



EMORY  
UNIVERSITY

Office of Research  
Administration  
FY21 Annual Report



Robert Nobles, DrPH, MPH, CIP  
Vice President for Research Administration

# Letter from VP for Research Administration

## Dear colleagues,

During another year of significant growth, the Office of Research Administration (ORA) maintained a strong focus on long-term goals of continuous improvement, transparency, and collaboration across the research enterprise.

## Supporting excellence in research and discovery

The University continues to top its personal best in attracting research funding because of our phenomenal faculty, research teams, and support infrastructures. In FY21, Emory attracted research funding of \$894.7 million, an increase of 7.6% as compared to FY20. External funding for research has grown more than 55% over the past five years. COVID-19 research funding remained significant, comprising 12 percent of the year's total research funding, rising by almost one-third over the previous year.

This spectacular growth, particularly in globally-impactful research that includes COVID-19 diagnostics, therapies, and vaccines, underscores the necessity of ORA's work to support our discovery enterprise.

## Navigating through COVID-19

Emory continues to be a leading national powerhouse for basic and applied research, especially as it relates to COVID-19. University researchers tested all three of the COVID-19 vaccines currently in use in the United States. Announced late in 2021, Emory researchers were

also instrumental in discovering Molnupiravir, the antiviral pill marketed by Merck that was found to reduce hospitalization and death in cases of COVID-19. The Emory Rapid Response Team, led by multiple offices within ORA, expedited and completely processed many COVID-19 studies in record time, which allowed researchers the ability to respond to all facets of local, national, and global clinical challenges related to the pandemic. I'm proud that through our responsiveness, the health and safety of the Emory research community remained our primary focus. Our very own Environmental Health and Safety team worked tirelessly to conduct assessments of research spaces while coordinating decontamination activities and verifying regulatory compliance to help ensure a safe work environment. I continue to celebrate the teams who committed themselves to these activities during the pandemic, thus propelling research at Emory.

## Evolving practices and embedding quality

ORA's primary role is to provide collaborative administrative systems and technical expertise to facilitate scholarship, research, and discovery within Emory's research enterprise. Our mission is clearly defined as we strive to increase operational effectiveness and advance engagement with stakeholders.

I'm proud of the achievements we made this year to implement, optimize, and improve processes that support the research enterprise. In an increasingly digital world, we've made investments in our infrastructure to

drive innovation, collaboration, and better support for our stakeholders. Some of our key achievements include:

- Strengthening connections with administrators and faculty through new committees and communications, including triennial meetings. These channels allow us to share strategy and quality improvement initiatives and obtain stakeholder feedback.
- Launching a new research compliance organization, Research Compliance and Regulatory Affairs, to sustain, standardize, and support Emory's growing research portfolio.
- Implementing new SOPs, improving responsiveness, and focusing on the issues identified by researchers as priorities, such as streamlining award set-up and post-award close-out processes.
- Modernizing enterprise software platforms designed for ease of use, data management and security, and increased collaboration. We now provide access to REDcap and OpenSpecimen software to all researchers to facilitate individual research and innovation.

Each of these developments brings ORA a step closer to achieving the objectives of our multi-year Strategic Plan and addressing the recommendations of external consultants. With the support of faculty and the research community, we are bringing down barriers to collaboration and putting in place a framework for future success.

## Looking ahead

It's said that there's nothing permanent, except change. We have onboarded more than 100 new staff into ORA, comprising team members at all levels of our organization. Some of these vacancies created opportunities for

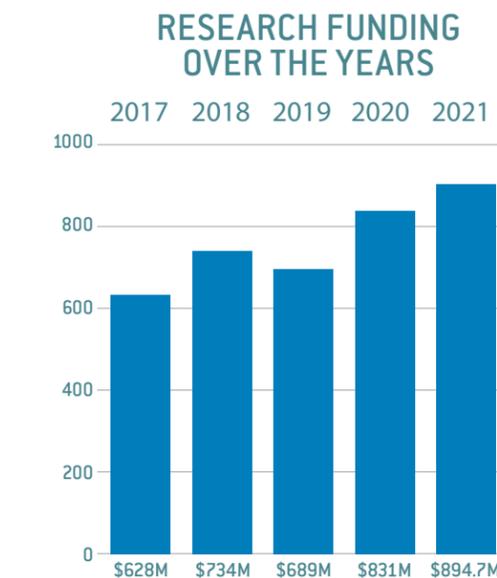
new ORA leaders, including Nicole Tannebaum (COI Director), Maria Davila (Research Integrity and Compliance Director), Esmerelda Meyer (IACUC Director), Lindsay Grasser (RAS Director), Teresa Sussman (Grants Director), Jannette Hannaman-Hayes (Contracts Director), Lisa Wilson (Senior Director), Tonya Jenkins (Associate VP of RAS), and Deepika Bhatia (Associate VP for Research Compliance and Regulatory Affairs). I am committed to ensuring that Emory University is a preferred destination for research administrators. With this in mind, we've undertaken initiatives to review our talent pipeline, enhance recruitment practices, and emphasize staff training and professional development.

My sincere thanks go out to each and every member of the ORA team. They've demonstrated resilience and commitment to serve our research partners during another year of non-stop progress and change.

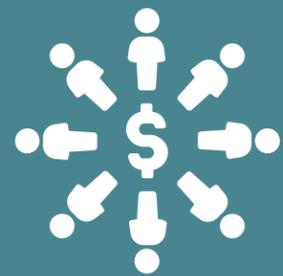
As we enter Fiscal Year 2022, we will relentlessly pursue opportunities to become measurably better in everything we do. Our researchers, faculty members, and partners can be assured of our determination to deliver support that matches the eminence of our researchers. Your voice is more important than ever. I encourage you to be in touch, share your feedback, and engage with us as we continue the journey to strengthening the foundation of research success.

