

Quarterly Research  
Administrator’s Meeting

Office of Research Administration

1/17/2019

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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

AGENDA

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Federal Sponsors &  
Prohibited Harassment

Duke

Office of  
Scientific Integrity

 @Duke\_OSI

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## Harassment: What is It?

- Harassment is a pattern of discriminatory behavior
- Harassment may take two forms:
  - Unwelcome severe or persistent 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](#)

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## 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

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## 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.



*"The scientific community has not sufficiently protected all of its members. This neglect must end."*  
Frances Collins, National Science Foundation

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## 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**



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## 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



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## NIH: Change in PD/PI Status

[NOT-OD-18-172](#)

- 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

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### Harassment and Discrimination Protections in NIH Training Applications

NOT-OD-19-029  
NOT-OD-19-056

- NIH institutional training grants (T15, T32, T34, T35, T36, 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 procedure 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](#) re policy on change in PD/PI status).



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### Harassment and Discrimination Protections in NIH Training Applications

NOT-OD-19-029  
NOT-OD-19-056

- This letter will be in addition to the content that is currently included in the Letters of Support describing the applicant institution's commitment to the planned program in order to ensure its success (e.g., providing facilities and a research environment conducive to preparing trainees for successful careers as biomedical research scientists; providing appropriate inter- or multidisciplinary research training opportunities and courses which will allow trainees to acquire state-of-the-art scientific knowledge)
- Must be included in the required institutional commitment letter of support and combined with all Letters of Support into a single PDF file
- Failure to provide the signed letter and place in the correct location of the application will result in rejection of the application



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### Institutional Process to Satisfy NIH Training Application Requirements

NOT-OD-19-029  
NOT-OD-19-056

- 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](mailto:lindsey.spangler@duke.edu)



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### 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



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### 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)

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### Revised Common Rule 45 CFR 46

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### 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

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### 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

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### 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

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### 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

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### Exemption categories

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

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### Revised common rule questions

- [Duke Health IRB website update](#)
- [Jody.power@duke.edu](mailto:Jody.power@duke.edu)
- [June.walker@duke.edu](mailto:June.walker@duke.edu)

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## Foreign Influence Update

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

(ORA Quarterly Meeting)

Jim Luther

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Science  
Home News Journals Topics Careers



**Foreign Influence**  
NIH investigating whether U.S. scientists are sharing ideas with foreign governments



**Rigor & Reproducibility**  
1,500 scientists hit the list on reproducibility



**Sexual Harassment**  
NIH director expresses concern but offers no new policy on sexual harassment



**Misconduct**  
Harvard, Brigham and Women's call into question on privacy research



**Georgia Tech's Finance Chief Is Out After Campus Gave 'Boat Load of Money' to Company That Paid Him**

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Science  
Home News Journals Topics Careers

# Foreign Influence



**August 2018**

NIH investigating whether U.S. scientists are sharing ideas with foreign governments

By Jennifer Kahn, David Holmbeck | Aug. 27, 2018, 11:15 PM

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## Foreign Influence / Entanglements



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.



NIH investigating whether U.S. scientists are sharing ideas with foreign governments  
Washington Post Staff Writer | July 27, 2018

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

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## 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"

**8/20/18:** **Foreign Influence Letter to Grantees** →

**8/23/18:** Dr. Collins - Statement on Protecting the Integrity of US Biomedical Research; Congressional Testimony & ACD

**October:** NIH sends individual letters to faculty; Senator Grassley letter to NIH

**December:** NIH Advisory Committee To Director (ACD) Report

"Lastly, we encourage you to reach out to an FBI field office to schedule a briefing on this matter."

**NIH Notices**

**12/22/17:** Maintaining Integrity in NIH Peer Review: Responsibilities and Consequences

**3/30/18:** FCOI: Investigator Disclosures of Foreign Financial Interests

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## 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.

Huawei faces new criminal investigation, bill in Congress
- NSF
 

by Matt Kopko | Jan 17, 2019 10:56am

  - **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.

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## China - Foreign Threats to Our Universities

June 2018

- 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

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## And then the Grassley memo

October 2018



*"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** 1) 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.

