Quarterly Research Administrator’s Meeting
Office of Research Administration
1/17/2019

AGENDA
Geeta Swamy – Federal Harassment and Discrimination Reporting
Jim Luther – Foreign Influence
Alyssa Dack – Government, GAP, & MSPAI Update
Darrell Queen – WBSE Setup
Michael Dickman – ORA Update
Special Guest Appearance

Federal Sponsors & Prohibited Harassment

Duke Office of Scientific Integrity
Harassment: What is It?

- Harassment is a pattern of discriminatory behavior
- Harassment may take two forms:
  - Unwelcome severe or pervasive conduct (verbal or physical) that creates a hostile work or learning environment, or
  - Unwelcome sexual advances, requests or other conduct that are used as a basis for decisions affecting an individual's education or employment
- Harassment can be based on age, color, disability, national origin, sex, gender identity, gender expression, race, religion, class, veteran status, institutional status, sexual orientation or any other protected basis
- Please take some time to review Duke's policy online

Harassment Reporting Requirements

- Harassment Policy administered and implemented by the Office for Institutional Equity (OIE)
- Need for central repository for harassment complaints
- Policy requires managers, supervisors, chairs, directors ("responsible officials") to notify OIE of all harassment complaints
- Failure to do so can result in:
  - Potential for harm to the community
  - Increased likelihood of policy violation and legal liability
  - Inconsistency in addressing concerns and complaints
- Notify Student Affairs about any student-on-student sexual harassment or sexual assault cases involving graduate or undergraduate students

Rationale

- NSF is committed to promoting safe, productive research and education environments
- NSF will not tolerate harassment, including sexual assault within the agency, at awardee organizations, field sites, or anywhere NSF-funded science and education is conducted.
- NSF considers the PI and any co-PI(s) to be in positions of trust and must comport themselves in a responsible and accountable manner during the award period whether at the awardee institution, online, or outside the organization, such as at field sites or facilities, or during conferences and workshops.
**NSF Award Term & Condition**

- Awardee institutions must report all forms of prohibited harassment, including but not limited to sexual harassment and sexual assault involving any NSF-funded PI or co-PI.
- Duke must report within 10 business days of determination or action:
  - Any finding or determination of harassment AND/OR
  - Any administrative action imposed relating to an investigation or finding of harassment.
- NSF has developed an electronic process for submission of the required notifications which goes directly to the Office of Diversity and Inclusion.
- Notifications must be submitted by an authorized organizational representative.

**NSF Award Term & Condition**

- NSF will consider in its review of each notification submitted:
  - Safety and security of personnel supported by the NSF award;
  - Overall impact to the NSF-funded activity;
  - Continued advancement of taxpayer investments in science and scientists; and
  - Whether the awardee has taken appropriate action to ensure the continuity of science and that continued progress under the funded project can be made.
- NSF may, if necessary, assert its oversight authority to:
  - initiate the substitution or removal of the PI/co-PI
  - reduce the award funding amount
  - suspend or terminate the award.

**NIH: Change in PD/PI Status**

- NIH Grants Policy Statement (GPS) 8.1.2.6 - Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the Notice of Award
- What constitutes a need to submit a change request?
  - Change that will impact individual’s ability to carry out the approved research at the location of, and on behalf of, the recipient institution.
  - Change in the individual’s status that the institution imposes after the time of award.
    - Restricted access to the institution or associated resources
    - Changes in their employment or leave status at the institution
  - Examples (not all inclusive nor exhaustive)
    - Departure from the project
    - Absence for a continuous period of 3 months or more
    - Reduction in time by ≥ 25%, percent from the level that was approved at the time of initial competing award
- Prior approval to change status must be submitted by an Authorized Signing Official.
Harassment and Discrimination Protections in NIH Training Applications

- NIH institutional training grants (T15, T32, T34, T35, T37, T90/R90, TL1, TL4)
- Applications must include a signed letter on institutional letterhead from a President, Provost, Dean, Department Chair, or other key institutional leader
- Required elements to demonstrate institutional commitment
  - ensuring that proper policies, procedures, and oversight are in place to prevent discriminatory harassment and other discriminatory practices
  - responding appropriately to allegations of discriminatory practices, including any required notifications to OCR (see NOT-OD-15-152), and
  - adopting and following institutional procedures for requesting NIH prior approval of a change in the status of the Program Director/Principal Investigator (PD/PI) or other senior/key personnel if administrative or disciplinary action is taken that impacts the ability of the PD/PI or other key personnel to continue his/her role on the NIH award described in the training grant application (also see NOT-OD-18-172 for policy on change in PD/PI status).

