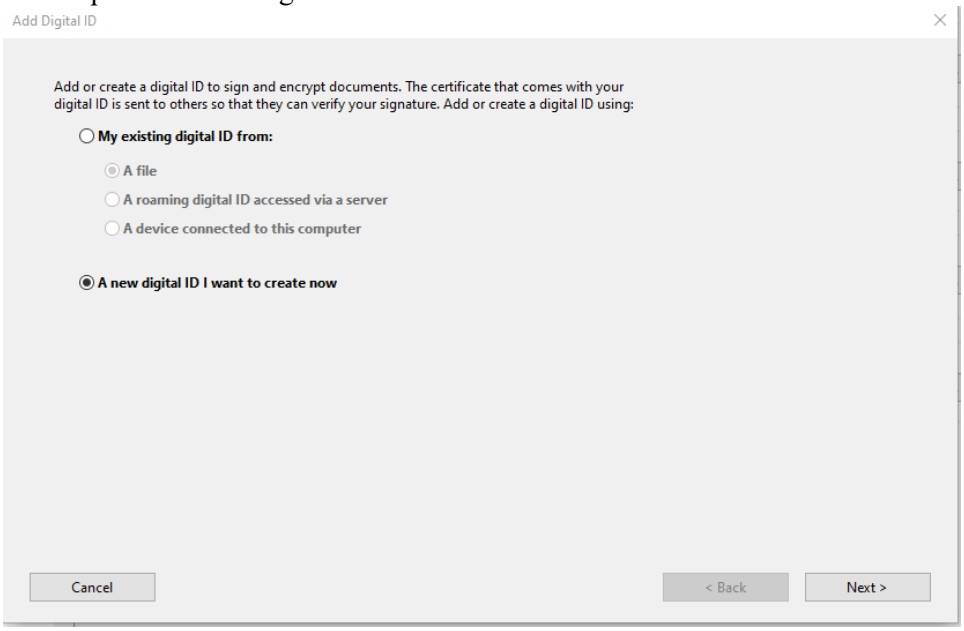
- Under “Identities & Trusted Certificates” click “More”



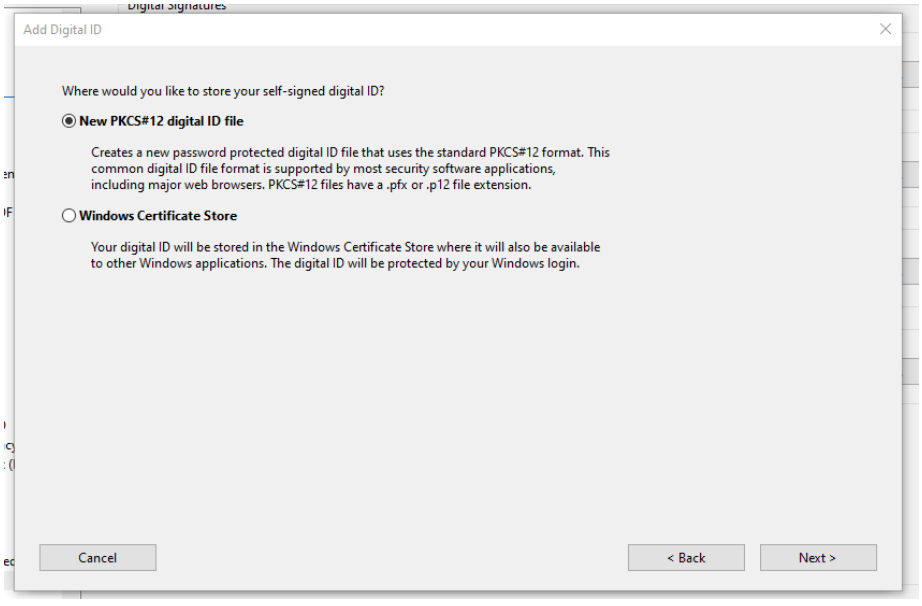
- Select “Digital IDs” on the left, and then click the Add ID button 



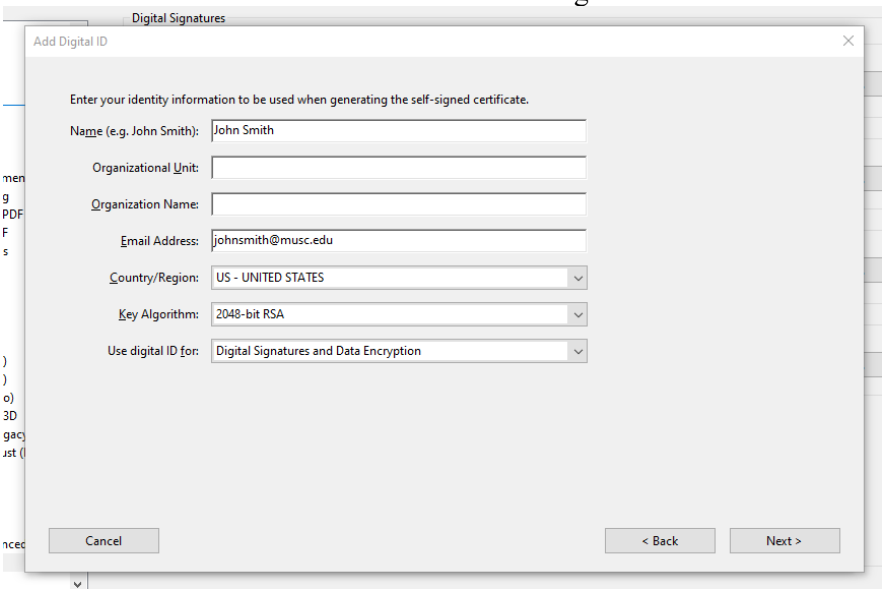
- Select the option “A new digital ID I want to create now” and click Next.



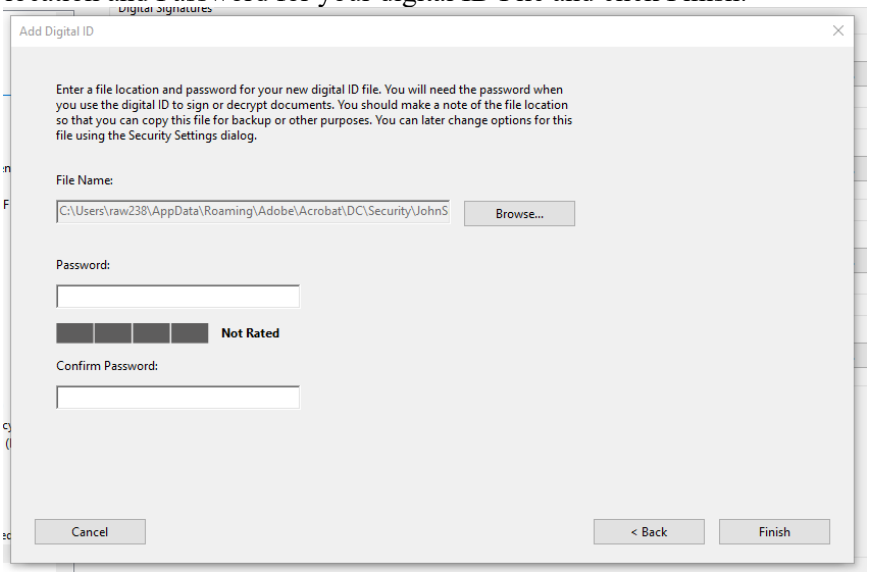
- Choose where to store your self-signed digital ID. The password protected ID file (first option) is the most common used. Then click Next.