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## 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."

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## 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.

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## 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

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## 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

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## 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

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## 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**

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## Questions

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## Update: Partial Federal Government Shutdown

January 17, 2019



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## 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)

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## Agencies with Normal Operations

- Department of Defense
- Department of Education
- Department of Energy
- Department of Health & Human Services (includes the NIH)

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## 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 process 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

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## 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**.

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## The Form

**Procurement of Goods and Services**  
**Capital Equipment Screening Form**

Applicability: Purchasing Capital Equipment >\$1,000, Reportable Sponsored Awards  
Administrative Process: Attach to Buy@Duke Shipping Cart  
Originating Authority: 2 CFR 200.313.3, 2 CFR 200.318 (d)  
Related Duke Procedures: CAP 200.100 Purchasing Capital Equipment on Sponsored Projects, CAP 200.372, Purchasing Goods on Sponsored Projects  
Effective Date: September 2018

PI: \_\_\_\_\_ Dept.: \_\_\_\_\_

WBSE1: \_\_\_\_\_ WBSE2: \_\_\_\_\_ WBSE3: \_\_\_\_\_

Is a trade-in involved? YES NO

VENDOR: \_\_\_\_\_

EQUIPMENT DESCRIPTION: \_\_\_\_\_

Federal regulations require Duke University to use capital equipment in the program or project(s) for which it was acquired (2 CFR 200.313.3). Additionally, regulations state that Duke is limited to acquisition of consumable or replaceable items (2 CFR 200.318 (d)). Using the below form, identify how the unique functions of the capital equipment will assist in meeting the aims of the project(s). If the equipment will benefit multiple projects, the below justification must describe the process for allocating costs.

JUSTIFICATION: \_\_\_\_\_

GMs must review documentation and this form. Any relevant documentation, such as written confirmation from the awarding sponsor or Contract Office Authorization, should be attached to the Buy@Duke Cart. Contact your Office of Sponsored Programs liaison with [alsp@duke.edu](mailto:alsp@duke.edu) questions or Plant Accounting for acquisition questions.

To the best of my knowledge, the capacity and specific functionality provided by this equipment is not currently available at Duke.

PI: \_\_\_\_\_

Department Representative: \_\_\_\_\_

Date Submitted: \_\_\_\_\_

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## The Form

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Originating Authority: 2 CFR 200.313.3, 2 CFR 200.318 (d)  
Related Duke Procedures: CAP 200.100 Purchasing Capital Equipment on Sponsored Projects, CAP 200.372, Purchasing Goods on Sponsored Projects  
Effective Date: February 2019

PI: \_\_\_\_\_ Dept.: \_\_\_\_\_

WBSE1: \_\_\_\_\_ WBSE2: \_\_\_\_\_ WBSE3: \_\_\_\_\_

Is a trade-in involved? YES NO

VENDOR: \_\_\_\_\_

EQUIPMENT DESCRIPTION: \_\_\_\_\_

GMs must review documentation and this form. Any relevant documentation, such as written confirmation from the awarding sponsor or Contract Office Authorization, should be attached to the Buy@Duke Cart. Contact your Office of Sponsored Programs liaison with [alsp@duke.edu](mailto:alsp@duke.edu) questions or Plant Accounting for acquisition questions.

To the best of my knowledge, the capacity and specific functionality provided by this equipment is not currently available at Duke.

PI: \_\_\_\_\_

Department Representative: \_\_\_\_\_

Date Submitted: \_\_\_\_\_

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Operational Info

What purpose does the equipment serve?

Think A/A/R

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## The Form

**Procurement of Goods and Services**  
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Related Duke Procedures: CAP 200.100 Purchasing Capital Equipment on Sponsored Projects, CAP 200.372, Purchasing Goods on Sponsored Projects  
Effective Date: February 2019

PI: \_\_\_\_\_ Dept.: \_\_\_\_\_

WBSE1: \_\_\_\_\_ WBSE2: \_\_\_\_\_ WBSE3: \_\_\_\_\_

Is a trade-in involved? YES NO

VENDOR: \_\_\_\_\_

EQUIPMENT DESCRIPTION: \_\_\_\_\_

JUSTIFICATION: \_\_\_\_\_

GMs must review documentation and this form. Any relevant documentation, such as written confirmation from the awarding sponsor or Contract Office Authorization, should be attached to the Buy@Duke Cart. Contact your Office of Sponsored Programs liaison with [alsp@duke.edu](mailto:alsp@duke.edu) questions or Plant Accounting for acquisition questions.