With appreciation for the partnership,

ROBERT NOBLES, DrPH, MPH, CIP  
Vice President for Research Administration



# FY21 Research Funding Highlights



**\$598M**  
Federal  
research  
funding

**\$131M**  
private and  
non-profit  
funding

**\$78M**  
industry-  
sponsored  
funding



**\$847M**  
total funding in  
the Woodruff  
Health Sciences  
Center

**\$526M**  
National  
Institutes of  
Health awards



**EPA**  
**\$1.7M**  
EPA



**\$5M**  
Asst. Secretary  
for Preparedness  
& Response



**\$7M**  
Human  
Resources and  
Srv. Admin

**55%**  
research  
support  
growth over  
past 5 years



**\$8.9M**  
Department  
of Defense



**\$1.4M**  
substance abuse and  
mental health services



**\$5.6M**  
Department of  
Veteran Affairs

**\$526.2M**  
NIH



**\$14.6M**  
National  
Science  
Foundation



**12%**  
increase in  
COVID-19 funding  
over FY20

# FY21 Top Research Funding Awards

School/ College	Award Amount
School of Medicine	\$607M
Rollins School of Public Health	\$127M
Yerkes National Primate Research Center	\$88M
Emory College	\$42M
Nell Hodgson Woodruff School of Nursing	\$20M



**\$894.7M**

total research  
funding awards



**3,669**

successful  
proposals funded,  
a new record

# ORA 2021-2022 Strategic Plan

The Office for Research Administration's primary purpose is to support the Emory research enterprise. By providing excellent service and technical expertise in proposal development and support, sponsored programs administration, and compliance requirements, ORA facilitates research efforts across campus. The ORA responsibilities extend from helping researchers to identify funding opportunities to negotiating contracts with external parties and financial administration for ongoing projects.

## Mission

To provide collaborative administrative support, efficient systems, and technical expertise to facilitate scholarship, research, and discovery within the Emory community from inception through application and dissemination.

## Vision

The Office of Research Administration will support the overarching mission of the research enterprise by executing three distinct areas of focus:

### Building a Robust and Resilient Infrastructure

- Update and communicate research policies and procedures.

- Adopt research information technology solutions.
- Collaborate with schools/units to build the necessary infrastructure for research administration.

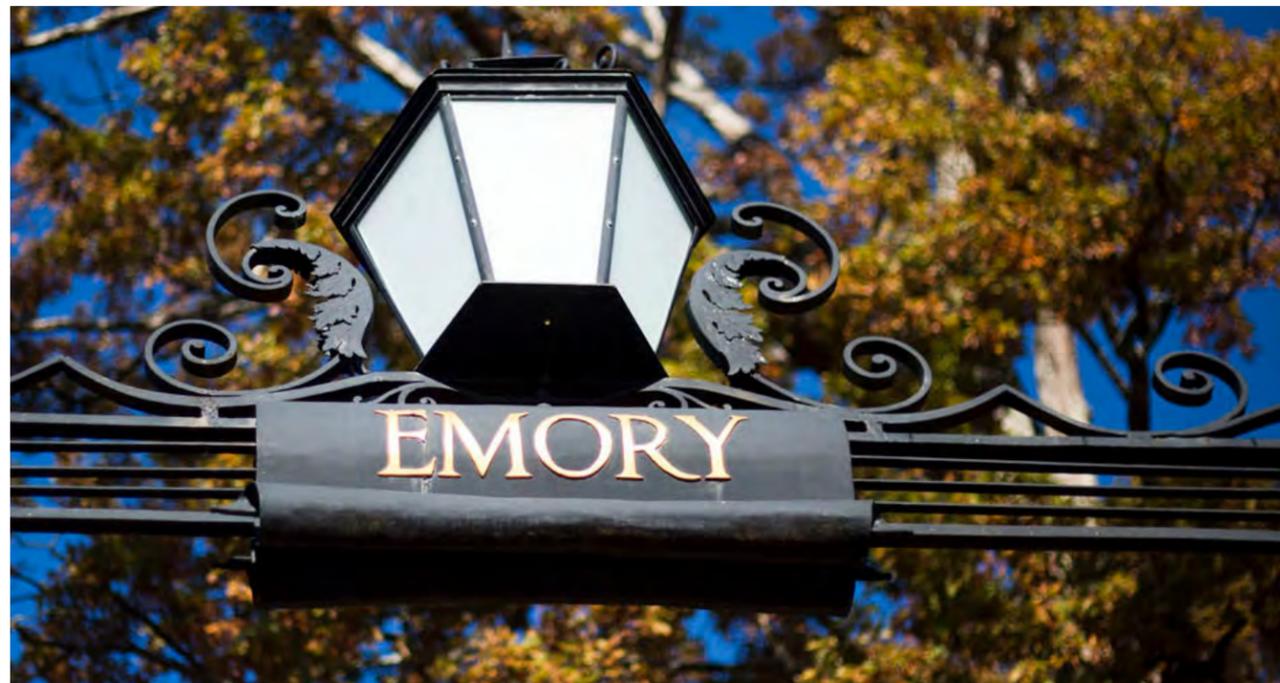
### Pursuing and Reaching Operational Efficiency

- Publish program and operational metrics.
- Undertake scheduled external program reviews.
- Solicit feedback from stakeholders on service through surveys, Faculty Advisory Board, and other methods.
- Implement continuous quality improvement projects led by the ORA Dragon Team.

### Recruiting and Developing a Strong and Supported Workforce

- Publish program and operational metrics.
- Provide a robust orientation, onboarding activities, and continued career development program.
- Initiative the One-ORA enterprise enhancing career ladders and movement across offices.

Additionally, everything we do will be underpinned by collaboration, transparency, and communication.





# Environmental Health and Safety Office

The Environmental Health and Safety Office (EHSO) engages the Emory community in managing environmental, health, and safety risks, reducing workplace injuries and illnesses, and reducing environmental impact by delivering professional value-added services and solutions that aid and assist the community.

## Achievements

### Risk Reduction through Design

As an active leading member of the Laboratory Design and Construction Committee, EHSO provided ten laboratory design reviews recommending high-performance, cost-effective controls across the building lifecycle.

### Continuous Improvement

Began implementation of the enterprise data management system, EHS-Assist. This will serve as an enterprise software solution to increase efficiencies, integrate data, and consolidate systems to improve data management.

Improved radiation human-use protocol approval time by 29.8% from 25.96 days to 18.23 days.

Continued the implementation of Radimetrics, a secure radiation dose management platform, to satisfy the Joint Commission Standards on dose reporting and protocol management for Emory's radiation-producing machines.

To meet increasing demand for "fit tests" for respirators for staff and students, EHSO implemented process improvements in scheduling, creating on-demand booking system, and purchased quantitative fit test machines, significantly reducing the failure rate.

### External Regulatory Inspection Preparation

EHSO worked extensively with Emory's 13 underground storage tanks (UST) owners to ensure they met the requirements of new regulations. Four of the USTs inspected by the Georgia Environmental Protection Division in FY21 fully passed their inspection, receiving Notices of Compliance.

The Center for Disease Control (CDC) conducted five import permit facility inspections related to research using SARS CoV2 strains. These permits are linked to over \$50 million in research funding. To assist researchers with these inspections, EHSO invested 100 hours of preparatory time in assisting researchers with these inspections.