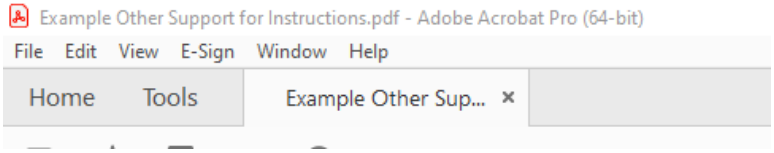
- Enter your Name and Email Address and click Next. Nothing else filled out should need to change.



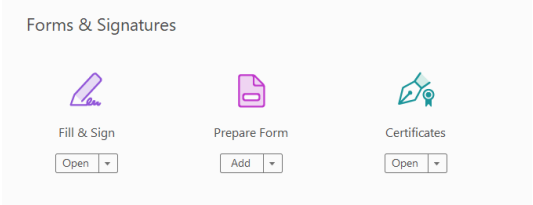
- Select a file location and Password for your digital ID File and click Finish.



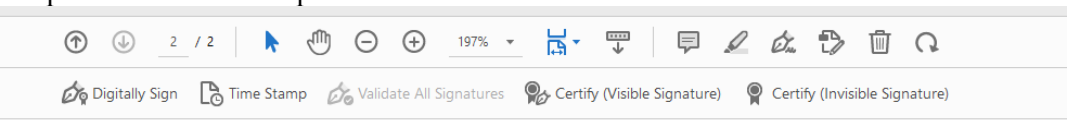
- Go back to the document in Adobe to sign. Click on Tools (upper left corner).



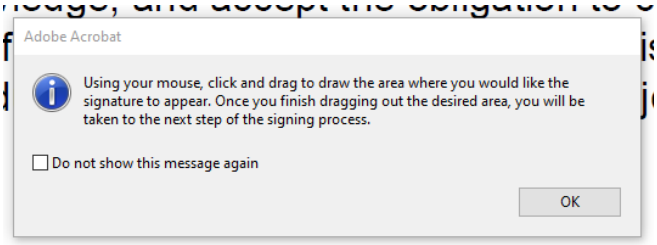
- Go to the Forms & Signatures section then the “Certificates” tool.



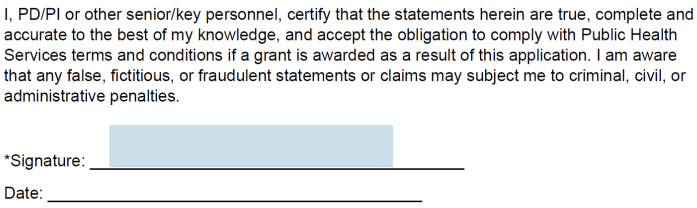
- Once you have selected the “Certificates” tool it will take you back to your document. The “Digitally Sign” option will be at the top.



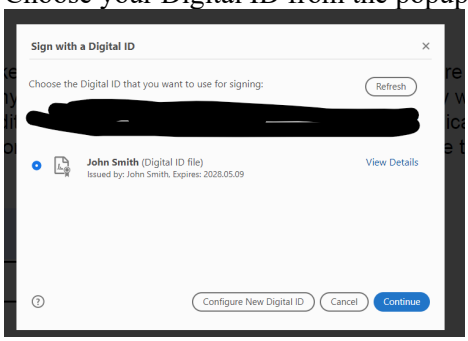
- This message will appear with instructions on how to use the tool. You can choose to not show the message again. Select OK.



- Click and Drag to Draw the area where you would like the Signature to Appear.



- Choose your Digital ID from the popup window and select Continue



- Make sure “Standard Text” is selected at the top. Enter the Password you created where it states “Enter the Digital ID PIN or Password”
- Select Sign in the bottom right. Save document.

IDC Waiver Request

Definition of Indirect Costs (IDC):

Also known as Institutional Overhead, and Facilities and Administration (F&A)

Necessary costs incurred by a recipient for a common or joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted, without effort disproportionate to the results achieved.

Some grants do not allow F&A/indirect costs on the grant or require a reduced F&A/indirect rate. If this is the case, an IDC Waiver Request must be submitted and approved prior to grant submission. Please plan for extra time for the GA to request an IDC Waiver from the Dean's Office.

The current F&A and Fringe Rate Agreement for MUSC can be found online or contact the GA.

When is an IDC Waiver requested?

- A waiver is requested if any IDC rate, besides the set Research F&A Rate, is requested on the budget.
-

Reasons to use a reduced F&A Rate?

- Sponsor requires a different F&A rate
- PI is applying to a grant with a low award amount and would like to request to waive indirect costs to make more room for other budget items
- Your project does not qualify as "Organized Research" but may fall under different F&A rate category (Other Sponsored Activities, Instruction, Non-Federal Clinical Trials, or Non-Federal, Non-Clinical Research)

Steps:

- Inform the DOS GA of the IDC policy for the grant submission or that you wish to request an IDC Waiver for the application.
- The IDC waiver needs to be requested at least 1 week prior to routing. The GA will request the approval of the IDC waiver, not the PI.
- **The IDC Waiver must be obtained fully signed by the Dean's Office before an application can be submitted and reviewed by ORSP.**
- The IDC waiver form needs to be submitted with:
    - Draft budget for the submission
    - IDC waiver form signed by the PI and Department Chair
    - The application guidelines showing that IDC is not allowed or allowed at a reduced rate.
- The Dean's Office will submit the IDC waiver to the Senior Associate Dean for Research for approval after it is routed to them by the Department GA.
- Once signed, the form will be routed back to the Department GA.
- The *approved* IDC waiver form will be submitted with the IPF when it is routed to ORSP.

Could my IDC Waiver be denied?

Yes, the Dean's Office could deny your request for multiple reasons. For example, you've requested too many waivers, IDC is allowed on grant at a lower rate but you requested to waive all costs.