To the best of my knowledge, the capacity and specific functionality provided by this equipment is not currently available at Duke.

PI: \_\_\_\_\_

Department Representative: \_\_\_\_\_

Date Submitted: \_\_\_\_\_

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

Can be a GM, BM or other designee

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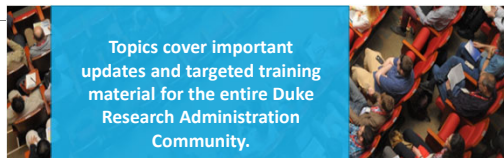
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## Other Revised GAPs

FALL 2018-JANUARY 2019:	SUMMER 2018
Direct Costing (200.320)	Procurement-related (110, 370, 372)
Cost Transfers, (200.150)	F&A Costs (200.330)
Rebudgeting (200.160)	Subrecipient Monitoring (200.280)
Document Retention (Sponsored Projects ONLY) (200.240)	Parent/Child Management (200.190)
Program Income (200.290)	Administering Commercially-Sponsored Projects and Gifts (200.440)
Service Center Administration (200.300)	
Processing Payments to Research Participants (200.420)	

## Management Of Selected Post Award Issues (MSPAI) 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*


## MSPAI 2019 Schedule

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

*Multiple dates at a variety of locations!*

Tentative Dates	Locations
April 8	Bryan Research Building
April 23	Hock Auditorium
May 6	Duke South 3031
May 15	200 Morris St. Downtown
May 30	Hock Auditorium
June 12	Erwin SQ. 837



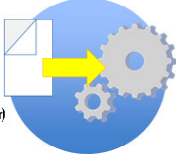


Duke SOM-RA  
Duke University School of Medicine

### 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 Rebud/CAS, Tasklist approver)



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Duke SOM-RA  
Duke University School of Medicine

### WBSE Create Form


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



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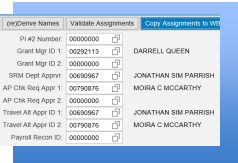


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### WBSE Create Form

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



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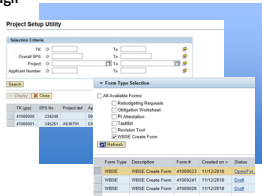
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### WBSE Create Form

- 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)



Form Type	Description	Form ID	Created On	Status
WBSE	WBSE Create Form	41000001	1/15/2019	Created
WBSE	WBSE Create Form	41000002	1/15/2019	Created
WBSE	WBSE Create Form	41000003	1/15/2019	Created

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### WBSE Create Form

## Go live in March of 2019

**MARCH 2019**

**11** Last Day for Paper Submission

**MARCH 2019**

**15** Go Live for Automated Process

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### 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



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WBSE Create Form

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

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# ORA NEWS AND REMINDERS

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## ORA Personnel Update

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

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# Collaborate!

Invite us to your staff meetings



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# SOM FELLOWS!

Daniel Jordan  
Lynn Ta  
Rimel Mwamba  
Spencer Lamb

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# COMMUNICATION TOOLS WITHIN SPS

Duke Quarterly Meeting  
January 17, 2019

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FELLOWSHIP EXPERIENCE

Daniel Jordan

Lynn Ta

Rimel Mwamba

Spencer Lamb



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COMMUNICATION BETWEEN ORA  
& DEPARTMENTS

Scenario

Modes of Communication

Staying in the Loop

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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

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### MODES OF COMMUNICATION

- Primary Modes:

- Email
- Phone Call
- In-Person




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### 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