Institutional Process to Satisfy NIH Training Application Requirements

- Letter drafted by Office of Scientific Integrity, OIE, HR/Staff & Labor Relations, General Counsel, and pre-award offices (ORA/ORS)
- President & Provost endorsement effective 1/1/2019
- Working to “combine” with institutional commitment letter
- Communication plan
  - Presentation to MCEC and Vice Chairs for Research across SOM
  - Presentation & distribution to grant managers across campus
  - Letter posted on University-wide NIH grant administration website
- Work group to develop informative communication with attestation for all PIs, mentors, and mentees involved with NIH training awards
- Questions? Lindsey.Spangler@duke.edu
Other Reporting Requirements

- May have an existing or future obligation to report similar or the same information to other agencies as well
- Howard Hughes Medical Institute (HHMI) must be notified of any issues involving individuals who are also employed by HHMI
- Potential expansion of NIH requirements
- Coordinating with OIE is the key

Summary

- Any and all allegations of potential harassment must be reported to OIE immediately
- Student-on-student cases should be reported to Student Affairs
- Ensure accuracy and timely reporting
- Minimize/eliminate multiple sources of data
- Ensure appropriate data privacy
- Working group
  - OIE, HR/Staff & Labor Relations, General Counsel, OARC, Scientific Integrity, Research Administration (ORA/ORS/ORC/OSP)

Revised Common Rule

45 CFR 46
Key Points

• Effective for all new studies submitted in iRIS on or after January 21, 2019
• Main changes
  – Expands exemption categories and changes the review processes
  – Eliminates declaration of grant concordance
  – Eliminates continuing review for most minimal risk research
  – Reframes informed consent information and adds required elements
  – Requires single IRB review for multi-site research

Exemption categories

1. Research in Established or Commonly Accepted Educational Settings
2. Educational Tests, Surveys, Interviews, Observations of Public Behavior
3. Benign Behavioral Interventions in Adults
4. Secondary Research for Which Consent is not required

Exemption categories

1. Research in Established or Commonly Accepted Educational Settings - REVISED
2. Educational Tests, Surveys, Interviews, Observations of Public Behavior - REVISED
3. Benign Behavioral Interventions in Adults - REPLACED
4. Secondary Research for Which Consent is not required REVISED
Exemption categories

5. Research and Demonstration Projects that Are Conducted or Supported by a Federal Department or Agency
6. Taste and Food Quality Evaluation and Consumer Acceptance Studies
7. Storage or Maintenance for Secondary Use for Which Broad Consent is Required
8. Secondary Research for Which Broad Consent is required

Revised common rule questions

- Duke Health IRB website update
- Jody.power@duke.edu
- June.walker@duke.edu
Foreign Influence Update

“Failure to disclose outside research support, relevant affiliations, or foreign components”

(ORA Quarterly Meeting)

Jim Luther
1. Diversion of intellectual property (IP) in grant applications to other entities, including other countries;
2. Sharing of confidential information on grant applications by NIH peer reviewers with others, including foreign entities, or otherwise attempting to influence funding decisions; and
3. Failure by some researchers working at NIH-funded institutions in the U.S. to disclose substantial resources from other organizations, including foreign governments, which threatens to distort decisions about the appropriate use of NIH funds.

Foreign Influence / Entanglements
August 23, 2018 – NIH Statement on Protecting the Integrity of U.S. Biomedical Research

CHRONOLOGY OF EVENTS

4/11/18: Congressional Testimony – “Scholars or Spies: Foreign - Plots Targeting America’s R&D”
6/22/18: Bloomberg Article – “Unprecedented Threat”
8/23/18: Foreign Influence Letter to Grantees

It's Not Just NIH…

- DoD - FY ’19 National Defense Authorization Act (NDAA) contains a number of provisions of relevance to science and security issues...
  - Sec. 885 requires DOD to develop procedures to limit foreign access to technologies through grants, contracts, cooperative agreements or other transactions...
  - Sec. 889 prohibits contracts involving telecommunications equipment produced by certain named entities, including Huawei Technologies and ZTE Corp.

- NSF
  - Four institutions are currently subject to OIG inquiries that relate to work with China and Chinese talent programs and whether there is information that should have been reported in current and pending support, biosketches, and collaborations and affiliations.

Lastly, we encourage you to reach out to an FBI field office to schedule a briefing on this matter.
China - Foreign Threats to Our Universities

• In 2008 China began a program called “Thousand Talents” which leverages its citizens that were educated or employed in the U.S. as conduits for the transfer of U.S. technology, intellectual property, and know-how back to China.

• The current pool of recruits in the program is thought to be 2,629 (44 percent of whom specialize in medicine, life or health sciences...)

