

OFFICE OF RESEARCH ADMINISTRATION

ANNUAL REPORT: FISCAL YEAR 2015



Introduction

The Office of Research Administration, again in FY15, had a record year for proposals and awards. This has been an ongoing trend year over year for the last decade. From FY05 through FY15, the volume of sponsored awards received by Emory University has increased by 76%, from \$325m to \$572m. During years of economic downturn, sequestration and federal funding decreases, this is truly a testament to what can be done when Emory faculty, the Office of Research Administration and other units across campus work together. While experiencing this growth in research activity and the associated increased volume of work for ORA departments, we have also continued to see increased regulatory burdens. We have continued to see increased federal regulatory burdens and increased volume across ORA departments. We have continued to maintain high levels of service with small increases in resources. Resource constraints continue to be a challenge, however each department in ORA has accomplished significant achievements over the last year, which are described in detail herein.

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Research Administration Services (RAS)

Research Administration Services began the year with four RAS units in various stages of maturation, and launched three additional units in FY15. The first two units, Cancer & Imaging, and Public Health, marked two years post-launch and reached the “steady state” phase of maturity. The Department of Medicine and the Department of Pediatrics units both reached their one year post-launch anniversary and continued to make positive strides toward also achieving steady state. Post-launch, the three newest RAS units, Basic Sciences (serving Biochemistry, Biomedical Engineering, Biomedical Informatics, Cell Biology, Human Genetics, Microbiology, Pharmacology, and Physiology), Yerkes (all departments), and ABOSS (serving Anesthesiology, Brain Health, Orthopedics, and Surgical Services) worked through the challenges inherent in this transformation. Throughout the year, the RAS implementation team continued to fine-tune the project and communication plans guiding the launches. In addition, the bulk of the planning to assimilate the School of Nursing research portfolio into the existing School of Public Health RAS was completed. This combined RAS will be the Public Health and Nursing.

Also in FY15, the RAS Central Operations team continued to expand and apply data analytics and metrics to monitor and evaluate the performance of the existing units using a flexible approach needed to accommodate unit-specific differences in daily operations. Highlights included having captured a full fiscal year of customer satisfaction surveys for pre-award services (monthly) and post-award services (bi-annually), and consistent monthly monitoring of the pre-award responsiveness to PIs intent to submit proposals, the 60 day reconciliations for all PI portfolios and deficit trackers for all awards. These operational metrics enabled all units to refine interactions with PIs and partnering departments, and incorporate ongoing continuous improvement efforts which enhanced consistency across the RAS organization as a whole.

RAS Central Operations Team and RAS units actively worked towards enhancing collaboration with other departments/areas (e.g., OGCA, OSP, OTT, SOM/department Finance groups, etc.) with the end goals being more effective, proactive communication and more clearly defined processes and roles and responsibilities, and specifically introduced the RACI. In an effort to support the touchpoints between RAS and FGC given FGC’s recent reorganization, as well as the transition of FSR responsibility to four of the seven RAS units will undergo in early FY16, we have set up bi-weekly one on one meetings with FGC leadership to discuss RAS/FGC transition issues and processes. We also worked closely with OSP on the Pre-Award vision project, completing several action items from that project. We worked closely with School of Medicine (SOM) Business and Finance Unit on a proposal review transition process ensuring the SOM RAS Units were well informed about the transition. OSP, FGC and OCR representatives attended RAS staff meetings to present or communicate on several topics of cross collaboration. This has opened up the lines of communications between RAS and Central RA and created a more collaborative environment. We developed and are finalizing several RACI matrices to assist in defining roles and responsibilities across pre-award and post award functions (Pre Award RACI, Post Award RACI, FSR RACIs). We also collaborated and will continue to collaborate with OSP, FGC, Accounts Payable and Purchasing on several special projects, seeking their input and expertise on design, education, training and processes.

The RAS Central Operation Team completed the design of a RAS Unit annual Health Check at the end of FY15. We will launch a pilot with the DOM RAS in September 2015. The Health Check is an annual assessment of the “health” of each RAS Unit. In the first year it will cover five key areas: Pre Award, Post Award, Records Management and Retention, and HR – People, Process, and Documentation, which encompasses an online Employee Satisfaction Survey. In the second year we will incorporate an additional key area, Stakeholder Engagement (Department, OSP, FGC). The Health Check is broken out into three phases: Phase I – Data Collection; Phase II – In Unit Assessment; and Phase III – Results and Action Plan. A completed Health Check combined with KPIs provides a comprehensive picture of a RAS Unit’s current state. The Health Check will also be the basis for launching a “RAS of the Year” Award as a means for promoting RAS competency, efficiency, transparency and growth. The Health Check will:

- Compliment KPIs
- Allow for a deep dive to see the full picture of Unit operational health
- Support training of new RAS employees
- Understand challenges with and identify gaps in SOPs to enable continuous improvement in processes and documentation
- Identify training opportunities and best practices for implementation
- Helps highlight stories of success and celebrate those successes

RAS Central Operations with the dedicated assistance of Learning and Organizational Development worked towards continuous goal of developing professional competencies of staff in line with outlined goals and objectives in FY15. We completed a learning needs analysis in January 2015 that identified three main areas of focus: onboarding of new hires, RAS specific training, and professional development. We focused on progress in these three areas during FY15.

In the focus area of onboarding, we began the development a video with an overview of RAS/Shared Services model for use on the RAS website and to welcome new hires. We also began the development and production of four online modules for onboarding new hires which will enhance the RAS Staff and Directors handbooks and provide a mechanism for tracking completion. In the focus area of RAS specific training, we implemented a biweekly tracking of required training completion with communication to RAS Directors of gaps in the training plans of their new staff members. We also developed an online module for Milestone process and delivered progress reporting process awareness training. We began developing a training approach for “training grants” through a working group and learning community. We began the process of collaborating with FGC on the FSR transition with a focus on updates to the FSR process, training, and job aids. We also collaborated with OSP and RAS Units on the development of a Proposal Preparation Toolkit and eNOA checklist. In the focus area of professional development, we provided DiSC team building sessions for each new RAS roll out and coordinated a Birkman session for C&I RAS. We began planning for a Director’s retreat in early FY16 that will utilize the Birkman Method and focus on professional development for RAS staff.

Challenges persist but are not insurmountable. As RAS units mature and address new operating procedures, and FIRA and general account clean-up, a new clean-up project for closing out awards, the adoption of responsibility for generating financial status reports, and the NIH subaccount

payment management system become the focus beyond standard operations. Additionally, providing flexibility and support during the re-organization of our sister organization Finance, Grants & Contracts, formerly Office of Grants and Contracts, and the splitting of contracts between Office of Sponsored Projects (federal) and Office of Technology Transfer (industry) has created an environment in which most staff are operating in multiple environments with transitioning roles and rules simultaneously. As a result, all involved look forward to the implementation of the remaining RAS units and ripening of the new structures.

And FY16 offers the opportunity to do exactly that as the RAS organization is well on its way to launching Hospital and Specialty Services (serving Dermatology, Ophthalmology, Gynecology and Obstetrics, Emergency Medicine, and Pathology), and ECAS et al (serving Business, ECAS, Law, Theology, and Oxford). Both are scheduled to launch in early 2016.

Into FY16, we will continue to identify training needs for existing and new functions across all of RAS and deliver training in an efficient and effective manner. We will again conduct a training needs analysis to better understand and gauge the training needs of RAS staff. Professional development will be a focus in FY16 through RAS leader participation in Emory's professional development offerings such as the Essentials of Leadership series, Emerging Leaders or Excellence through Leadership programs. We will be collaborating with OSP, FGC and the Controller's office to restructure the RAE Certification program as well as exploring the development of a RAS specific Award Management series training program.

The RAS Health Check pilot will be complete in early in FY16, which will lead to the full launch of the RAS Health Check beginning on February 2016. SPH, C&I, Pediatrics, Basic Science and Yerkes RAS Units will go through a Health Check in FY16. We anticipate the results of these Health Checks will give us a complete picture of the "health" of each Unit complimenting the KPIs. We will also announce a RAS of the year based on these results.

Lastly, in FY16 we will begin to build and deploy a model to effectively support Federal Contracts here at Emory. In early FY16 we plan to circulate an initial report developed in FY15 to ORA Leadership and select advisory Faculty and CBOs to gather feedback and buy in on the next steps for the project. We will then create a work plan based on the action items and deliverables and form a working group to assist with developing and executing the deliverables. We are hoping to be able to launch most of the deliverables of this project by the end of FY16.

		Fiscal Year 2015			
		Proposals		Awards	
		Number	Direct Dollars	Number	Direct Dollars
Current	RAS - Cancer & Imaging	457	\$ 63,534,122	318	\$ 25,489,991
	RAS - Public Health & Nursing	652	\$ 177,213,657	417	\$ 87,320,958
	RAS - Medicine	510	\$ 109,146,678	418	\$ 60,156,406
	RAS - Pediatrics	476	\$ 68,750,188	410	\$ 40,164,406
	RAS - Basic Science	563	\$ 104,074,167	351	\$ 70,300,529
	RAS - Yerkes	216	\$ 63,244,595	120	\$ 36,555,981
	RAS - ABOSS	494	\$ 81,398,698	442	\$ 46,787,072
	RAS Total	3368	\$ 667,362,105	2476	\$ 366,775,343
	Total University	3961	\$ 774,815,945	2923	\$ 439,837,964
	RAS Percent of Total	85%	86%	85%	83%

***Note:**

Basic Science launched in January

Yerkes launched in February & July, post and pre award respectively

ABOSS launched in August

School of Nursing joined Public Health in August

Office of Sponsored Programs (OSP)

In a very competitive and uncertain funding environment, Emory's total awards received has grown by an impressive 9.7% (from last year) to \$572.4m. The number of proposals processed through OSP increased by 3.9% from 3,813 to 3,961. The number of subcontracts issued by OSP has continued to increase in FY15 with a 6.1% increase from FY14 and a 34.8% increase from FY11.

FY15 brought a number of changes for OSP. OSP continued to work closely with the RAS organization to further streamline processes and procedures. During late FY15, OSP was reorganized to better align the focuses of offices within the Office of Research Administration. The PreAward administration for non-industry contracts was combined with the OSP Grants Team. The responsibilities related to the PreAward administration of industry contracts was moved to the Office of Technology Transfer.

During this period, significant effort has been provided to several other projects including the Compass Upgrade Project, the implementation of Uniform Guidance and the development of a new subrecipient monitoring program. The Compass Upgrade Project is anticipated to bring numerous improvements for pre and post award research administration. With a higher level of knowledge related to the PeopleSoft system at Emory and the additional insights gained by OSP/OGCA and others speaking to other institutions/consultants, working with ORACLE and reviewing current configuration, OSP/Emory is now in a strong position to improve how the PeopleSoft System works for Emory. Significant improvements to the system are in development.

OSP has worked closely with the RAS Team to develop new strategies to work efficiently in the new structure with the focus on how to best support our researchers. While we are in the early stages of this new structure (with not all of the RAS units implemented) and are still refining processes, we are already seeing the improvements of working within this new structure. The implementation of Uniform Guidance has been challenging with pieces of information coming at different times from the federal agencies (some significantly after the original date of implementation). The final federal research terms and conditions have still not been released. Proposed Research Terms and Conditions have recently been released for part of the federal agencies and are currently under review. The guidance that has been issued by agencies has not been consistently "uniform" between the agencies. Despite all of this, OSP has provided clear and regular communication/education that has included monthly newsletter articles, numerous presentations and an online video. These efforts were completed as part of a coordinated effort with OGCA and members of the research community, which OSP led. A new online module is under development. These initiatives are anticipated to continue to demand time from OSP over the next year. In addition, the HHS transition to a new payment management system will also have a very large impact on the workload of OSP, OGCA, and RAS with the requirement to closeout and re-setup two years of NIH awards.

During FY16, OSP looks forward to expanded opportunities to improve processes and systems through the Compass Upgrade as well as the further refinement of processes as the RAS Units complete their implementation. Other areas of heavy focus will include the continued implementation of Uniform Guidance, further participation on Business Intelligence and leading a

comprehensive redevelopment of the central research administration educational program which will better support the new research support structure within Emory.

ACCOMPLISHMENTS

- 1. Fully implement the OSP/OGCA Service Kiosk (SAM) – Phase 1 and Phase 2** The SAM Kiosk was live and functional during FY 15. Throughout the year we collected information and feedback on its use and worked with IT Group to improve the system. Consistent with these efforts, a number of bugs with the system were resolved. Additionally, important new functionality was added to the system in the form of an audit log and comment area. Through these latter enhancements, campus users can readily see detailed information on the status of their requests. Finally, significant work was done to prepare the system to allow direct integration with data from the Compass financial system. The IT work required for this change is pending further reviews of the SAM Kiosk System and its future.
- 2. Complete subcontract/subaward manual and revised subaward template:** This goal was partially achieved in FY15 as efforts related to subaward/subcontracting processes shifted out of necessity toward addressing the Uniform Guidance requirements related to Subrecipient Monitoring. As part of the Uniform Guidance related work, revised subaward templates were drafted to ensure that all subaward documents issued conformed with UG requirements. The revised templates include the standard federal subaward template, the federal subaward template used for international/foreign subrecipient organizations, and the federal subaward templates used for conduct of multi-site clinical trials where an Emory faculty member is the Sponsor/Investigator. Additionally, policy and process documents were completed to memorialize the details of the Subrecipient Monitoring program. The subcontract/subaward manual will be finalized in FY16.
- 3. Finalize completion of OSP Policy and Procedure Manual to address changes necessitated through the roll out of RAS.** Revision to the OSP Policy and Procedure Manual will remain a goal in FY16. While much work had been done to finalize the manual with respect to the roll out of the RAS, the restructuring of the OSP Contracts group (with non-industry contracts remaining in OSP and industry contracts moving to OTT) will necessitate additional updates to the manual. The restructuring of OGCA will also render many references in the manual out of date. Finally, throughout FY15, we have also developed, on an ad hoc basis, several additional detailed policy and process documents related to various processes of the office. It will be important to incorporate these documents into the overall Policy and Procedure Manual, either by inserting their full text within the manual itself, or as referenced appendices to the manual.
- 4. In a joint effort with OGCA and research community participate and lead implementation of Uniform Guidance (including ensuring that changes are properly communicated and training, as needed, is developed and available):** OSP led this process working closely with other central offices and the research community to develop a plan to address the needs for the implementation of Uniform Guidance. This includes providing the communication and training to ensure that the Emory research community was prepared for the changes. This will be an ongoing process as we still await release of final research terms and conditions, which may bring further changes and clarification.
- 5. Participate in preparation activities for DHHS payment management system changes:** OSP has worked closely with other areas to develop plans to support and communicate this change.

6. **Refine performance standards and processes based on what we learned through their first application this year:** OSP has updated standards based upon what was learned from first year and this will be an ongoing process.
7. **Participate in Compass Upgrade project.** OSP has continued to actively participate on this project and anticipates fairly significant improvements to the system with the upgrade.
8. **Reduce average award setup time from 11 days to 10 days or less by improving efficiencies through revised procedures, tools and templates as well as other efforts to assist staff in improving setup time.** – The average award set-up time for FY15 was 9 business days. This is especially notable given the 9.7% increase in award funding during FY15. This target figure will remain a goal for FY16.

Other Accomplishments

1. **Education: Modify RAE Certification program to support the transitional time where there will be both RAS and departments supporting the local administration of sponsored programs. Develop and publish short videos covering how to handle various tasks providing on demand training over the web to research administrators throughout the institution.**

The RAE Certification Program has added additional distance learning opportunities for its RAE maintenance/recertification requirements. These additional distance learning opportunities include the online viewing of ERAZ in ELMS and group viewings of NCURA webinars.

During FY15, OSP/OGCA:

- Provided 58 classes which included 313 hours of classroom training. 1129 Emory Research Administrators attended the classroom sessions.
- Offered 9 web facilitated courses including NCURA webinars, ERAZ online ELMS version, and RAE online prerequisite classes. 236 participated in these training opportunities.
- Certified 44 staff in the RAE program.

Additional educational programs have converted into Emory's Learning Management System including new hire programs. OSP/OGCA have also provided a high level of effort towards the development of the training programs necessary for the RAS Units as well as participating in the planning for the training program for the Compass Upgrade project.

2. **ELMS Tool:** Implemented electronic ELMS OSP training tool which ensures that new Emory research administrators are automatically enrolled in required training courses.
 - a. Also provides RAS training with weekly reports that identify training completions by staff member. (This was previously a manual process.)
 - b. Also improved the quality and accuracy of grants training SACS/Score Card reports.
3. **Subrecipient Monitoring Program:** OSP led the development and implementation of a new subrecipient monitoring program which addresses the requirements of Uniform Guidance.
4. **Business Intelligence:** OSP staff has also participated on the DW/BI initiative, including attending regular design meetings to guide the development of standard reports to be available from the BI system. OSP staff members have also participated in the development and testing processes for new reports that are now the official ORA reports for Awards, Proposals and Expenditures. In

addition to these standard reports, a number of new reports have been developed to support various research initiatives including proposal submissions, survey data requests, and trends in University research. The ability to create analysis reports and respond to internal and external data requests is now significantly more efficient.

5. **Compass Improvements and Enhancements:** OSP has continued to review, identify and evaluate ways to improve how Compass functions.
6. **PreAward Vision Project:** OSP worked closely with RAS to conduct a review of preaward processes and identify areas that could be improved and/or streamlined. From this, a plan was developed and implemented to address the issues identified. Significant progress has been made on these items (most completed/achieved).

Funding Highlights and Milestones

- A total of \$572.4 million was awarded from all extramural sources of sponsored research and training in FY15, which reflected a 9.7% increase from FY14.
- Of that total, \$439.8 million (76.8%) and \$132.6 million (23.2%) were awarded in direct and indirect costs, respectively. FY14 reflected a 76%-to-24% split.
- Of the total of \$572.4 million awarded, \$1.2 million was awarded from federal ARRA funds. In FY14, ARRA funded awards totaled \$1.2 million.
- The School of Medicine received \$362.9 million reflecting approximately 63.4% of the total dollars awarded. The total for the School of Medicine represents a 13.2% increase from FY14. Of this total, \$198.6 million was awarded from the National Institutes of Health, reflecting a 3.16% increase from FY14 in NIH Funding received by the School of Medicine.
- The Rollins School of Public Health received \$90.0 million reflecting approximately 15.7% of the total dollars awarded. This total represents an increase of 23.2% from FY14.
- The Yerkes National Primate Research Center received \$66.6 million reflecting approximately 11.6% of the total dollars awarded. This total represents a decrease of 9.2% from FY14.
- Emory College received \$31.1 million reflecting approximately 5.4% of the total dollars awarded. This total represents a decrease of 7.8% from FY14.
- The Nell Hodgson Woodruff School of Nursing received \$14.3 million reflecting 2.5% of the total dollars awarded. This total represents an increase of 16.4% from FY14.
- The total funding in the Woodruff Health Sciences Center was \$537.1 million reflecting 93.8% of the total \$572.4 million awarded to the University.
- The federal government, Emory's largest sponsor, awarded \$374.9 million reflecting 65.5% of total dollars awarded. This was a 5.2% increase from FY14.
- The private sector, Emory's second largest sponsor, funded \$94.1 million in research (16.4% of the total dollars awarded). This reflected a 47.5% increase from FY14.
- Third in providing research support was funding from corporations which granted \$44.9 million (7.8% of total). Corporate sponsored funding decreased 11.9% from FY14.
- Of the federal agencies, the National Institutes of Health (NIH) was again Emory's largest sponsor of research awards. NIH awarded \$299.2 million (a .13% decrease from FY14). The NIH support accounted for 79.8% of total federal dollars obligated to Emory and 52.3% of all funding received.
- Since FY09, Emory has grown from \$484.3 million in FY09 to \$572.4 million in FY15; this represents an increase of 18.2%.

- The ten departments that with the highest level of awards received \$316.9 million or 55.4% of the total dollars awarded.
 - Department of Medicine with \$78.1 million (increased 16.7%)
 - Department of Pediatrics with \$51.9 million (decreased 10.3%)
 - Department of Micro Immunology with \$30.5 million (increased 102.3%)
 - Department of Pathology with \$26.1 million (increased 20.4%)
 - Department of Global Health Institute with \$24.6 million (increased > 100%)
 - Yerkes, Emory Vaccine Center with \$28.8 million (decreased 20.9%)
 - Department of Global Health with \$21.9 million (increased 3.7%)
 - Department of Hematology/Oncology with \$21.2 million (increased 18.9%)
 - Department of Neurology with \$20.9 million (increased 10.4%)
 - Department of Epidemiology with \$18.6 million (decreased 15.9%)
- The total number of proposals submitted to all sponsors was 3,961 reflecting a 3.9% increase from FY14. The total dollars requested increased in FY15 to \$1,027.6 million, reflecting a 16.86% increase from FY14 (\$879.3 million).
- Of the \$1,027.6 million in proposal requests during FY15, \$702.1 million (63.3%) was requested from federal sources.
- A total of 1,080 subcontracts were issued by Emory on research grants and contracts during FY15. This was an increase of 6.09% from the amount issued in FY14 (1018) and an increase of 34.8% since FY11 (801).

GOALS & PRIORITIES FY 2016

1. **Compass Upgrade:** OSP will continue to be very actively involved in development and testing for the Upgrade –as well as participate in development of training materials.
2. **PMS P-Account Transition:** OSP will be very involved in this transition. It will require significant additional effort by OSP staff to meet the requirements for PANs and re-setup approximately two years worth of HHS awards.
3. **RAS Transition:** OSP will continue to work closely with RAS to streamline processes and seek opportunities to improve efficiency.
4. **Complete the activities related to Uniform Guidance implementations:** Further action will be required for significant revisions to Emory’s Sponsored Programs Manual and training programs. As the final Research Terms and Conditions are released, additional communication, education, and other action will be required. OSP will lead these activities.
5. **Significant revisions to RAE Certification Program:** The certification program will be completely redeveloped to ensure it best supports the new RAS structure within Emory. Significant revisions are also required to address the impact of the implementation of Uniform Guidance.
6. **Work closely with OTT to refine and finalize the transition of responsibilities and processes to a new OSP/OTT shared structure.**

IACUC Office (IACUC)

The IACUC Office began the year staffed with 5 full-time employees including IACUC Director Larry Iten, DVM; the IACUC Associate Director, David Martin, PhD; three Research Protocol Analysts (RPAs); Musa Hasan, MS, CPIA; Tiesha Murray, BS, CPIA; and Jessica Goldman, BS, CPIA. Jessica Goldman achieved CPIA certification this year. The IACUC Office was ably supported by administrative staff of the ORA Business Operations Team; primarily Adrienne Brutscher, BS, and Katherine Upshaw, M.Ed.