Post Award

You are awarded a grant, now what? The Post-Award team hosted in the Department of Surgery manages your awards which includes keeping track of expenses to ensure no overspending, processes payment of personnel, build and manage study trackers, ensure compliance with the award and MUSC policies, submit federal financial reports with help from The Office of Grants and Contract Accounting (GCA) and more.

GCA/ Post Award

Grants and Contracts Accounting (GCA)

As a unit of the Division of Finance and Administration, Grants and Contracts Accounting (GCA) is responsible for post-award administration of sponsored grants and contracts awarded to the University. GCA's main responsibilities are:

- Sponsored financial reporting, invoicing, administration, and cash management;
- Applying cost accounting standards and principles to sponsored programs expenditures;
- Developing and negotiating the University's Facilities and Administrative (F&A), and Fringe Benefits Cost Rates;
- Developing policies and procedures and related education programs to ensure compliance.

For more information click here.

Oversight and Management of Project Expenditures

When authorizing and charging expenses to a sponsored project the Principal Investigator and the department research administration is responsible for ensuring that:

1) The charge is necessary and provides a benefit to the project
2) The charge is allowable under sponsor and MUSC guidelines
3) Project funds are available
4) The charge is appropriately documented as required by university policy or sponsor terms of award
5) The charge has been processed through the appropriate MUSC departments receiving any required institutional approvals

Additionally, principal investigators and department research administration should complete a complete review of the sponsored project account monthly in order for adjustments to be made in a timely manner. Any erroneous charges must be addressed promptly and corrected by the appropriate transfer, within 90 days of ledger posting unless exceptional circumstances warrant a later transfer.

Expenditures should be monitored against the awarded budget. The responsibility for clearing overdrafts and unallowable expenses belong to the PI and department research administration. Under no circumstances should a different sponsored project be charged for an overdraft. If additional time is needed to complete a project and funds remain in the budget, the PI may request a no-cost extension. Requests for extensions must be initiated by the PI and pre-award administration and processed within the terms of the award. In some cases, MUSC officials are authorized to approve a no-cost extension, in other cases prior approval from the sponsor is required. Requests for extensions should be submitted within a month of the project's end date.

Progress Reports

Progress Report guidelines and instructions vary depending on the sponsor. Federal awards typically have hard set deadlines for progress reports and milestones that must be met, while non-federal sponsors vary with what is required. For questions, reach out to the Dept Post-Award Team.

Research Performance Progress Report (RPPR)

Overview

The RPPR is used by recipients to submit progress reports to NIH on their grant awards.

This page provides an overview of the annual RPPR, the final RPPR and the interim RPPR and provides resources to help you understand how to submit a progress report.

The PI is able to complete the RPPR in eRA Commons, except for the following sections which are completed by the Dept GA:

- D.1: Current project personnel
  - The GA will handle to ensure the institutional effort system matches the effort check.
- D.2.c: Other Support (file upload of Other Support for all Key Personnel)
  - The GA will work with PI for Other Supports and will review the documents before submitting, to make sure they follow guidelines.
- G.10: Estimated Unobligated Balance Greater than 25%
  - To make sure this is an auditable Research Administrator number – the GA will work with the Post Award team to find this balance.
    - If needed, PI will complete… G.10.b Provide an explanation for unobligated balance (700 Characters)
    - If needed, PI will complete… G.10.c If authorized to carryover the balance, provide a general description of how it is anticipated that the funds will be spent. To determine if carryover is authorized for any federal grant, see the Notice of Award for policies. (1300 Characters)
- H.1: Budget
  - The GA will work with the PI to create an Internal Budget and then enter it into eRA Commons to make sure it balances.

RPPR Checklist

DUE DATE AND AWARD INFORMATION	
Submission deadline	**RPPR reports are due 60 days prior to the end of the period of performance. Once entry is complete, route to your Grants Administrator (GA).**
FORMATTING INSTRUCTIONS	
Document format	PDF only, some information can be cut and pasted from a Word document directly into the eRA Commons RPPR form.
Font type/size	✔ Arial, Helvetica, Palatino Linotype or Georgia typeface ✔ Black font color ✔ 11-points or larger
Line spacing	✔ No more than 6 lines of type within a vertical space of 1 inch ✔ Only single column formatting

	Page size	8.5 x 11
	Margins	0.5" all sides ("Narrow"). No information in margins.
	Instructions	RPPR Instruction Guide
	Policy Guide	NIH Grants Policy Statement – Part II, Subpart A, Section 8.4.1 Reporting http://grants.nih.gov/grants/policy/nihgps/index.htm
	DESCRIPTION	***REVIEW REQUIREMENTS***
A	**Cover Page**	The majority of the information in the Cover Page is pre-populated from data in eRA Commons
		Changes to the contact information (address, email) for the PI must be made in their eRA Commons Personal Profile
		Recipient ID: can be left blank
	☐	**Change of Contact PD/PI:** Choose Yes or No. If yes, enter in eRA Commons ID for new Contact PI
	☐	**Signing Official** – select Megan Cleary from the drop-down menu
	☐	**Administrative Official** – select Raegan Whiteside from the drop-down menu
	☐	**Human Subjects** – Choose Yes or No
		✔ HS Exempt – Choose Yes or No ✔ Exemption number – enter #, if applicable ✔ Phase III Clinical trial – Choose Yes or No
	☐	**Vertebrate Animals** – Choose Yes or No
	☐	**Human Embryonic Stem Cells (hESC)** – Choose Yes or No
	☐	**Inventions/Patents** – Choose Yes or No
B	**Accomplishments**	Allows the agency to access whether satisfactory progress has been made during the reporting period
	☐	**B.1 What are the major goals of the project?** ✔ 8,000-character limit (~3 pages) ✔ Does not usually change from previous year's RPPR. ✔ NIH recommends 1 page.
	☐	**B.1.a. Have the major goals changed since the initial competing award or previous report?** 8,000-character limit
	☐	**B.2 What was accomplished under these goals?**
		✔ Upload pdf file (2-page maximum) ✔ For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results, including major findings, developments, or conclusions (both positive and negative); and 4) key outcomes or other achievements. Include a discussion of stated goals not met.
	☐	**B.3 Competitive Revisions/Administrative Supplements** (if applicable)
		✔ Add revision/supplement # ✔ Add revision/supplement title ✔ Describe specific aims for this revision/supplement (700-character limit) ✔ Describe accomplishments for this revision/supplement (700-character limit)
	☐	**B.4 What opportunities for training and professional development has the project provided?**
		✔ If the research is not intended to provide training and professional development opportunities or there is nothing significant to report during the reporting period, select **Nothing to Report**.
		✔ For all projects reporting graduate students and/or postdoctoral participants in Section D., describe whether your institution has established Individual Development