EHSO initiated a review and compliance audit of air permits for all Emory locations as part of the Clean Air Act. Prompt corrective actions were initiated to guide facilities on data collection and the correct submittal process to the state; and permit application guidance for at least one facility, resulting in a successful inspection with no findings.

## 2022 GOALS

- Develop a comprehensive Occupational Medicine Program that effectively addresses the institution's needs.
- Align information technologies by implementing an enterprise EHS software solution that will integrate all programs and provide a single interface for use by EHSO personnel and stakeholders, in which common data collection, tracking, and reporting can be achieved.
- Develop engaging, interactive, and stakeholder-specific training.
- Standardize core processes across EHS units and committees.
- Establish a High Hazard Chemical Committee.
- Revise the Inspection Programs by reevaluating the self-inspection process and refining the risk-based protocol based on the activities that occur within the space.



## EHSO by the Numbers



**435,151 GALS**

FUEL STORAGE OVERSIGHT



**6.3**

MILLION LBS Tier II chemicals inventoried



**1,807**

RESPIRATOR FIT TESTS

**367,301 LBS**

HAZARDOUS WASTE 103,667 lbs from research laboratories



**2,752**

INSPECTIONS

92% compliance rate for research

**166**

RSC HUMAN-USE PROTOCOLS



**1,213**

IBC/RHSC PROTOCOLS



**392**

CHEMICALS IN ANIMALS PROTOCOLS



**11,255**

TRAINING ENGAGEMENTS

98% compliance rate for research

# Institutional Review Board

The IRB facilitates ethical and compliant human subjects research. Along with supporting the University's ethics review committee, they are the central component of Emory's multi-tiered Human Research Protection Program. The IRB maintains a toolbox of documents designed to aid researchers in preparing submissions and project implementation.

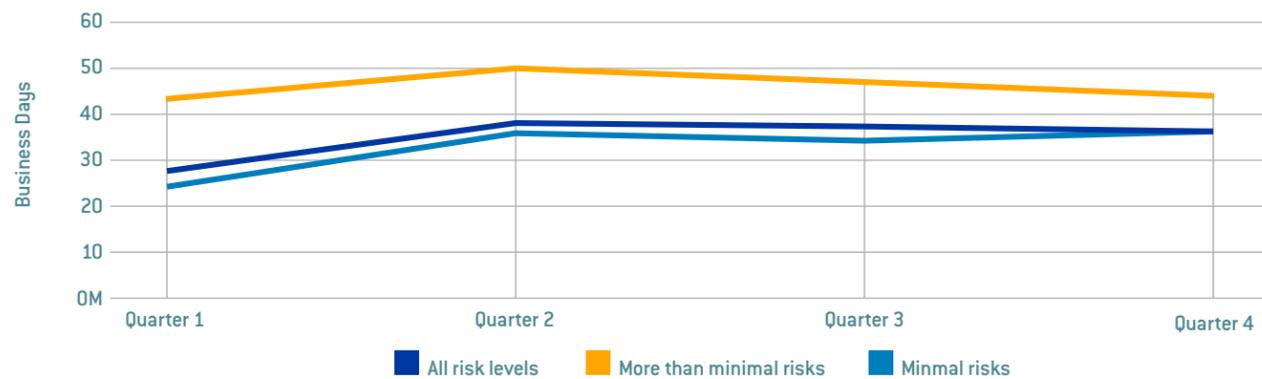
## Achievements

Despite staffing issues and other challenges, the IRB took on the role of single IRB (sIRB) for several new Emory-led multisite studies. Team members met intensively with study teams and developed new procedures for review of sIRB studies and collecting and disseminating study documents.

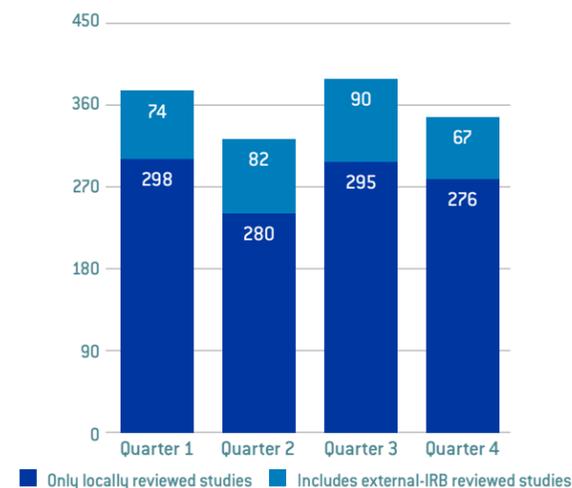
As a partner in the Rapid Response Team, the IRB helped quickly move through 10 Rapid Response protocols involving COVID-19 research.

The IRB onboarded seven new team members as most of our staff became fully-remote for the foreseeable future, increasing employee satisfaction.

FY21 APPROVAL TIMEFRAME NEW STUDIES



FY21 NEW STUDIES SUBMISSIONS



## 2022 GOALS

- Meet the needs of lead PI's for multisite, federally-funded studies that require single IRB review, as we rebuild a reliance team.
- The IRB (with legal and compliance partners) will help researchers safely navigate the international data protection laws that are growing in number.
- Collaborating with IT's implementation of EPIC and OnCore to include IRB approval status, streamline recruitment, and give input on data confidentiality considerations.





# Office for Clinical Research

The Office for Clinical Research (OCR) contributes to many operational aspects of conducting clinical research at Emory. Their roles include research staff trainings, clinical trial invoicing, pre-award activities, and maintenance of updated study data in a variety of internal and external systems. In these workstreams, they cross boundaries to meet the needs of researchers through service excellence.

## Achievements

Due to efforts of our OCR ClinicalTrials.gov team and investigators for PI-initiated studies, Emory was recognized nationally for continued 100% compliance since 2019 with results reporting in ClinicalTrials.gov.

The Pre-award team negotiated a 17% median and 39% mean total difference between the negotiated sponsor's budgets and sponsor's initial offers, a 21.9% increase from FY20. This resulted in a total dollar difference of \$19,856,900 between the OCR negotiated sponsor budget and sponsor's initial offer for 360 studies (contingent on meeting target accrual).

The OCR Education team launched the new intermediate level Financial Management and Research Billing

Compliance course for the clinical research study team in collaboration with ORA partners, Controller's Office, and EHC's Clinical Trial Billing Department.