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### COMMUNICATION VIA SPS

Tools within Proposal Actions: Department  
Tools within Proposal Actions: ORA

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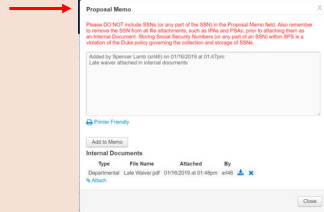
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## TOOLS WITHIN PROPOSAL ACTIONS: DEPARTMENT

- Use memos, internal documents, and budget notes to communicate unique circumstances
- Memos
  - Mention of waivers
  - Use of other submission portals
  - Review at PCA




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## TOOLS WITHIN PROPOSAL ACTIONS: DEPARTMENT

- Use memos, internal documents, and budget notes to communicate unique circumstances
- Internal Documents
  - Proof of required cost share
  - Proof of F&A rate
  - Sub-award packet
  - Application package (if other submission portal)




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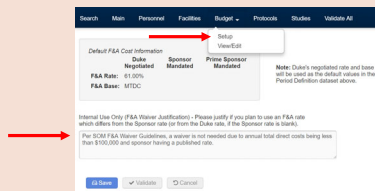
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## TOOLS WITHIN PROPOSAL ACTIONS: DEPARTMENT

- Use memos, internal documents, and budget notes to communicate unique circumstances
- Budget Notes
  - Proprietary information
  - Personnel Inflation Rate
  - F&A Rate
  - Fringe Benefit Rate




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### 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

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### 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 \_\_\_\_\_.

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### 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 extra communication.

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## TOOLS WITHIN SPS: REQUEST FOR COLLABORATION

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




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## TOOLS WITHIN SPS: REQUEST FOR COLLABORATION

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




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## COMMUNICATION TOOLS WITHIN SPS

Duke Quarterly Meeting  
January 17, 2019

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https://medschool.duke.edu/research/research-support-offices/office-research-administration/award-management/effort-management

### OS Review - Single Point of Contact (SPOC)

SoM Other Support SPOC list (Updated November 16, 2018)

- Individuals designated as Key personnel are responsible for maintaining correct and up-to-date OS.
- Each SOM departmental SPOC is responsible for reviewing and certifying that OS documents are correct and up-to-date, verifying effort between SES and the individual's cost distribution to ensure compliance. When a SPOC approves an OS, they provide an approval line at the bottom of the document to demonstrate certification. (i.e., Approved by [Initials here] [Date here])
- The Owning Org of the application is responsible for submitting OS documents for all Key personnel to ORA, ensuring as needed that OS documents have been certified by SPOCs from other departments (campus OS do not have the SPOC certification requirement).
- ORA is responsible for reviewing and submitting OS documents to Sponsors (or returning to the Owning Org for inclusion with documents going to a Sponsor).

Provide updates to the SPOC contact list to [gcmil@mc.duke.edu](mailto:gcmil@mc.duke.edu)

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## DUKE FORMS FOR NIH K AWARDS

NIH National Institutes of Health  
Research Training and Career Development

About DBRW Career Path Programs Institute  
Training Fellowships Career Development Other

### Research Career Development Awards

RTCD Home » Programs

To provide institutional research training opportunities (including international) to trainees at the undergraduate, graduate, and postdoctoral levels.

1. Select Role 2. Select Career Level **APPLY FILTER**  
☐ Awardee ☐ Appointee  **RESET FILTER**

**K01 Mentored Research Scientist Career Development Award**  
 For support of a postdoctoral or early career research scientists committed to research, in need of both advanced research training and additional experience.  
[Details](#) [View Current Funding Opportunities](#)

**K02 Independent Research Scientist Career Development Award**  
 For support of an early to mid-career scientists with research funding, in need of additional research time committed to research.

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## KTPE Form

- ORA Forms Page
- Three tabs
  - Blank Form
  - Sample Form
  - Instructions and Resources
- Required for K Award applications
  - Attach in SPS internal docs

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EDM 484 Program Manager  
June 2015, Evin-Squire Plaza

**INSTRUCTIONS (please complete all yellow shaded cells as applicable):**  
 Enter average hours worked per week in hours field (cell F15).  
 Enter TPE distribution among the 3 entities in the Duke, PDC & VA fields (cells E16-18).  
 Enter distribution of Duke effort in Columns D (cells D24-32).  
 Cell D24 (highlighted in pink) must be  $\geq 75\%$  for mentored Ks and cell F24 (highlighted in pink) must calculate to  $\geq 30$  hours.