		Plans (IDPs) for those participants. Do not include the actual IDP; instead include information to describe how IDPs are used, if they are used, to help manage the training for those individuals.
	☐	**B.5 Describe how the results have been disseminated to communities of interest.**
		✔ If nothing to report, check "Nothing to Report" box ✔ Or, complete text field with 8,000-character limit (~3 pages) ✔ NIH Recommends 1 page.
	☐	**B.6 What do you plan to do for the next reporting period to accomplish the goals?** ✔ 8,000-character limit (~3 pages) ✔ NIH Recommends 1 page
C Publications	☐	**C.1 Publications**
		✔ Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, and monograph) during the reporting period resulting directly from this award? ✔ If yes, select publications from list associated with the project. ✔ If publications selected are not in compliance, go to the NIH RPPR Frequently Asked Questions webpage at http://grants.nih.gov/grants/rppr/faqs.htm#3568 for more information and instructions about how to become compliant. ✔ The RPPR can be submitted with non-compliant publications; however, NIH will not release the new Notice of Award until all publications are in compliance. ✔ Make sure all investigators have updated their publications on "My NCBI"
	☐	**C.2 Website(s) or other Internet site(s)**
		✔ For awards not designed to create or maintain one or more websites, select **Nothing to Report**. A description is only required for awards designed to create or maintain one or more websites. Limit the response to this reporting period.
	☐	**C.3 Technologies or techniques**
		✔ Identify technologies or techniques that have resulted from the research activities. Describe the technologies or techniques and how they are being shared. Limit the response to this reporting period.
	☐	**C.4 Inventions, patent applications, and or licenses** ✔ Have inventions, patent applications and/or licenses resulted from the award during this reporting period? ✔ If yes, has this information been previously provided to the PHS or to the official responsible for patent matters at the grantee organization? ✔ Reporting of inventions through iEdison is strongly encouraged.
	☐	**C.5 Other products and resource sharing**
	☐	**C.5.a. Other Products**
		✔ Identify any other significant products that were developed under this project. Describe the product and how it is available to be shared with the research community. Do not repeat information provided above. Limit response to this reporting period. ✔ Examples of products are: audio or video products; data and research material (e.g., cell lines, DNA probes, animal models); databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware. ✔ If nothing to report, check "Nothing to Report" box or upload Response
	☐	✔ **C.5.b Resource Sharing**
		✔ If the initial research plan addressed, or the terms of the award require, a formal plan for sharing final research data, model organisms, Genome Wide Association Studies data, or other such project-specific data, describe the progress in implementing that plan. For sharing model organisms, include information on the

			number of requests received and number of requests fulfilled during this reporting period. If the sharing plan is fully implemented, provide a final statement on data sharing. If nothing to report, check "Nothing to Report" box or upload Response
D	**Participants**		***Only Section D.1 is required for Final/Interim RPPR**
		☐	**D.1 What individuals have worked on the project?**
			✔ Provide or update the information for (1) PD/PI(s) and (2) each person who has worked at least one calendar month per year on the project during the reporting period (160 hours or 8.3% effort). ✔ Do not include Other Significant Contributors or Consultants that did not certify effort to the grant. ✔ Use calendar months only. Do not enter summer or academic months. ✔ Postdoctoral and graduate student personnel must have an active eRA Commons profile. Contact your GA if an account needs to be set up. ✔ Do not report personnel for whom a PHS 2271 Appointment form has been submitted through xTrain. ✔ GA can provide an effort certification report that includes a projection for all personnel certifying effort to the grant through the end of the current budget period. Enter the average amount for each person certifying 1 calendar month or more.
			✔ TO ENTER PERSONNEL INTO GRID: ○ If personnel being entered is considered key personnel, a post-doc or graduate student, enter eRA Commons User ID and click on Populate from Profile button (eRA Commons ID is not required for allied health staff) ○ Answer Yes or No to Senior/Key Personnel question ○ SSN # and DoB information does not need to be entered ○ Enter Degree Information ○ Use drop down menu to select Role ○ Enter calendar month(s) including a single decimal point. ○ Answer Yes or No to the question "Is the individual's primary affiliation with a foreign organization?" ✔ **Click Add/New** button to save information entered into personnel grid
E	**Impact**	☐	**E.1 What is the impact on the development of human resources**
			✔ Applicable for Education awards, D43, DP7, K30, R13, R25, T14, T36, U13, and U2R
			✔ Describe how the project made an impact or is likely to make an impact on human resource development in science, engineering, and technology. For example, how has the project: 1) provided opportunities for research and teaching in the relevant fields; 2) improved the performance, skills, or attitudes of members of underrepresented groups that will improve their access to or retention in research, teaching, or other related professions; 3) developed and disseminated new educational materials or provided scholarships; or 4) provided exposure to science and technology for practitioners, teachers, young people, or other members of the public?
		☐	**E.2 What is the impact on physical, institutional, or information resources that form infrastructure?**
			✔ Describe ways, if any, in which the project made an impact, or is likely to make an impact, on physical, institutional, and information resources that form infrastructure, including physical resources, institutional resources, or information resources.
		☐	**E.3 What is the impact on technology transfer?**
			✔ Applicable for R41, R42, R43, R44, U43, U44, UT1, and UT2 awards
			✔ Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including: 1) transfer of results to entities in

			government or industry; 2) instances where the research has led to the initiation of a start-up company; or 3) adoption of new practices.
			E.3.a Commercialization Activities
			✔ Report on the status of commercialization activities resulting from the award
			E.3.b FDA Interactions
			✔ Report on interactions with the Food and Drug Administration during the reporting period related to technology that is the subject of the award.
		☐	**E.4 What dollar amount of the award's budget is being spent in foreign country(ies)?**
			✔ If nothing to report, check "Nothing to Report (zero dollars)" box ✔ If there is something to report, add dollar amount ✔ Do not report foreign travel, purchases, etc., unless part of a first-tier subaward to a foreign country.
F	**Changes**	☐	**Section not required for Final/Interim RPPR**
G	**Special Reporting Requirements**	☐	**G.1 Special NoA Terms and Funding Opportunity Announcement Reporting Requirements**
			✔ Address any special reporting requirements specified in the award terms and conditions Notice of Award or Funding Opportunity Announcement.
		☐	**G.2 Responsible Conduct of Research**
			✔ Not applicable
		☐	**G.3 Mentor's Report**
			✔ Not applicable
		☐	**G.4 Human Subjects** (if applicable)
			✔ Add the inclusion enrollment data and/or clinical trial information, as applicable ✔ If yes, provide current IRB approval number to GA
		☐	**G.5 Human Subjects Education Requirement** (if applicable)
			✔ Are there personnel on this project (prime + collaborators) who are or will be <u>newly involved</u> in the design or conduct of human subjects research? ✔ If yes, provide name(s) of individual(s); title of the human subjects education program completed by each individual; and a one-sentence description of the program. ✔ At Gillette the training program is conducted through UMN and it is a web-based educational course designed to provide all personnel involved in human subject research with training about human subject protection. ✔ Text box has 1,300 char. limit
		☐	**G.6 Human Embryonic Stem Cells (hESCs)** (if applicable)
			✔ If yes, enter hESC registration number
		☐	**G.7 Vertebrate Animals** (if applicable)
			✔ If yes, provide current IACUC approval number to GA
		☐	**G.8 Project performance site**
			✔ Site information will auto-load into RPPR ✔ If all fields are not complete, you may receive an error message. Your GA can assist with completing the required information (DUNS, Congressional District, Address, etc.) - Common errors seen are duplicates of performance sites (which can be deleted) and/or loss of Congressional Districts and UEI information. Make sure these are added back
		☐	**G.9 Foreign Component –** if applicable
			✔ If not applicable, check "No foreign" component box ✔ Or, add organization name, country of foreign component, & description