Office of Research Administration, the IACUC Office and the Morehouse School of Medicine teamed up to host the IACUC 101/201 IACUC Conference at the Emory Convention Center on April 8-9, 2015. Dr. David Wynes kicked off the conference with the welcoming speech that set the proper tone of networking and asking questions of the expert roster of faculty assembled for this conference. Many of the Emory IACUC members were in attendance. The conference was well attended and received outstanding post-conference evaluations. The majority of the preparations, contracts and logistical work was completed by the ORA Business Operations Team and was greatly appreciated.

The Post-approval Monitoring Program (PAM) continues to improve as increasing numbers of PAM reports are completed. Monthly reports of trends are reported to the IACUC by the Associate Director.

The IACUC Office continues to facilitate several subcommittees of the IACUC including the Executive IACUC, the Noncompliance Investigation Subcommittee and many policy subcommittees. During FY15, the IACUC created seven new policies and continues to make revisions to the already existing policies. Most of this effort was the result of the implementation of the numerous changes in the 8th edition of the "Guide for the Care and Use of Laboratory Animals" and the 13th edition of the "AVMA Guidelines for Euthanasia of Animals."

The TOPAZ Web P&R System includes all protocol data in electronic format allowing us to provide some historical data regarding protocol processing. On 9/1/2015, there were 601 approved protocols stored in the system. A total of 1,039 protocol submissions of all types (initial reviews, amendments, annual reviews and 3 year renewals) were processed by the IACUC Office and reviewed by the IACUC during the past 12 months. This reflects an insignificant increase of 2 reviews of all types from the previous year so volume remains steady. A total of 67 initial protocol submissions were processed during the last 12 months which is a decrease from 72 the previous year. The number of 3-Year Renewals remained steady with 89 renewal submissions just slightly down from 94 the previous year.

Protocol "submission to approval" times for all types of review continue to be tracked historically. A reduction in this time interval is the trend for which we strive. As long as we do not sacrifice the quality of review, the shorter the time interval is the better. However, the implementation of the numerous changes in the new "Guide for the Care and Use of Laboratory

Animals” and the new “AVMA Guidelines for Euthanasia” continues to impact the protocol “submission to approval” review times on renewals. The learning curve continues for the principal investigators and research staffs as the IACUC implements the mandatory changes required by these two updated guidance documents. It is interesting to note from these figures that it now takes one day longer to “clean up” a 3 year renewal protocol to meet the new guidelines than it does to review a new initial protocol submission; but it is 5 days less than the year before. Overall for all types of reviews, “submission to approval” times are slightly less than the previous year. The table below demonstrates the mean time interval in calendar days for each type of review:

**Protocol Submission to Approval Intervals
Means in Calendar Days**

Types of Review	FY12	FY13	FY 14	FY 15
3 Year Renewal by Designated Member Review Process (IACUC meeting not required)	42	38	65	60
3 Year Renewal by Full Committee Review Process (IACUC meeting required)	56	46	57	57
Amendment submitted, Reviewed by IACUC Office only or the IACUC Office with Veterinarian	2	1	1	1
Amendment submitted, Reviewed by Full Committee Review process (IACUC meeting required)	24	17	19	19
Amendment submitted, Reviewed by Designated Member Review process (IACUC meeting not required)	32	28	40	38
Annual Review of Protocols with AWA regulated species	8	5	8	8
Initial Review by Designated Member Review Process (IACUC meeting not required)	43	44	43	42
Initial Review by Full Committee Review Process (IACUC meeting required)	60	52	59	59

Our primary goal for this year is to implement the upgraded protocol review system TOPAZ Elements. The server housing this new software is centrally located. The form has been completely overhauled allowing for much better reporting capabilities, increased user-friendliness, available templates for standard procedures, more drop-down lists and less text fields, much less duplication and better organization for more effectiveness for both the research faculty as well as the IACUC reviewers. We are hopeful that the “go live” date for the new form will be during early 2016.

Institutional Review Board (IRB)

The Emory Institutional Review Board, an AAHRPP-accredited IRB, is made up of seven panels that review study submissions (including one panel dedicated to socio-behavioral research), and an eighth panel that reviews reports of noncompliance and unanticipated problems. We have approximately 110 members including Emory faculty, administrators, and community members. Of those, seven are faculty Co- or Vice-Chairs, who dedicate a portion of their time to doing expedited reviews, and running board meetings. Supporting the Committees is a staff of 21 full time employees, with varied backgrounds such as JD, MPH, MD, MDiv, and which includes former clinical research personnel. Twelve of our staff are Certified IRB Professionals, the standard certification for our field.

In the past fiscal year, a main focus was our application for AAHRPP reaccreditation, the gold standard quality indicator for Human Research Protection Programs. We are optimistic that another five years will be added to our nearly eight years of accreditation thus far. Preparing the application included extensive edits to the IRB's Policies and Procedures as well as Standard Operating Procedures. Meanwhile, the Veterans Administration made significant revisions to their human research handbook, leading to yet more changes to our P&P's.

As Emory enjoyed a remarkably good year in federal grant dollars, the Emory IRB has endeavored to keep up with the accompanying volume of study submissions by continuing to streamline our processes, described further below. Meanwhile, some growing areas of research, and newly released federal guidance documents, have challenged the IRB to evolve in our approach. These include mobile medical apps, electronic consent, social media research, proliferation of data and specimen repositories across Emory, Big Data, genetic research and data sharing, and research in acute care settings where consent may not be feasible. The IRB has collaborated with researchers in these areas to try to facilitate ethical and compliant conduct of these types of studies, when there are not always clear rules.

As reported last year, we continue to rely more on central IRB's, which requires ever-changing SOP's for communication among IRB offices and study teams, and for ensuring that local Emory requirements are met (traditionally the purview of the Emory IRB). Thus far, efficiencies that promised to be the benefit of using central IRBs have yet to be realized, except in rare instances.

Picture of the Past Year

1. Our overall customer satisfaction rate is 4.41 out of 5 on our online survey, slightly higher than FY14 (the link is offered on all emails from staff as well as upon completion of initial IRB approval). Satisfaction with IRB staff interactions is at 4.54 out of 5.
2. Our monthly webinars have continued to be well-attended, and are archived on our website.
3. The IRB website now offers more guidance on what types of projects do *not* require IRB oversight, including certain quality improvement activities, as well as a web form for requesting a determination as to whether IRB submission is needed. This material was

developed in collaboration with faculty and administrators from several areas of Emory University and Emory Healthcare.

4. With greater attention being paid by federal regulators, the NIH, and ethicists to certain issues in research (e.g. genetics, incidental findings, data sharing, cell line creation), we provided a new selection of template language for informed consent in each of these areas, alongside guidance and links to resources.
5. Special attention has been paid to drug and device studies where the IRB must determine if an IND or IDE is required. The IRB now requires justification forms from researchers, to minimize our risk of error.
6. As part of our AAHRPP reaccreditation process, we became aware of the need for more guidance on how to comply with the varying regulations of the different federal agencies. We now have P&P chapters, and checklists, for agencies including the Department of Justice, Department of Energy, EPA, and Department of Education.
7. The IRB collaborated with other Emory offices to better support and communicate about studies taking place abroad, to improve adherence to foreign regulations, export controls, and other requirements.
8. A boon to researchers, the Emory IRB, in concert with CHOA and the AVAMC, extended the effective period of CITI training certifications to three years, from two. Emory also agreed to likewise extend the effective period of the Key Concepts in Clinical Research and Clinical Research for Coordinators certifications.
9. The eIRB submission system was moved to the same login process as many other Emory systems, eliminating the need to request a separate user account for eIRB. New users with University or Healthcare accounts now access eIRB simply by logging in with their netID and password. The set of departments in eIRB was also completely updated to match PeopleSoft, vastly reducing incorrect department listings for users and improving the departmental review process.

Our Numbers

- a) Number of active studies that undergo expedited review: 2,249
- b) Number of active studies that undergo full board review: 1,512
- c) Total active studies under Emory IRB review: 3,761
- d) Number of new protocols submitted to the Emory IRB via the eIRB system in FY15: 1,355 (compared to 1,320 in FY14 and 1,306 in FY13)
- e) Number of amendments submitted to the IRB: 4,387 (compared to 5,581 in FY14 and to 6,151 in FY13; decreases are mainly due to the new process for submitting study staff change requests)
- f) Number continuing review applications submitted to the IRB: 2,730 (compared to 2,651 in FY13)
- g) New studies received during FY15
 - i) that required full board review: 314 (compared to 260 in FY14, and compared to 292 in FY13)
 - ii) that were reviewed via expedited procedure: 583 (compared to 623 in FY14, and compared to 646 in FY13)
- h) Submissions of exempt studies: 169 (compared to 107 in FY14 and 157 in FY13)

- i) Number of reports submitted to IRB (potential noncompliance and/or unanticipated problems): 694 (compared to 569 in FY14) (of which 350 were handled via administrative review only, as not potential UPs or serious/continuing noncompliance)
- j) Number of cases of noncompliance and/or unanticipated problems reviewed at full board: 96 (compared to 54 in FY14)
- k) Number of those that were determined to be serious or continuing noncompliance: 7 (compared with 8 in FY14)
- l) Number of those that were determined to represent an Unanticipated Problem Involving Risks to Subjects Or Others: 30 (compared with 22 in FY14)
- m) Mean number of calendar days between new study receipt by IRB and¹:
 - (1) review at full board meeting: 38 (vs 40 from prior year)
 - (2) Full board approval: 63 (vs 58 from prior year)
 - (3) Expedited review: 29 (vs 26 from prior year)
 - (4) Expedited approval: 37 (vs 35 from prior year)
 - (5) Exemption determination: 36 (vs 34 from prior year)
- n) Number of education/outreach presentations: approximately 6 presentations, and 9 webinars (with average of 40 attendees each)

Our goals for the upcoming year

1. **Become reaccredited after successful AAHRPP site visit:** The IRB has been through two previous AAHRPP site visits (from initial accreditation and another reaccreditation) and with this experience we should be well prepared. At the site visit we will need to show that we have trained our staff, members, and researchers (as applicable) on any new policies and procedures implemented since the last site visit, so we will ensure we have done that.
2. **Improve tracking and metrics for studies reviewed by a central or commercial IRB, and where Emory relies on other IRB for single studies:** Our dedicated team of analysts continues to develop better ways of doing this, so that reports on Emory research do not omit studies not under Emory IRB review.
3. **Continue to revise and improve eIRB submission form guidance and instructions to reduce need for clarifications and corrections:** IRB staff have long identified many areas for improvement in our eIRB forms. Speed of changes depends on IRB staff time as well as availability of LITS and eIRB vendor resources. Other eIRB changes are planned that are important for the University and the IRB, and will be prioritized alongside our form improvements (e.g. moving to Shibboleth for user accounts, and cleaning up unnecessary clutter in the system).
4. **Plan for adapting IRB policies and procedures and reviewer tools to evolving regulations, specifically the newly-released NPRM from OHRP:** After a long delay, OHRP appears ready to move ahead with revisions to the human subjects regulations also known as the “Common Rule” (because they have been adopted by many federal agencies). These regulations form the basis of most of the IRB’s policies and procedures, therefore major updates to our P&Ps may be required if the Common Rule is indeed revised. The changes may affect: the scope of projects requiring IRB review; the level of IRB review required,

¹ From most recent AAHRPP annual report, compiled June 2014

initially and annually, for different types of projects; the scope of projects requiring informed consent from participants (may include use of deidentified biospecimens); the use of a single IRB of record for more or all multisite studies; and requirements for data security protections.

5. **Continue to improve efficiency and refine turnaround goals for different types of submissions:** The IRB shall continue to experiment with changes in workflows and division of duties among analysts, as the volume of submissions remains steady or increases, while regulatory requirements to consider for different types of submissions become more complex. This goal acknowledges that not all IRB submissions are equal and thus workflows and turnaround expectations cannot be the same for all.
6. **Develop more specific performance expectations for each staff role,** to engender greater trust among the staff and better inform performance evaluations
7. **Increase IRB membership among the most-needed specialties, pediatrics and oncology, as well as MD members in general.** Given the busy lives of faculty IRB members, it is challenging to find members who can attend IRB meetings consistently. This results in overloaded reviewers and slower turnaround times.

Office of Research Administration --- Information Technology (ORAIT)

Research Administration Information Technology (ResAdmin IT) serves as a facilitator, intermediary, and “translator” on behalf of ORA units with the University’s central IT units. ResAdmin IT negotiates and monitors the ORA service level agreements with central IT for all ORA departments. Staff members work in close collaboration with each ORA unit to understand their objectives, day-to-day activities, and long-term program roadmap. In addition, the team provides tiered application support for the ORA units around each units’ IT enterprise-class applications as well as working with the ORA units to establish IT priorities and requirements.

These IT enterprise-class applications include commercial systems such as Huron/Click for IRB, BioRAFT for EHSO and TOPAZ Web P&R for IACUC as well as LITS systems for conflict of interest (eCOI), and SAM Kiosk for OSP. ResAdmin IT also directly supports software applications unique to ORA units e.g., Inteum used in OTT for tracking intellectual property records.

Accomplishments

ORAIT staff collaborated with Emory’s research community through transparent and efficient research administration services. This was achieved by presenting data to ORA units to enable them to better aware of day-to-day activities and better suited to address potential issues. We continued to develop an in-depth understanding of ORA business process encapsulated in enterprise level applications.

ORAIT staff extended and improved our strategic partnership with businesses and organizations aligned with Emory research priorities through leveraged LITS and vendor resources to automate eIRB expiration notifications to researchers, automate the eIRB study states to Expired when Expiration Date is reached equaling an FTE cost savings , changed the eIRB backup methodology to where backups take 30 minutes per night verses 16 hours on Friday, and streamlined eCOI infrastructure producing a cost savings. eIRB authentication method was transitioned to Shibboleth. This allows Emory Healthcare and Emory University network account holder to access the eIRB without having to request access or a sponsored account

ORAIT invested in the training and development of all staff and leadership within the division. We funded and tracked required training in areas related to each staff member’s job responsibility. Such training included:

- Facilitating Requirements for Business Analysis
- Oracle Database 11g - Administration I
- Agile Requirements and Fundamentals for Business Analysis
- Accelerated Training in Health IT (AT-HIT)
- Award Reconciliation and Review Tool (ARRT) training
- Essential Skills for Business Analysis

Other Accomplishments

- Refactored the IACUC, OHS questionnaire web service
- Partnered with ORA Business Operations and F&A IT to streamline IT ordering and installation
- In conjunction with the Compass technical team, restructured the PeopleSoft eNOA feed used for merging and uploading eNOA data and documents to Milner's web based eNOA management system – ComSquared. The restructure included new fields capturing the submitting School, Division, and Department
- Leveraged the new eNOA Fields from Compass in order to re-engineer user access security for the ComSquared eNOA system. The re-engineering effort afforded a more secure, streamlined, consistent, and maintainable access control structure for Emory's eNOAs
- Partnered with EHSO in the procurement and ongoing implementation of BioRAFT, a cloud-based solution offering modules covering Biosafety, Radioisotope, and Equipment (Lab).
- Neared completion of an initiative to eliminate individual desktop printers. Desktop printers are being replaced with divisionally shared, enterprise grade, multifunctional devices
- Completed the move and merge of Office of Compliance's TimeMatters system with that of General Councils, which is supported by F&A IT. The merger afforded a greater economy of scale, eliminated duplication of support effort, enhanced overall system availability, and reduced ongoing support costs
- Restructured team in the attempt to better align core skills with the projected IT staff needs of the ORA division
- Served on the Research Admin IT Governance Committee, Topaz Elements Executive Committee, OnBase Steering Committee, and the IT Advisory Committee

Strategic Challenges

While demand has increased for ResAdmin IT assistance, the limited bandwidth of IT staff can, at times, be a rate-limiter for initiatives in ORA units. Consequently, this often impacts the ResAdmin IT team's ability to deliver IT services.

Goals for FY16

- Refactor OSP Contract web-based service
- Migrate services to cloud-based hosting where possible
- Provide better data extraction methods to customers
- Continue to develop an in-depth understanding of ORA business process encapsulated in enterprise level applications
- eCOI Triage
- Topaz reimplementation (IACUC)
 - Provide assistance when needed in the creation of the new IACUC Topaz Web P&R form. Partner with DAR, LITS, and Yerkes to implement a centrally hosted Topaz environment, including, not limited to, IACUC Web P&R form thus eliminating the need for using VPN off-campus

Office of Research Administration Business Operations (ORABO)

The ORA Business Operations Team provides financial management, accounting, human resources support, operational support including event coordination, website management, marketing, communication, training support and administrative support for all divisions of the Office of Research Administration. Our mission is to innovatively and proactively provide business and administrative services and solutions that support sustainable and efficient use of all resources.

Over the last year, we have been successful in developing ORABO into a cohesive team running efficiently and effectively while streamlining processes and delivering high levels of customer services and excellence in all we do. Additionally, we have focused on process integration, which has provided us the opportunity to move to a more collaborative approach, integrated with the goals, mission and vision of ORA. This intentional collaborative focus has provided the opportunity to be a more proactive and strategic business partner with the departments we support.

FY15 Accomplishments

- Streamlined the processing of Material Transfer Agreements for OTT
- Increased support for the central RAS team
- Decreased the frequency of errors in expense reports and invoice payment from 8-12% pre-ORABO to 2-4% over the last year
- Reduce processing time for invoices, travel expenses, journals and pay request from 48 hours to 24 hours
- All financial forms were changed to fillable PDF forms for ease of use and increased efficiency
- Implemented ORA wide New Employee Orientation Training
- Streamline the processes associated to onboarding, from recruiting to pre-start to where to go on the first day at Emory.
- Conducted compensation market reviews and salary analyses for 36% of ORA division among four departments, decreasing the risk of losing employees due to compensation issues or salary inequity.
- Implemented the first exit interview process and analysis determine trending causes leading to potential issues related to work processes, work conditions or working relationships.
- Streamlined the purchasing process for equipment and supplies, which lead to cost savings and reduction in redundancy.
- Coordinated more than 100 events and committee meetings requiring preparation of the room for food, equipment or both. This effort has saved numerous hours of preparation time, which usually had to be done by the trainer or meeting leaders. One of these events included the IACUC 101 2 day Conference. Attendees provided evaluations in which they rated the coordination, venue, accommodation, meeting facilities as one of the best they have experienced in this type of conference.

Opportunities and Goals for FY16:

- Continue to evaluate and improve processing time and errors across business functions; particularly in Finance and HR
- Focus on professional development and training plans for leadership and managers to develop leadership talent pipelines within ORA.
- Explore opportunities to synergize efforts with other departments to revise the new employee orientation, if needed, to make it fully representative of ORA departments.
- Develop consistency in appearance for the Website
- Increase ORA's visibility by implementing methods for community outreach such as social media outlets and participation in University events.
- Develop and implement the first ORABO newsletter to disseminate information relevant to ORA business operations.

Conflict of Interest Office

Accomplishments

Complete bug and enhancement fixes in eCOI and identify necessary adjustments for policy change in 2016 or identify potential new vendor software resources:

A small patch was developed and implemented in November 2014. It covered only 30% of the items in the approved Business Case but used all the funding. LITS/RWIT deferred developing reporting capabilities within the eCOI system to ORA -IT. They provided ORA-IT with data downloads for development of reports within ORA. A few initial reports were developed in the Spring 2015, but further development and data verification has been delayed due to turnover in personnel at COI Office and ORA-IT Office. We will continue working with ORA-IT to develop reporting capabilities with the current system to assist with Quality Assurance reviews and developing a process for streamlining transaction disclosures.

Due to continued difficulties with completing bug and enhancement fixes, we have begun to review external vendors to find a more effective and cost efficient system. Several vendors have developed systems that are comparable to our system and an external developer would be more dynamic in responding to changes in the regulations, software enhancements, and browser improvements. Additionally, AAMC is developing software that interfaces with most commercial systems for institutions, journals, and continuing education accrediting agencies. This system would greatly assist our faculty members with the numerous organizations and entities outside of Emory for which disclosures are required.

Provide general and focused training based up metrics and Quality Assurance data: The COI staff provided 17 training programs for faculty, staff, and postdoctoral fellows. We will continue to provide training programs with renewed emphasis for administrative units (Deans' offices, RAS groups, department research coordinators, ORA units). A retrospective review of a 2009 grant identified areas that can be improved, especially in the coordination of management plan implementation when several offices are involved.

We continue to perform Quality Assurance reviews of PHS grants. We and CTAC have determined that CTAC's review of COI information as part of their quality audits were not accurate due to their reviewers misunderstanding of the COI policy and requirements. We will determine whether there are more effective methods by which they could assist our office in ensuring compliance with policies and regulations.

Evaluate current policies, procedures, and metrics to determine how to relieve investigators of administrative burdens: Committee members and COI staff identified some potential changes to policy 7.7 and 7.9. Changes will be discussed with Provost's Office and procedure changes will be evaluated in light IT restraints. The ICOI policy revisions will be completed by August and implemented in FY2016.

Goals for FY16

- Evaluate new COI software systems.
- Develop reports from data download of current eCOI system that would assist Quality Assurance Program and support streamline procedures for transactional reporting.
- Revise University COI Policies & Procedures when new IT solutions are identified.
- Continue to provide training and expand as needed to meet campus needs.
- Assist with transition of Office of Research Compliance to University Compliance by determining whether ORA operational functions might be able to be absorbed with current staff's skill set.