OCR Education team hosted Research Matters, a quarterly clinical research educational seminar, that contributed and presented clinical and scientific research related to DEI, COVID, Men's Health, and LGBT+ communities.

Analyzed the cost of clinical trials with no enrollment, developed reports/dashboard on clinical trials with no/low enrollment, and developed clinical research feasibility tools for an annual departmental review including a feasibility SOP, feasibility checklists, and sample AHC feasibility review.

## 2022 GOALS

- Identify current pain points and seize opportunities for process improvement within the new Epic and OnCore implementations and future state.
- Facilitate analysis, design, data migration, testing, training, and implementation of research components of EHC's Epic electronic medical record and technical/professional billing system, e.g. research clinical operations and research billing compliance.
- Develop OnCore CTMS training curriculum (including integration/processes with Epic) for ORA departments and clinical research community and train them to effectively operationalize their processes to use the system prior to implementation with an ongoing Help Desk to triage calls, and authority to grant access to OnCore.
- Facilitate analysis, design, data migration, testing, training, and implementation for OnCore Clinical Trials Management System including study and subject management by clinical research teams, calendar builds, coverage analysis (PRA), budget development, invoicing, accounts receivable, and accounts payable for non-federal/industry clinical trials and those clinical trials with EHC or GHS billable items and services.

# Key Metrics

**10** COVID-19 studies routed, approved through RRT

**341** clinical research studies activated in ERMS and PowerTrials

**825** New studies submitted

**581** PRAs completed

**786** Pre-Award Reviews completed

**2,181** amended signed consents to PowerChart

**10,315** OnStudy subjects added to PowerTrials

**1,139** Emory-sponsored studies in ClinicalTrials.gov

**8,090** signed informed consent documents

**107** Educational seminars/courses with **1,779** attendees

# ORA Information Technology

Research Administration Information Technology (ORA-IT) serves as a technology facilitator, intermediary, and project liaison on behalf of ORA departments with various third-party vendors and the University's central IT division (OIT), focusing on system administration and solution delivery. Staff members work in close collaboration with ORA departments to understand and enhance IT offerings to optimize service delivery.

## Achievements

Introduced Microsoft Teams and SharePoint to the division and migrated from Emory Box to SharePoint/One Drive.

Applied ServiceNow automation to enable a more intuitive experience for employees creating application support requests. This effort provided the additional benefit of increasing the reporting metrics for ORA-IT.

Continued the decommissioning process of legacy software to reduce costs and decrease security concerns.

Moved from on-site based storage to cloud-based storage for the Conflict of Interest Office (COI) and initiated the eCOI modernization project.

Implemented Qualtrics for the Senior Vice President of the Office of Research Administration.

Moved to DocuSign enterprise license from divisional use.

## SERVICENOW SOFTWARE KEY METRICS



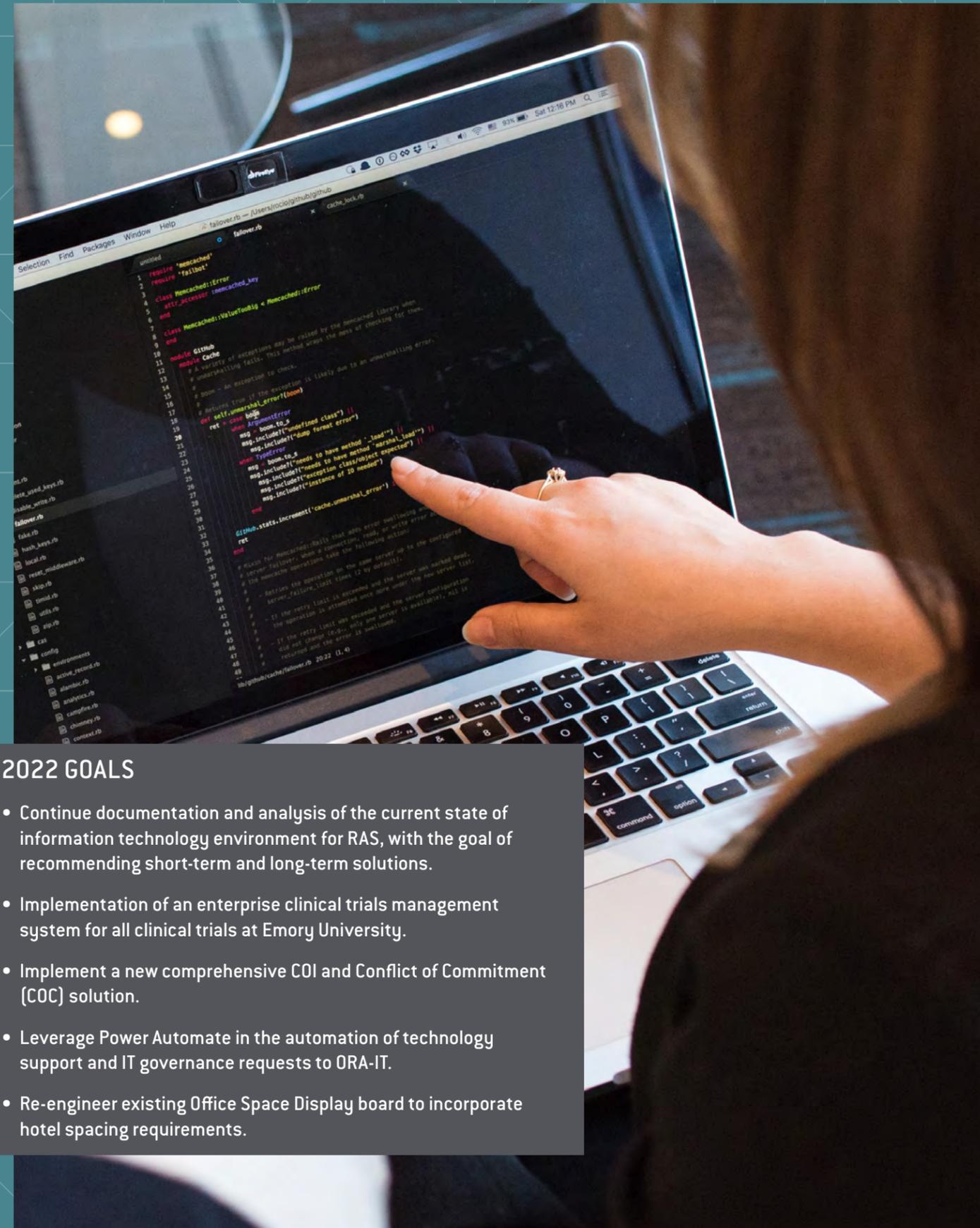
### AVERAGE TIME TO RESOLVE AN INCIDENT/REQUEST

ORAIT average – 3 days/49 minutes



### NUMBER OF IT INCIDENTS/REQUEST ADDRESSED

261 incidents/requests



## 2022 GOALS

- Continue documentation and analysis of the current state of information technology environment for RAS, with the goal of recommending short-term and long-term solutions.
- Implementation of an enterprise clinical trials management system for all clinical trials at Emory University.
- Implement a new comprehensive COI and Conflict of Commitment (COC) solution.
- Leverage Power Automate in the automation of technology support and IT governance requests to ORA-IT.
- Re-engineer existing Office Space Display board to incorporate hotel spacing requirements.