		☐	**G.10 Estimated Unobligated Balance**
			G.10.a Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year's total approved budget? If yes, provide the estimated unobligated balance.
			✔ Check with Finance Analyst to confirm whether or not there will be greater than 25% of the current year's total approved budget
			G.10.b Provide an explanation for the unobligated balance.
			G.10.c. If authorized to carryover the balance, provide a general description of how it is anticipated that the funds will be spent.
		☐	**G.11 Program Income**
			✔ If yes, add anticipated amount and sources
		☐	**G.12 F&A Cost**
			✔ If yes, provide an explanation (1,300 character limit)
H	**Budget**	☐	**Section not required for Final/Interim RPPR**
I	**Outcomes**	☐	**I.1. What were the outcomes of the award?** **Provide information regarding cumulative outcomes or findings of the project. This should be a concise summary of the outcomes or findings that:** • Is written for the general public in clear, concise, comprehensible language • Is suitable for dissemination to the general public • Does not include proprietary, confidential information or trade secrets, and includes up to 6 (six) optional images ***Limited to 8000 characters (approx. 3 pages)**

Effort Reporting Requirements

(has not been updated post OurDay go live)

As a recipient of Federal Agreements, MUSC must have systems and procedures in place to ensure compliance with applicable regulations concerning the documentation of the distribution of salaries and fringe benefits charged to sponsored programs and facilities and administrative (F&A) cost activities. Additionally, as a recipient of Medicare/Medicaid funds, MUSC is required to document clinical and hospital administrative activities in order to comply with Medicare/Medicaid Cost Reimbursement requirements.

https://isserve.musc.edu/effort/

The Activity Reporting Systems was development in accordance with the applicable regulations contained in Office of Management and Budget (OMB) Circular A-21 (Cost Principles for Educational Institutions), Section J.10, entitled "Compensation for Personal Services." The Quarterly Activity Reporting System is used as the basis for distribution of salaries and wages for monthly-paid faculty and staff. Under this system, the distribution of salaries and wages are initially charged to UDAK projects based on a budgeted salary distribution. This distribution must subsequently be supported by quarterly after-the-fact electronic activity reports that reflect the employee's reasonable estimate of his/her activities being compensated. Monthly paid employees must also document clinical and hospital administrative activities for Medicare/Medicaid Reporting through this system.

Activity Reports are considered delinquent if not completed within **60 days** after the due date. Sponsored Projects UDAKs listed on any delinquent activity reports will be subject to suspension of expenditure privileges, including personnel charges, until all delinquent reports are submitted.

Processing for delinquent effort report with the Department of Surgery will consist of the following:

- The Division of Research Administration will notify the faculty member of his/her outstanding effort report.
- The appropriate Division Head will be notified of the delinquent effort report for additional actions as needed.
- The Research Division Chair will be notified to consult the faculty member regarding the ramification of their actions.

If the effort report continues to be delinquent, the Department Chair will be notified and will begin process to implement sanctions, i.e. Suspension of expenditure privileges; including personnel charges until all delinquent reports are submitted.

No Cost Extension (NCE)

When a final award period is ending but the research is still ongoing and there are funds available, a no-cost extension may be requested of the sponsor. If approved, the end date of the grant will be extended without an increase in funds.

Request needs to be sent to sponsor at least 30 days prior to the original end date of an award; the Principal Investigator (PI) should request an extension of the award about 2 weeks before that. This request will go through the DOS GA and then ORSP.

For multi-PI awards, ALL Principal Investigators must concur with the request in writing or via e-mail.

Steps

1. A letter of request must include:
    - Grant number/Award ID
    - Project Title
    - Requested new end date
    - Remaining balance (see below)
    - Justification of why NCE is needed
    - PI signature
    - Dept Chair signature
        - The DOS GA will get this
    - Assistant Director ORSP (David Azbill) signature
        - ORSP contact will get this
2. Further justification needed in letter of request:
    - Provide indication if the level of effort for any key personnel (listed in Notice of Award) would be reduced by more than 25% of the level originally proposed (may require sponsor approval depending on award terms)
        - If effort is reduced more than 25%, indicate whether these reductions of effort would have any effect on the overall scope of the project
    - Indication of any changes in project personnel (internal and/or external) planned during the NCE period
    - If applicable, indication whether the human/animal/biohazards approvals would be maintained and kept current during the extension period
3. Post-Award and Pre-Award administration will calculate the estimated total amount of remaining funds (including F&A)
    - Please provide ample time for post-award and pre-award to get the balance together.

4. Put together a budget & budget justification for use of the estimated remaining funds during the extension period.
    - Work with the GA to create this.
5. External contributors designated as "Investigators" may need to provide annual FCOI disclosures prior to the NCE being processed

*There may be additional information required, or a longer lead time for the request, depending on the terms and conditions of the particular award and/or sponsor. The specific award terms should be reviewed or the assigned ORSP GA can be contacted for assistance.

Project Close-Out

The Office of Grants, Contracts, and Accounting (GCA) prepares and submits final financial status reports with the assistance of the PI and departmental staff. Before submitting the financial report to the sponsor GCA will forward a copy to the PI and department staff. The PI should review the financial report to ensure accuracy. The PI and department are also responsible for ensuring that all necessary financial adjustments and documentation are received promptly after the end of the award.

Extramural Award Close-Out Policy

- Follow the link for information and requirements regarding extramural award close outs provided by MUSC ORSP. This includes close outs of federal and non-federal awards.
- Also includes information on:
    - Final Technical Reports
    - Final Invention Reports
    - Final Financial Reports
    - Delinquent Non-Financial Reports
    - Roles & Responsibilities for Final Reporting Requirements (PI/PDs vs ORSP vs Department vs GCA)

Leaving the Institution?