• The undersecretary for research and engineering (DoD) stated “We have seen the Chinese target top talent in American universities and research labs of the private sector, including defense contractors and the U.S. government.”

Bloomberg article U.S. Faces “Unprecedented Threat” From China on Tech Takeover, 6/22/2018 by Anthony Capaccio

And then the Grassley memo...

“Chuck Grassley wants Clarity, Transparency, and the Details from NIH on Foreign Threats to the Research Grant Process”

The letter from Grassley requests details about:
• Background checks of researchers and institutions prior to awarding NIH grants
• Investigations of potential violations of rules concerning foreign affiliations and financial contributions
• Any instances within the past five years where foreign actors mounted systematic programs to influence NIH researchers and peer reviewers; (2) foreign actors worked to divert intellectual property produced by NIH-supported research to other countries; (3) foreign actors contributed resources to NIH-funded researchers in ways which could impact the integrity of the research.

Foreign Influence

• Grassley Receives Response from NIH On Foreign Threats to Research Grant Process
  – Posted Jan. 08, 2019 (Received Dec. 21, 2018)
  – “I appreciate the National Institutes of Health’s response to my letter about foreign threats in our research systems, however it left many of my initial questions unanswered, including how much taxpayer money is dedicated to oversight functions within NIH... that would root out and stop waste, fraud and abuse...”
  – “… This is an issue that deserves much more attention from government oversight efforts. Moving forward, I will continue seeking answers on these and other important questions.”
Foreign Component

- The performance of any significant scientific element or segment of a project outside of the United States… whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to,
  - (1) the involvement of human subjects or animals,
  - (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or
  - (3) any activity of the recipient that may have an impact on U.S. foreign policy...

- Examples of other grant-related activities that may be significant are:
  - Collaborations with investigators at a foreign site anticipated to result in co-authorship,
  - Use of facilities or instrumentation at a foreign site, or
  - Receipt of financial support or resources from a foreign entity.

Implications → Broad and Deep...

- Proposal & Reporting
  - COI, Other Support, DPAF, BioSketch, Progress Reports, Publications, etc.
- Faculty
  - Consulting/Outside Activities, IP, Appoints & Affiliations
- Campus & Building Access
  - Lab visitors, visiting scholars (short and long term), Background checks/Vetting Process
- Other
  - Gift Policy (e.g. Huawei), Relationship with DKU and NUS

Duke University

- NIH letter to faculty in August
- FBI meetings/communications
- Faculty Communication (under development)
  - Let us know if you are contacted
  - Let your departmental administrators know if you have relevant relationships (partial list in the memo)
  - Inform faculty that there is “more to come”
- NIH Letter to SOM Faculty Member about specific concerns
- Under Development:
  - Training and Communication
  - Website with internal and external links to information
  - Foreign Influence Symposium (March), Tools & Checklist, Mapping the Space
Summary

- It's Not Just NIH, But It is the Current Focus
- It's Not Just China, But It is the Current Focus
- Some Stakeholders Have Fundamental Misunderstandings
  - Key Elements are at the Core of Faculty Research and Collaboration
- Internal Controls Implications are Broad and Complex
  - Developing a Solution at Scale is Overwhelming for Institutions and Agencies

Actual Breaches are Minimal, But Potential Risk is Significant

Remember

- NIH Concerns
  - Diversion of intellectual property (IP)
  - Integrity of peer review process
  - Failure to disclose substantial resources
- Definition of Foreign Component
  - Performance outside the US; regardless of use of funds
  - Human subjects or animals
  - Travel for data collection, etc.
  - Impacts U.S. foreign policy...
  - Collaborations result in co-authorship;
  - Use of facilities or instrumentation
  - Receipt of financial support or resources
- Much More To Come

Questions
Update: Partial Federal Government Shutdown

January 17, 2019

Affected Federal Entities

DEPARTMENTS OF:
- Agriculture
- Commerce (includes NOAA)
- Homeland Security (includes TSA)
- Interior (includes National Park Service, U.S. Geological Survey, Fish & Wildlife Service)
- Justice
- State
- Transportation

AGENCIES:
- Environmental Protection Agency (EPA)
- Food & Drug Admin (FDA)
- NASA
- National Endowment for the Arts (NEA)
- National Endowment for Humanities (NEH)
- National Science Foundation (NSF)

Agencies with Normal Operations

- Department of Defense
- Department of Education
- Department of Energy
- Department of Health & Human Services (includes the NIH)
Information for the Duke Community

If you hear something, say something: alert pre-award offices if you/your PI receives sponsor instruction. (This includes subawards)

Keep working: the shutdown does not affect reporting deadlines/expectations.

