RCRA Newsletter

Research Compliance News from your Trusted Partners

May 2025, Issue 109

Human Research Participant Payments

Emory's Finance Division has implemented changes to the ClinCard system to ensure accurate reporting of participant information. Additionally, alternative methods of payment over $25 now require approval.

Updates to the ClinCard System:

- Entering a participant for ClinCard payment will trigger the system to perform a validation of the entered SSN or TIN against an IRS database.
- Validation of SSN or TIN will be performed the first time any new participant is added to ClinCard at a rate of $1 per validation
- The system will provide a warning message to the user if a participant's information can't be validated, or no information is entered.
- If proceeding with invalid or incomplete information, the system will assume that the user elected to move forward because the participant is a non-US Resident without a TIN or SSN and will withhold from the payment the participant's tax liability based on the non-US Resident IRS rate of 30%, which will be submitted to the IRS on the participant's behalf.

Questions? Contact:

- General ClinCard inquiries: emoryclincards@emory.edu.
- Tax-related questions: Susan Clark at sclar38@emory.edu.

Budget adjustment requests or other subject payment options:

- For any industry-contracted studies, contact WISC at wisctrials@emory.edu.
- For federally funded studies, contact your School and Unit RAS.
- For all others, contact OCR at ocr_preaward@emory.edu.

Research Security Updates

NIH Public Access Policy - Effective Date Accelerated

On April 30, NIH released an update to its guidance on the NIH Public Access policy for implementation of the 2022 Nelson Memorandum, accelerating its effective date to July 1, 2025. All other elements of the policy remain unchanged.

Summary of Changes:
The biggest difference between the new NIH Public Access Policy and the current one that's been in effect since 2008 (updated in 2013) is that the new one requires immediate public access to journal articles reporting on the results of NIH-funded research (the current policy allows a 12-month post-publication embargo). Delayed access in the form of embargoes is disallowed; public access must coincide with the formal publication of the article. Researchers can comply with the public access requirement by depositing either their final peer-reviewed manuscript or their final published article in PubMed Central. Most major publishers will deposit articles on behalf of authors. You can learn more about this process at this PubMed Central information page for authors.

View full RCRA page on the NIH Public Access Policy

DOD Requirements Updated

In May 2025 the **Department of Defense (DoD) updated its decision matrix** for countering unwanted foreign influence as part of a Risk-Based Security Reviews policy. The policy identifies 4 risk factors: (1) participation in a Malign Foreign Talent Recruitment Program (MFTRP) or co-authorship with a participant in an MFTRP; (2) funding sources from foreign countries of concern; (3) patent applications or patents filed outside the US; and (4) affiliation with an entity on US restricted entity lists

DOE has also updated the requirement for research security training within 12 months prior to submitting a proposal.

NIH Foreign Subaward Policy

NIH is establishing a new award structure that will prohibit foreign subawards from being nested under the parent grant. This new award structure will include a prime with independent awards that are linked to the prime that will allow NIH to track the project's funds individually, while scientific progress will be reported collectively by the primary institution, under the Research Performance Progress Report. NIH anticipates implementing the new award structure by no later than September 30, 2025, prior to Fiscal Year 2026.

SciENcv Adoption by NIH Postponed

SciENcv adoption by NIH has been postponed until further notice. Information including resources and workshop recordings can be found here.

RCRA Newsletter

Research Compliance News from your Trusted Partners

May 2025, Issue 109

Office of Research Integrity and Compliance (ORIC): Destruction of Controlled Substances is back at Emory!

We're pleased to announce that in March, EHSO launched the Onsite Controlled Substance (CS) Destruction Program - similar to what some may remember as 'Day of Destruction'.

This enhanced program provides a safe, compliant, and convenient way to dispose of expired or unused CS directly in your lab. Streamlined processes, expert oversight, and improved accessibility means better service for you. Here is a quick overview of the process:

To participate, the DEA Registrant must:

1. Enroll in the program using this form - **PI Enrollment Form: Onsite CS Destruction Program**
2. Take the training along with all labs staff participating in the program - **Onsite CS Destruction Training (Course title is Onsite Destruction of Controlled Substances)**

More news from the CS/DD Corner

Federal Funding and Regulatory Updates

The Office of the Senior Vice President for Research (SVPR) continues to monitor the federal fiscal outlook as it relates to research funding closely. The Office of SVPR will share updates and announcements that impact the Emory research ecosystem, specifically grant-seeking activities, proposal preparation, changes to agreements, the review and award-making process, and post-award considerations.

We have an internal website with previous internal communications related to federal changes and agency information we have received, but your official agency website will be the ultimate resource.

Research COI News You Can Use

Annual Management Plan Review

Beginning in July, the Conflict of Interest and Commitment Office (COI/COC) conducts an Annual Review of active conflict of interest (COI) management plans for situations where the Research Conflict of Interest Committee (RCOIC) determines that management is required for an existing conflict. This includes any individual responsible for research design, conduct, or reporting.

Active **COI Management Plan(s)** are reviewed **annually** to verify the information regarding the issued management plan.
As part of this process, the conflicted individual plays a key role in answering questions to update the COI/COC office with pertinent information about the conflict situation. The conflicted individual will receive an **email** with a link to the **COI Annual Management Plan Review Form**.
The COI/COC Office requires you to complete the form accurately and promptly to update your financial interest status and comply with the management plan provisions.