- Have a Laboratory? Lab Close Out Policies and Checklist
- Have a Grant and Leaving MUSC?
    - Various steps must take place prior to leaving or transferring institutions. Prior approvals, close-out of grants, final reporting, transfer of grants to a new PI or institution, closing of IRBs, etc. The sooner the process is started, the better. Experience has shown that the transfer of an award takes months to accomplish. If information and materials are not submitted in a timely manner, the PI, or new PI, may experience delays in resuming the project.
    - Each funding agency has specific instructions and requirements which may not remain consistent, so additional time is also helpful to research what is needed per grant per sponsor.
        - Transfer a Grant to a New PI

- Transfer a Grant to a New Institution
- Transfer a Grant that has a Subcontract

Transfer a Grant to a New PI

It is the PIs responsibility to initiate the process when a grant is to be transferred to a new PI. **Grants can only be transferred to a new PI if the PI is at the institution the award is housed**.

Reason for transfer? PI is going to a new institution that can't support the project, the PI is leaving the institution and not going to another institution to transfer the grant to, project has to be completed at MUSC (EX: patient participants in Charleston), etc.

Steps for Non-Federal Grant Transfer to New PI

Step	Responsibility	Notes
Request for Grant Transfer	PI notifies Dept Grants Admin and ORSP	This notification must come well in advance as the process is lengthy. Failure to provide timely notification may result in significant delays
Notify Granting Agency	ORSP	ORSP will notify the Program Officer/Contact at the granting agency.
Contact New PI	Dept Grants Admin/ORSP	The Department Grants Admin and/or ORSP will be in contact with the new PI and/or their department (if applicable) to receive materials needed.
Collect Needed PI Change Documents	Dept Grants Admin will work with PI, new PI and ORSP to collect items.	Letter of Support: Signed by Dept Chair showing support of the request to change PI on project Budget: Updated with the new PI demonstrated Approval from Sponsor: ORSP will obtain

Steps for Federal Grant Transfer to New PI

Step	Responsibility	Notes
Request for Grant Transfer	PI notifies Dept Grants Admin and ORSP	This notification must come well in advance as the process is lengthy. Failure to provide timely notification may result in significant delays
Prior Approval from NIH	ORSP *Only the signing official (SO) at MUSC can initiate and submit the Change of PD/PI request. The request can only be made for a grant year that is currently*	Prior approval is needed in order to add or remove a PD/PI to/from a research project. This approval can be requested from the NIH through the "Prior Approval, Change of PD/PI" feature in eRA Commons.

	awarded, and within the budget period.	
Collect Needed PI Change Documents	Dept Grants Admin will work with PI, new PI and ORSP to collect items.	See NIH Grants Policy on Change of PD/PI for more information
		Scientific Justification - Justification related to scientific project including any proposed changes in scope Biographical Sketches - for any new individuals proposed for the project Other Support - for any new individuals proposed for the project eRA Commons ID for any new PD/PIs Budget - Include new PD/PI and any other changes resulting from PD/PI change Statement - "the request for approval should include mention as to whether change(s) in PD/PI or Senior/Key Personnel is related to concerns about safety and/or work environments (bullying, retaliation, or hostile working conditions)"

Transfer a Grant to a New Institution

All transfers begin at the institution the PI is leaving and it is the PIs responsibility to initiate the process.

Step	Responsibility	Notes
Request for Grants Transfer	PI notifies the Dept Grants Admin and ORSP	This notification must come before the anticipated start date at the new organization. Preferably several months in advance as this is a lengthy process.
Notify Granting Agency	ORSP	ORSP will notify the Program Officer/Contact at the granting agency.
For Non-Federal Awards…		
Reach out to Sponsor	Dept Grants Admin/ORSP	Depends on sponsor. The Department Grants Admin and ORSP will reach out to sponsor for approval and for what is needed.
For Federal Awards… See NIH Grants Policy on Change of Recipient Organization for more information.		
Prior Approval from NIH Needed	ORSP	"NIH prior approval is required for the transfer of the legal and administrative responsibility for a grant-supported

		project or activity from one legal entity to another before the completion date of the approved project period (competitive segment)." Failure to provide timely notification to the NIH may result in disapproval of the request or significant delays in processing.
NIH to approve transfer request*	NIH	The NIH's decision to authorize a transfer will be based on: a) The original organization has relinquished the project. b) The facilities and resources at the new location allow for the successful performance of the project. c) The investigator plans no significant changes in research objectives and level of expenditures from those described in the previously approved project
Collect Needed Change of Institution Request Documents**	From the Original Awarded Institution	Statement – "as to whether the change in recipient institution is related to concerns about safety and/or work environments (e.g. due to concerns about harassment, bullying, retaliation, or hostile working conditions) involving the PD/PI." An Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant - PHS 3734 relinquishing statement May be submitted in paper or electronically via the eRA Commons. Acceptance of a relinquishing statement by NIH **does not guarantee approval** of a transfer application for the continued funding of a project Final FFR Expenditure Data and a Final Invention Statement - No later than 120 days after the end of NIH support of the project. Final FFR Expenditure Data should not be submitted until the original institution has received a revised **NoA** for the relinquished grant

Collect Needed Change of Institution Request Documents**	New Recipient/Transfer to Institution: *Encourage the other institution to complete all actions on their end as quickly as possible to avoid delays in research time.* See link for full list of what is needed from the new recipient institution – list depends on if change of institution application is submitted electronically or as a paper application.	A change of institution application - Provide the Grants Management Officer (GMO) "with a change of institution application which may be submitted using the PHS 398 or PHS 416-1 paper application forms, or electronically via Grants.gov using the Parent Funding Opportunity Announcement." The beginning date of the grant at the new institution should be the day following the Date of Relinquishment on the 398 form. eRA Commons - The PI's affiliation will need to be updated in eRA Commons to include the new institution.
Revised NOA received	NIH to original recipient institution	A change of recipient organization is approved by the NIH when **a revised NOA is issued to the original recipient institution**. This NOA will reflect the revised budget/project period end dates, deletion of any future-year support, and deobligation of remaining funds, if applicable. "A deobligation of funds will be based on the estimated grant expenditures through the relinquishment date, as determined from the relinquishing statement or the available balance in the Payment Management System (PMS), whichever is less."
Issue NOA	NIH to new recipient institution	"This NOA will reflect the **direct cost** balance reported on the relinquishing statement plus applicable **F&A costs**, if funds are available." "If the change of recipient organization occurs on the anniversary date of the project, the **NoA** to the new recipient will reflect the previously committed **direct cost** level plus applicable **F&A costs** if funds are available." "If the change of recipient organization occurs during the course of the budget

		period, the policy of the awarding **IC** will determine if the **NoA** to the new recipient will reflect the **direct cost** relinquished by the former recipient plus applicable **F&A costs** or the total costs relinquished by the former recipient. This amount is subject to change as a result of the closeout of the original grant and may be adjusted downward."