K Award:  
 Department: \_\_\_\_\_

	Total Professional Effort	Hours
Duke	0	0
PDC	0	0
VA	0	0
<b>Total Professional Effort</b>	0%	0

Enter total average hours worked per week

Duke Activities	Duke	TPE	Hours	Description/Notes
Sponsored Research	0%	0	0	K Award: mentored K01 or K02
K Award	0%	0	0	
Other	0%	0	0	
Other	0%	0	0	
Other	0%	0	0	
Administration	0%	0	0	
Teaching/Instructional	0%	0	0	
Deep Research	0%	0	0	
Clinical	0%	0	0	
Other	0%	0	0	
<b>Duke Total</b>	0%	0	0	

Note: Consistent effort requires approval from Program Official (MPO)

Completed by: \_\_\_\_\_  
 Date: \_\_\_\_\_  
 Printed on June 1, 2015

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### 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

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

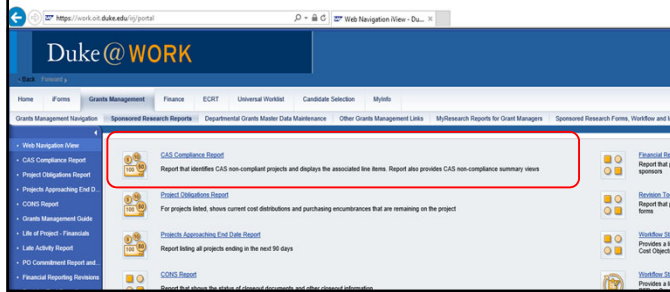
- CAS remediation items pending approvals will NOT be considered as completed CAS remediation actions
  - e.g. waiting on PI to review and approve ReC Form in workflow
- SOM will process the write-off JV for un-remediated CAS items one business day prior to the 12 PM (noon) cutoff for keyed JVs per the 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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CAS Remediation Calendar Fiscal Month	Fiscal Accounting Period/Initial Charge	Department/Center/Institute Time Period to Submit CAS Rebudget Request/Remove Charge	RCC Monitoring Report (Close of Period)	Corrective Action by Management Center	SOM-RA Preaward JV Write-off as of Fiscal Month
July	01	Period 02 - Period 04	05	06	07
August	02	Period 03 - Period 05	06	07	08
September	03	Period 04 - Period 06	07	08	09
October	04	Period 05 - Period 07	08	09	10
November	05	Period 06 - Period 08	09	10	11
December	06	Period 07 - Period 09	10	11	12
January	07	Period 08 - Period 10	11	12	01
February	08	Period 09 - Period 11	12	01	02
March	09	Period 10 - Period 12	01	02	03
April	10	Period 11 - Period 01	02	03	04
May	11	Period 12 - Period 02	03	04	05
June	12	Period 01 - Period 03	04	05	06

CAS Remediation Period FM 03/2019 (JUL 2018)  
JV Cutoff for FM 07/2019 (JAN 2019) 02/05/19 (Tues)  
JV Write-off 02/04/19 (Mon)

## Avoid CAS Remediation Write-offs and the RCC CAS Remediation Report by Reviewing the CAS Compliance Report




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## 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 GL Groupings located under [https://finance.duke.edu/research/documents/CAS\\_GLGroups.pdf](https://finance.duke.edu/research/documents/CAS_GLGroups.pdf)

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## 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](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](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](mailto:christina.jackson@duke.edu)  
 (919) 684-0577

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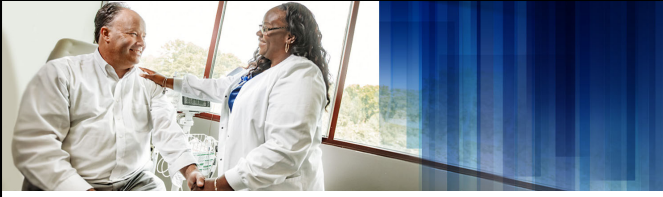
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Duke (F&A Waiver Revision) and NIH

## CLINICAL TRIAL DEFINITION

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### 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

<https://finance.duke.edu/research/documents/secured/FAWaiverGuidelines.pdf>

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### 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.