Proposal deadlines are in effect: submitted materials will be processed once the agency resumes operations. (FYI, grants.gov is still operational)

Watch for further updates: Office of Government Relations blog; emails via the RCC Listserv

Policy Management Initiative

GAP REVISIONS

Capital Equipment: GAP and Screening Form

One Equipment Screening Form, applicable to all purchases of Capital Equipment of more than $5,000

An expanded equipment description section (what purpose will the equipment serve on the project)

The form will no longer require routing to Surplus and Supply Chain

Form will ask for review by a Department Representative. A signature will indicate that the form is appropriately completed.

Form is now required for all reportable projects.
What purpose does the equipment serve?

How does this satisfy the scientific or programmatic aims of the project?
Other Revised GAPs

**FALL 2018-JANUARY 2019:**
- Direct Costing (200.320)
- Cost Transfers (200.150)
- Rebudgeting (200.160)
- Document Retention (Sponsored Projects Only) (200.240)
- Program Income (200.290)
- Service Center Administration (200.300)
- Processing Payments to Research Participants (200.420)

**SUMMER 2018:**
- Procurement-related (110, 370, 372)
- F&A Costs (200.330)
- Subrecipient Monitoring (200.280)
- Parent/Child Management (200.190)
- Administering Commercially-Sponsored Projects and Gifts (200.440)

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**Management Of Selected Post Award Issues (MSfAI) FY2019**

Topics cover important updates and targeted training material for the entire Duke Research Administration Community.

Training required for all RCC certificate holders (RAA, AGM, FCC, RAI)

Covers 3 of your 15 required Continuing Education Credit Hours for FY19

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**MSfAI 2019 Schedule**

Registration in the LMS will be available by the end of February

Multiple dates at a variety of locations!

<table>
<thead>
<tr>
<th>Tentative Dates</th>
<th>Locations</th>
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<tbody>
<tr>
<td>April 8</td>
<td>Bryan Research Building</td>
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<td>April 23</td>
<td>Hock Auditorium</td>
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<td>May 6</td>
<td>Duke South 3031</td>
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<td>May 15</td>
<td>200 Morris St. Downtown</td>
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<td>May 30</td>
<td>Hock Auditorium</td>
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<td>June 12</td>
<td>Erwin SQ 337</td>
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WBSE Create Form

Automation replaces paper process

- Applies to all sponsored projects currently managed through SPS
- Integrates SPS and SAP
  - Initiated in SPS
  - Form generated in SAP for review, approval, and code setup
- Routes for departmental approval (same as Robud/CAS, Tasklist approval)

Department/Center/Institute initiates:

- WBSEs in advance of award
- New award with pre-award spending
- Awards with annual renewals
- Sub codes for existing WBSEs

Central Office initiates:

- WBSEs at Award In Progress/Award

WBSE Create Form

Facilitates key element assignment from set up

- Assigning workflow approvers ensures FAM controls are in place
- Ensure the right number of WBSE(s) created
- Programmatic Attribute, CRU, and other master data elements are assignable by department prior to code creation
WBSE Create Form

- Transparency to review the status of the WBSE throughout the approval process
  - Dedicated WBSE Create Form Display on the Grants Management Tab
  - Trackable through Management Form Overview

- Notification of Creation Occurs in Real Time
  - All parties currently notified will still be notified
  - GM1 now included if assigned during creation

WBSE Create Form

Go live in March of 2019

- March 11, 2019 - Last Day for Paper Submission
- March 15, 2019 - Go Live for Automated Process

WBSE Create Form

- Training will be held as lecture hall demonstrations
- Topics include requesting a WBSE, and how to track the form through the approval process
- A total of 4 sessions will be offered
  - March 5, 2:00-3:30 P.M. - Hock Auditorium
  - March 8, 9:00-10:30 A.M. - Bryan Research 103
  - March 27, 2:00-3:30 P.M. - Bryan Research 103
  - March 28, 9:00-10:30 A.M. - Duke North 2002
- Sign up for your preferred location/date via the LMS
WBSE Create Form

In addition to training, reference guides and videos will be available after Go Live!

ORA NEWS AND REMINDERS

ORA Personnel Update

- Arrivals
  - Erinn Nichols
- Departures
  - Frankie Alexander
  - Rachel Monteverdi
- Openings
  - Training Coordinator

Martin Friedman
Research Admin

Broderick Grady
Assoc.Dir – International

Adam King
Research Admin Mgr (RAM)
Collaborate!