COI Metrics

Year	2014-2015	2013-2014	2012-2013	2011-2012
Transactional Disclosures	20,308	18,315	18,356	17,274
No Conflict	20,116	17,644	17,626	16,996
Sent to COI	188	164	143	278
Individuals to COI review	81	84	73	112
Consulting Agreements	1,044	1,054	1186	909
Individuals reporting	500	493	570	424
Sent to COI	79	71	45	35
Individuals to COI review	57	59	41	29
Total Managed Cases	154	150	145	
PHS	38	43	57	
Total New Cases	56	64	72	
Individuals	36	37	40	
PHS Cases	16	10	23	
FCOI Reports	6 New 17 Annual	7 New 33 Annual	36 (includes 5 subcontractors)	29 (plus 7 subcontractors)
FCOI Individuals	12	22	19 (plus 3 subcontractors)	21 (plus 4 subcontractors)
Training Presentations	19		30	47

Environmental Health and Safety Office (EHSO)

EHSO has enterprise-wide responsibility for developing, implementing and maintaining EHS programs to control occupational exposures and to oversee the implementation of mandated laws, regulations, and guidelines promulgated by the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), the Georgia Department of Natural Resources (DNR) and other regulatory agencies. EHSO supports the university's mission through oversight and guidance for the use, storage and disposal of materials used in research, clinical, academic and operational activities. EHSO provides support through six specialties and functions, detailed in the following.

Highlights and Accomplishments by EHS Program

Environmental Health and Safety Management System (EHS-MS), Training and Communications

Emory's EHS-MS provides a systematic approach to managing EHS related risks and identifying opportunities to continually improve EHS performance. The system provides direction to ensure that corporate EHS values are consistently applied across the institution by providing a common framework that connects business planning, implementation, measurement and performance improvement that offers guidance in systematically managing Emory's EHS matters. This program area was expanded in FY14 to combine the EHS-MS program with the Training and Communications programs. The Training and Communication programs are responsible for providing educational and outreach resources to educate and assist the Emory community in EHS matters. Combining these programs under one umbrella further enhances the continual improvement of the EHS-MS system. Resource growth during this transition resulted in a new resurgence in program development towards the end of FY15.

Accomplishments

- Hired for Environmental Health and Safety Management System Coordinator and Communications Specialist positions
- Completed an internal Gap Analysis of all 18 elements of the Emory EHS-MS system which identified areas for increased efficiency and effectiveness within the system itself.
- EHSO program areas completed 11 Objectives and Targets and developed action plans for 11 new ones.
- Resources were set in place to expand the EHS-MS system, and internal and external communications using education, social media and marketing tools.
- Over 16,000 student and employee training completions in the areas of environmental compliance, and occupational safety and health occurred.
- Expansion of training delivery mechanisms to include videos and other creative outputs to increase impact and retention of EHS information

Environmental Compliance

The Environmental Compliance Program provides service to the Emory Enterprise through compliance assistance with environmental regulatory requirements. This program evaluates

and manages the environmental outcomes of Emory operations with the goal of minimizing environmental impact and in the interest of stewardship of resources.

Accomplishments

- A vendor based management model was recently implemented to collect hazardous waste from generation site on the campus and manage waste chemical that were collected.
- Hazardous Waste Managed
 - Hazardous Waste (pounds) 138,577
 - Universal Waste (pounds) 24,918
 - Requests for chemical waste removal 2,348
- As part of an effort to close the ground water contamination site located at the North Decatur Building this project was entered into the GA EPD Voluntary Remediation Program. At this time the groundwater remediation equipment has been removed from the site and EHSO is in the process of preparing closure reports. Once completed the site will be removed from the HSI and the impacted area will be under a property use restriction covenant.
- Work is underway with Emory University Hospital Midtown to replace aging underground storage tanks. Developed a solution in conjunction with EUHM Facilities Management and an external engineering consultant.
- RAM Procurement and Waste Management:
 - Requisitions Approved 522
 - Requisitions Rejected 19
 - Replacement value \$367,322.82
 - Packages processed and delivered 372
 - Radioactive waste collections performed 230
 - Radioactive waste shipped (pounds) 1728
 - Decayed radioactive waste disposed of (pounds) 5399
- 398 compliance evaluations were conducted. These evaluations are designed to engage site managers and assure that the site is following regulatory guidelines.
- Evaluations are underway to determine alternate methods to dispose of biomedical waste. This includes point of generation decontamination, central management of containers, and central autoclave.
- Participated in developing a “Green Labs” initiative in conjunction with Sustainability and Campus Services. The pilot of this program was recently was launched.
- Preparing a web based Hazardous Waste Pickup Request for the site along with an iPad waste tracking form.

Radiation Safety

The purpose of the Radiation Safety program is to enable safe use of ionizing radiation at Emory University and protect staff, public, and environment from its harmful effects. The specific responsibilities of the Radiation Safety Office, to ensure that this purpose is being met, are based on the ALARA principle: to keep all exposures As Low As Reasonably Achievable. The Radiation Safety Office operates in collaboration with the physicians, staff, and management to

provide policy and procedures, training, radiation protection measurements, facility support and customer service while maintaining compliance with applicable regulations.

Ionizing radiation is used for research, diagnosis and treatment in three basic forms at Emory: unsealed sources of radioactivity, sealed sources of radioactivity and radiation-producing machines. Radioactive materials are licensed by the Georgia Department of Natural Resources (DNR) via the Emory Broad Scope License GA 153-1 for Emory University, License GA 1442-1 for Emory Heart Centers and GA 1359-1 for Emory Southern Heart Specialists. All radioactive materials' receipt, use, and disposal is inventoried and recorded in the Radiation Safety database or the clinical department's patient record management systems. X-ray devices are regulated by the Georgia Department of Community Health.

Accomplishments

- Completed corrective action plan for PI refresher training
- Submission of shielding designs for EUH, EUHM, EOSC, The Emory Clinic at Johns Creek, and Winship Cancer Institute
- License documentation for relocation of PET unit for Emory Southern Heart
- Updated analytic equipment
- Benchmarked radioactive seed localization procedures
- Located and permitted analytic x-ray machines
- Complex inpatient therapy for patient with cognitive issues and patient on dialysis
- Afterloader (HDR) at EUHM shutdown and device removed
- Partnership with SIR annual meeting fluoro dose workshop
- Discussion with NTI for irradiator replacement/disposal
- Inspection of Mammography Quality Standards Act with no observations relating to medical physics or radiation safety
- Joint Commission inspection of EUOSH and EUH with no observations relating to medical physics or radiation safety
- On-site training of law enforcement response in response to attempted diversion theft, etc.
- Participation in Radiation Injury Treatment Network exercise leading to Emory joining the network as a full member
- Supported a hot lab relocation at EUH Nuclear Medicine
- Documentation of physician Training and Experience support to Emory Johns Creek and Emory St. Joseph's
- 266 x-ray machine inspections
- 68 audits of clinical use of radioactive material
- 225 Human Research studies approved

Research/Biosafety

The Research Safety Office provides consulting services, training programs and regulatory compliance support to all University community members. This is accomplished by review of protocols using biological toxins, recombinant DNA, infectious agents or human cells, tissues, etc., and by providing Bloodborne Pathogen, Biosafety and Lab Safety Training to identified personnel, correcting lab signage, and conducting lab inspections.

Accomplishments

- Improvement of laboratory inspection process through the implementation of supporting documents and reporting tools.
- Full implementation of Score card system which reflects results of the EHSO Lab Validation Inspection and the EHSO Lab Post Validation Inspection.
- Electronic Protocol Management System for Biosafety Protocols-platform is hosted by BioRAFT (emory.bioraft.com) project started late spring of 2015. Starting January 2016 all Biosafety protocol submissions will be through electronic platform.
- Completion of laboratory signage program based on GHS. All laboratory signs updated for alignment with the new Globally Harmonized System (GHS).
- Ebola Virus Disease Management: Participation in the preparation to receive and care for patients with Ebola Virus Disease at the Serious Communicable Disease Unit (SCDU) at Emory University Hospital. Provided support services in the following areas:
 - Risk Assessment including multiple satellite sites affiliated with Emory Healthcare
 - Personal protective equipment (PPE) training
 - Diagnostic lab sample management
 - Waste management
 - Compliance assistance

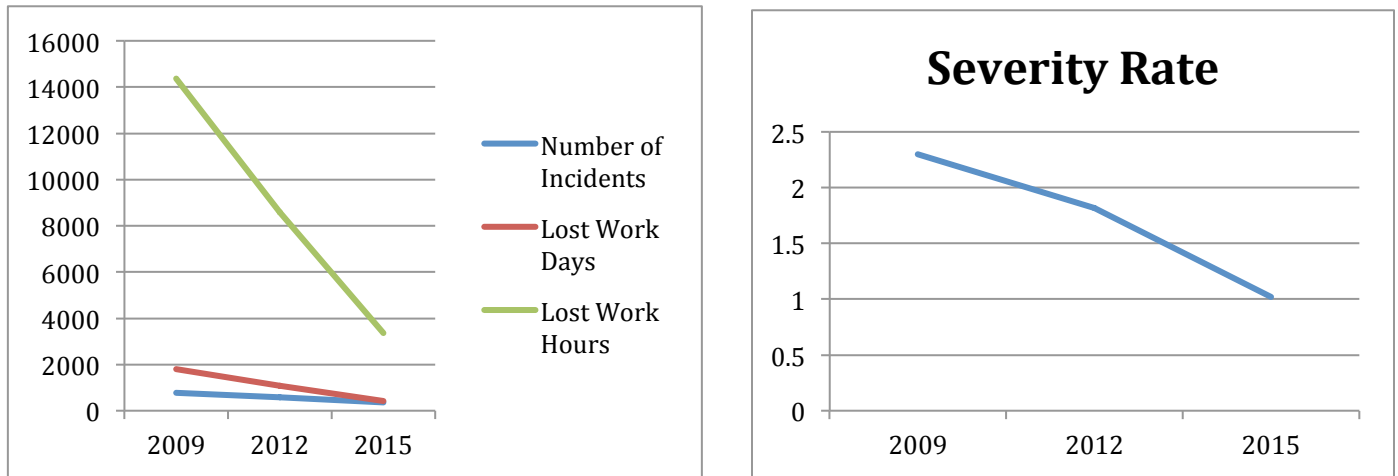
Safety and Industrial Hygiene Group

The Safety and Industrial Hygiene staff assists the Emory University community in maintaining a workplace that is as free as practical of known safety and health hazards. Our Indoor Air Quality (IAQ) professionals are called upon to investigate various customer concerns ranging from foul odors and stagnant air to extreme temperatures, colds, and other sinus related issues. The work environments range from manholes to roof tops, steam plants to laboratories and landscape to residence halls. Our General Safety staff conducts accident investigations, ergonomic surveys, safety audits, and develops and implements safety programs and procedures. Our staff works closely with Campus Services and University staff to control and eliminate safety hazards and train Emory employees. We also work closely with the Worker's Compensation staff to review and investigate accidents. We trend accidents to verify lagging indicators of hazardous conditions in order to evaluate and establish control strategies. We conduct safety audits and assessments to measure compliance.

General Safety Accomplishments

- Continuous reduction of time away from work due to injury.
 - A steady decrease in the number of recordable incidents can be observed, most likely attributed to an increase in reporting of all incidents (no matter how small). Since all reported incidents are investigated, recommendations for remediations are made before a serious injury occurs.
 - The number of days spent away from work (restricted or lost work days) continues to have a steady decrease.
 - Our Severity Rating (total number of lost workdays divided by the total number of recordable incidents) went from 2.3 in 2009 to 1.02 in 2015.

Figure 1: Incidents



- Safety and Industrial Hygiene Staff completed a second round of Occupational Safety and Health Administration (OSHA) 30-hr training for General Industry Safety and Health Standards for Campus Services’ Safety Liaisons. In addition, the OSHA-30 Hour training was extended to The Emory Clinic (TEC) safety staff and TEC contractors.
- Continuous implementation and improvement of fall protection on main campus rooftops: Fall protection was installed on Cox Hall and the 1599 Clifton Rd. Building.
- Developed a Sprain/Strain Safety Campaign to increase awareness and decrease work-related incidents resulting in sprains/strains.
- Safety and Industrial Hygiene Staff liaised with the Occupational Safety and Health Administration (OSHA) regarding employee concerns and hospitalizations.

Industrial Hygiene Accomplishments

- Remediated and removed hazardous materials from McTyeire Hall on Emory’s main campus, Oxford Campus’ Branham and East Halls, and Briarcliff Campus’ gatehouse and five (5) cottages in preparation for demolition.
- Identified a gap in respiratory fit testing and implemented procedures to correct it.
- EHSO Spill Response Team was revamped and advertised throughout laboratories and Campus Services.

Yerkes

The Yerkes National Primate Research Center conducts essential basic science and translational research to advance scientific understanding and to improve the health and well-being of humans and nonhuman primates.

Accomplishments

- Reviewed/revised greater than 60 Yerkes specific SOPs
- Completed CDC import inspection of BSL-3 TB labs.
- Yerkes Safety Committee meet quarterly, reviewed injury/illness and exposure trends, safety training and level 3 containment monitoring results.
- Conducted fire, severe weather and animal out of primary containment drills at main center and field station.

- Containment Coordinator conducted weekly inspection of all (4) BSL-3 and ABSL-3 facilities. Completed annual training for level 3 facilities that included Researchers, Animal Care, Veterinary Medicine and Facilities Management.
- Occupational Health Program provided greater than 800 TB tests, 210 new orientation health assessments, 70 respirator medical clearances and added approximately 330 samples to the serum bank.
- Successfully completed the NIH P-51 5 year grant site review and inspection.

Industry Leadership Positions held by EHSO staff

- CSHEMA Immediate Past President, Board Member, Community of Practice Co-Chair
- External Advisory Board on Lab Safety to the Director of CDC
- APLU/AAU Lab Safety Task Force
- Deputy Convener for the development of the ISO Biorisk Management Standard
- Technical writing team, ISO Biorisk Management Standard
- CDC Bi-annual Meeting Steering Team
- Occupational Health Colloquium: Preventing and Treating Biological Exposures Steering Committee
- Coordinator of 3rd edition of "Environmental Compliance Assistance Guide for Colleges and Universities"
- CT Quality and Safety Committee Co-Chair

Challenges, Opportunities and Goals for FY16

- Though keeping up with Healthcare has always been a challenge, EHSO's involvement in preparation for and response to Emory Healthcare's treatment of patients afflicted with Ebola Virus Disease dramatically redirected our resources during FY15. Though this resulted in an increased workload for EHSO members, an exponentially stronger relationship with Emory Healthcare resulted which will have lasting effects. This increased collaboration will make on-going enhancements to the SLA during FY16 more effective.
- Increasing focus on Research EHS Compliance – specifically increased pressure on research with Bio-hazardous materials and high-risk chemical hazards.
- Finding staff well trained in academic EHS programs and retaining knowledgeable staff. All EHSO programs experienced turnover in staff during FY15, which resulted in the delay of some goal completion.
- Continue to evaluate and define our roles and responsibilities within EHC, TEC and ESA. Streamline SLA process to better accommodate ever-changing EHC.
- Evaluate and improve EHS electronic interfaces. Heavy support for BioRaft implementation.
- Improve Internal and External Communications
- Continued support for EHS Management system for quality and process improvement of our programs
- Explore more creative and effective training methodologies and continue to professionally and technically develop staff.

Office of Technology Transfer (OTT)

Introduction

The Office of Technology Transfer celebrated its 30th anniversary this year with an ambitious social media campaign, a new video and section on our website. Two of my favorite historical facts include the more than 100 students that have worked with the office and the 29 countries in which we executed an exclusive or non-exclusive license agreement. Over the last 30 years, we received 3,232 disclosures of new inventions, filed 2,671 patents in the US alone, and executed 700 license agreements resulting in 39 products to market that generated over \$853M in licensing revenue to support scientific research & education at Emory.

In FY15, we received 230 disclosures of new inventions and filed 141 US patent applications. We received a record high 37 issued US patents which will help supply licensing opportunities in years to come. We executed 41 AUTM-reportable license agreements of which 8 have high net worth potential. Licensing revenue hit \$7.9M driven by royalties from our Baxalta-licensed product for acquired hemophilia and Emory's license to EGL Genetic Diagnostics, LLC. EGL Diagnostics generated \$39M in non-licensing revenue to Emory from the sale of most of its interest in the joint venture with Eurofins.

It has been a landmark year in Office of Technology Transfer as we expanded our responsibilities to include the industry contracts group (6 FTEs) that formerly reported through our Office of Sponsored Projects. This group is responsible for negotiating clinical trial, research, research-for-service, and confidentiality agreements with industry. In FY15, industry funding came from 454 agreements resulting in \$44.9M in funding. Industry funding contributed to Emory's record high \$572M in research funding this year.

We look forward to further leveraging our approach to industry relations through a newly created position dedicated to the pursuit of public/private partnerships. This position is shared with the Office of Development & Alumni Relations and will better coordinate industrial opportunities and knowledge from these seemingly disparate functions. A primary focus of this position is to proactively match university researchers with their industry collaborators to secure more research partnerships.

The alignment of technology transfer, industry contracting, and public/private partnerships will allow us to utilize a more comprehensive approach to industry relations at Emory. In the new year, we expect to adopt targets focused on all aspects of industry partnerships that will be more achievable than ever before given the alignment of these important activities.

Highlights and Milestones

- OTT celebrated its 30th anniversary this calendar year with a celebration campaign that included a blog series, social media highlights, a video, a special section on the website, and a video.
- Emory Genetics Laboratory (EGL) and Eurofins Scientific (Eurofins), a global leader in bio-analytical testing and genomic services, enters into a joint venture that calls for Eurofins to acquire a controlling interest in EGL. Pending regulatory approvals, EGL will be re-named EGL Genetic Diagnostics, LLC.
- FDA approves Baxter's Obizur (formerly OBI-1), a recombinant porcine sequence antihemophilic factor, for acquired hemophilia A. The Approval was based on data showing 100% of 28 Patients responded to treatment within 24 Hours. The drug product

hit the market 22 years after the 1st patent filing and the underlying technology changed hands 5 times.

- The National Football League, GE, and Under Armour selects the iDETECT team as one of the seven winners of the Head Health Challenge II, a competition for new innovations intended to speed diagnosis and improve treatment for concussions. Each winning team will receive a \$500k grant and will have the opportunity to receive an additional \$1 million to advance their work.

Company Milestones

- AKESOGen makes annual list of America's fastest-growing private companies, the Inc. 500.
- RFS Pharma, LLC announces the closing of its merger with Cocrystal Pharma, Inc. (OTCBB: COCP), a biotechnology company developing novel antiviral therapeutics for human diseases. The shareholders of Cocrystal and of RFS Pharma each own approximately 50% of the combined company on a fully diluted basis following the merger.
- Clearside Biomedical, Inc. completes \$16 million Series B financing. The financing included new investor RusnanoMedInvest (RMI) and existing investors Hatteras Venture Partners, Santen Pharmaceuticals Co. Ltd., Mountain Group Capital and GRA Venture Fund.
- Clearside Biomedical, Inc. announces a favorable End-of-Phase 2 review with the FDA on its lead drug triamcinolone acetonide (TA) administered via injection into the suprachoroidal space (SCS) for the treatment of macular edema associated with non-infectious uveitis. Agreement was reached with the FDA for the overall development plan with a single pivotal Phase 3 clinical trial, and the company is finalizing plans to initiate this global study.
- NeurOp, Inc. enters into a strategic collaboration with J&J's Janssen Pharmaceuticals, Inc. to better understand how modulating the NMDA (N-methyl-D-aspartate) receptor impacts pathways related to different central nervous system disorders.

Office Milestones

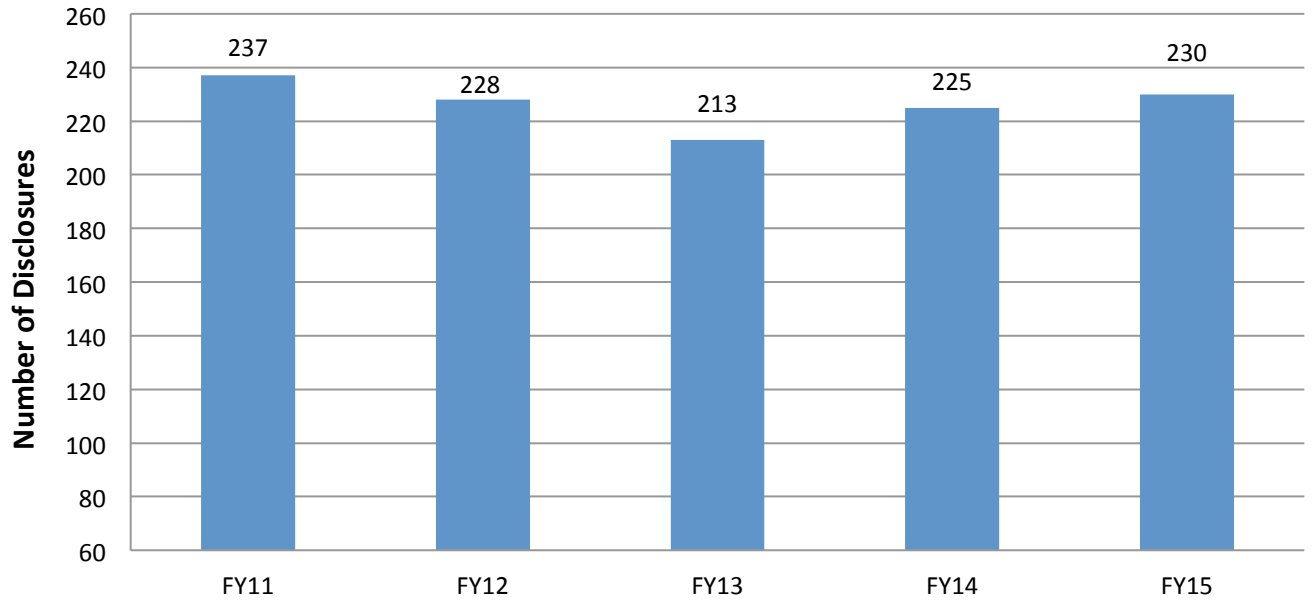
- OTT enters into a three year agreement with DAR to share the position of Director of Public and Private Partnerships.
- OTT assumes leadership of the industry contract function and staff from OSP.
- Emory completes the Kauffman Foundation certification processes and becomes a Kauffman FastTrac® TechVenture™ training site.
- OTT hosts J & J Innovation's campus visit. A group of 11 people from J & J met with 26 faculty members individually.