*Additional Note for NIH Award Approval: "A change of recipient request normally will be permitted only when all of the permanent benefits attributable to the original grant can be transferred, including equipment purchased in whole or in part with grant funds… NIH will consider whether there is a continued need for the grant-supported project or activity and the impact of any proposed changes in the scope of the project… will also consider the length of time, the percentage of funds, and the amount of work remaining in the project period… If these conditions or other programmatic or administrative requirements are not met, the NIH awarding IC may require peer review or may disapprove the request and, if appropriate, terminate the award."

**NIH may request additional information

***A change of recipient that involves the transfer of a grant to or between foreign organizations or international organizations also must be approved by the IC's Advisory Council or Board.

Transfer Grant that has a Subcontract:

- When a **subcontract** is involved on a project that is being moved to a new institution, a termination date will need to be established between the prime awarded recipient and the subcontracted organization to ensure a smooth transition to the new institution.
- **Once the original subcontract has been terminated, and monies transferred to the new institution, a subcontract will need to be initiated with the new institution**

NIH Public Access Requirements

Compliance with the NIH Public Access Policy

NIH Public Access Policy ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed *upon acceptance for publication*. To help advance science and improve human health, the Policy requires that these papers are accessible to the public on PubMed Central no later than twelve (12) months after publication.

Applicability

This policy applies to peer reviewed articles that arise in whole or part from direct costs funded by NIH (FY 2008 and beyond) that were accepted for publication on or after April 7, 2008. The NIH Public Access Policy also requires that, as of August 21, 2009, NIH applications, proposals and progress reports must include the PubMed Central reference number (PMCID) or the NIH Manuscript Submission (NIHMS) reference number when citing an article that falls under the policy and is authored or co-authored by the investigator, or arose from the investigator's NIH award, *even if the investigator is not an author*. A PMCID is required for applicable journal articles **three (3) months post-publication**.

(Must be included on NIH biosketch and Reference pages for grant submissions)

Compliance with this Policy is a term and condition of the grant award and cooperative agreement, in accordance with the NIH Grants Policy Statement. For contracts, NIH includes this requirement in all R&D solicitations and awards under Section H, Special Contract Requirements, in accordance with the Uniform Contract Format.

Also, when citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant, and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal – In Process."

Definitions & Acronyms

Further definitions here.

→ Budget Period:
- Time interval from the start date of a funded portion of an award to the end date of that funded portion during which recipients are authorized to expend the funds awarded. Typically, 12 months. Different than a "project period" or "period of performance"

→ Carryover
- Unobligated Federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried forward to another budget period to cover allowable costs of that budget period (whether as an offset or additional authorization). Obligated, but unliquidated, funds are not considered carryover.

→ Cayuse
- Cayuse 424 is a platform-independent software solution for submission of applications via Grants.gov. Cayuse is a web application that can be accessed directly from a PC or a Mac desktop. The system is easy to use, is highly intuitive, and has robust functionality to support the creation and submission of error-free grant applications to NIH, DOD, NSF, CDC and AHRQ.
- Cayuse SP is designed to allow the electronic creation, tracking, and management of proposals and awards along with other aspects of research operations. Directed proposal development, electronic approval systems, and easy access to reporting foster research collaboration for research enterprises of all sizes. Cayuse SP provides a framework that helps research managers track and report on the activity at every level of the research organization.
- By responding to questions about sponsors, subcontractors, compliance, export control, and other institution-specific questions, proposal creators cover the required areas of proposal development quickly and effectively; and administrators can review all the relevant data.
- For more information and guides click here.

→ Collaborative Institutional Training Initiative (CITI)
- All investigators and key personnel who participate in the design, conduct, or reporting of human subjects research (including exempt research) must be appropriately trained in the protection of human subjects. The university uses the Collaborative Institutional Training Initiative (CITI) web-based human research course to satisfy the requirement for MUSC researchers for training in human research subjects protection. Initial and continuing education (every 3 years) are required as explained below.
  Training must be completed prior to receiving initial or continuing IRB review of research proposals.

→ Conflict of Interest (COI)
- A cross-cutting issue that affects many policy areas such as peer review, financial conflict of interest, and responsible conduct of research. There are different uses of this term throughout this document. It generally means that a competing personal interest could affect, or could appear to affect, an individual's judgment or could cause the individual's impartiality to be questioned. Conflicts of Interest (actual or potential) may arise in the objective review process or in other activities or phases of the financial assistance process.

→ Cost Share:

- A cost share is a portion of the direct costs of a project paid by the department, rather than the sponsor/award. This is often requested for PI effort support when a grant is too small to support PI effort as well as additional costs needed.
- If you would like to request a cost share, please inform the GA as soon as possible. The GA will request the cost share from Jamie Meyer and Katie Castello, including costs and justification, prior to grant submission and budget finalization. The cost share must be approved before the application is submitted to ORSP.

→ Direct Costs:
- Costs that can be identified specifically with a particular sponsored project, an instructional activity, or any other institutional activity, or that can be directly assigned to such activities relatively easily with a high degree of accuracy.
- Include but are not limited to, salaries, travel, equipment, supplies, etc.

→ Division of Lab Animal Resources (DLAR)
- The enterprise authority overseeing laboratory animal research. DLAR provides consistently high standards of laboratory animal care, promoting the welfare and stewardship of animals used in biomedical research to meet the evolving needs of a competitive research environment.

→ Effort[1]
- Effort is your work on a project, whether the sponsor pays your salary or not.
- Effort support can be funded directly on the grant, or it can be cost shared by the department.
- When you write yourself into a grant proposal, you are committing your effort to the sponsor.
- Effort is measured as a percent of the individual's total University employment obligation. Percent effort represents the proportion of time an individual spends on each University activity and is expressed as a percent of the individual's total University activity.

→ Facilities and Administration (F&A)
- Also known as Institutional Overhead or Indirect Costs.
- Necessary costs incurred by a recipient for a common or joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted, without effort disproportionate to the results achieved.
- Some grants do not allow F&A/indirect costs on the grant. If this is the case, an IDC Waiver request must be submitted and approved prior to grant submission.
- The current F&A and Fringe Rate Agreement for MUSC can be found online or contact the GA.

→ FDP Clearinghouse[2]
- This publicly available website provides online organizational profiles containing entity-based information needed by pass-through entities when they are issuing subawards or monitoring their subrecipient entities. It is the result of the FDP Pilot Project that effectively demonstrated a significant reduction of administrative burden.