# Office of Sponsored Programs

The Office of Sponsored Programs (OSP) supports University researchers with proposals, non-industry contracts, and awards for Federal grants, foundation grants, corporate grants, government contracts (Federal, State, and local), incoming and outgoing subcontracts of the awards.

## Achievements

OSP made significant progress on the Subrecipient Monitoring Workstream. Consensus was reached across stakeholder units on key policy concerns that allowed final decisions to be made. The project will be completed and initiated in FY22.

OSP leadership undertook a comprehensive assessment of the structure of the office to position the office to support the anticipated growth in the research enterprise and redeployment of the Industry Contracting Group (ICS) into OSP. This restructuring was a significant undertaking and included the creation of two Director roles within OSP which were filled by existing OSP leaders.

The Industry Contracting Group (ICS) transitioned from the Office of Technology Transfer into OSP during FY21. With assistance from Huron Consulting Group, OSP worked to stabilize performance across the teams and to recruit new staff to fill the vacancies. Work to complete the new operating model, including continuing

recruitment and integration of the team fully into OSP (including into the existing OSP Career Path), will continue in FY22.

Several significant corporate relationships were achieved:

- Execution of a new Master Research Agreement with LifeBell, Inc.
- In collaboration with the Office of Clinical Research, execution of a new Master Rate Card with GSK, to help streamline budgeting for clinical trials.
- Completion of the Novartis Global Scholars Program Master Agreement.
- Study start-up of the MOTIVATE study at three sites.

The OSP Non-Industry Contracting team achieved the renewal NIH contract for the NIAID Centers of Excellence for Influenza Research and Response (CEIRR) with a total contract value of \$77.9M across all time and quantity options over the 7-year potential period of performance.

## 2022 GOALS

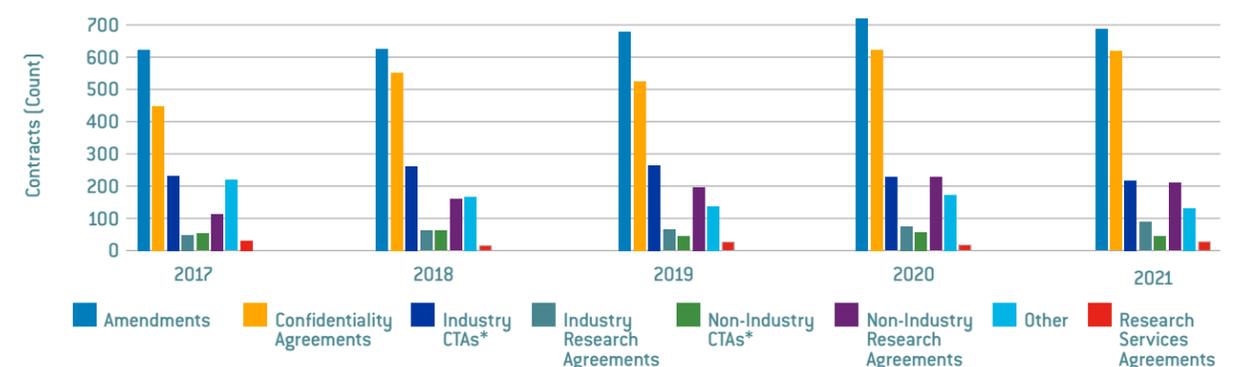
- **Ongoing recruitment and training.** Efforts will be undertaken to fill all open OSP positions, including leadership positions, and to deliver significant onboarding and process training. OSP has robust training plans across all teams.
- **Adapt to increasing federal regulations.** The U.S. federal government is the largest source of funding for Emory University. Federal regulations and policies that govern sponsored research continue to accelerate. These include a continuing focus on issues related to foreign influence and a significant disclosure requirement for individuals participating in sponsored research. These requirements represent significant administrative burden across the research administration infrastructure.
- **Research contracting.** Effectively manage the transition of agreement related to internally or unfunded collaborations, and the contracts needed to support them.



## CONTRACTS RECEIVED BY FISCAL YEAR



## CONTRACTS EXECUTED BY FISCAL YEAR



\*Clinical Trial Agreements

## 2022 GOALS

- Launch contractConnect campus-wide for MTA and DUA submission to reduce data entry and errors by OTT staff.
- Reduce time for technology evaluation of inventions submitted to OTT.
- Increase the number of invention disclosures from Emory personnel.
- Work with Emory leadership to review and revise Emory's process for handling IP associated with consulting agreements.
- Complete the Patricia/Minuet integration project and launch a new agreement portal that will facilitate workflow for MTAs and DUAs.

# Office of Technology Transfer

The Office of Technology Transfer (OTT) works collaboratively with the Emory community and industry to build and nurture partnerships that effectively move ideas from lab to the marketplace for the benefit of society.

## Achievements

Engaged with the ORA Dragon Team to map the process for Material Transfer and Data Use Agreements (MTA/DUA).

Migrated MTA/DUA data into the Minuet Database that houses all OTT agreements for better data collection and reporting.

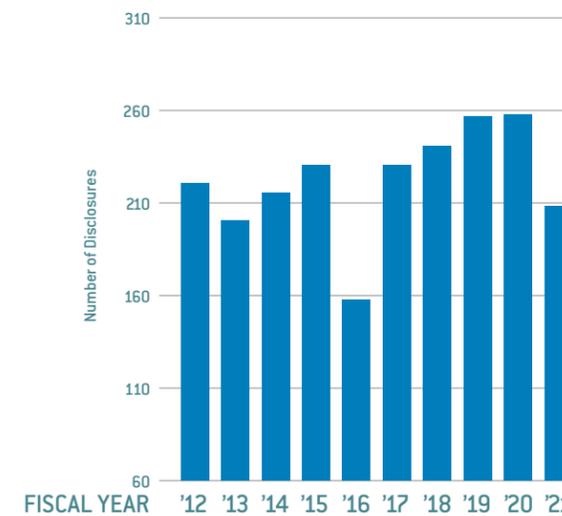
Enhanced data collection around MTAs/DUAs to improve real-time analysis of throughput, volume, and contract queue.