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## 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 a clinical trial by Duke’s definition, but not NIH’s

Questions: [ORC\\_Industry\\_Contracts@duke.edu](mailto:ORC_Industry_Contracts@duke.edu)

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SPS - Proposals

Search Main Personnel Facilities Budget Protocols Studies Validate All

IRB IACUC IBC

Human Subjects

\* Will human subjects be used at any time during the project period, either at Duke or at any participating subrecipient and/or site location? ☒ Yes ☐ No

If Yes to Human Subjects

Clinical Trial Questions

\* Will human participants be involved at any performance site? ☒ Yes ☐ No

\* Will any participants be prospectively assigned to an intervention? ☒ Yes ☐ No

\* Is any study designed to evaluate the effect of the intervention on any participants? ☒ Yes ☐ No

\* Is the effect that will be evaluated a health-related biomedical or behavioral outcome? ☒ Yes ☐ No

This research does not meet the definition of a Clinical Trial.

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## 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.

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## 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?

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SPS - Proposals

Search Main Personnel Facilities Budget Protocols Studies Validate All

IRB IACUC IBC

Human Subjects

\* Will human subjects be used at any time during the project period, either at Duke or at any participating subrecipient and/or site location? ☒ Yes ☐ No

If Yes to Human Subjects

Clinical Trial Questions

\* Will human participants be involved at any performance site? ☒ Yes ☐ No

\* Will any participants be prospectively assigned to an intervention? ☒ Yes ☐ No

\* Is any study designed to evaluate the effect of the intervention on any participants? ☒ Yes ☐ No

\* Is the effect that will be evaluated a health-related biomedical or behavioral outcome? ☒ Yes ☐ No

\* Does this research involve more than one study? ☐ Yes ☒ No

This research meets the definition of a Clinical Trial.

\* Is this an NIH-defined Phase III Clinical Trial? ☐ Yes ☒ No

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## NIH Definition of Clinical Trial

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

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ERRORS

SPS REMINDERS

SPS

Michael Dickman (m247)


Welcome to SPS


Proposals - Create/edit proposals, access info

Awards - Create/edit awards (ORACRS), view award information

Utilities - Edit select proposal fields (e.g., protocol, naming org, agency due date, WBSEs)

Standard Reference - Edit standardized data (i.e., limited person data, SP/SAP sponsor mappings)





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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 1<sup>st</sup>, 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 1<sup>st</sup>, 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



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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


This proposal contains errors and cannot be routed until they have been resolved

Errors

Studies

Study 1

- Study 1 - Protocol Synopsis - Has FDA-Regulated Intervention: Must be Yes
- Study 1 - Protocol Synopsis - Outcome Measures: At least one must be defined
- Study 1 - Protocol Synopsis - Study Design - Allocation Type: Must be Randomized
- Study 1 - Protocol Synopsis - Study Design - Intervention Model: Must be Clinical
- Study 1 - Protocol Synopsis - Study Design - Interventions: At least one must be defined
- Study 1 - Protocol Synopsis - Study Design - NIH-Defined Phase: Must be defined for Clinical Trials
- Study 1 - Protocol Synopsis - Study Design - Primary Purpose: Must be defined
- Study 1 - Protocol Synopsis - Study Design - Study Phase: Must be defined
- Study 1 - Protocol Synopsis - Study Design - Will Study Use Maximal Effort: Must be Yes
- Study 1 - Protocol Synopsis - Subject Participation Duration: Must be defined



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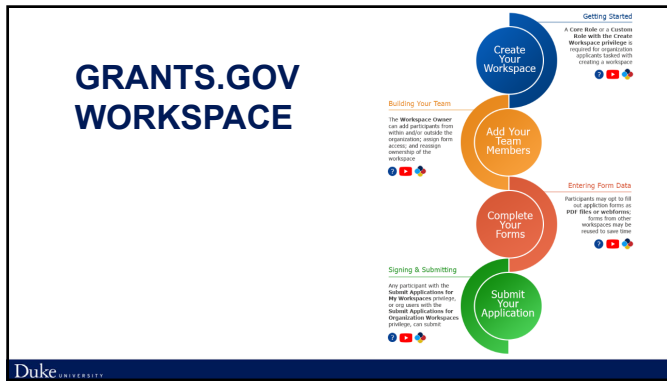
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## Grants.gov Open During Shutdown



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.