Statistical Milestones

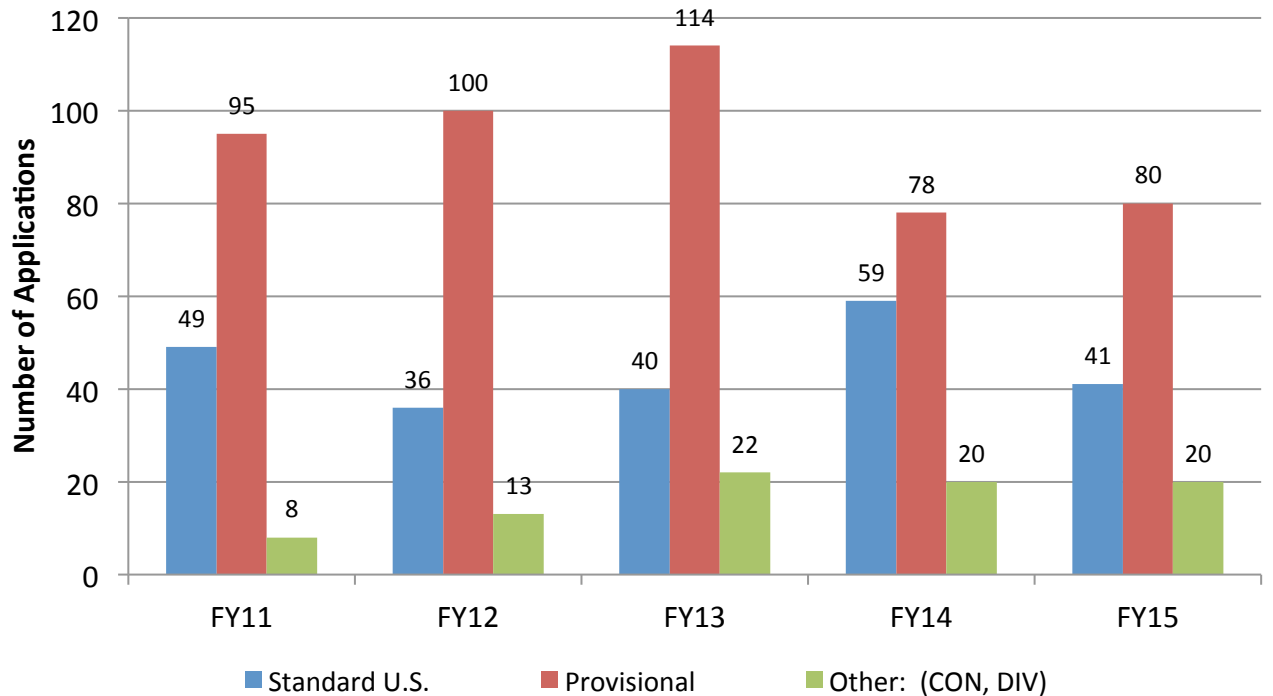
- Received the second highest number of disclosures at 233, with the largest of 237 in FY11.
- Received the highest number of issued patents at 37, surpassing the previous high of 35 from last year.

By the Numbers

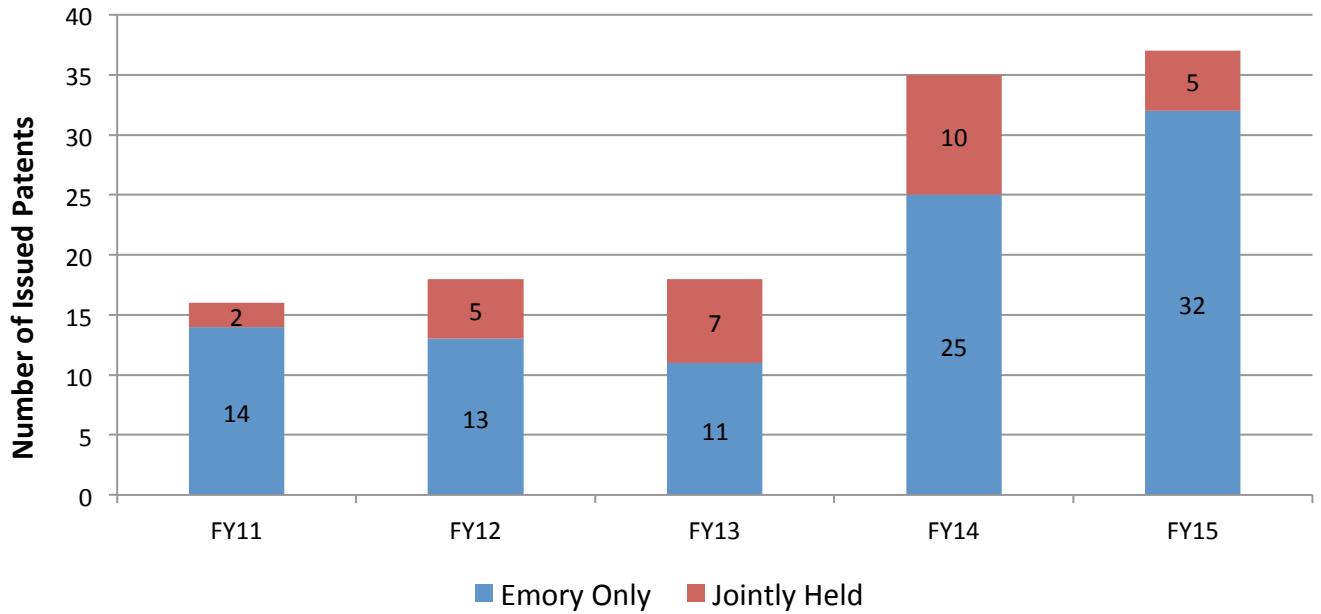
Number of Invention Disclosures



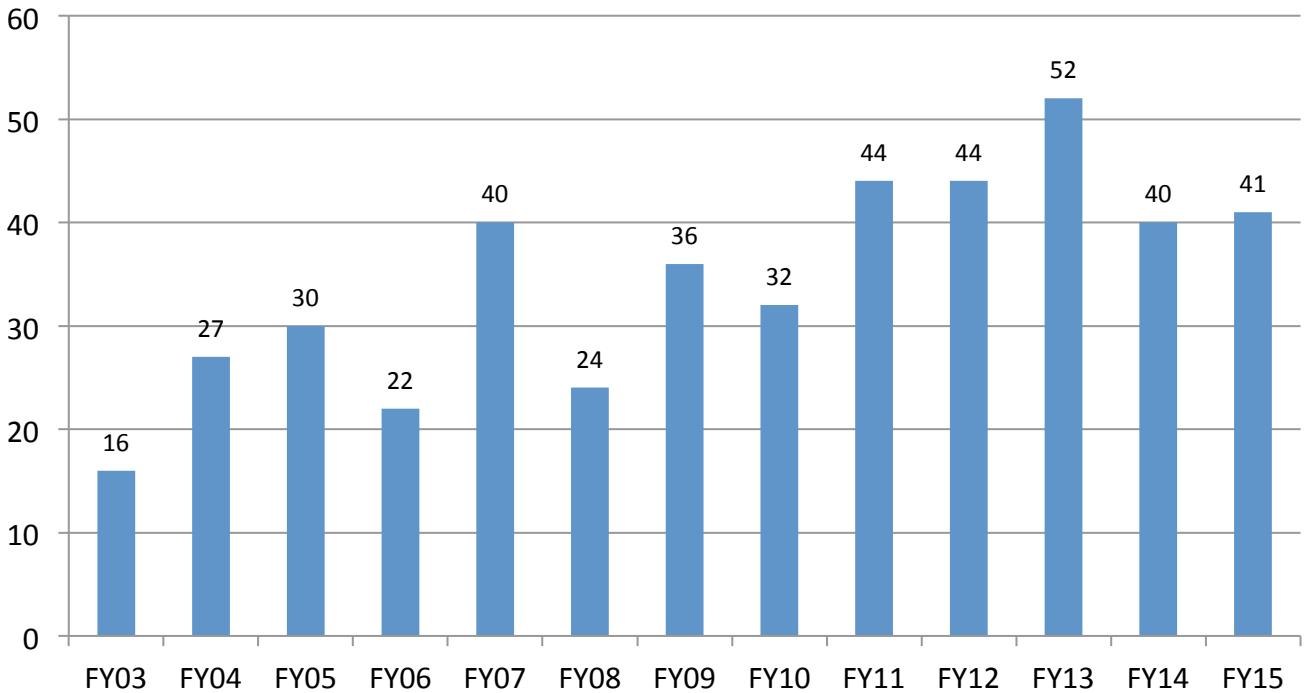
Number of U. S. Patent Applications



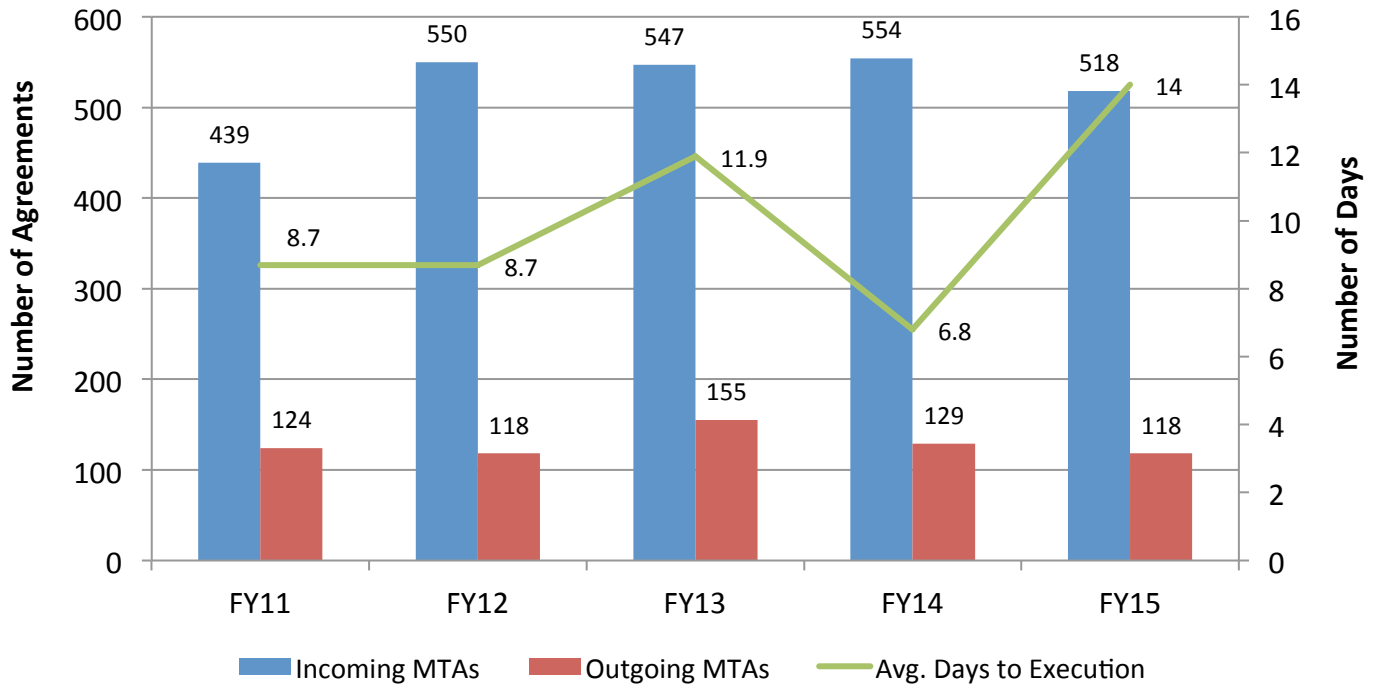
Number of U.S. Issued Patents



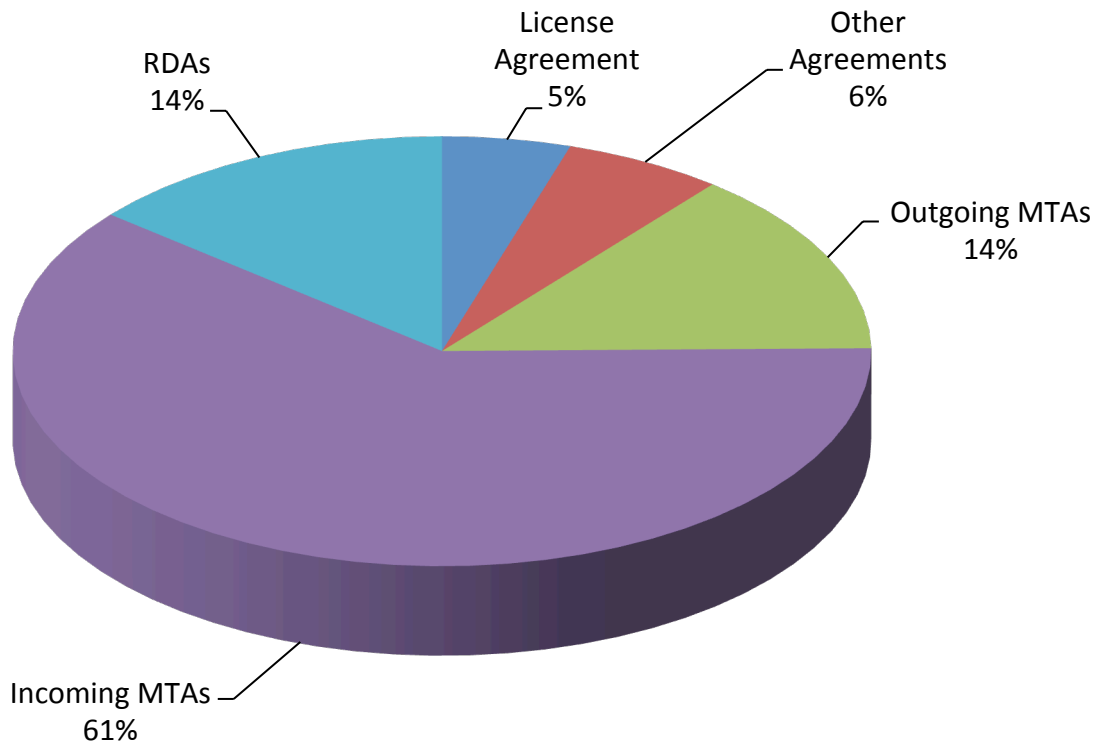
AUTM Reportable Agreements



Material Transfer Agreements



Network of Agreements



Summary of Expenditures and Revenues Since FY92

Fiscal Year	Total Patent Expenses	Reimbursed Patent Expenses	Reimbursed Past Patent Expenses	License Revenue *	Return on Patent Expense Investment **
1992	\$(243,554.87)	\$137,868.56		\$978,181.83	\$872,495.52
1993	\$(316,315.79)	\$174,066.98		\$1,278,731.43	\$1,136,482.62
1994	\$(448,767.07)	\$182,100.50		\$1,083,398.45	\$816,731.88
1995	\$(585,415.31)	\$245,178.91		\$2,637,146.69	\$2,296,910.29
1996	\$(1,210,632.63)	\$777,391.86		\$2,316,793.30	\$1,883,552.53
1997	\$(1,066,584.60)	\$284,074.69		\$2,115,559.48	\$1,333,049.57
1998	\$(1,524,810.61)	\$551,263.85		\$5,313,706.40	\$4,340,159.64
1999	\$(2,332,896.46)	\$500,948.48		\$15,437,285.00	\$13,605,337.02
2000	\$(3,266,373.14)	\$671,767.20		\$10,671,921.65	\$8,077,315.71
2001	\$(4,568,569.50)	\$4,005,408.35		\$3,608,156.91	\$3,044,995.76
2002	\$(7,155,792.41)	\$889,586.94	\$145,248.51	\$29,557,916.39	\$23,436,959.43
2003	\$(2,565,067.46)	\$931,626.59	\$349,629.66	\$22,737,389.16	\$21,453,577.95
2004	\$(2,190,578.77)	\$835,926.24	\$234,408.31	\$22,517,830.24	\$21,397,586.02
2005	\$(1,852,482.44)	\$605,011.07	\$244,028.90	\$45,656,765.15	\$44,653,322.68
2005 ***				\$540,000,000.00	\$540,000,000.00
2006	\$(2,063,712.70)	\$951,051.43	\$199,565.42	\$17,769,294.77	\$16,856,198.92
2007	\$(2,453,499.56)	\$1,141,245.12	\$447,385.29	\$17,681,765.35	\$16,816,896.20
2008	\$(3,407,280.35)	\$1,996,440.95	\$159,154.30	\$19,020,361.20	\$17,768,676.10
2009	\$(3,114,110.79)	\$1,419,785.07	\$133,225.73	\$15,027,391.01	\$13,466,291.02
2010	\$(3,319,879.82)	\$1,849,685.53	\$127,178.28	\$14,382,136.46	\$12,886,311.94
2011	\$(3,586,175.60)	\$2,409,734.70	\$167,126.17	\$15,899,106.74	\$15,116,602.86
2012	\$(3,343,594.80)	\$2,095,020.52	\$208,089.82	\$25,630,179.86	\$24,559,683.76
2013	\$(2,674,550.02)	\$1,372,763.95	\$54,508.61	\$4,124,414.34	\$2,894,486.02
2014	\$(2,593,775.06)	\$1,311,112.08	\$83,103.49	\$9,816,203.06	\$8,546,207.91
2015	\$(2,331,229.99)	\$952,215.22	\$87,580.91	\$7,948,858.99	\$6,644,998.21
Total	(\$56,621,597)	\$14,547,792	\$1,666,918	\$853,210,494	\$821,010,832

* License Revenue includes Emory's Share only; amounts distributed to other institutions not included.

** Return on Patent Expense Investment is equal to the sum of License Revenue, Reimbursed Past Patent Expenses, and Reimbursed Patent Expenses minus the Total Patent Expenses.

*** Revenue received in connection with the monetization of future FTC royalties.

Internal Distribution of Licensing Revenue for FY15

Directly to PI'S	\$3,543,844.06
PI Labs	\$1,650,319.91

College	\$ 299,595.75
College Departments	\$ 494,370.75
Chemistry	\$ 494,370.75

School of Medicine	\$ 614,571.57
School of Medicine Departments	\$ 737,543.51
SOM Department Breakout	
Biochemistry	\$ 2,606.30
Cardiology	\$ 188,484.70
Cell Biology	\$ 4,613.29
Dermatology	\$ 1,938.30
Emergency Med	\$.00
Genetics	\$ 12,304.69
Hematology	\$ 3,176.25
Dept. of Medicine	\$ 50.00
Microbiology	\$ 10,524.92
Pathology	\$ 680.63
Neurology	\$ 14,634.77
Pediatrics	\$ 190,794.16
Pharmacology	\$ 162,321.90
Psychiatry	\$ 513.16
Radiation Oncology	\$ 67,340.00
Radiology	\$ 73,405.74
Surgery	\$ 4,154.70

Yerkes	\$405.00
Yerkes Departments	\$668.25
Yerkes Department Breakout	
Microbiology	\$ 668.25
General University Share	\$2,011,214.01
Legal Expenses	\$.00
Misc. Expenses	\$ 40.00
Total Distributed	\$ 9,352,532.81

Office for Clinical Research (OCR)

OCR had a very exciting and productive FY15. We offer many services to support the clinical research enterprise through five functionally distinct teams: pre-award, data integration and integrity, clinicaltrials.gov, invoicing, and education and outreach. These teams accomplish many functions across the clinical trials life cycle encompassing research participant safety, research billing compliance, clinicaltrials.gov compliance, and financial accountability. Both pre-award and post-award functions are performed within these teams, working closely with our colleagues across Emory University and Emory Healthcare. In the last few years, OCR has seen a shift in clinical trials submitted to OCR from more federally-funded studies to more industry-supported studies. The volume of these non-federal studies increased from 266 in FY14 to 401 in FY15, resulting in a 51% increase. This increase in volume has impacted the workload of all of the OCR teams. OCR has also experienced a greater use by sponsors of Contract Research Organizations (CROs) from 89 in FY14 to 150 in FY15, a 69% increase, resulting in more protracted negotiations and additional delays on the pre-award team.

Our mission is to organize and enhance operational processes that support the efforts of the clinical research team and to facilitate the timely initiation, execution, management, and completion of clinical trials at Emory. OCR continuously evolves to meet the needs of our research community through continuous process improvement with a focus on high quality, efficiency, communication, and transparency. The outcomes of these small, rapid cycles of improvement are evidenced in our accomplishments listed below.

Education and Outreach Team

Function

The OCR education and outreach team is responsible for the content and coordination of Emory's mandatory clinical trials training for investigators, research nurses, and clinical research coordinators.

Accomplishments

- Awarded 2015 Best of Atlanta Award for Education from the Atlanta Business Recognition Organization.
- Created 3 remaining advanced elective courses for clinical research staff to support mandatory requirement for recertification every three years. Facilitated completion of elective modules being developed by ORA colleagues.
- Obtained AHA BLS Healthcare Provider instructor status to provide BLS certification for clinical research coordinators required for their continued employment (attended outside courses at their own expense). There were 137 EU research staff who attended the BLS course in FY15.
- In FY15, provided 77 educational seminars/courses for 1,863 attendees (660 attendees on-line and 1,203 attendees in-person) who were awarded 12,074 total CMEs/CEUs.

Goals for FY16

- Develop and implement a mandatory training curriculum for EU clinical research staff to document clinically relevant research information in the Emory electronic medical record (EeMR), including licensed research nurses, unlicensed clinical research

coordinators, and clinical research coordinators with other licenses, e.g. LPN, COMT, EMT. Develop process to notify credentialing of completed training so access to EeMR can be granted proactively.

- Create a CITI organization-specific module (with continuing education credits) to replace the current mandatory on-line training modules in eLMS for clinical research faculty and staff. The modules will provide content that is foundational, customized to Emory policy, and serve as a precursor to possible future CTSA/NIH GCP training requirements.
- Review and maintain OCR website content to ensure updated information is available for our users. Incorporate pertinent new policies, guidance, and initiatives in clinical research discussed at the Clinical Research Coordinator Advisory Committee, Clinical Investigator Advisory Committee, Clinical Trials Operations Committee, and Clinical Trials Executive Committee.

