RCRA Newsletter

Research Compliance News from your Trusted Partners

February 2025, Issue 108

NEW: Changes to the ClinCard System

Beginning in January 2025, the Finance Division will implement changes to the ClinCard system to ensure accurate reporting of participant information.

Summary of Changes:

- 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.

NIH SciENcv - Workshops Jan. through May!

Starting in May 2025 investigators *must* use SciENcv to format NIH and NSF key personnel documents.

SciENcv(Science Experts Network Curriculum Vitae) is an application in My NCBI that helps you create and manage documents in support of grant applications with participating agencies. In SciENcv you can document your education, employment, research activities, publications, honors, research grants, and other professional contributions. The adoption of this common researcher profile system for Federal grants is intended to reduce administrative burden for researchers.

Click image for full infographic

We recommend you allow ample time to transition to SciENcv before the mandate. Visit our website for a list of resources including video training and written instructions.
Take advantage of our SciENcv Workshop Series! Join us to learn, discuss, and ask questions about how SciENcv is changing the grant preparation process. Please **view the flyer to register in advance.** There will be a session every month through May.

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.

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Office of Research Integrity and Compliance (ORIC): News and Tips

Have you registered your Georgia Board of Pharmacy or DEA license with ORIC yet?
If not, or if you have not provided your information in the last year, submit your information using these forms:
GBP License
DEA License

Storing drugs? - Check your license!
If you have a Georgia Board of Pharmacy (GBP) or DEA license, make sure your drugs are stored in the location in your license. If you notice a discrepancy, contact us at oric@emory.edu so we can help you!

ORI updated interactive videos "The Lab" and "The Research Clinic"
The Office of Research Integrity (ORI) have updated their interactive videos showing different scenarios in where a research misconduct issue may occur. ORI said that "The Lab and The Research Clinic better reflect current standards of appropriate workplace behavior in research settings." Find the videos below.
The Lab
The Research Clinic

IACUC Semiannual Inspections: December 1, 2024-May 31, 2025

Frequent findings:

- Expired drugs, materials, substances
- Unlabeled drugs, substances
- Incomplete logs (cage cards, surgery logs, procedure logs)

- Investigators are receiving training verification reports for personnel listed in their IACUC protocols. Training requirements are determined according to the animal species and procedures or roles assigned. The goal is to have 100% training compliance before the next AAALAC site accreditation visit early in 2026.

- Transition from eIACUC to Insight
  - Discovery starts in March 2025
  - The IACUC will be asking for software testers
  - Go-live scheduled for Summer of 2026

Minors Participating in Research @ Emory

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.

Current Minors in Research Approval Process:

- The minor cannot begin participating in research activities until Program Effectiveness/RCRA provides final approval.
- Email researchcompliance@emory.edu to obtain the Minors Registration Form.
- PI/sponsor contacts RCRA Program Effectiveness directly or reaches out to their school. The school will forward the PI/sponsor to Program Effectiveness.
- Program Effectiveness provides the PI with the Minors Registration Form and the required trainings.
- Once the sections have been completed by the PI, the minor, the minor's parent/guardian, and the minor's school official, Program Effectiveness reviews the Form for completion and forwards the Form to the other necessary Emory offices.
- Once all of the required trainings and signatures have been completed, Program Effectiveness will provide final approval.

Upcoming Minors in Research Approval Process:

- The Minors' Registration form will be available online through the research portal.
- 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.

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Title IX, Reporting, and Applicability to Research

Title IX is covered under Emory policy 8.2 - Sex and Gender-Based Harassment and Discrimination Policy and prohibits sex and gender-based discrimination in funding, hiring, and participation in federally funded research projects. This promotes inclusive research environments, ensuring that gender bias does not affect peer review, publishing, or grant opportunities.

Institutional Obligations:

- Universities must ensure that research programs do not create or tolerate gender-based discrimination.
- Funding Equity: Compliance offices must monitor and address disparities in grant distribution and research resources.
- Harassment & Retaliation Prevention: Research settings, including labs and fieldwork, must be free from sexual harassment and discrimination.
- Ethical research practices must ensure that study designs do not disproportionately disadvantage or exclude participants based on sex or gender.

Reporting:

To report a Title IX violation, contact any of the following:

- University Title IX Coordinator: nicole.babcock@emory.edu
- Department of Title IX: titleix@emory.edu
- Online reporting form on website

In your report, be sure to include the name of the Complainant (affected party), Respondent (accused party), date of time of incident, and any other details of the incident you can include.

Contact:

For more information, training, FAQs, and other resources, visit Emory's Title IX website

Information on Restricted or Prohibited Party Screening.

Understanding Restricted or Prohibited Party Lists

Restricted or Prohibited Party or Exclusion Lists refer to lists maintained by U.S. federal government agencies. These lists include individuals and entities excluded from receiving federal contracts, subcontracts, and certain types of federal financial and non-financial assistance and benefits. They also encompass lists from federal agencies responsible for export control regulations and trade-related sanctions, identifying persons subject to export restrictions or prohibitions. Engaging in activities or transactions with parties on these lists may be restricted or prohibited altogether.

The Importance of Restricted Party Screening (RPS)

Restricted Party Screening (RPS) is a due diligence process to determine whether parties involved with Emory appear on any restricted or prohibited party list. University activities and transactions that require RPS include financial transactions with external parties; procurement and purchasing; international shipping; international collaborations or engagements, and hosting visitors.

Tools for Screening

Screening against RPLs is essential to ensure Emory does not violate federal regulations by engaging in unauthorized activities with listed entities. Emory uses Descartes Visual Compliance, a cloud-based licensed software, to screen against these lists.

Contact the Export Control Office for Help

contact the Export Control Office (exportcontrol@emory.edu) for:

- Access to Descartes Visual Compliance software
- Training in the use of screening software
- Evaluating screening results
- Guidance on whether an activity or transaction should be subject to screening

Research COI News You Can Use

Deadline Approaching Soon for Annual Certification

The deadline to complete this mandatory requirement is 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 the summer. INSIGHT is a comprehensive application that manages the grant and research funding process.
The system will centralize 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**