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## Electronic Submission Tools

In order of preference:

- 1) GRANTS.DUKE
  - Most NIH FOAs
  - Other federal agencies such as DOD, DOE, ONR
- 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

Grants.Duke S2S Proposal Preparation S2S Tracking Status

Application Submission System & Interface for Submission Tracking (ASSIST) sponsored by the National Institutes of Health

GRANTS.GOV™

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## 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

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### 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



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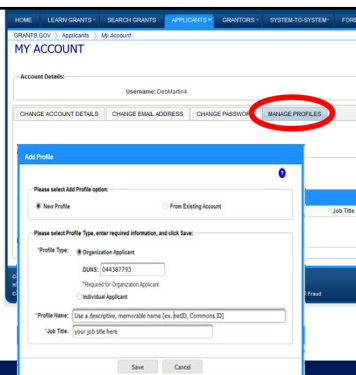
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### STEP 2: ADD ORGANIZATION APPLICANT PROFILE

- 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



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### STEP 3: CONFIRM PROFILE AND ROLE

- ORA receives notification via automatic email
- ORA rep confirms profile and assigns Workspace Manager role

Subject line: New Grants.gov Applicant Sally R. User may need roles - Action may be Required  
The following person added himself/herself to your Organization in Grants.gov.

Name: Sally R. User  
Username: Sally.R.User  
Job Title: Grant Manager  
Email: Sally.R.User@duke.edu  
Phone: 9196840000  
DUNS: 0443877930000

Various features in Grants.gov require authorization, such as submitting grant applications, managing Workspaces, etc. To provide this authorization, you can assign this person one or more roles by logging in to Grants.gov and selecting Manage Applicants.

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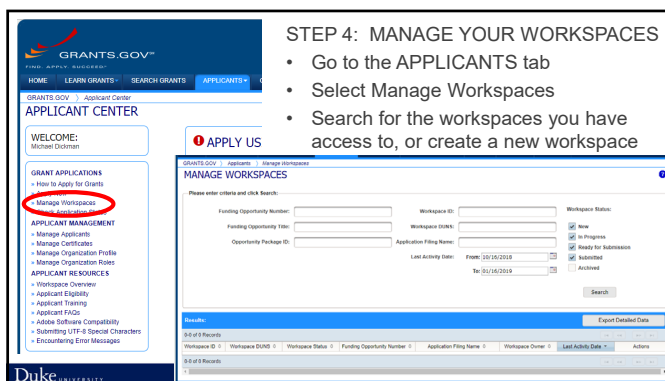
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### STEP 4: MANAGE YOUR WORKSPACES

- Go to the APPLICANTS tab
- Select Manage Workspaces
- Search for the workspaces you have access to, or create a new workspace



The screenshot shows the Grants.gov Applicant Center interface. On the left, the 'APPLICANT CENTER' sidebar includes a 'GRANT APPLICATIONS' section with a red circle around 'Manage Workspaces'. The main content area is titled 'MANAGE WORKSPACES' and contains a search form with fields for 'Funding Opportunity Number', 'Workspace ID', 'Funding Opportunity Title', 'Application Filing Name', and 'Last Activity Date'. There are also checkboxes for 'New', 'In Progress', 'Ready for Submission', 'Submitted', and 'Archived'. A 'Search' button is at the bottom of the form. Below the form, there is a table with columns for 'Workspace ID', 'Workspace Name', 'Funding Opportunity Number', 'Application Filing Name', 'Workspace Owner', and 'Last Activity Date'. The table shows 0 of 0 records.