Pre-award Team

Function

The OCR pre-award team is responsible for laying the foundation for research billing compliance by developing the prospective reimbursement analysis (PRA) based upon the Medicare (CMS) regulations for qualifying clinical trials.

Accomplishments

- The team has worked diligently on improving pre-award's performance metrics and has achieved a median of 16 business days (mean of 20) in FY15 from receipt to submission for non-federally funded studies including time spent by the OCR, sponsor, and investigator. Our target was 22 days.
- In the past year, the pre-award team negotiated higher budgets than the sponsor's initial offer by a median of 22.3% (mean of 35.9%), equating to an additional \$13,618,733 if the target enrollment is met.
- Budget development and negotiation for non-federal studies without EHC billable items and services, and budget development for non-negotiable non-federal studies were added in FY15.
- Nine out of twelve pre-award staff have achieved their Certification in Healthcare Compliance (CHRC), and the remaining three will be scheduled for the CHRC training within the next year. Five staff have attended the Emory Healthcare Quality Academy.

Goals for FY16

- Update all pre-award SOPs for PRA, budget development and negotiation, and pre-award document routing.
- Complete PRAs and budgets with a median turnaround time of 20 days for industry studies and 13 days for all studies. Continue to explore process improvement initiatives to ensure high quality PRAs and budgets that cover costs.
- Analyze two prospective study budgets developed by pre-award and compare to what was actually invoiced and charged to the study account to determine if study costs were covered.

Opportunities

- Experiencing more protracted sponsor budget negotiations due to the economy and a sponsor reliance on CROs.
- Transition pre-award access database into ERMS to eliminate redundancy, increase consistency, and improve workflow.

Data Integration and Integrity Team

Function

The OCR data integration and integrity team maintains the authoritative list of active clinical trials and active research participants for Emory. The team provides clinically relevant research information for our EHC colleagues to facilitate the safety of patients participating in clinical trials.

Accomplishments

- As of August 31, 2015, there were 1,567 active clinical trials (per the NIH definition) conducted by Emory faculty with 14,097 research participants flagged as on-study.
- During FY15, 8,469 research participants were entered and flagged in EeMR as participating in a clinical trial, on the same day as consent, for centralized review according to the PRA (7,920 removed from EeMR when off-study). There were 6,505 signed informed consent documents uploaded to EeMR, 500 PRAs (new and revised), 289 "Clinical Research Key Points", and 193 "IDS Drug Data Sheets" uploaded in FY15. These study level documents were uploaded within 24-48 hours of notification of award to provide clinically relevant research information at the point of service to support patient safety.
- Maintained a systematic internal QA audit monthly for patient entry into EeMR and signed consents uploaded to EeMR with 99% accuracy.
- Facilitated timely ERMS enrollment of research participants on same day as consented by escalating monthly reports on late enrollment to PIs and departments based upon risk stratification due to the critical impact on research billing compliance and patient safety.
- Facilitated transition of active ESJH studies transferred from community physicians to Emory faculty to applicable ORA departments.
- One data integrity staff member obtained the HCCA CHRC certification for a total of three staff certified; two staff attended the Quality Academy course, for a total of five staff.

Goals for FY16

- Upon notification of an award by OSP, continue to enter studies and study level documents in EeMR within 24-48 hours. Review daily to assure timely receipt and escalate if not received within 5 business days.
- Upon ERMS notification by CRC, continue to enter research participants into EeMR on same day, which triggers 100% bill hold. Follow-up to assure signed patient consent received within 24 hours and loaded into EeMR (escalate if not received within 5

business days). Notify EHC Making Data Healthy when duplicate records created if unable to match according to EHC requirements.

- To maintain data integrity, continue to reconcile the research studies and participants between ERMS and EeMR monthly, consistently off-studying patients and closing studies in both ERMS and EeMR upon closure in IRB.

Opportunities

- Coordinate with IT to develop a more robust data collection of pertinent study information in ERMS, streamlining the pre-award and data integrity teams' process flow.

ClinicalTrials.gov Team

Function

The OCR ClinicalTrials.gov team identifies studies approved by an Emory health sciences IRB to determine if Emory is the sponsor of an investigator-initiated study that meets the FDA definition of an applicable clinical trial or meets the requirements of an ICMJE-governed journal for future publication or follows NIH requirements. The team ensures these clinical trials are registered in ClinicalTrials.gov and study records are updated as mandated. In addition, the team updates ERMS with the NCT number for all Emory clinical trials to facilitate Medicare billing and reimbursement.

Accomplishments

- ClinicalTrials.gov team served as the PRS Administrator role for ClinicalTrials.gov and assumed registration and results entry of all active study records in ClinicalTrials.gov on behalf of Emory Responsible Parties and study teams. Facilitated the development of a database for tracking ClinicalTrials.gov studies and distribution of a new report of active clinical trials within ClinicalTrials.gov to the PIs and departments. In FY15, the team processed 5,392 ClinicalTrials.gov queries (340 by ERMS study activation review; 5,136 by email; 114 by telephone; and 2 in person).
- As of August 31, 2015, Emory was listed as the sponsor in ClinicalTrials.gov for 698 studies with outstanding queries in 22 of these studies. The ClinicalTrials.gov team has made tremendous progress this past year in dramatically reducing the number of study records for Emory-Owned studies requiring attention.
- Proactively reviewed the eIRB database for health science studies approved by the IRB to determine if they were entered into ClinicalTrials.gov as required by the ICMJE, NIH and FDAAA.
- Developed a process in response to a new Medicare regulation. Updated ERMS and EeMR with NCT number required on any claims for patients participating in a clinical trial to ensure reimbursement of claims per CMS requirements (otherwise, the claim is rejected).
- On behalf of Emory University, drafted a letter to formally respond to the NIH policy request for public comments and Notice of Proposed Rule-Making released in November 2014 on proposed and significant changes to requirements for ClinicalTrials.gov.

- Maintained internal controls to assure all clinical research studies with billable services were submitted to OCR for a PRA per the Dean’s mandate. Proactively reviewed the eIRB database for new health science studies approved by the IRB to determine whether they met the NIH definition of a clinical trial or had EHC billable items and services to assure OCR submission and entry into ERMS, as appropriate.

Goals for FY16

- Continue PRS Administrator role for ClinicalTrials.gov to assist PIs with user names, facilitate study registration, and update information in ClinicalTrials.gov per the mandate. Maintain process to update ClinicalTrials.gov number in ERMS and update IRB number in ClinicalTrials.gov for tracking purposes.
- Create a formal process for identification and notification to Responsible Parties of clinical trials that potentially need to be registered in ClinicalTrials.gov per FDAAA, NIH, or ICMJE requirements.
- Coordinate with IT to develop more robust web-based database in ERMS for ClinicalTrials.gov to allow for metrics and tracking of study records.
- Facilitate resolution of problem records with PI and department for Emory-owned studies in ClinicalTrials.gov and reduce the overall percentage of problems to (and maintain at) 10% or less of study records.

Opportunities

- Proactively strategize and plan for a final decision and publication of proposed changes in ClinicalTrials.gov as a result of the NIH Policy and FDA Notice of Proposed Rule-Making, and the anticipated increase in study volume for both registration and results reporting for Emory-owned studies.
- Transition ClinicalTrials.gov Rosetta access database into ERMS to eliminate redundancy, increase consistency, and improve workflow.

Clinical Research Accounts Team

Function

In an effort to standardize the invoicing, accounts receivable, and accounts payable process for clinical trials, the SOM made a decision to transition the financial reconciliation for all industry-supported clinical research in all SOM departments and divisions to the OCR Clinical Research Accounts team. The team invoices the sponsor per the PRA; tracks payments owed by the sponsor for non-invoiceable items; receives checks directly from the sponsor; verifies monies are deposited in the correct study accounts; verifies accuracy of the charges debited to the grant account according to the PRA; provides monthly reports to the PIs, departments, and school; and processes vendor payments, subject stipends and travel reimbursements. The team has received \$96,242,257 to date across all departments since its inception in 2009 for a total of 1,229 study accounts reviewed to date.

Accomplishments

- Recruited, hired, and oriented an additional 8 FTEs to accommodate new work for the SOM. Conducted random QA of CRFMs and their reconciled studies to assure quality and consistency.

- Successfully transitioned all DOM industry-supported studies to OCR.
- During FY15, reviewed 756 total studies and 2,345 total research participants with invoicing activity with a 97.2% reconciliation rate. Received a total of \$17,608,049 owed from clinical trials during FY15 with another \$11,641,090 not yet received from outstanding non-federal invoices, non-invoiceable visits, and monies withheld as of 8/31/2015. Also, paid \$2,763,943 in study expenses.
- Reconciled clinic and hospital charges for assigned grant accounts utilizing the EHC clinical data warehouse.

Goals for FY16

- Continue baseline performance measures and random QA audits monthly for all departments to ensure 95% of all assigned studies are reconciled within 30 days. Perform monthly QA audits of new staff during their first six months of hire.
- Establish quarterly invoicing outreach meetings with study teams and administrators to obtain feedback and facilitate customer relations.
- Complete transition of all study financials for industry sponsored research accounts in the SOM.

Clinical Research Support Services Team (NEW program in FY16)

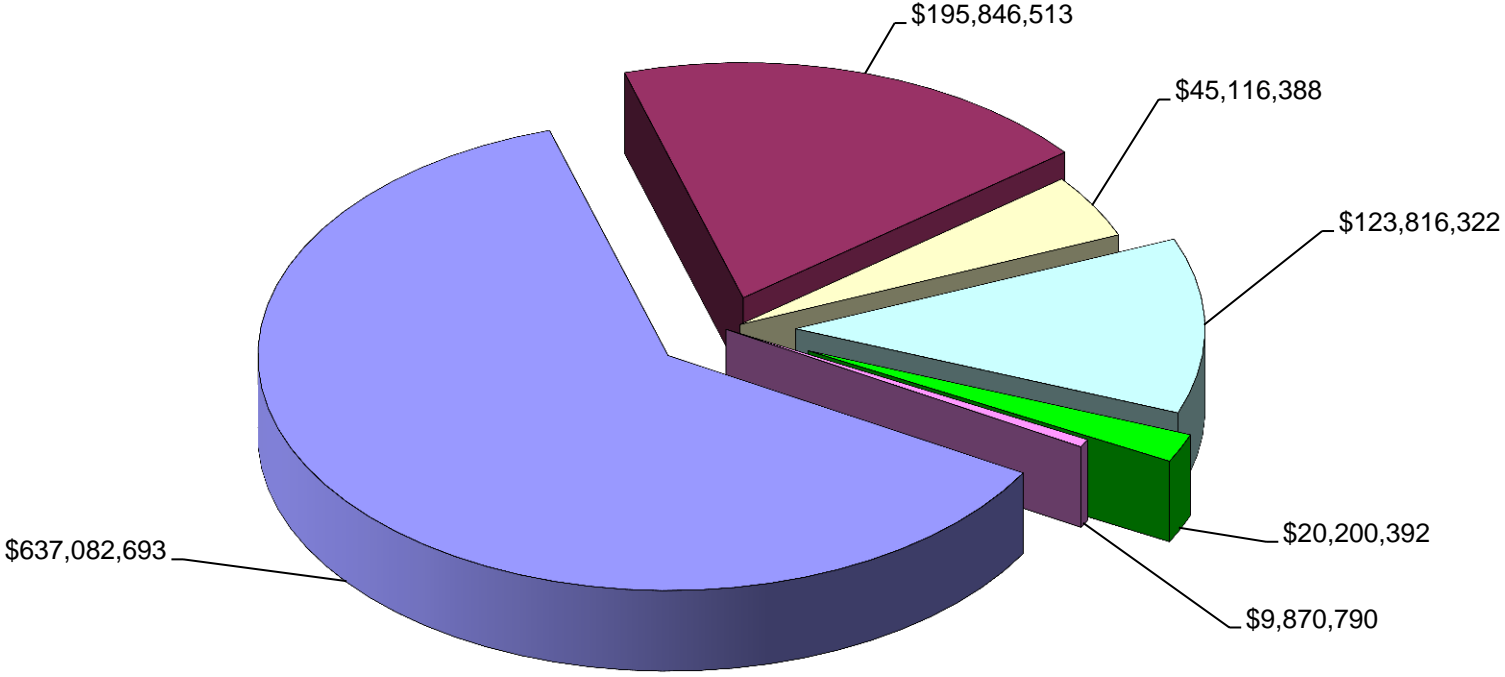
Function

We are at the beginning of a two-year pilot for development of a Clinical Research Support Services program. Initially, the program will be limited in scope with 1 FTE and focused on non-federal human subjects research (funded through Emory University) that meets the NIH definition of a clinical trial and intersects with OCR, IRB and OTT. This person will assist investigators conducting clinical trials by effectively facilitating the Emory-required pre-award approval processes across departments, thereby accelerating study initiation while educating and guiding targeted faculty in the Emory-required approval processes.

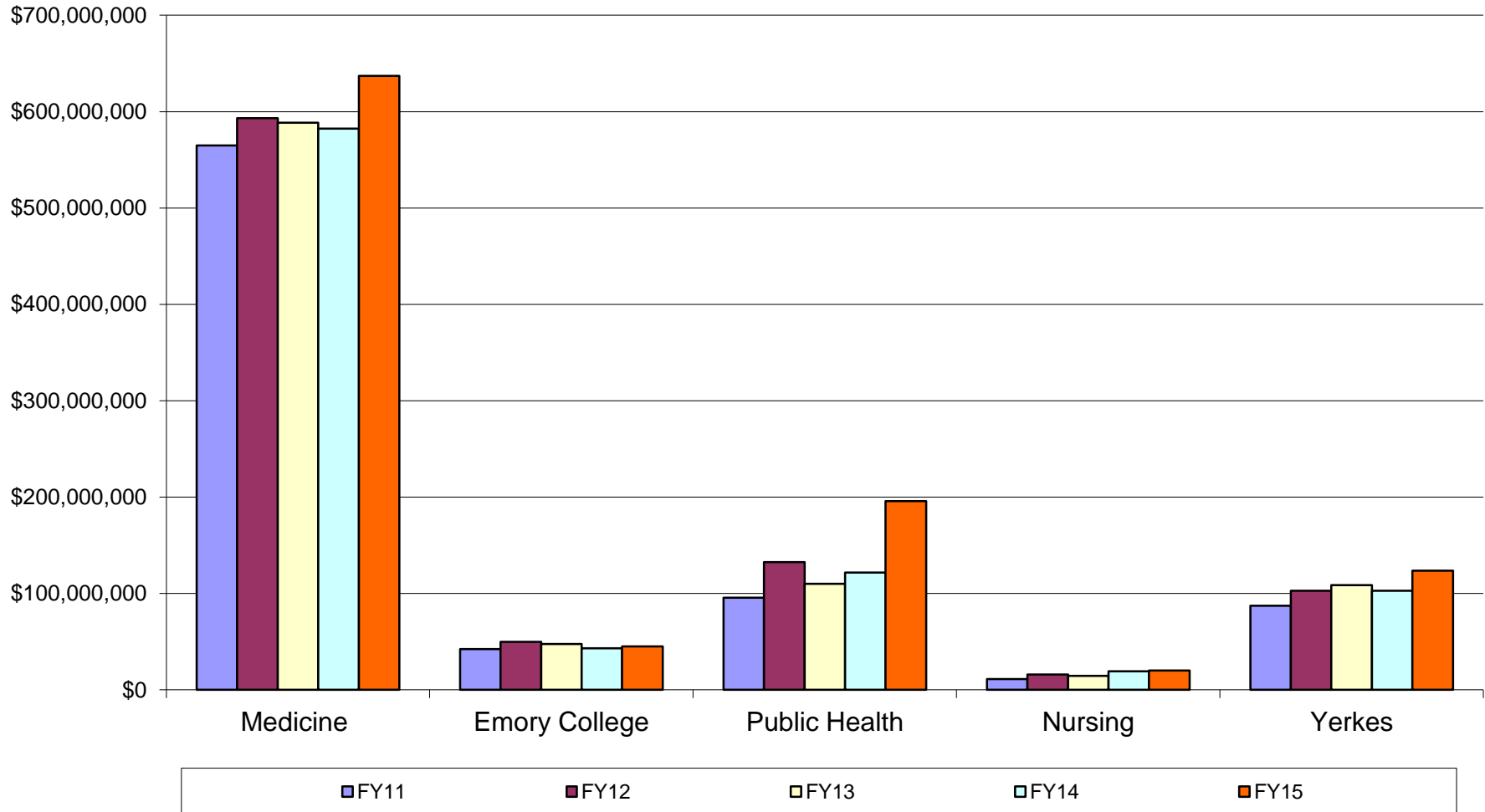
Goals for FY16

- Serve as advocate for investigators seeking pre-award approvals for industry-supported clinical trials.
- Continue collaboration with industry sponsors to facilitate pre-award processes and improve performance metrics to become premier research site.
- Identify and escalate any data-driven gaps, trends, system or people problems evident in the pre-award approval process as they become visible. Track and report performance metrics monthly for departments. Utilize existing clinical research oversight committees to improve the clinical trials process.
- Coordinate and facilitate a virtual working group including representatives from departments responsible for pre-award approvals.
- Expand and maintain an “Investigator’s Guide to Clinical Research” to educate and guide faculty.