Invite us to your staff meetings

SOM FELLOWS!
Daniel Jordan
Lynn Ta
Rimel Mwamba
Spencer Lamb

COMMUNICATION TOOLS WITHIN SPS
Duke Quarterly Meeting
January 17, 2019
COMMUNICATION BETWEEN ORA & DEPARTMENTS

Scenario
Modes of Communication
Staying in the Loop

The grant manager has a question about the required paperwork for an R21 submission. What mode of communication would you suggest they use?

- Email
- Phone
- In Person
- Other
MODES OF COMMUNICATION

- Primary Modes:
  - Email
  - Phone Call
  - In-Person

STAYING IN THE LOOP

- Instances in which a lack of communication can lead to complicated situations:
  - Pre-Award Process
  - Non-standard submission portals
  - Multi-PI projects
  - Just In Time
  - Award Notifications

COMMUNICATION VIA SPS

Tools within Proposal Actions: Department
Tools within Proposal Actions: ORA
TOOLS WITHIN PROPOSAL ACTIONS: DEPARTMENT

- Use memos, internal documents, and budget notes to communicate unique circumstances

  - Memos
    - Mention of waivers
    - Use of other submission portals
    - Review at PCA

- Internal Documents
  - Proof of required cost share
  - Proof of F&A rate
  - Sub-award packet
  - Application package (if other submission portal)

- Budget Notes
  - Proprietary information
  - Personnel Inflation Rate
  - F&A Rate
  - Fringe Benefit Rate
TOOLS WITHIN PROPOSAL ACTIONS: ORA

- Memos and internal documents are the starting point of the ORA Review
- Budget notes are also noted in Proposal Actions Field
- Proposal Actions tool is used to communicate information that is pertinent to the proposal but does not have a specified location in SPS
  - Example: Non-federal FOA
  - Example: Non-Standard F&A
  - Example: Form signature requests

KNOWLEDGE CHECK

A non-federal proposal does not have an FOA attached, therefore the ORA Liaison is not able to verify the sponsor requirements.

This may result in __________.
TOOLS WITHIN SPS: REQUEST FOR COLLABORATION

- Necessary state to make changes
- Provides feedback
- Enhances quality of proposals

TOOLS WITHIN SPS: REQUEST FOR COLLABORATION

- Opportunity to increase likelihood of a favorable sponsor review
- Important for training opportunities

COMMUNICATION TOOLS WITHIN SPS

Duke Quarterly Meeting
January 17, 2019
Provide updates to the SPOC contact list to gcmail@mc.duke.edu

**DUKE FORMS FOR NIH K AWARDS**

- ORA Forms Page
- Three tabs
  - Blank Form
  - Sample Form
  - Instructions and Resources
- Required for K Award applications
  - Attach in SPS internal docs
Write-off Policy Effective with RCC CAS Remediation for Period 11 (May) FY 2018

- Enforcement of the Revised CAS Policy and Process issued November 9, 2010 (revised 03/30/2011)

- Upon notification by ORA of un-remediated CAS items per the monthly RCC CAS Remediation Report, department must complete action prior to the next month’s JV cutoff per the fiscal calendar.
Write-off Policy Effective with RCC CAS Remediation for Period 11 (May) FY 2018

- Examples of completed CAS remediation actions:
  - JV posted to SAP
  - iForm reflected as processed in the iForms
  - ReC Form approved and posted to SAP

Write-off Policy Effective with RCC CAS Remediation for Period 11 (May) FY 2018

- CAS remediation items pending approvals will NOT be considered as completed CAS remediation actions
  - e.g. waiting on PI to review and approve ReC Form in workflow
- SOM will process the write-off JV for un-remediated CAS items one business day prior to the 12 PM (noon) cutoff for keyed JVs per the Accounting Closing Schedule
- Reminder - per the CAS process, write-off will disqualify the item and any related or future charges to the associated G/L group

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<tr>
<th>CAS Remediation Calendar</th>
<th>Fiscal Month</th>
<th>Fiscal Accounting Period/Initial Charge</th>
<th>Department/Center/Institute Time Period to Submit CAS Rebudget Request/Remove Charge</th>
<th>RCC Monitoring Report (Close of Period)</th>
<th>Corrective Action by Management Center</th>
<th>SOM-RA Preaward JV Write-off as of Fiscal Month</th>
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Avoid CAS Remediation Write-offs and the RCC CAS Remediation Report by Reviewing the CAS Compliance Report

CAS Remediation Policy and Process

Reminders

- CAS budget justification must link to scientific aims and articulate the item/role is integral to the project
- Check “Admin Sal” box under the personnel tab in SPS if administrative/clerical salaries are included in the budget
- Appropriate GL for Admin/Clerical CAS requests is GL 600066
- SOM $500 threshold - CAS charges totaling less than $500 per G/L group in a budget period cannot be requested and cannot be charged
- Approval required to increase previously approved CAS budget if expenses exceed the current CAS budget by $2,500 AND 200%