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### 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



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**Resources to Help You Set Up Your Workspace**

Reference the following content when planning out your internal application workflow:

**Workspace Process Timeline**

This infographic provides an overview of decision points applicants face when applying with Workspace.

[VIEW INTERACTIVE GRAPHIC >](#)

**Workspace Roles and Access**

Role	Workspace Project	Workspace Role	Workspace Design	Workspace Review	Workspace Publish
Workspace Project	✓	✓	✓	✓	✓
Workspace Role	✓	✓	✓	✓	✓
Workspace Design	✓	✓	✓	✓	✓
Workspace Review	✓	✓	✓	✓	✓
Workspace Publish	✓	✓	✓	✓	✓

This resource explains the roles, privileges and access levels that can be used when completing a grant application.

[VIEW INFOGRAPHIC >](#)

<https://www.grants.gov/web/grants/applicants/workspace-overview.html>

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## NIH UPDATE

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## NIH Fiscal Policies for FY19

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-031.html>

- 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.

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## 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.

Foreign travel for consultation is not considered a foreign component.

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

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### 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.
- Describe special resources or characteristics of the research project (e.g., human subjects, animals, disease equipment, and techniques), including the reasons why the facilities or other aspects of the proposed project are more appropriate than a domestic setting.
- Begin the section with a heading indicating "Foreign Justification" and name the file "Foreign Justification."

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### 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

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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

Grants.Duke

S2S Proposal Preparation

S2S Tracking Status

Admin

Other Attachments (if applicable)

Cover Letter

View

Attach

Item 12 - Other Attachment 1

View

Attach

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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](#))

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PHS Assignment Requests

- NIH is added PHS assignment request form effective May 2016 <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-008.html>
- 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

Other Attachments (if applicable)

PHS Assignment Requests (optional)

EditView

Cover Letter

View

Attach

Item 12 - Other Attachment 1

View

Attach

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**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.

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**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.

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**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

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## 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.

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

Career Level	Years of Experience	Stipend for FY 2019	Monthly Stipend
Predoctoral	All	\$24,816	\$2,068
Postdoctoral			
	0	\$50,004	\$ 4,167
	1	\$50,376	\$ 4,198
	2	\$50,760	\$ 4,230
	3	\$52,896	\$ 4,408
	4	\$54,756	\$ 4,563
	5	\$56,880	\$ 4,740
	6	\$59,100	\$ 4,925
	7 or More	\$61,308	\$ 5,109

Career Level	Stipend for FY 2019	Monthly Stipend
Freshmen/Sophomores	\$9,360	\$780
Juniors/Seniors	\$13,104	\$1,092

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## 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 ...*

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## 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?

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## Include the Fees!

**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-18-673)**  
 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.

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## Summary of Significant Changes to the NIH GPS October 2018

NOT-OD-19-021



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Home

Important NIH Info

Search this site

Home

Summary

Updates NEW

NCE Request Process

Carryover Request Process

Detailed Budget Requirements

Subrecipient Process

Tools and Resources

Frequently Asked Questions

Memos and Communications

Research Process

Assessment Committee (RPAC)

Town Hall Series NEW

Approved Corrective Action Items NEW

**Duke University NIH Grant Administration Guidance**

In response to recent changes in requirements from the NIH, several new efforts to enhance proposal development, submission, financial oversight, and research integrity have been introduced to further strengthen Duke's research infrastructure and administration. As a reminder, the following is now required for all Duke NIH awards:

- **Detailed budgets** - for all modular applications (at Just-in-Time) and RPPRs effective April 1
- **Carryover requests** - prior NIH approval for all effective May 15
- **No cost extension requests** - prior NIH approval for all for existing grants effective April 1

This website provides information and guidance necessary for faculty and grant managers across Duke to comply with NIH's requirements. We will continue to keep you updated via this website as we learn more from NIH. [See Updates](#) for latest information.

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**PROFESSIONAL DEVELOPMENT AND TRAINING UPDATE**

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**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

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## Pizza and Proposals

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



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## 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




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## 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

Anonymize Response, Do NOT record any personal information and remove panel association (not recommended).




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