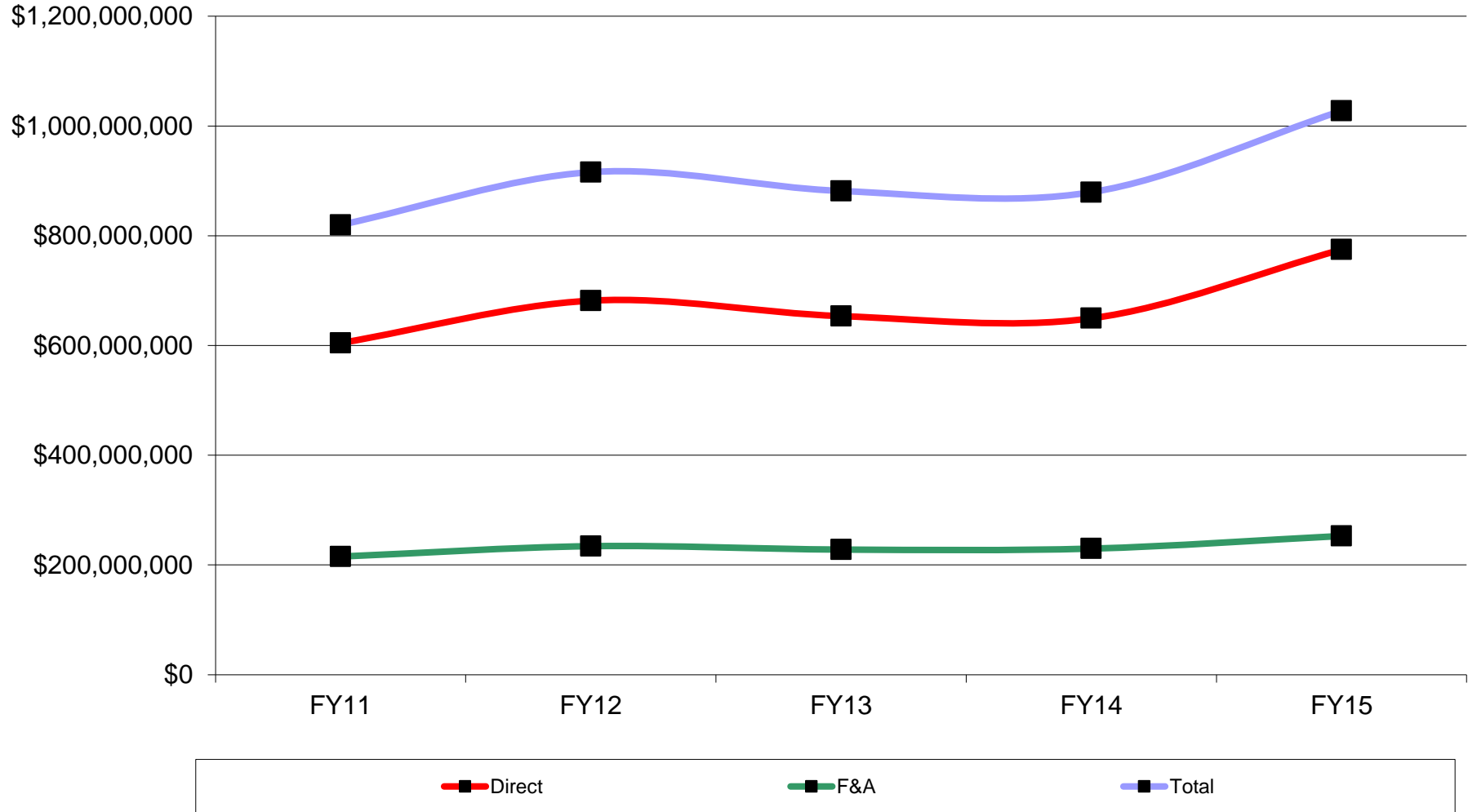
Total Dollars Requested \$1,027,637,702



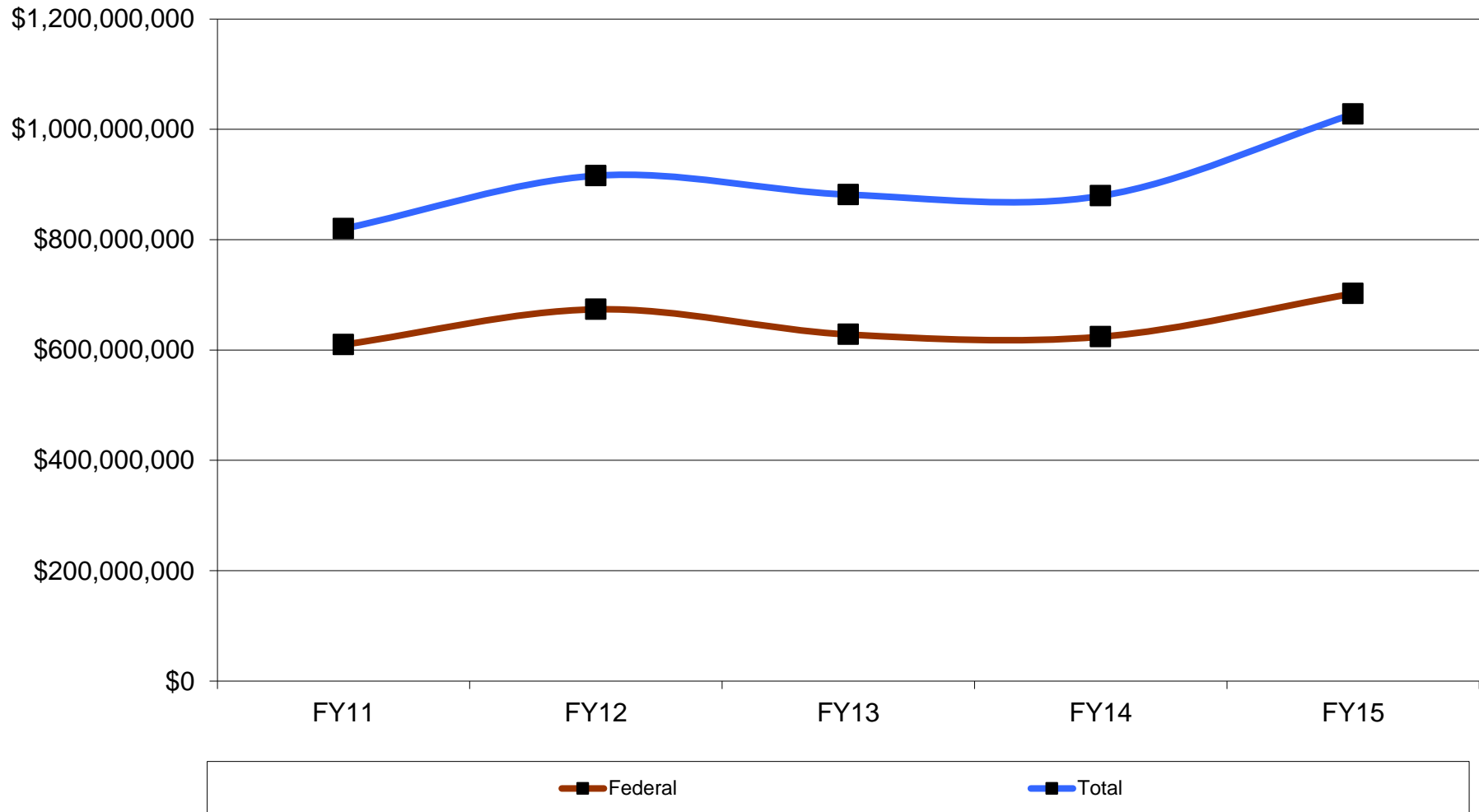
Total Sponsored Research Requested



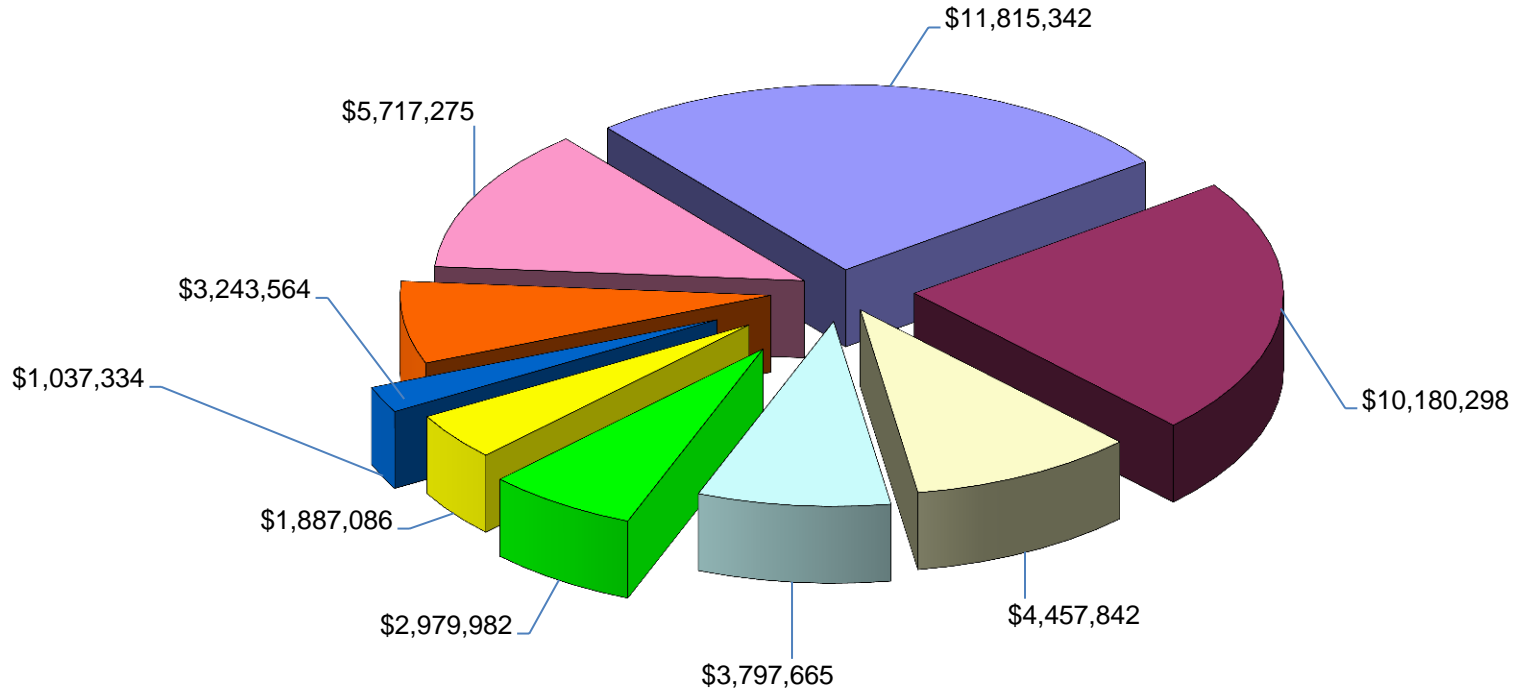
Growth in Sponsored Research Requested (Direct, F&A and Total)



Growth in Sponsored Research Requested (Federal and Total)

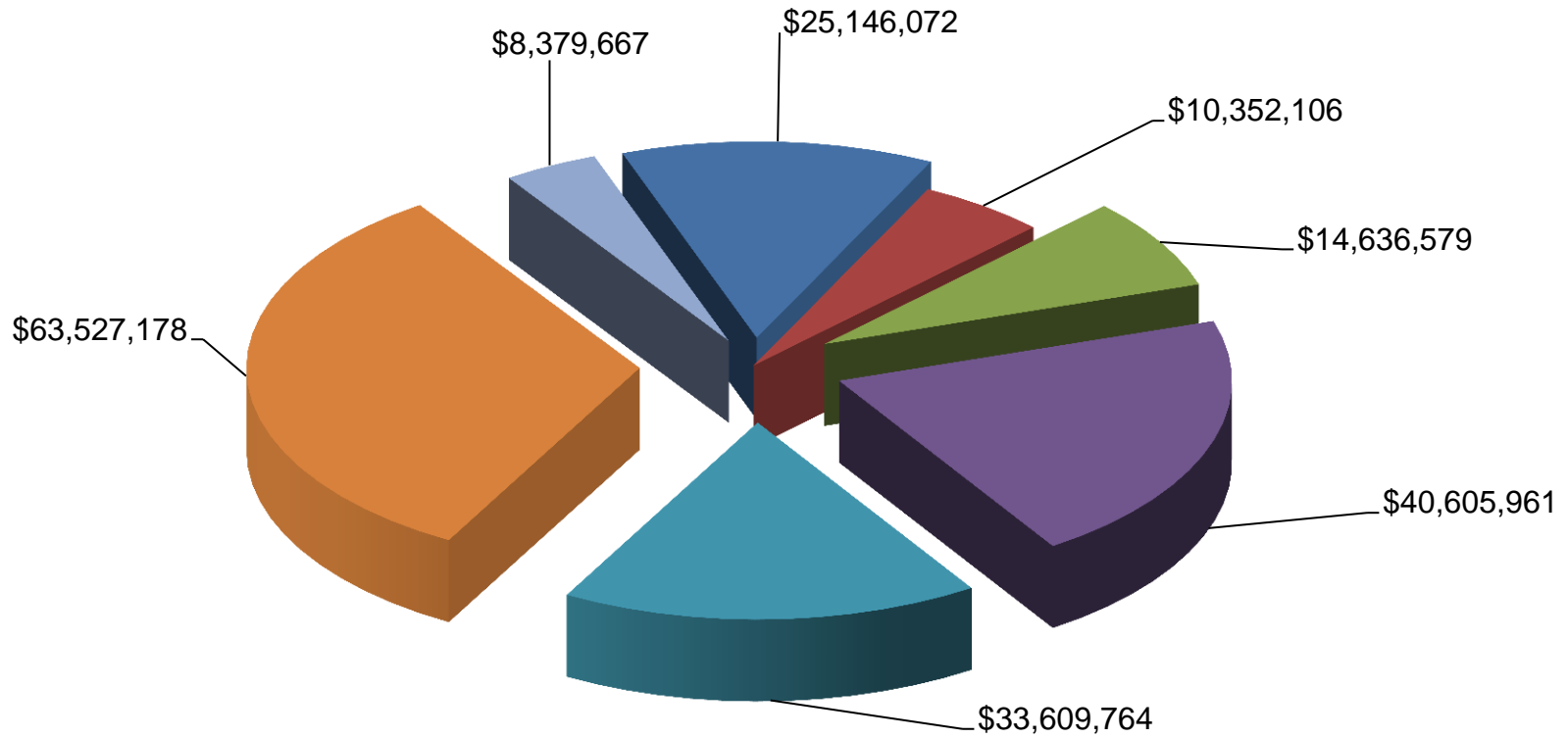


Emory College Total Dollars Requested \$45,116,388



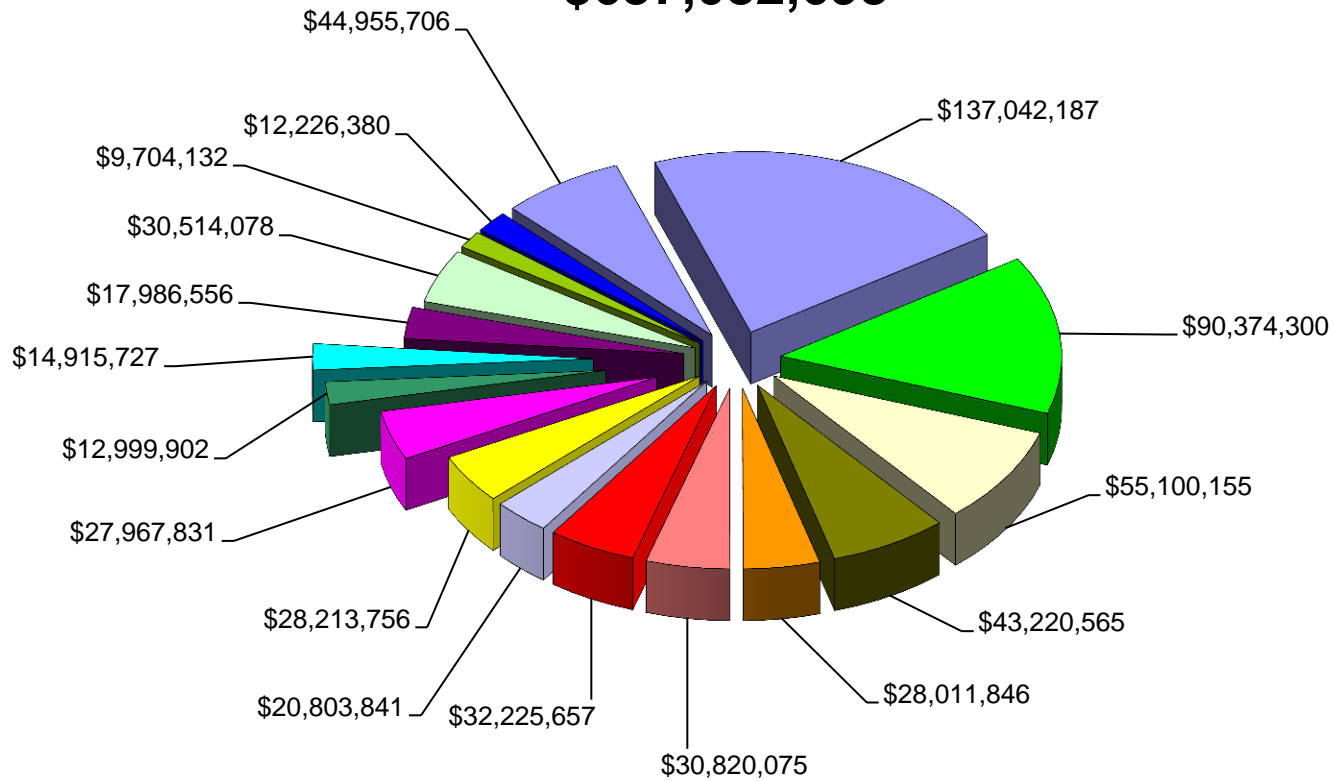
■ Chemistry \$11.8	■ Biology \$10.2	□ Psychology \$4.4
□ Physics \$3.8	■ Anthropology \$3.0	■ Mathematics & Computer Science \$1.9
■ Center for Science Education \$1.0	■ Environmental Science \$3.2	■ All Others \$5.7

Rollins School of Public Health Total Dollars Requested \$195,846,513



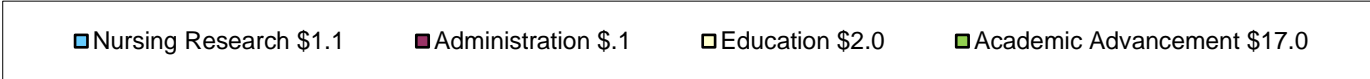
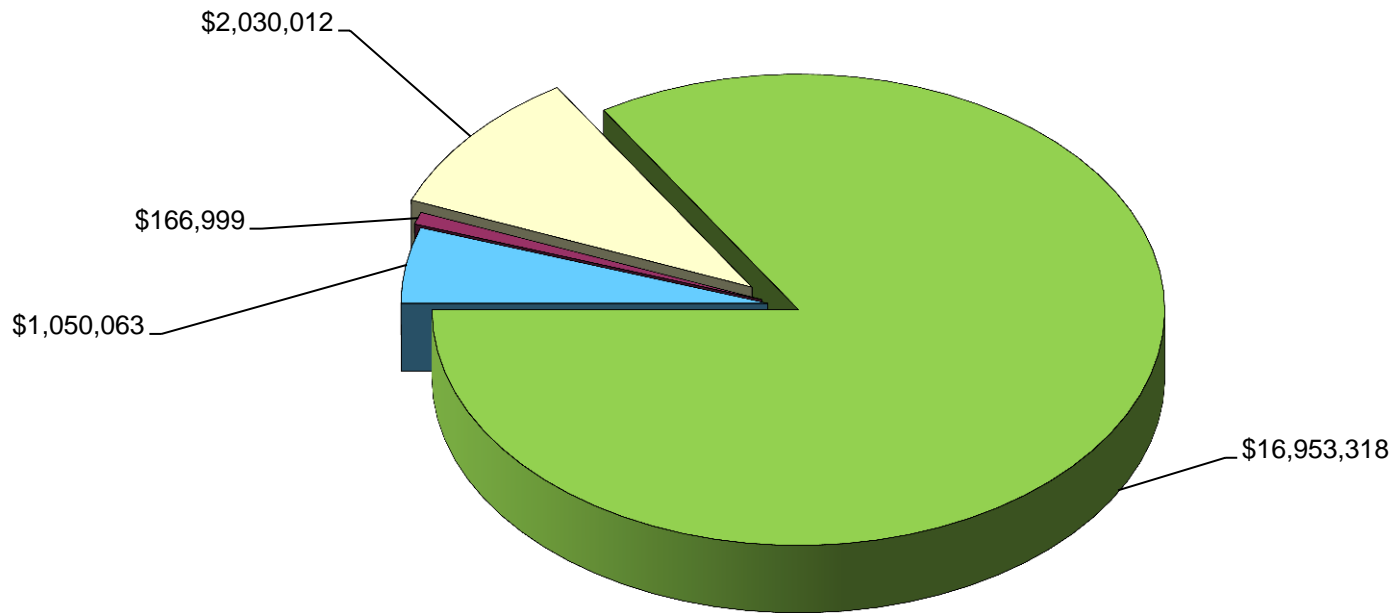
Beh. Science & Health Education \$25.1	Biostatistics \$10.3	Environmental & Occupational Health \$14.6
Epidemiology \$40.6	Global Health \$33.6	Global Health Institute \$63.5
Health Policy & Management \$7.6		

School of Medicine Total Dollars Requested \$637,082,693

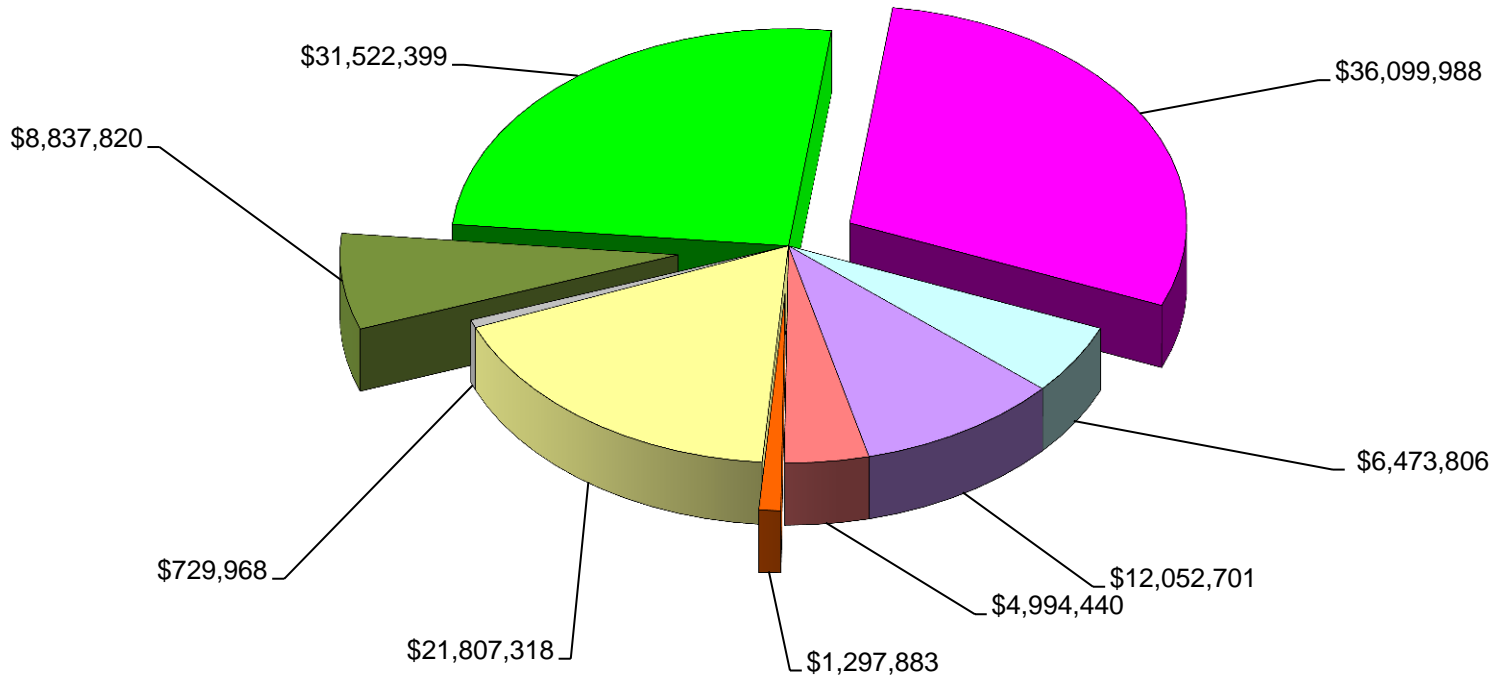


■ Medicine \$137.0	■ Pediatrics \$90.4	□ Hematology & Medical Oncology \$55.1
■ Pathology \$43.2	■ Microbiology & Immunology \$28.0	■ Neurology \$30.8
■ Genetics \$32.2	□ Pharmacology \$20.8	■ Psychiatry \$28.2
■ Surgery \$28.0	■ Cell Biology \$13	■ Physiology \$14.9
■ Biochemistry \$18	■ Radiology \$30.5	■ Ophthalmology \$9.7
■ Biomedical Engineering \$12.2	■ All Others \$45.0	

