Office Hours Overview

I. Welcome

II. Sponsor Policy Updates

    I. Research Security

    II. NIH Resubmission Markup Policy

III. Data Use and Materials Transfer Agreement Routing

IV. Open Q&A with panel of ORA Staff

National Security Presidential Memo (NSPM-33)

- Issued by White House in Jan. 2021

- Implementation Guidance issued by Office of Science and Technology Policy (OSTP) Jan. 2022

- Directs agencies/departments to focus on:
  - Disclosure Requirements and Standardization
  - Digital Persistent Identifiers
  - Consequences for Violation of Disclosure Requirements
  - Information Sharing
  - Research Security Programs (institutions >$50M in annual funding)

Disclosure Requirements and Standardization

- Standardization of requirements, forms and formats ([forms](#) out now)
- Collection of information related to financial conflicts of interest within R&D award application processes
- Exclusions from disclosure requirements within R&D award application processes
- Requirements for disclosing participation in foreign programs
- Requirements to update disclosures after award
- Institutional certifications

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Research Security Programs Standards- DRAFT

- Institutional certification of program- self certification through SAM

- Foreign Travel Security

- Research Security Training

- Cybersecurity

- Export Control Training

Resource:

COGR Quick Reference Table of Research Security Requirements

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DOD Funding Decision Matrix

Mitigation Plans

- Triggered by funding applications that indicate funding/support to a covered individual from CHIPS Act countries of concern (Russia, Iran, North Korea, China), or OFAC Sanctioned countries (Venezuela, Cuba, Syria)
- Includes in-kind support (funding directly to a visitor from country of concern)

- Flows from a June, 2023 DoD publication titled [Countering Unwanted Foreign Influence in Department-Funded Research at Institutions of Higher Education](#)
  - Includes DOD's Decision Matrix to Inform Fundamental Research Proposal Mitigation Decisions table

ORA Support

- We will be following guidance developed by the Office of General Counsel
- ORA Grants Team will assist faculty in meeting this requirement as part of the JIT process and/or when foreign addendum forms are submitted for our review

For discussion: *How can ORA best educate faculty and research staff on this topic?*

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Changes to NIH Resubmission Policy

- Per NIH Notice NOT-OD-24-061, effective May 25, 2024, NIH will no longer allow the use of markups (highlighting, bracketing, etc.) to indicate changes in resubmission applications. Changes must only be outlined in the Introduction, through a summary of substantial additions, deletions and changes to the application—without markups. It must also include a response to weaknesses raised in the Summary Statement.

> This Notice informs the applicant community that, effective May 25, 2024, this guidance replaces previous guidance on marking changes in Resubmission applications. The use of markups such as bracketing, indenting, highlighting, bolding, italicizing, underlining, margin lines, change in typography, font, or font color, or any other type of markup should not be used to identify changes in Resubmission applications.

- NIH Guidance on Formatting Attachments
    - Marking Up Attachments
- NIH Resubmission FAQs
- Application Guide/How to Apply
- Standard Due Dates

Changes to NIH Resubmission Policy

Activity Codes	Program Description	Cycle I Due Date	Cycle II Due Date
P Series *All - new, renewal, resubmission, revisions*	**Program Project Grants and Center Grants** NOTE: Applicants should check with the relevant Institute or Center (IC), since some do not accept P series applications for all three receipt/review/award cycles.	January 25	May 25
R18, U18 R25 *All - new, renewal, resubmission, revision*	**Research Demonstration** **Education Projects**	January 25	May 25
T Series D Series *All - new, renewal, resubmission, revision*	***Institutional* National Research** **Service Awards** **Other Training Grants** NOTE: Applicants should check with the relevant Institute or Center (IC), since some do not accept T series applications for all three receipt/review/award cycles.	January 25	May 25
C06/UC6 *All - new, renewal, resubmission, revision*	**Construction Grants**	January 25	May 25
G07, G08, G11, G12, G13, G20, R24, S06, S11, S21, S22, SC1, SC2, SC3, UG1, U10, U19, U24, U2C, U41, U42, U45, U54, U56 *All - new, renewal, resubmission, revision*	**Other Activity Codes**	January 25	May 25

Data Use Agreement (DUA) Routing

o Data Use Agreements do not include funding, but may include <u>nominal costs</u> to cover the transfer of the data. DUA requests should be submitted to ORA for review via the <u>DUA Request Form</u>. No Fibi record is needed.

   o PDF versions of the DUA Qualtrics form are available for reference on the <u>ORA website</u>, but all DUA requests must be submitted in Qualtrics.
   o There are three versions of the PDF forms: <u>incoming data</u>, <u>outgoing data</u>, and a <u>combination of both incoming & outgoing</u>

o Funded agreements that include Data Use language should be submitted to ORA as a new contract (Fibi PD record) via the <u>Fibi</u> routing system

o Outgoing DUA requests that involve JHU sending human subjects data to a <u>commercial entity</u> will be triaged to and reviewed by the CRC office.

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Materials Transfer Agreement (MTA) Routing

Office of Research Administration (ORA)
- Collaborations, human biospecimens, Protected Health Information (PHI)
  - Collaboration: performance of same project, creating deliverable, joint publication, etc.
  - Outbound human biospecimen MTAs will require the submission of a [Biospecimen Transfer Information Sheet](#) to the JHM IRB (more on this process [here](#))
- Fibi Service Request record required

Clinical Research Contracting (CRC)
- IRB approved study involving a commercial entity
  - Outbound human biospecimen MTAs will require the submission of a [Biospecimen Transfer Information Sheet](#) to the JHM IRB
- Fibi Service Request record required

Johns Hopkins Technology Ventures (JHTV)
- "One-way" transfers not involving an IRB – JHU PI is not involved in the provider or recipient's study
- MTA Intake Forms: [JHU receiving material](#) and [JHU sending material](#)

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Q&A Panelists

ORA Panelists:

- Tom Burns, Associate Dean for Research Affairs

- Daryl Carson, Associate Director (Contracts)

- Mike Harmon, Assistant Director (Contracts)

- Rhanota Edwards, Assistant Director (Outgoing Subawards)

- Arlette Langer, Sponsored Agreement Manager (Contract Specialists)

- Amy Rost, Sr. Grants Associate (Grants)

- Jessica Atlass Roscoe, Sr. Operations Manager

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