Collaborated on the transfer of industry contracting to the Office of Sponsored Programs so that industry-funded and non-industry funded contracts are aligned.

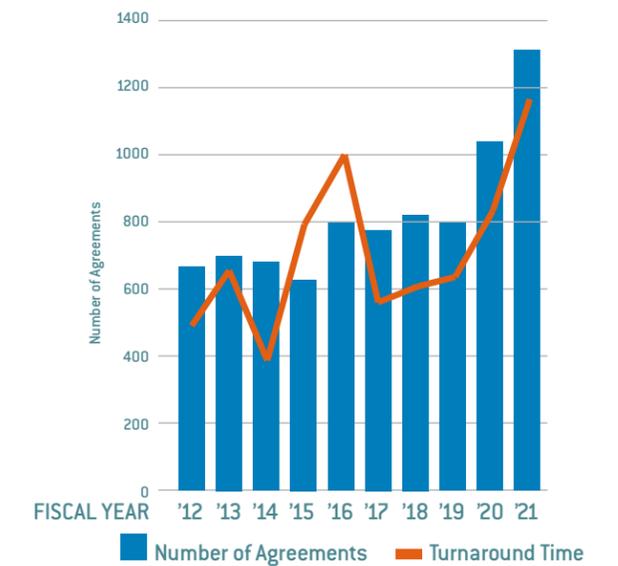
Beta tested contractConnect for MTAs/DUAs with Childrens Health Care of Atlanta and planned for campus-wide launch.

Provided rapid response for all RADx program agreements handled by OTT.

### NUMBER OF INVENTION DISCLOSURES



### MATERIAL TRANSFER/DATA USE AGREEMENTS BY FISCAL YEAR



# Research Administration Services

Research Administration Services works in partnership with the Emory research community to provide exceptional research administration services that are customer-focused, compliant, collaborative, and sustainable. RAS provides expertise in the compliance and administrative requirements of the grant life cycle. RAS support allows researchers to concentrate on the science/study and still be excellent stewards of sponsored funds and outcomes.

## Achievements

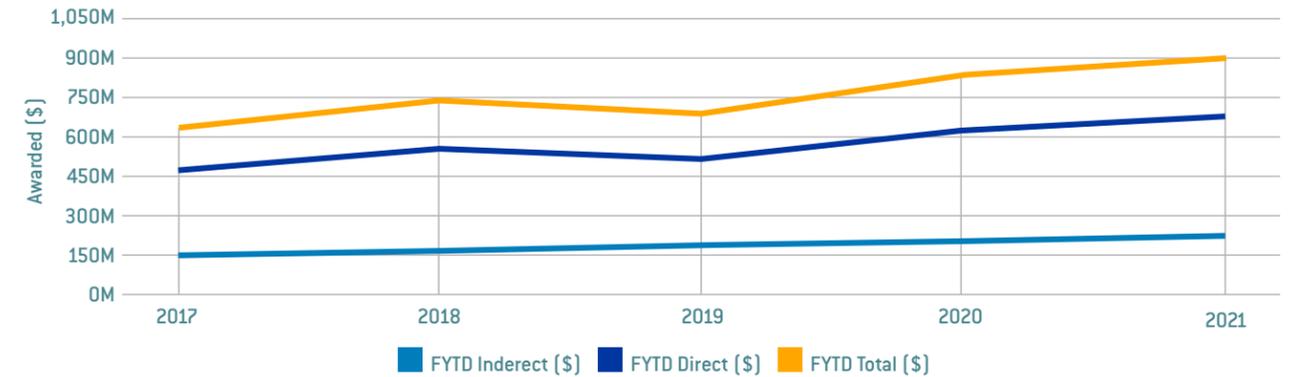
Implemented FORT enhancements. FORT (Financial Outlook Reporting Tool) is the software used to reconcile sponsored projects and provide an overview of a PI's sponsored portfolio. The enhancements incorporated include an Award Summary page, a resource page with links to commonly used resources, and enhancements to the Project Summary and Project Detail pages.

In partnership with OSP, developed Other Support Guidance for implementation of the new NIH Other Support guidance.

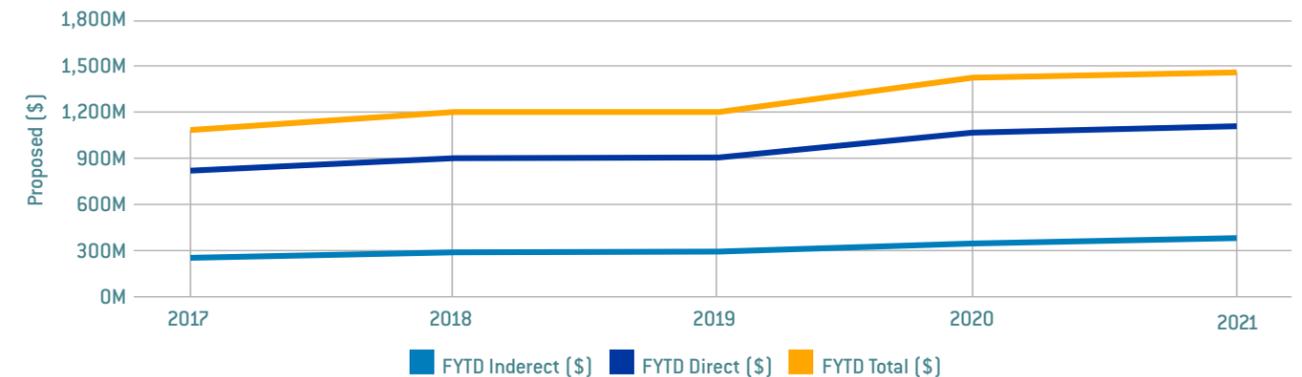
## 2022 GOALS

- Achieve and maintain 5% or less vacancy percentage across RAS.
- Enhance RAS onboarding and training.
- Develop RAS Training calendar/cohort.
- Develop and/or enhance engagement plans with faculty.
- Complete review and launch updated standard operating procedures (SOPs).

## 5-YEAR AWARDS TREND



## 5-YEAR PROPOSALS TREND





# Research Grants and Contracts

Research, Grants and Contracts (RGC) is responsible for central oversight and expertise related to post-award financial services of sponsored projects, including ensuring that invoicing, financial reporting to sponsors, and financial compliance are maintained in partnership with the schools and units.