Nell Hodgson Woodruff School of Nursing Total Dollars Requested \$20,200,392

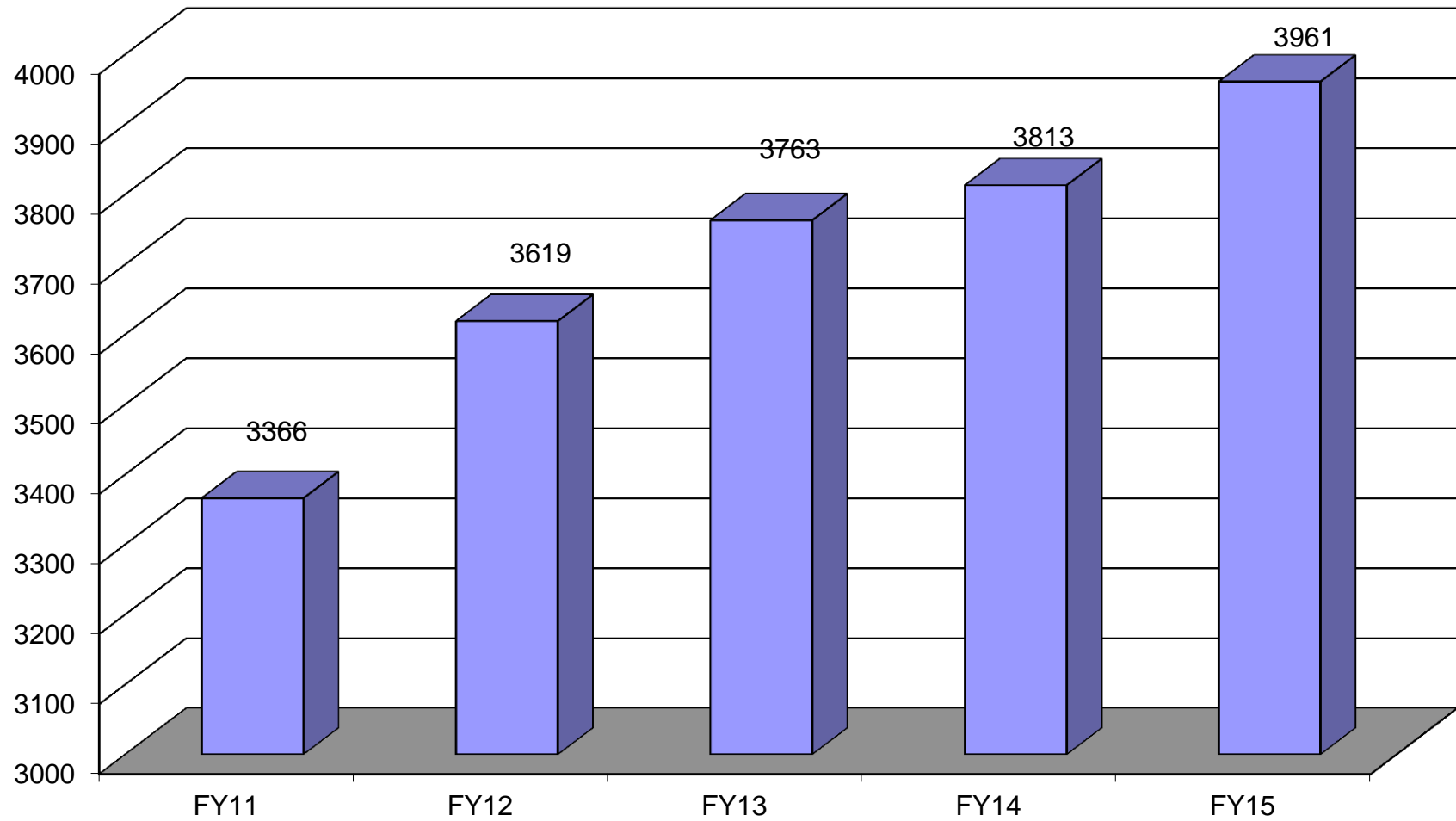


Yerkes National Research Primate Center Total Dollars Requested \$123,816,322

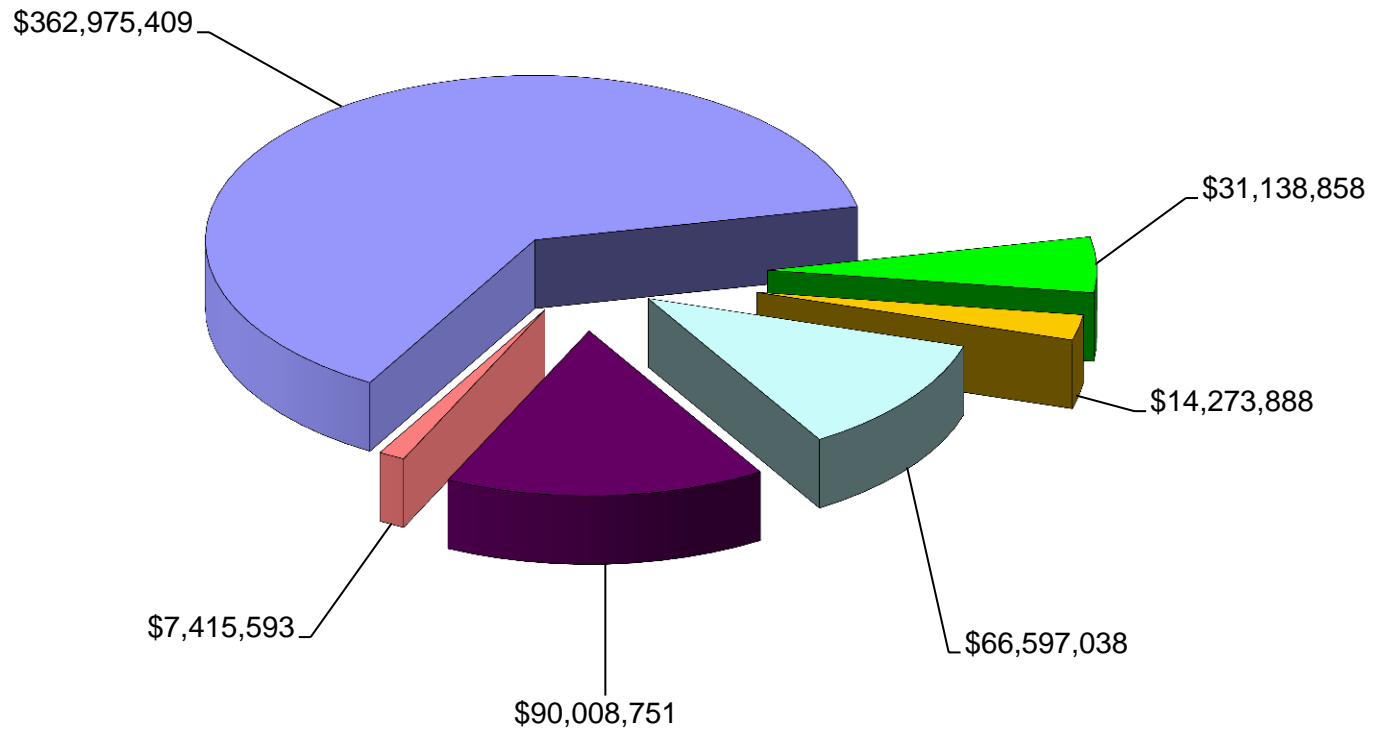


■ Division of Neuroscience \$8.8	■ Vaccine Research Center \$31.5	■ Division of Microbiology & Immunology \$36.1
■ Division of Psychobiology \$6.5	■ Behavioral Neuroscience \$12.1	■ Sensory Motor Systems \$5.0
■ Behavioral Management \$1.3	■ Director's Office \$21.8	■ Other \$.7

Proposals (Processing Totals)

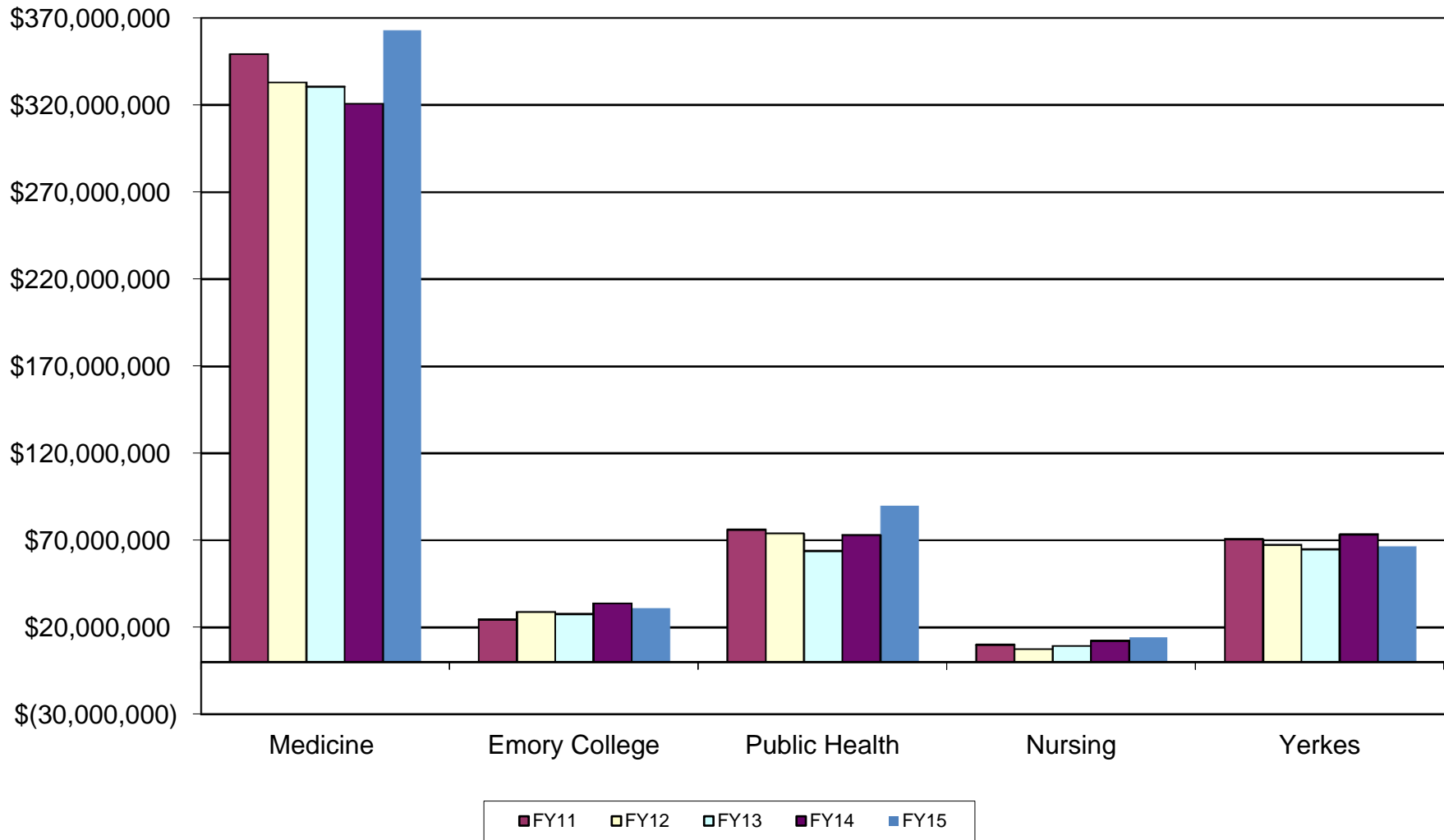


Total Sponsored Research \$572,409,537

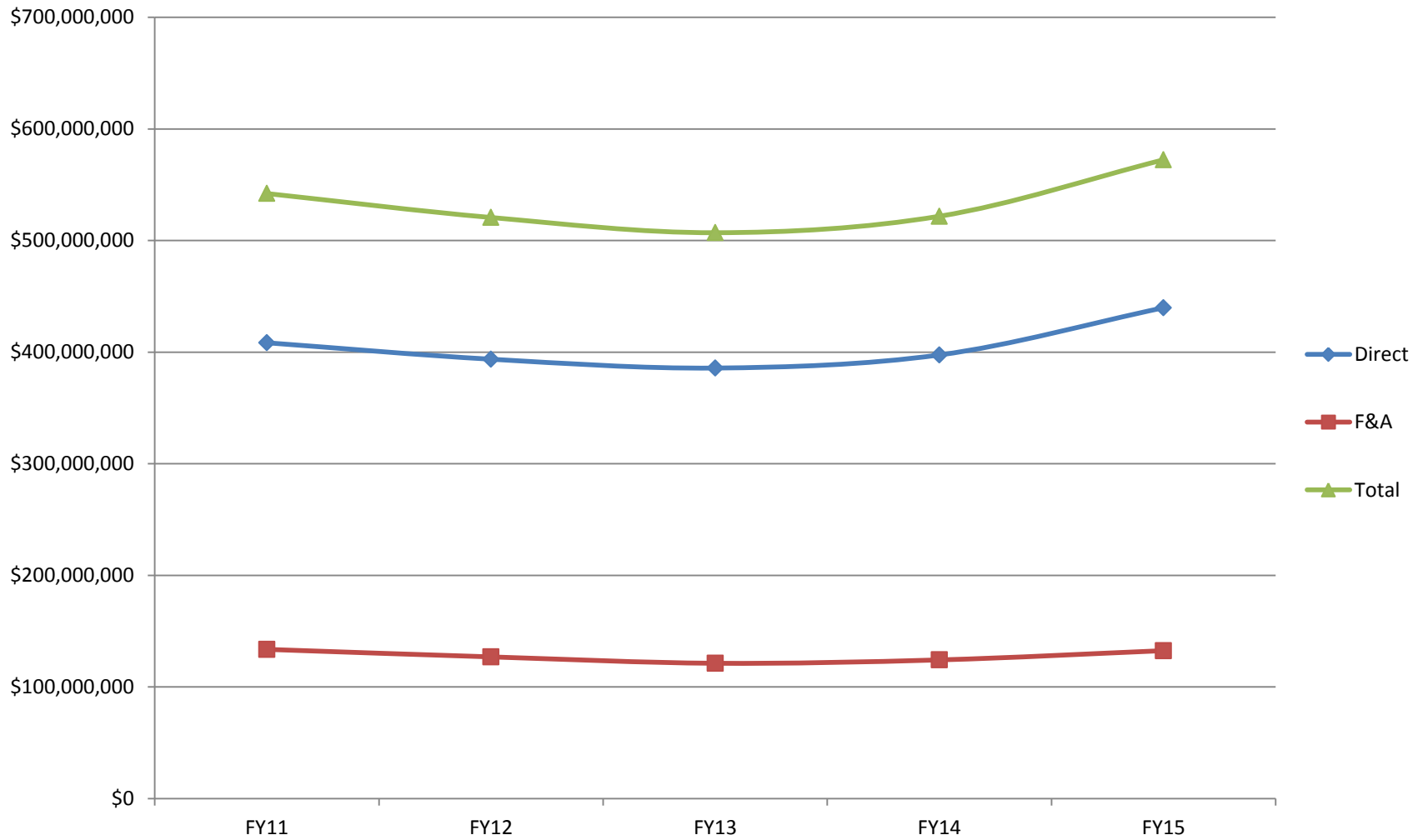


■ Medicine - \$363.0 ■ Emory College - \$31.1 ■ Nursing - \$14.3 ■ Yerkes - \$66.6 ■ Public Health - \$90.0 ■ All Others - \$7.4

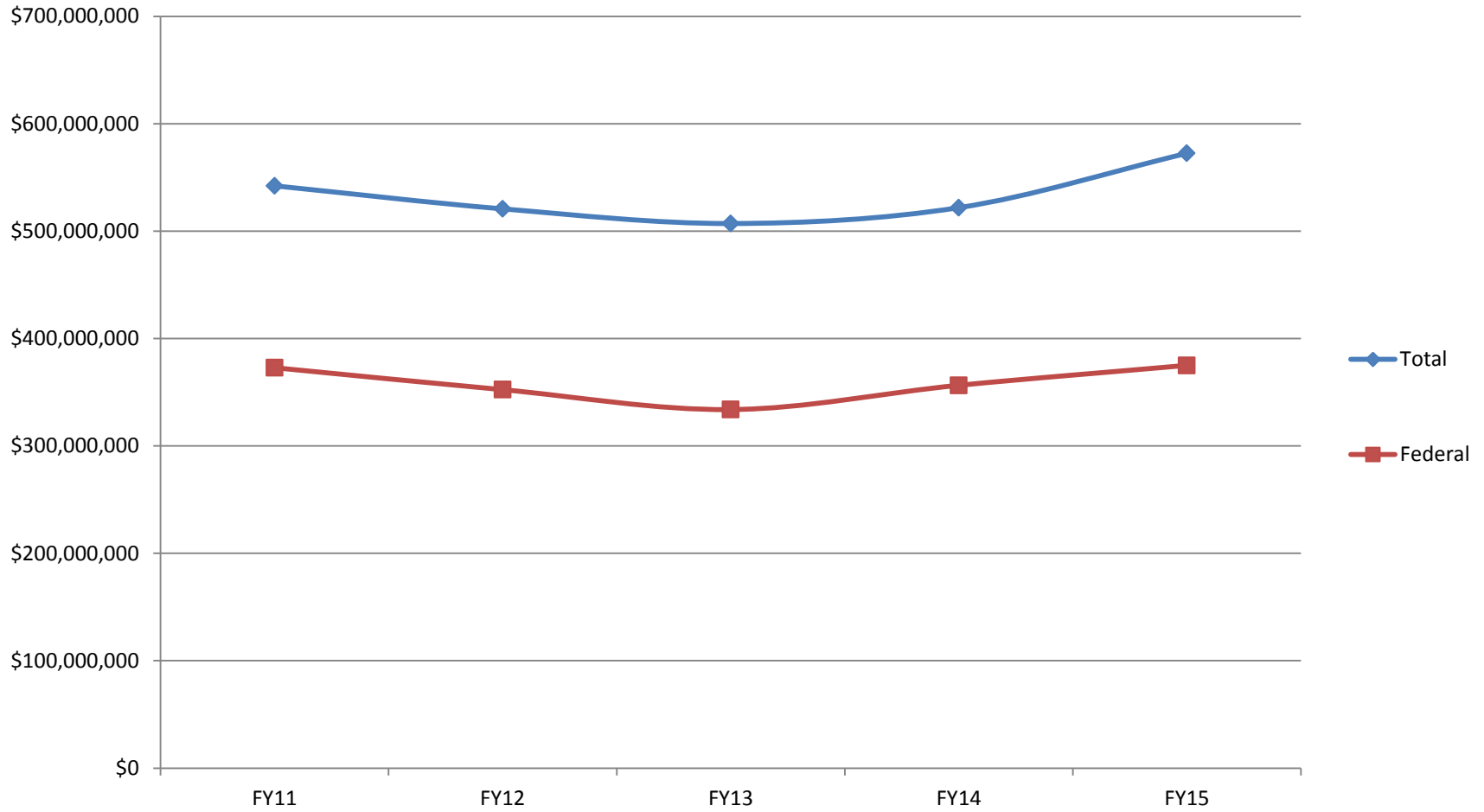
Total Sponsored Research Awarded



Total Sponsored Research Awards

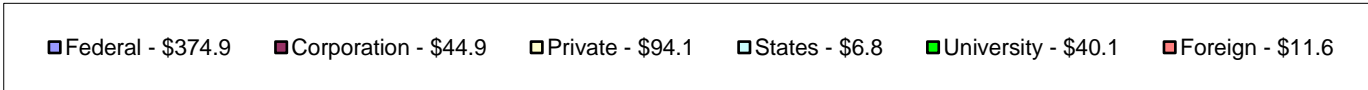
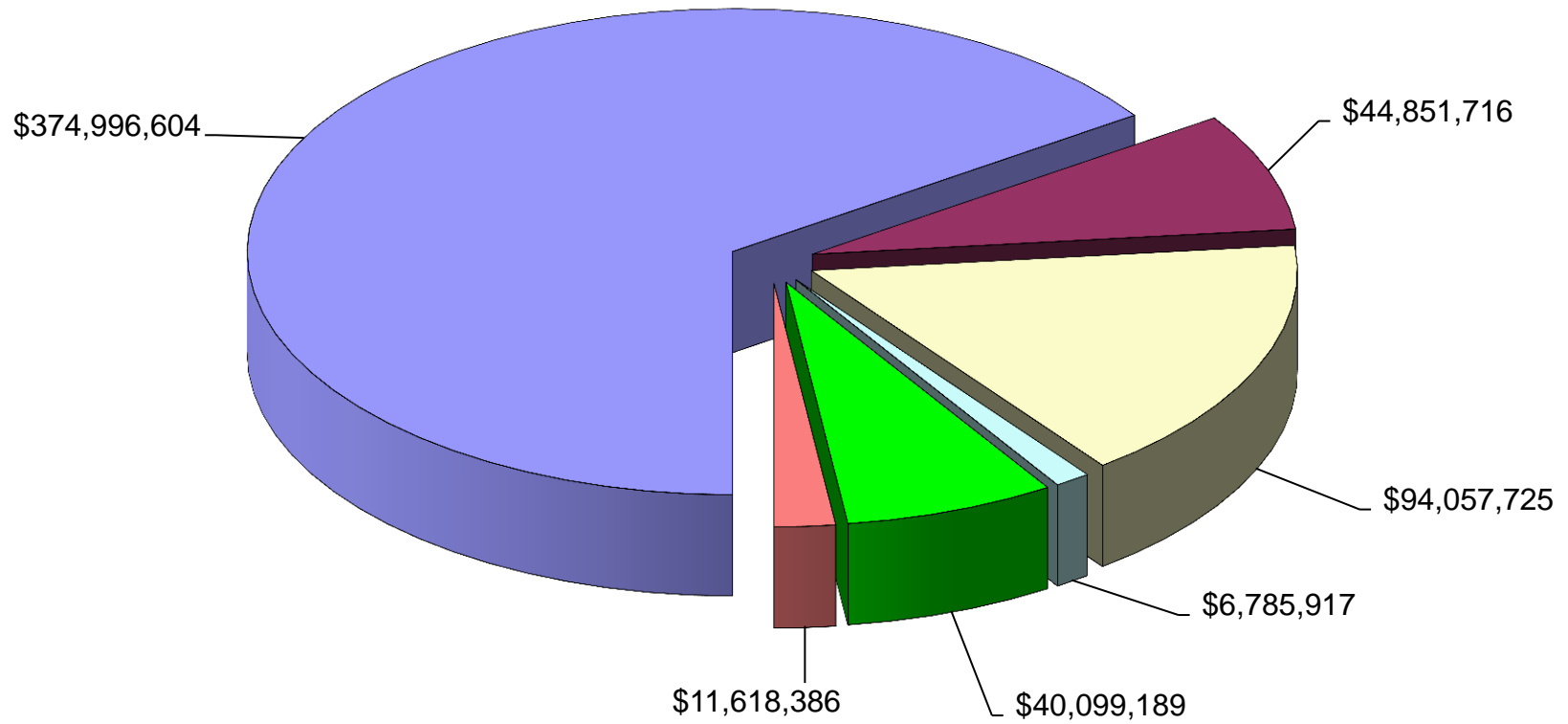


Growth in Sponsored Research (Emory's Obligations for R & D Awards)