[1] Robert C. Anderson, Assistant Director Research and Sponsored Programs, Univ. of Wisconsin – Madison, "Effort Reporting: Top 10 Things a P.I. Should Know," published in NCURA

[2] https://fdpclearinghouse.org/

- Data included for each published organizational profile has been certified as correct by an applicable institutional official, reviewed for accuracy by the FDP Expanded Clearinghouse Subcommittee, and includes the following:
    - Most recent Single Audit
    - F&A and fringe benefit rates
    - Suspension and debarment
    - PHS financial conflict of interest policy
    - Federalwide Assurance number and other compliance-related information
    - Federal identifiers (DUNS/UEI, EIN, CAGE, etc.), and
    - Organizational contact information (authorized official, FFATA, financial, COI, etc.) that are commonly needed for various types of subawards.

→ Fringe
- Compensation over and above an employee's direct wages or salaries is called a fringe benefit. This may be monetary in terms of bonuses and allowances or nonmonetary, such as paid holidays, sick leave, pension plans.
- The current F&A and Fringe Rate Agreement for MUSC can be found online or contact the GA.

→ Full-Time Equivalent (FTE)
- The number of days per week and/or months per year representing full-time effort at MUSC.

→ Institutional Animal Care and Use Committee (IACUC)
- The PHS Policy on Humane Care and Use of Laboratory Animals incorporates the U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training, and requires the grantee to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals. An Institutional Animal Care and Use Committee (IACUC) appointed by the Chief Executive Officer or designee, is federally mandated to oversee the institution's animal program, facilities, and procedures (Public Law 99-158, Sec. 495). IACUC review and approval is required for all PHS supported activities involving live vertebrate animals prior to funding.

→ Indirect Costs (IDC)
- Also known as Institutional Overhead or F&A.
- Necessary costs incurred by a recipient for a common or joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted, without effort disproportionate to the results achieved.
- Some grants do not allow F&A/indirect costs on the grant. If this is the case, an IDC Waiver request must be submitted and approved prior to grant submission
- The current F&A and Fringe Rate Agreement for MUSC can be found online or contact the GA.

→ Internal Processing Form (IPF)
- The internal proposal entered in Cayuse SP that the DOS GA submits to ORSP for approval prior to grant submission (IPFs must be routed to ORSP three business days before the sponsor deadline). This is done for ALL applications (excluding some internal grant submission).

→ Institutional Review Board (IRB)

- An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the organization with which it is affiliated. The Institutional Review Board has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction.

→ Just in Time (JIT)
- Received when a grants submission is under consideration for funding. This **does not** mean that the application has been funded. It just means a good score was given to the application and it is being considered.
- If a JIT is given, the sponsor may request additional information and documents. Most commonly, key personnel's other support is requested as well as IACUC or IRB protocols/status.

→ Memorandum of Understanding (MOU)
- A University/VA MOU is required when submitting NIH-sponsored grant or contract applications for all MUSC faculty with a joint MUSC and VAMC appointment

→ Modified Total Direct Cost (MTDC)
- All direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and subawards up to the first $25,000 of each subaward (regardless of the period of performance of the subawards under the award).
- MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of $25,000. Other items may only be excluded when necessary to avoid a serious inequity in the distribution of **indirect costs**, and with the approval of the cognizant agency for **indirect costs**.

→ National Institute of Health (NIH)
- The National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services, is the nation's medical research agency — making important discoveries that improve health and save lives. NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

→ No-Cost Extension
- An extension of time to a project period and/or budget period to complete the work of the grant under that period, without additional Federal funds or competition. See NIH Standard Terms of Award and Prior Approval Requirements.

→ Notice of Funding Opportunity (NOFO) (used to be FOA, Funding Opportunity Announcement)
- Refers to a formal announcement of availability of federal funding through financial assistance program.

→ Notice of Award (NOA) or Award Letter
- The official, legally binding document, signed (or the electronic equivalent of signature) by a **Grants Management Officer** that:
  - notifies the recipient of the award of a grant;
  - contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and,

        - provides the documentary basis for recording the obligation of Federal funds in the NIH accounting system.

→ Office of Research and Sponsored Programs (ORSP)[3]
    - Reporting to MUSC's Vice President for Research, the Office of Research and Sponsored Programs (ORSP) assists faculty and staff with the administrative processes involved in obtaining and conducting extramurally-funded programs. ORSP reviews and approves grant and contract proposal submissions; reviews, negotiates, and officially accepts all sponsored program agreements/awards; and provides post-award support services and guidance with the goal of maintaining regulatory, institutional, and sponsor compliance. ORSP serves as the official point of contact for sponsored programs and is the authorized signatory for all sponsored project activities at MUSC.

→ Other Support
    - Includes all resources made available to researcher or senior key personnel in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant.
    - Other support does not include training awards, prizes, start-up support from the US based institution, or gifts.
    - Note: Gifts are resources provided where there is no expectation of anything (e.g.., time, services, specific research activities, money, etc.) in return.

→ Parent Announcement:
    - NIH-wide FOA enabling applicants to electronically submit an investigator-initiated grant application for a specific activity code, e.g., Research Project Grant (Parent R01).

→ Pass-through Entity (PTE)
    - A non- Federal entity that provides a subaward to a subrecipient to carry out part of a Federal program.

→ Person Months
    - The metric for expressing the effort (amount of time) PD/PI(s), faculty and other senior/key personnel devote to a specific project. The effort is based on the type of appointment of the individual with the organization; e.g., calendar year, academic year, and/or summer term; and the organization's definition of such.
    - For instance, some institutions define the academic year as a 9-month appointment while others define it as a 10-month appointment.

→ Project Period or Period of Performance
    - Total estimated time interval between the start of an initial award and the planned end date, which may include one or more funded portions (or budget periods), as well as no-cost extensions, renewals, carryover, etc.
    - The project period is identified in the NOA.

→ Public Health Service (PHS)
    - Umbrella organization in the U.S. Federal Government consisting of 8 HHS health Agencies, the Office of Public Health and Science, and the Commissioned Corps (a uniformed service of more than 6,000 health professionals). The NIH is the largest Agency within the PHS

[3] https://research.musc.edu/resources/orsp

→ Research Performance Progress Report (RPPR)
    - The RPPR is used by recipients to submit progress reports to NIH on their grant awards. This page provides an overview of the annual RPPR, the final RPPR and the interim RPPR and provides resources to help you understand how to submit a progress report.

→ Signing Official (SO)[4]
    - A SO has institutional authority to legally bind the institution in grant-administration matters by providing signature approval on grant application submissions. The SO monitors grant related activities within the extramural organization and may have a number of titles. The SO can also create additional accounts for personnel at their institution, including new signing official accounts.
    - ORSP is MUSCs Signing Official for all grants.

[4] https://www.era.nih.gov/erahelp/commons/Commons/roles/SO.htm