## Achievements

Implemented new Post Award Setup Analysis Review pages within Compass to provide a more uniform and systematic method to ensure timely and accurate information gathering necessary for complete and accurate award setup, specifically:

- Delivered email notification functionality directly from Compass.
- Responses can be sent directly from Compass.

Improved processes for managing and setting up sponsored awards with automatic and reoccurring payments.

Completed successful National Science Foundation Office of Inspector General Audit (\$12M scope).

Consolidated and improved automated institutional closeout process.

Refined new hire remote onboarding curriculum and internal assessments.

## 2022 GOALS

- Advanced automated close-out letter notifications at 90 days prior to award end date, 30 days prior to award end date, and on award end date.
- Implement and enforce the updated/new closeout policies (Sponsored Award Closeout Policy, Sponsored Award Small Balance Write Off Policy, Sponsored Award Overrun Policy, and Sponsored Award Residual Balance Transfer Policy) and change the practice of including projections on final invoices and financial reports.
- Refine the manual invoice process to eliminate invoices issued outside of COMPASS and properly record A/R to reduce inefficiencies in the invoice and cash management process.
- Participate in the implementation of OnCore for clinical trial invoicing.
- Develop and communicate a monitoring process to manage conversions from PANs to awards.



**3.84**

Average Business Days:  
RGC Post Award Setup

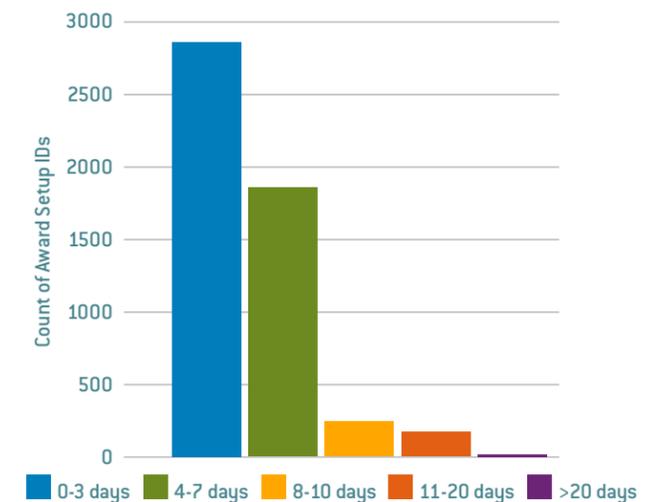


**5,110**

Number of  
Award Setups

## Post Award Setup Results

AWARD SETUP PROCESSING TIMES  
COUNT BY NUMBER OF BUSINESS DAYS TO COMPLETION



# Research Compliance and Regulatory Affairs

The Office of Research Compliance and Regulatory Compliance (RCRA) was formed in 2021 to establish a competent and comprehensive research compliance and regulatory program to facilitate Emory University's research mission.

## Achievements

The RCRA office oversees the provision of regulatory and compliance training and enterprise-wide communications, and the coordination, monitoring, and reporting for all research-related compliance activity across Emory University. It consists of four units:

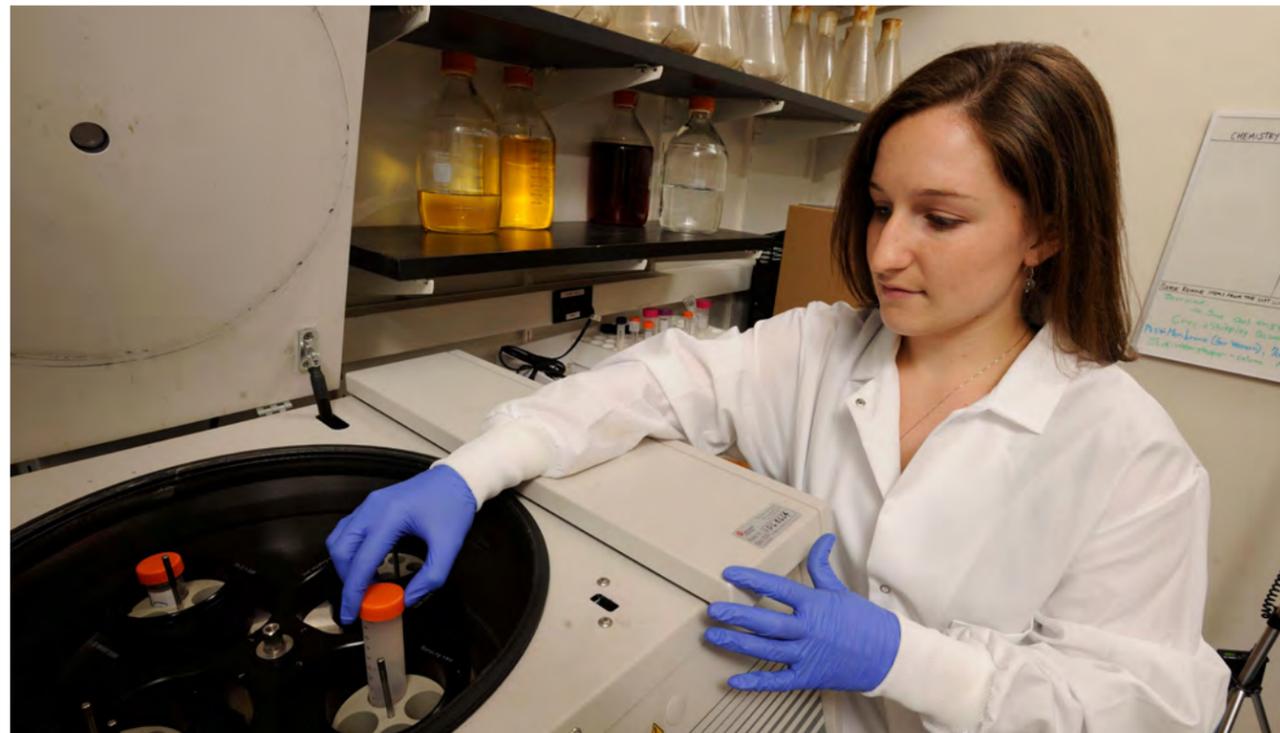
- Research Conflict of Interest and Conflict of Commitment
- Export Controls

- Research Integrity and Compliance
- Institutional Animal Care and Use Committee

The RCRA team is leading needs assessments of Emory's research compliance infrastructure, in coordination and collaboration with the Vice President for Research Administration, Chief Compliance Officer, and Senior Vice President for Research, to strategically identify and address any gaps or issues in a proactive manner.