CAS Remediation Policy and Process Key References

RCC Policy on Directly Charging Clerical And/or Administrative Costs to Federal Awards
https://finance.duke.edu/research/policies/cas.php

Revised CAS Policy and Process from James Luther dated November 9, 2010, rev. 3/30/2011
https://finance.duke.edu/research/documents/secured/cas_revised.php

Duke Financial Services Calendars & Schedules
https://finance.duke.edu/resources/calendars.php

Clarification of SOM Management Center’s Exception of the $500 Threshold for clerical and administrative supplies charged to federal grants
https://medschool.duke.edu/sites/medschool.duke.edu/files/field/attachments/CAS_Memo_021712.pdf

Specific Questions – Contact SOM-RA Special Projects:
Christina Jackson christina.jackson@duke.edu
(919) 684-0577
CLINICAL TRIAL DEFINITION

Duke (F&A Waiver Revision) and NIH

Duke Industry Sponsored Clinical Trial Definition and F&A Rate

• Effective January 1, 2019
• Does not retroactively apply to any studies active or currently under negotiation with an industry sponsor
• Will be used for Duke F&A rate determination purposes only


Duke Industry Sponsored Clinical Trial Definition and F&A Rate

The controlled, clinical testing in human subjects (including prospective data collection) of a drug, device, treatment, diagnostic, intervention, or preventive measure to assess its safety, efficacy, benefits, costs, adverse reactions, and/or outcomes.
Duke Industry Sponsored Clinical Trial Definition and F&A Rate

- SPS “human subjects/clinical trials” questions follow the NIH clinical trial definition and are still required to be answered for industry-funded clinical studies
- Studies could possibly be defined as clinical trials by Duke’s definition, but not NIH’s

Questions: ORC_Industry_Contracts@duke.edu

NIH Definition of Clinical Trial

NOT-OD-15-015
https://grants.nih.gov/policy/clinical-trials/definition.htm

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

- Studies intended solely to refine measures are not considered clinical trials.
- Studies that involve secondary research with biological specimens or health information are not clinical trials.
NIH Definition of Clinical Trial

Use the following four questions to determine the difference between a clinical study and a clinical trial:

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

Note that if the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial, even if:

- You are studying healthy participants
- Your study does not have a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study is utilizing a behavioral intervention
SPS REMINDERS

SPS COI Reminder

The start of every new year marks the start of a new COI filing period. Anyone required to complete a COI form who has not filed by May 1 will be considered out of compliance.

If a proposal is currently in or being set to Awarded:

- Prior to May 1st, you will receive a warning for each participant subject to the COI check who is not compliant for the new Calendar year, but was compliant for the previous year.
- After May 1st, you will receive an error for each participant subject to the COI check who is not compliant for the new Calendar year (even if they were compliant for the previous year).
- We will always generate an error if a participant subject to the COI check is not compliant for both the new Calendar year and the previous year.

SPS Forms E Human Subjects Issues

SPS will not route if you’ve started, but not completed entering data in the studies tab.

Two Solutions:

- Do NOT start entering or delete studies tab information before validate and route; or
- Wait to lock/route until the studies tab information is complete.
Grants.gov Open During Shutdown

During the lapse in federal appropriations, the Grants.gov system remains in an Operational status. Additionally, the Grants.gov Support Center remains available to provide assistance to applicants.

Electronic Submission Tools

In order of preference:
1) GRANTS.DUKE
   • Most NIH FOAs
   • Other federal agencies such as DOD, DOE, DNR
2) ASSIST
   • NIH T32 applications
   • SAMSA, Some CDC
   • NIH grants that require cost sharing or matching contributions
3) Grants.Gov Workspace
   • HRSA
   • Other Federal Agencies with FOAs that are not supported via Grants.Duke
What is Workspace?