For additional information, visit: COI/COC Disclosure Requirements | Emory University | Atlanta GA

Annual Certification

The deadline to complete this **mandatory requirement was February 28, 2025**. This requirement is a verification report of whether or not you have an outside activity, relationship, or interest with an external organization related to your institutional responsibilities. Please visit our webpage at Annual Certification | Emory University | Atlanta, GA, for more information.

Pre- Approval Requests (PARs)

The COI/COC Office will transition to a new system, "Insight," in August 2025. INSIGHT is a comprehensive application that manages the grant and research funding process. The system will centralize various elements including: IRB approval, contract management, regulatory compliance, study budgeting, and financial management into a single application.

Please review eDisclose and address any pre-approval requests (PARs) in pre-submission or clarifications required. **The COI/COC Office will migrate current submissions into the new system.** Please work with your department liaisons to address outstanding PARs.

Walk-In Wednesday

Please join our COI/COC Office for ***virtual Walk-In Wednesday (WIW)*** sessions on the **4th Wednesday** of each month from 11 a.m. to 12 p.m. COI/COC Office members will happily answer any questions during these sessions and periodically host COI/COC learning sessions. **Join via this link**

RCRA Newsletter

Research Compliance News from your Trusted Partners

May 2025, Issue 109

IACUC Site Inspection Cycle: June 1st, 2025- November 30th, 2025

- **Frequent site inspection findings:**
  - Expired drugs, materials, substances
  - Unlabeled drugs, substances
  - Incomplete logs (cage cards, surgery logs, procedure logs)

- **AAALAC site visit expected early spring 2026 as part of the re-accreditation process.**
  The IACUC office is providing training verification reports associated with each IACUC protocol for researchers to take action in completing pending requirements and annual OHS screening. Additional information can be found on the IACUC SharePoint site.

- Starting May 2025, and in collaboration with the School of Medicine Division of Animal Resources (SOM DAR) team, researchers in the SOM DAR (non-EPC) veterinary unit utilizing species covered by the Animal Welfare Act (ferrets, spiny mice, hamsters, gerbils, guinea pigs, boles, rabbits, and swine) need to review their monthly animal usage and confirm USDA pain categories to prevent last-minute complications during the preparation of the ***Annual Report due to the USDA before December 1st***. This report is submitted by the IACUC office on behalf of the Institutional Official.

Export Control Office Updates

Transition to Export Control & Research Cybersecurity Office
We are pleased to announce the expansion of our Export Control Office to include Export Control & Research Cybersecurity. This expansion aims to provide comprehensive support and oversight for Controlled Unclassified Information (CUI) and Cybersecurity Maturity Model Certification (CMMC) in research projects, in collaboration with Emory OIT/Information Security teams.

Electronic Export Information (EEI) Filing Requirements
On September 27, 2020, the Bureau of Industry and Security (BIS), Department of Commerce, mandated full compliance with a final rule that expanded EEI filing requirements for exports to China, Russia, and Venezuela. EEI is data that the US Census Bureau and Customs and Border Protection require to be filed before exporting goods from the U.S. to a foreign country.
Generally, EEI filing is required for goods valued at more than $2,500 or those that need a U.S. government export license. This requirement applies equally to items shipped using courier services like FedEx and to items hand-carried by travelers.

EEI filing is now mandatory for all items on the Commerce Control List (CCL) destined for China, Russia, or Venezuela, regardless of the shipment's value. The CCL includes commonly used items such as laptops and cellphones, with no exceptions for items taken to these countries temporarily.
The Export Control Office will file EEI for Emory employees shipping or hand-carrying Emory-issued laptops, cellphones, or other equipment. This applies to travelers taking these items on a short-term basis and to any international shipment valued at or above $2,500 or requiring a U.S. government export license.
Please contact the Export Control Office *at least two days* before travel or shipping with the following information:

- Date of travel or shipping
- Item(s) that will be shipped or hand-carried
- Airport from which the outbound flight will depart
- Address while abroad

Minors Participating in Research Activities

Policy 7.21 Minors Participating in Research Activities at Emory University:

- Defines a Minor as any person who is a minimum of 15 years of age, but who has not attained 18 years of age and who is not enrolled in an Emory University or Oxford College regular catalog course or degree program. For the purposes of this policy, “Minor” should only include rising and current juniors and seniors attending a Georgia high school.
- States that Minors are permitted to enter laboratories or participate in research activities at Emory University only if they are participating in an approved program (hosted by a PI/sponsor who has received pre-approval for the project); and
- Requires PIs/sponsors who will host Minors in their lab complete a Minors Registration Form.

NEW Minors in Research Approval Process:

- The Minors’ Registration form is now available online.
- The PI/sponsor will need the minor’s name and email to begin the form.
- After saving the minor’s information, the minor will receive an email link to complete their portion of the form and to enter their parent’s and school official’s email.
- The parent and school official will receive links to complete their portions of the form.
- The PI will then receive an email notification that the minor, parent, and school official have completed their portions of the form and asking the PI to go in the portal to complete the remaining sections of the form.
- Once the PI completes the form, internal review will be triggered based on applicability (EHSO, research security/export control, and IACUC).
- Once the internal Emory offices have signed off, RCRA will issue final approval. The minor can begin participating in research activities only after RCRA issues approval.