## 2022 GOALS

- Initiate the development and implementation of a proactive, comprehensive, and integrated compliance strategy that supports the success of Emory's entire academic research enterprise.
- Work with investigators, administrators, and regulatory agencies to ensure the efficient and effective implementation and enforcement of research compliance policies and regulatory trainings.



# Conflict of Interest and Commitment

## Achievements

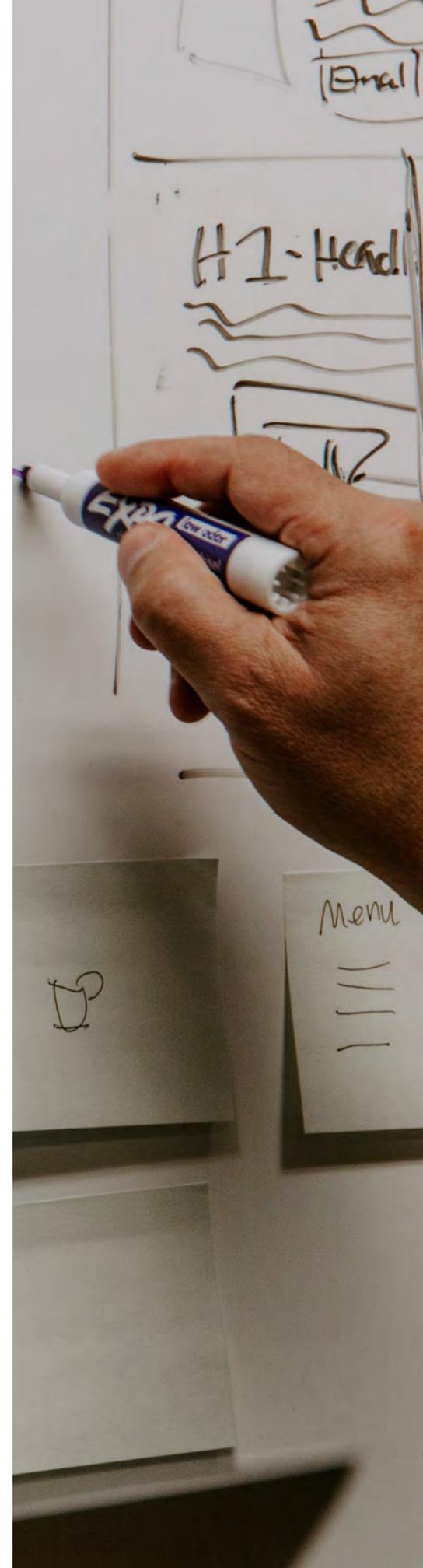
Performed a gap analysis on Conflict of Interest (COI) processing and developed a timeline to implement resources efficiently.

Planned design, configuration, and workflows for eDisclose system and completed early stages of eDisclose implementation.

Partnered on Conflict of Commitment (COC) task force with drafting of institutional policy for conflict of commitment.

## 2022 GOALS

- Implement eDisclose system.
- Based on recommendations from external COI assessment:
  - Implement new processes and templates to improve effectiveness and efficiency.
  - Ensure consistency in COI decision making.
- Training for Deans and Department Chairs on COI and COC for adequate management of conflicts within schools and departments.
- Finalize and implement COC policy.



# Institutional Animal Care and Use Committee

## Achievements

Continued to provide a high level of support to the animal research community during the COVID-19 pandemic.

Ensured compliance with regulatory agencies such as USDA-APHIS, OLAW, and Department of Defense.

Reorganized the IACUC office to include an operations manager to focus on IACUC protocol life cycle (from pre-submission to approval), and a research integrity manager to spearhead semi-annual inspections, noncompliance investigations, and post approval monitoring.

Moved forward in establishing an autoclave validation program and improving the occupational health and safety questionnaire (OHS) for personnel handling animals and/or in proximity where animals are used.

## 2022 GOALS

- Continue to improve consistency in IACUC protocol review as charged by the Faculty Task Force.
- Review the Post-Approval Monitoring program by conducting a gap analysis and determine a road map for improvement.
- Review the occupational health and safety program associated with researchers who handle laboratory animals and determine areas for improvement.

# IACUC by the Numbers

**315**  
RESEARCHERS CLEARED FOR OCCUPATIONAL HEALTH & SAFETY (EXCLUDES YERKES)



**1,295**  
PROTOCOLS REVIEWED\*



**17**  
PROGRAM REVIEWS



**1**  
VIRTUAL USDA INSPECTION



**28**  
SITE INSPECTIONS OF ANIMAL FACILITIES AND PI-MANAGED LABS



**41**  
INVESTIGATIONS OF NON-COMPLIANCE/ADVERSE EVENTS



**2**  
ANNUAL REPORTS SUBMITTED TO USDA AND OLAW

\*New protocols, amendments, triennial and annual reviews



# Export Controls

## Achievements

**Review for Sponsored Research:** Launched a new process for reviewing proposals at the submission stage that provides a more robust and comprehensive export control review and facilitates advance planning for complex international research projects and activities.

**International Travel:** Developed an EC travel briefing for international travelers and partnered with the Emory Travel office to incorporate it in the travel booking systems.

**International Shipping:** Established a Standard Operating Procedure for reviewing international shipping activities and filing Electronic Export Information (EEI) where required by the U.S. Foreign Trade Regulations. The export control team now has oversight of the University's Automated Commercial Environment (ACE) account, a U.S. Customs system that allows monitoring of international shipments by freight forwarders. The team is also able to make EEI filing for hand-carried items.

## 2022 GOALS

- Develop a comprehensive Deemed Export Review and Screening process for international visitors and non-immigrant employees that will be implemented alongside a university-wide visitor approval process.
- University-wide Export Control Policy.
- Establish a process for reviewing controlled biologics.

# Research Integrity and Compliance

## Achievements

Created internal Standard Operating Procedures (SOPs) for our new office to cover the multiple responsibilities of our office.

Updated the Research Misconduct Assessment process by engaging different stakeholders and reviewing existing gaps.

Transferred the responsibility of the Embryonic Stem Cell Committee (ESCRO) from the SOM to our office.

Created new educational content that has been presented in different forums.

## 2021 GOALS

- Ensure newly internal SOPs cover all areas of job duties and responsibilities.
- Update Emory Research Misconduct Policy and improve the communication of our current process to deal with research misconduct allegations.
- Review and improvement of the Responsible Conduct of Research (RCR) training.