- Shared, online environment where members of a grant team may simultaneously access and edit different forms within an application
- Grants.gov's version of NIH's Assist or Duke's Grants.Duke

STEP 1: REGISTER

- Create a personal account
- Do not register another account if you already have a Grants.gov account
- At this point, you CANNOT yet create or manage workspaces

STEP 2: ADD ORGANIZATION

- Go to Manage Profiles tab in My Account
- Click the Add Profile button in the Manage Profiles tab
- Select either the New Profile or From Existing Account radio button
- Select Organization Applicant and enter the DUNS number
- Enter a descriptive Profile Name. You may have multiple profiles, so be sure to use a descriptive, memorable name
- Enter your Job Title
STEP 3: CONFIRM PROFILE AND ROLE
• ORA receives notification via automatic email
• ORA rep confirms profile and assigns Workspace Manager role

STEP 4: MANAGE YOUR WORKSPACES
• Go to the APPLICANTS tab
• Select Manage Workspaces
• Search for the workspaces you have access to, or create a new workspace

STEP 6: ORA REVIEW AND SUBMISSION
• Must add ORA rep as a Participant in order for ORA to review your Workspace
• Communicate in Proposal Memo that the application will be submitted via Workspace; include Workspace ID #
• ORA must submit the application
NIH Fiscal Policies for FY19


- NIH received a 5.6 percent increase over the FY 2018, for a total of $39.3 billion in program level funding.
- Non-competing continuation awards made in FY 2019 will generally be issued at the commitment level indicated on the Notice of Award.
- Out-year commitments for continuation awards in FY 2020 and beyond will remain unchanged.
- Increase stipends by approximately 2 percent for NRSA.
- Salary Limit: Executive Level II currently set at $189,600.
NIH Definition
Foreign Components

The performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Examples of other grant-related activities that may be significant are:
- collaborations with investigators at a foreign site anticipated to result in co-authorship;
- use of facilities or instrumentation at a foreign site; or
- receipt of financial support or resources from a foreign entity.

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- receipt of financial support or resources from a foreign entity.

https://grants.nih.gov/grants/glossary.htm#ForeignComponent

G.220 - R&R Other
Project Information Form

6. Does this project involve activities outside of the United States or partnerships with international collaborators?
- This field is required.
- Applicants to NIH and other PHS agencies must check “Yes” if:
  - the applicant organization is a foreign institution or
  - if the project includes a foreign component
- If you check “Yes” to Question 6, you must include a “Foreign Justification” attachment in Field 12, Other Attachments.
- Begin the section with a heading indicating “Foreign Justification” and name the file “Foreign Justification.”

SPS Fields Regarding Foreign Components

Two different places
- Federal Info tab
  - Transmits SF424 application
  - If “Yes”, must include foreign
    justification other attachment in
    Grants.Duke
- Clearances tab
  - Does not transmit to NIH
  - Duke reporting purposes only
Grants.Duke
Foreign Justification Attachment
• Attach Foreign Justification in Other Attachments
  Item 12
• Does not lock when SPS is PCA
• Remind PI to include before releasing application

NIH Cover Letters
• The Cover Letter should be used for any narrative information
  you want to relay to NIH receipt and referral staff, such as:
  – Reason for late application
  – Explanation of why a Subaward isn’t active in all periods of the proposed
    project
  – Statements regarding agency approval documents (e.g., requests over
    $499,999)
  – Intent to submit a video as part of the application (NOT-OD-12-141)
  – Indication that the proposed study will generate large-scale human
    or non-human genomic data (NOT-OD-14-111 and NOT-OD-15-027)

PHS Assignment Requests
• NIH is added PHS assignment request form effective May 2016
• Captures the following information:
  – Funding component assignment preference
  – Study section preference
  – Individuals who should not review your application due to conflicts
  – Scientific areas of expertise need to review your application
Note: This information was previously included in the Cover Letter
PHS Assignment Requests

- Requests made in the PHS Assignment Request Form may be used to expedite the processing and assignment of applications
- NIH receipt and referral staff are only looking for assignment requests in the PHS Assignment Request Form
- NIH does not guarantee to honor requests, though they try to do so whenever possible
- Do NOT include assignment request in the Cover Letter

PHS Assignment Request Form

- CSR withdrawing applications for non-participating IC’s at increased rate
- Duke has appealed with limited success
- If assignment request is included in cover letter (wrong place), Duke will not appeal NIH assignment

Reimbursement of F&A Costs

NIH GPS 7.4

- Updated to more clearly state the existing requirement that if a consortium is with a for-profit entity, such as a small business, the organization must have an established F&A cost rate before they can charge F&A costs
- Reminder: an institution of higher education (IHE), nonprofit organization, or state or local government that has never received a negotiated indirect cost rate may elect to charge a de minimis rate of 10% MTDC which may be used indefinitely
Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects

NOT-OD-18-116, NIH GPS 4.1.15.7
Updated to state that individuals of all ages, including children and older adults, must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them.

Inclusion of Women and Minorities as Subjects in Clinical Research

NOT-OD-18-014, NIH GPS 4.1.15.8
Updated to include a requirement that recipients conducting applicable NIH-defined Phase III clinical trials ensure results of valid analyses by sex/gender, race, and/or ethnicity are submitted to Clinicaltrials.gov.

