UNIVERSITY of WASHINGTON

MRAM

January MRAM Q&A

Greetings Colleagues,

<u>Meeting materials</u> are available for your review along with a list of links shared during the session. Q&A from our session are included here for reference and will be available with the other meeting materials shortly.

Within a week or so following every MRAM, an email like this one typically goes out with Q&A from the session and a link to the meeting materials.

- Diversity in Clinical Trials
- OSP Update
- <u>NIH Controlled-Access Genomic Data & NIST SP 800-171</u>
- Research Security Update: Malign Foreign Talent Recruitment Programs Prohibition & Statement

Diversity in Clinical Trials

Q: So these regulations are only for new trials, not ongoing trials?

A: The UW Diversity in Clinical Trials policy only applies to new clinical trials that submit to HSD on or after January 1, 2026, for either UW IRB review or requesting authorization to use an external IRB for review. More information is available on the <u>UW Human Subjects</u> <u>Division Diversity and Clinical Trials</u> webpage. However, researchers should consider these requirements now in the context of their study design and budget planning to ensure they have sufficient resources to meet the new requirements when the policy goes into effect.

OSP Update

Q1: Is there written guidance we can send corporate and other sponsors regarding Intellectual Property (IP) right requirements?

A1: Yes, we recommend these two resources: <u>Agreement Considerations and Principles</u>, which covers several areas, including IP. As well, the University's <u>GIM 40 policy on</u> <u>Disposition of UW Intellectual Property in Sponsored Program Agreements</u> which covers UW's position on IP in depth.

Q2: Can you share how long the temporary positions will be employed?

A2: The two Program Coordinator positions are one year. The two Subaward Administrator positions are 18 months. We are assessing longer term needs.

Q3: Is there any summary available of the most common reasons ASR/MODs are returned?

A3: ASR/MOD Reasons for Returns from OSP:

- 56% Incomplete: Returns to resolve missing or unclear information, clarifications on submission type, or requests for additional documentation.
- 22% Sponsor Requirements: Non-compliance with sponsor guidelines.
- 15% Previous Comment not resolved: Unresolved issues flagged in a prior comment were not attended to; general reminders to review prior feedback.
- 7% SAGE Budget not aligning with action: Incorrect or missing project end dates, timeline misalignments in budget submissions, missing budget documents, errors in budget calculations.

Q4 : Wondering if there is a list or map for subaward modifications that outlines the UW internal procedures for getting amendments fully executed? To clarify, I mean behind the scenes tasks like routing a change order through Procurement, etc. That way we know where modifications are is in the process.

A4: Since much of the work OSP is doing is outside of systems, being handled via email with our subrecipients, there is not a comprehensive map to follow a particular subaward modification. However, our administrator generally copies the department contact on emails with the subrecipient for visibility. Once the PO has been created or amended, the Grant Manager would see it in Workday. Our <u>Subawards Checklist Job Aid</u> has a high level description of the subaward modification process.

Q5: For ASR/MODs, what is a target steady state number of days in OSP? As well, for Subs, what is the target steady state number of days that a request is "in OSP" status, and then "OSP Assigned" status?

A5: Unilateral federal awards and federal pass-through typically move through the process

faster, and once we have returned to a target steady state, typically can be a two week turnaround. This is because they usually do not involve any negotiation. Having said that, there are reasons we may not be able to process a federal award/federal pass-through award that quickly, such as extremely high volumes overall, compliance holds, we are waiting on the sponsor to confirm a piece of information, we are waiting on budget detail from a department, or if a bilateral award we may be waiting on signature. For non-federal ASRs/MODs, there is a lot of variation depending on the sponsor type, terms of the award, or action involved. For subawards, prior to Workday implementation, our goal was to fully assign all subaward actions (that were complete and correct) twice a week. That was not always possible, but the most a complete action would take for assignment was about 2 weeks.(For reference, as of 1/10/25, the oldest "Last in OSP" date for subaward actions was 9/20/24.) After assignment, the subaward or amendment was generally issued within another week. We would hope to get back to that state. However, with the additional tasks that OSP now has related to subawards, we do not know yet if that will be entirely possible.

Q6: We have a time sensitive funding situation with a corporate sponsor. What should we tell them about how long the review process will take?

A6: Please explain the time sensitive situation within the SAGE item. This alerts OSP. The review process will depend on the agreement itself and the nature of the project. Once we have those details we can better assess. See <u>Urgent OSP Requests: Award Setup</u>, <u>Modifications, Subawards</u> for more information.

Q7: Is there a preferred length of time before campus follows up on emails to OSP that go unanswered for some time? I hate to annoy or issue these as urgent, but I'm getting the questions from PIs on my end as well and am trying to manage their expectations, understanding the backlogs. OSP Help often moves them forward, but then it's radio silence for a while and it's hard to know what to do.

A7: Please review guidance <u>Urgent OSP Requests: Award Setup, Modifications,</u> <u>Subawards</u>. If you have not received a timely response and there is no action needed on your part (i.e. item is returned to you), please notify the appropriate manager as listed on that webpage. If you want to understand backlogs, please see our week over week report on <u>OSP Volume: Awards, Modifications, and Subawards</u>.

Q8: When waiting for an ASR to be set up, can we set up an advanced budget? At one point, I believe we were asked not to, but curious if that has changed?A8: Yes, you should be able to set up an Advance. Please review guidance from <u>GCA on</u> Advance Awards.

NIH Controlled-Access Genomic Data & NIST SP 800-171

Q: As NIST SP 800-171 applies to CUI beyond just controlled-access human genomic data, will projects using CUI but *not* genomic data also have access to the new compliant IT environment being set up?

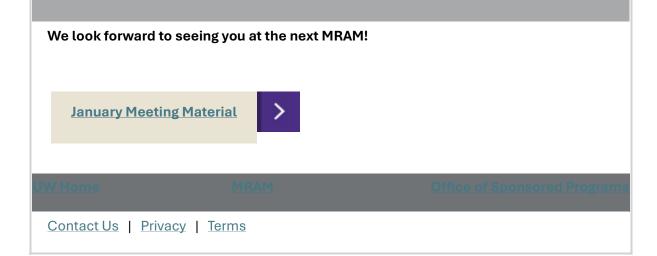
A: Yes. This third-party cloud solution will meet <u>NIST SP 800-171 requirements</u>. The University is looking at making this available for projects at UW that involve access/use of Controlled Unclassified Information (CUI). However, we are phasing this in, and expansion for all CUI will require changes to the contract with the third-party provider. Office of Research and UWIT will continue to provide updates on this over the year.

Research Security Update - Malign Foreign Talent Recruitment Programs Prohibition & Statement

Q : Will the Financial Conflict of Interest (FCOI) and Malign Foreign Talent Recruitment Program (MFTRP) disclosures be exclusive of each other? So if a PI completes the FCOI but doesn't complete the MFTRP will the eGC1 not be able to be submitted as Ready to Submit (RTS)?

A : An investigator will not be able to complete their FIDS disclosure unless the MFTRP certification is completed. In other words, the proposal will not be able to be marked Ready to Submit (RTS) unless both the MFTRP certification and SFI disclosures have been made.

It is best to ensure researchers who potentially will be involved in federally funded research understand the limitation early. If they have any concern or doubt as to whether something they've been offered or are receiving (e.g. funding, appointment, lab space provided by a country of concern) is a MFTRP, to reach out to research@uw.edu ahead of time.



This email was sent to <u>stonewil@uw.edu</u> Unsubscribe or change your email preferences