Ruth L. Kirschstein National Research Service Awards (NRSA) - Trainees

NOT-OD-18-154, NIH GPS 11.3.6.2
Updated to state that request for part-time training must be signed by the trainee, the AOR and the training grant PD/PI. The request for part-time training must provide a justification of the need for a reduced level of effort and the expected duration of the period of part-time training.
FY19 NRSA Stipends, Tuition/Fees and Other Budgetary Levels

- NOT-OD-19-036

- 2% increase of stipend levels for fiscal year (FY) 2019 awards for undergraduate, predoctoral, and postdoctoral trainees and fellows
- Training Related Expenses and the Institutional Allowance for postdoctoral trainees and fellows have been increased.
- Training Related Expenses and Institutional Allowances for predoctoral trainees and fellows and the Tuition and Fees for all educational levels remain unchanged.

**FY19 NRSA Stipends, Tuition/Fees and Other Budgetary Levels**

<table>
<thead>
<tr>
<th>Career Level</th>
<th>Years of Experience</th>
<th>Stipend for FY 2019</th>
<th>Monthly Stipend</th>
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</thead>
<tbody>
<tr>
<td>Predoctoral</td>
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<td>Postdoctoral</td>
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<td>7 or More</td>
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</table>

**NRSA Tuition… and Fees?**

Section A. Tuition and Fees

- NOT-OD-19-036 and NOT-OD-18-175

"Postdoctoral Trainees and Fellows: an amount per postdoctoral trainee or fellow equal to 60% of the actual tuition level at the applicant institution, up to ….”

- NOT-OD-17-084

Undergraduate and Predoctoral Trainees and Fellows: an amount per predoctoral trainee equal to 60% of the level requested by the applicant institution, up to …
NRSA Tuition… and Fees?

QUESTION:
The language under the Tuition and Fees section of the NRSA notice for fiscal years 2019 and 2018 changed from the 2017 notice and specifically mentions tuition. Does this language change mean only tuition, not fees should be included when calculating the budget in my proposal?

Include the Fees!

NRSA Tuition… and Fees?

QUESTION:
The language under the Tuition and Fees section of the NRSA notice for fiscal years 2019 and 2018 changed from the 2017 notice and specifically mentions tuition. Does this language change mean only tuition, not fees should be included when calculating the budget in my proposal?

NIH Grants Policy Statement 11.2.9.5 Tuition and Fees

“Tuition and fees are provided under the following policy: … an amount equal to 60% of the level requested by the sponsoring institution.”

NOT-OD-19-036
Tuition and Fees, Training Related Expenses, and Institutional Allowance for Kirschstein-NRSA Recipients:
The NIH will provide funds for Tuition and Fees, Training Related Expenses, and Institutional Allowance as detailed below…

Example FOA Language (PA-18-073):
NIH will contribute to the combined cost of tuition and fees at the rate in place at the time of award.

NIH Research Training and Career Development FAQs

https://researchtraining.nih.gov/resources/faq

Question: How does the fellowship or training grant applicant determine the amount of tuition and fees to request in an application?
Answer: Applicants should request the full amount of tuition and fees and should not calculate award costs (see NOT-OD-10-173). At the time of award, the Institute/Center will apply the appropriate formula.

Summary of Significant Changes to the NIH GPS

October 2018

NOT-OD-19-021
PROFESSIONAL DEVELOPMENT AND TRAINING UPDATE

Other Professional Training Opportunities

- NCURA FRA/PRA Meeting
  - Las Vegas, NV; March 11-15
- NCURA Region III
  - Hollywood Beach, FL; May 5-8
- NIH Seminar
  - Baltimore, MD; May 15-17
- SRA Western/Southern Section Meeting
  - San Diego, CA; March 10-13
- SRA NC Chapter Meeting
  - Winston Salem, NC; April 15
Pizza and Proposals

- January 28, 2019, Noon
- Erwin Square 837
- Open hours to collaborate with ORA
- Registration through LMS
- Watch for emails

LMS Registration & Credit

- If you are not on the roster &/or signed up less than 2 business days prior to our meeting, give us 2 business days to add you to the system (remember to sign in legibly & with Net ID)
- Those who did not sign in will be listed as 'no shows' in LMS within 3 business days

LMS Credit Quarterly Mtg & Survey

- To receive credit, each person who signed in will be sent a Qualtrics "By Invitation Only" link
- This link can be only be used once per person (Qualtrics records your information)
- Please put some thought into your responses
- Note: The credit should be listed in LMS within 14 days after survey is completed