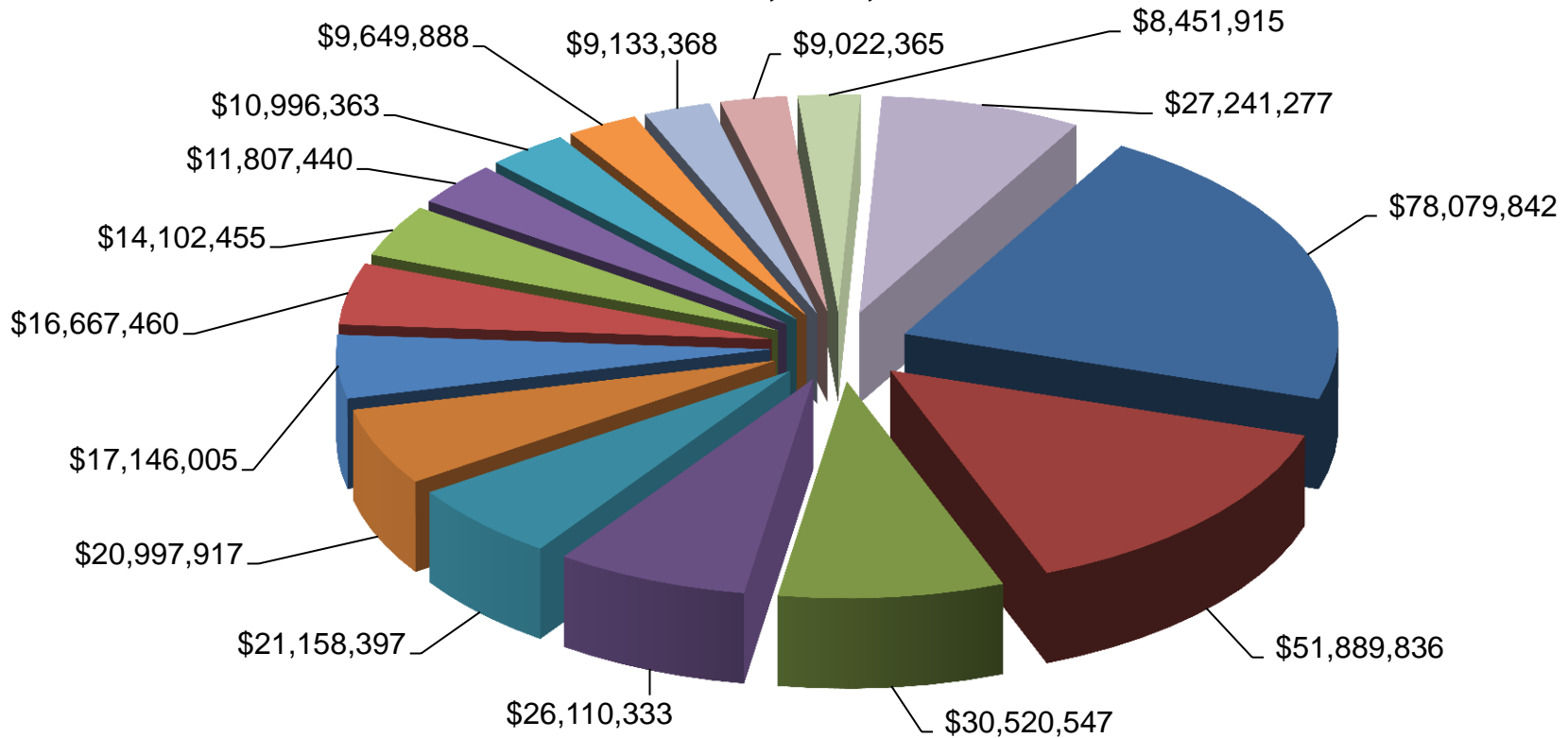


Sources of Sponsored Research

\$572,409,537

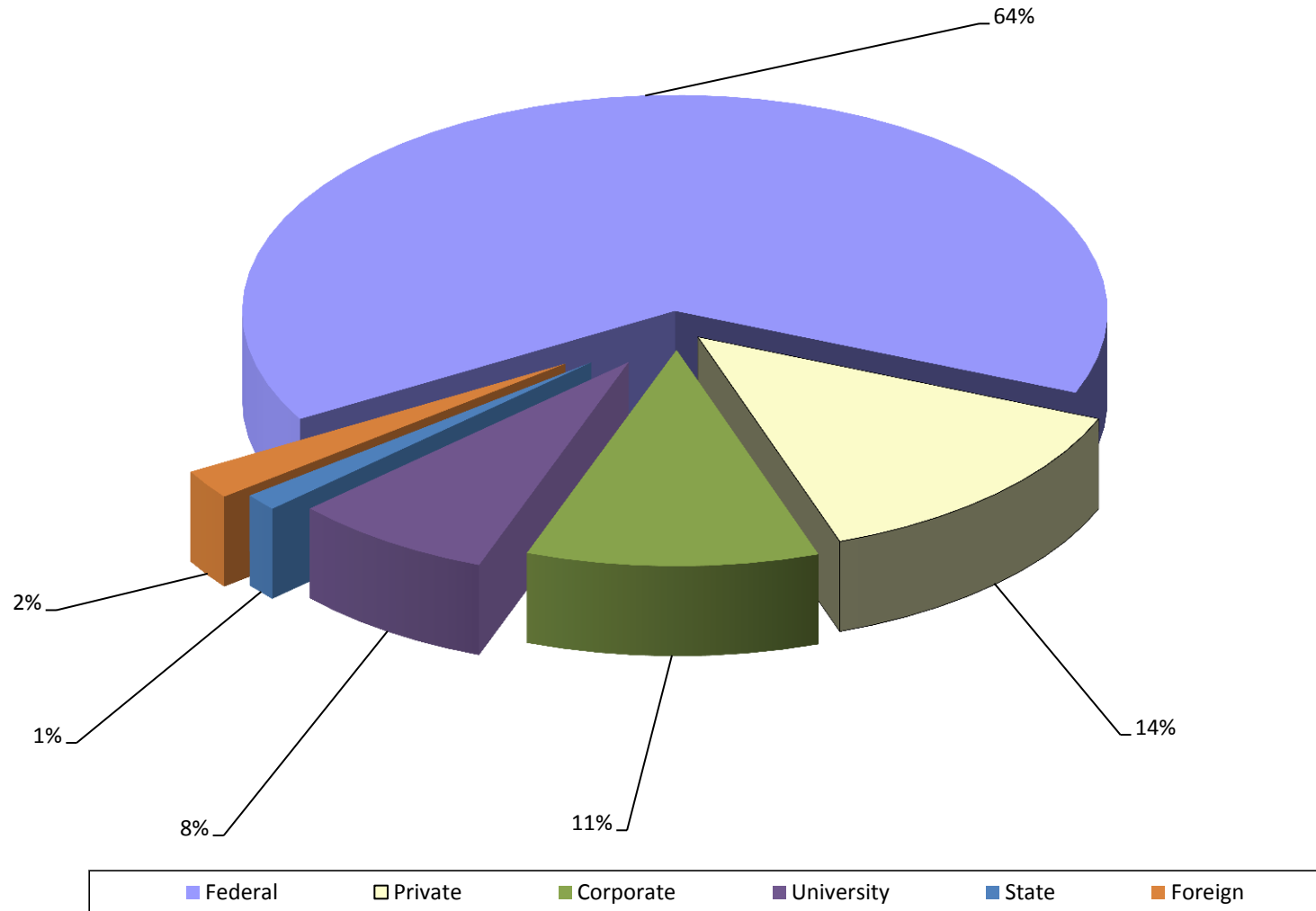


School of Medicine Total Research Awards \$362,975,409

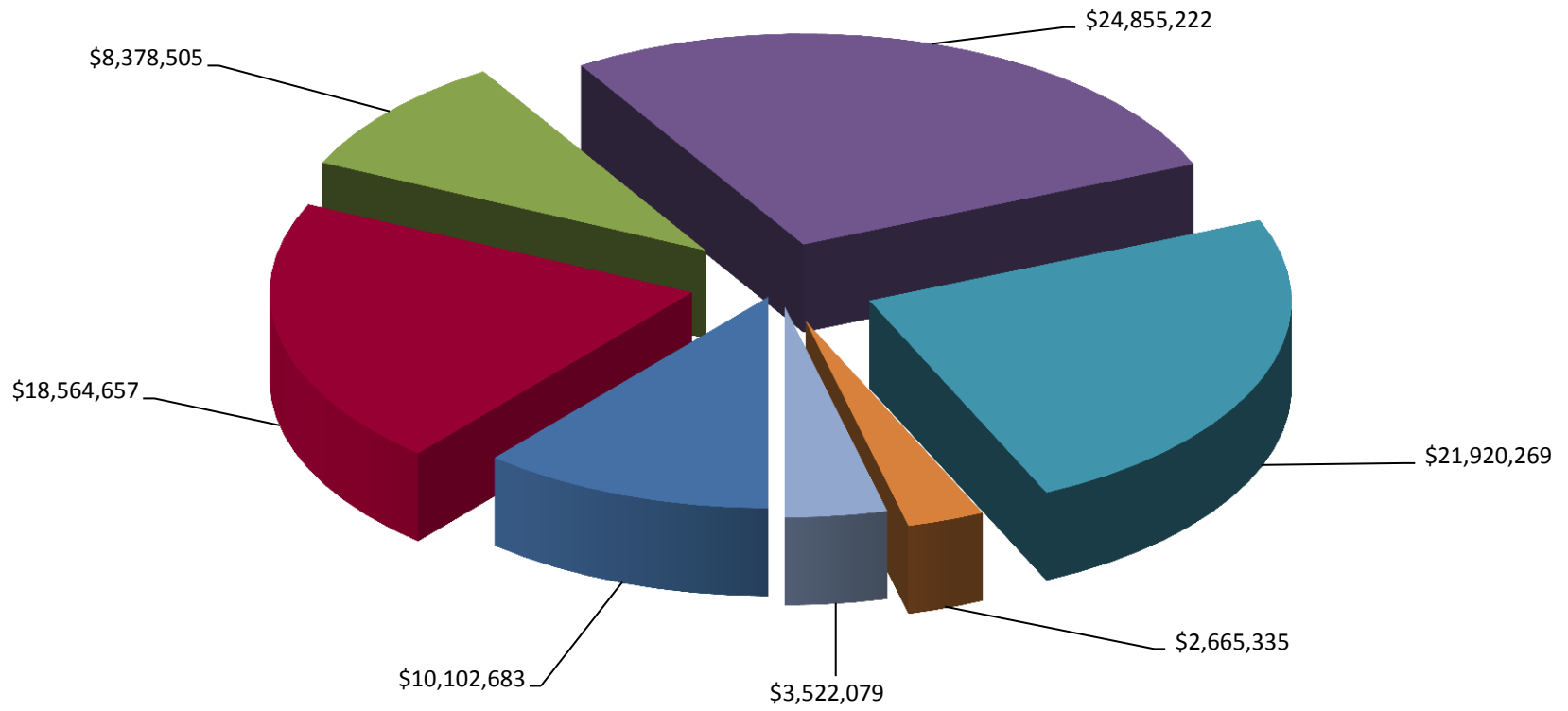


■ Medicine \$78.1	■ Pediatrics \$51.9	■ Micro Immunology \$30.5	■ Pathology \$26.1
■ Hematology & Medical Oncology \$21.2	■ Neurology \$21.0	■ Human Genetics \$17.1	■ Surgery \$16.7
■ Psychiatry \$14.1	■ Pharmacology \$11.8	■ Radiology \$11.0	■ Physiology \$9.6
■ Cell Biology \$9.1	■ Ophthalmology \$9.0	■ Biochemistry \$8.5	■ All Other \$27.2

Sources of School of Medicine Funding

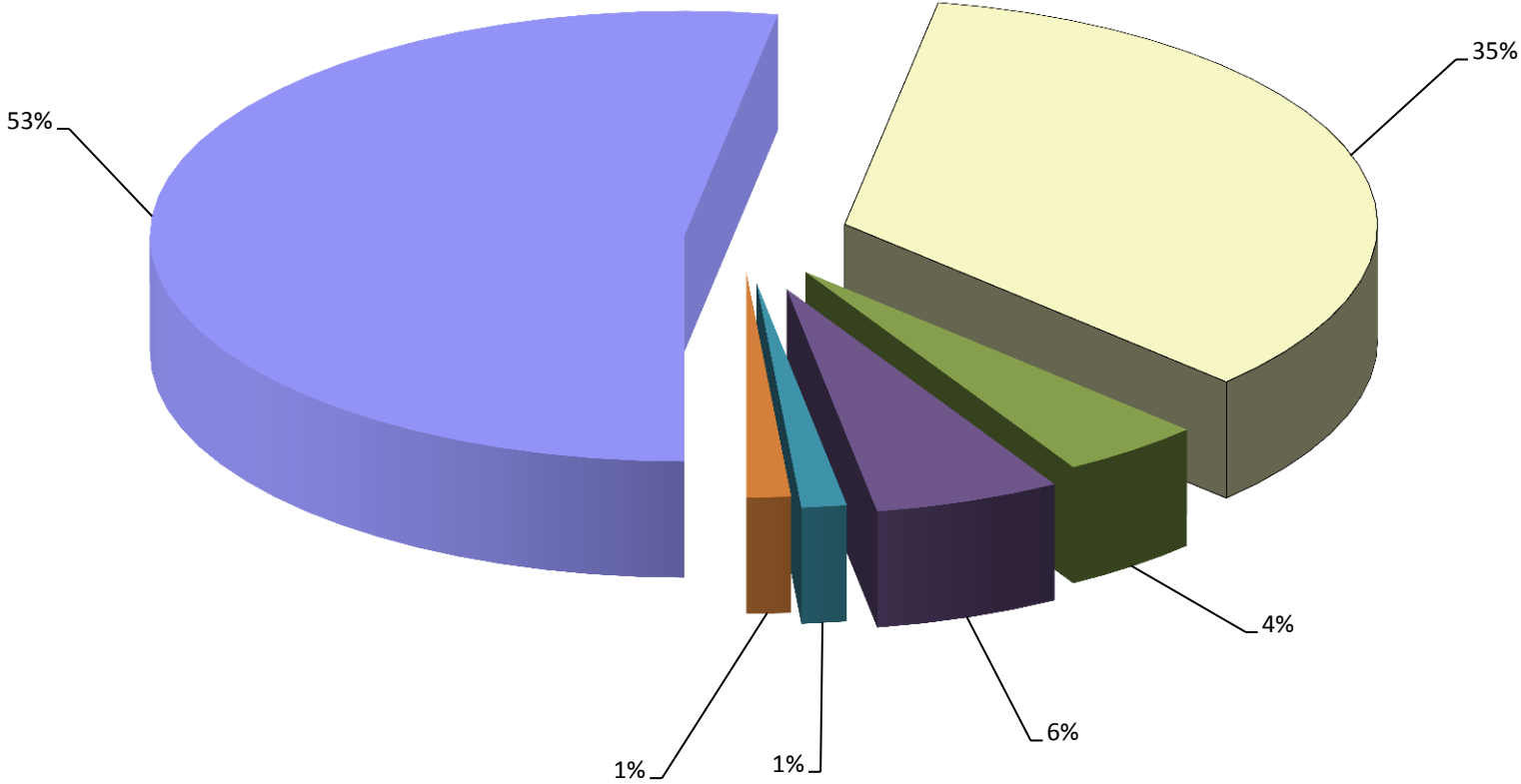


Rollins School of Public Health Total Research Awards \$90,008,751

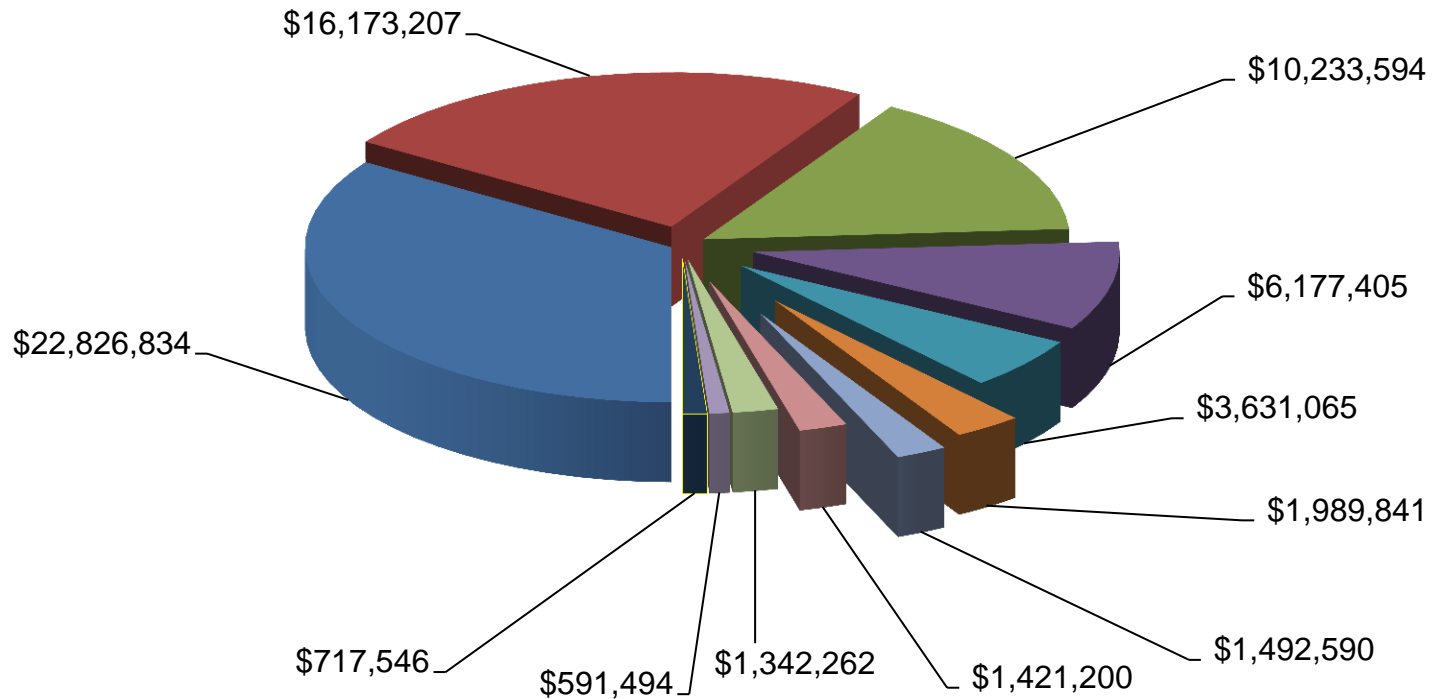


Beh. Science & Health Education \$10.1	Epidemiology \$18.6	Environmental & Occupational Health \$8.4
Global Health Institute \$24.9	Global Health \$21.9	Health Policy & Management \$2.7
Biostatistics \$3.5		

Sources of Rollins School of Public Health Funding

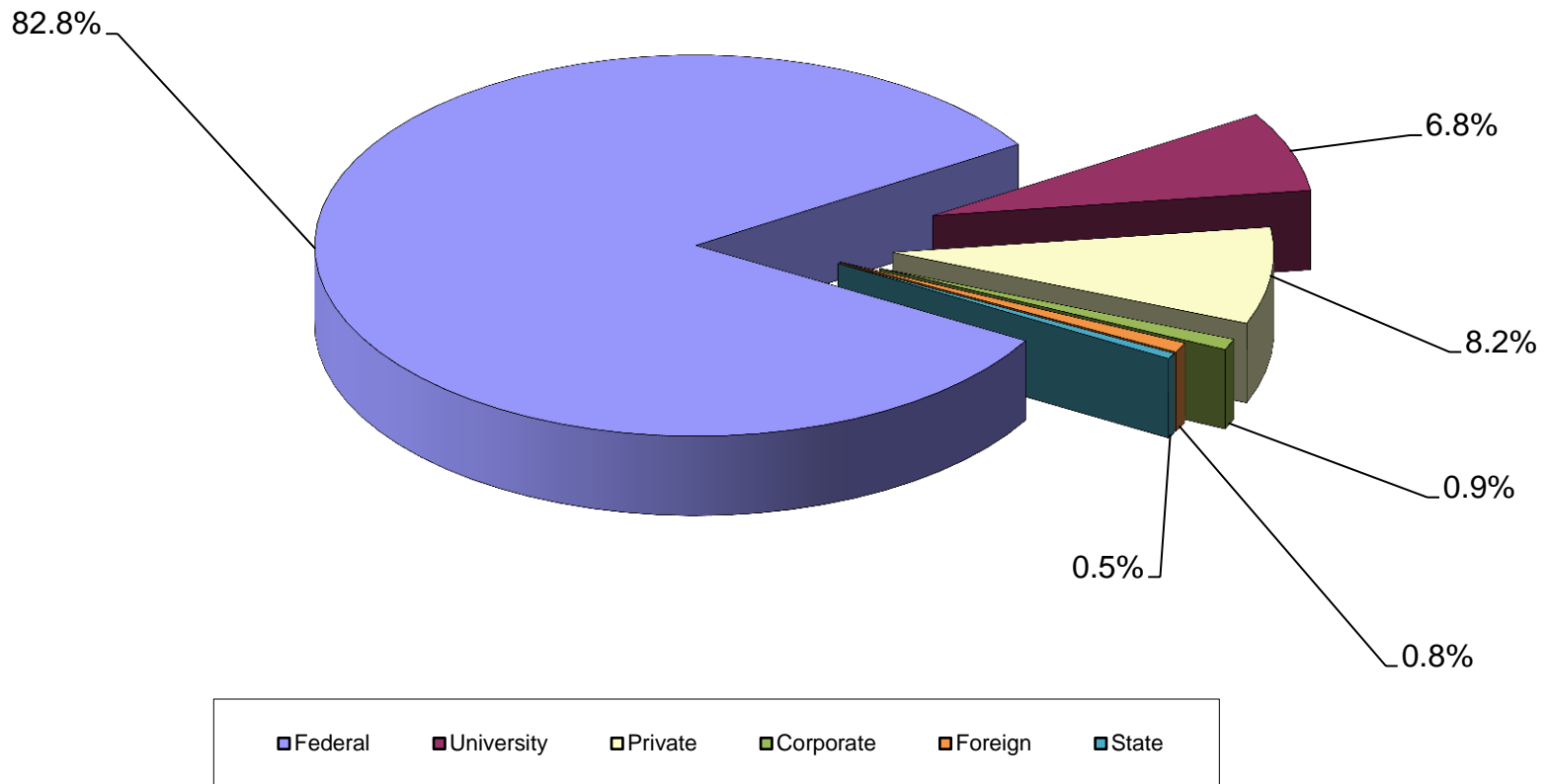


Yerkes National Research Primate Center Total Research Awards \$66,597,038

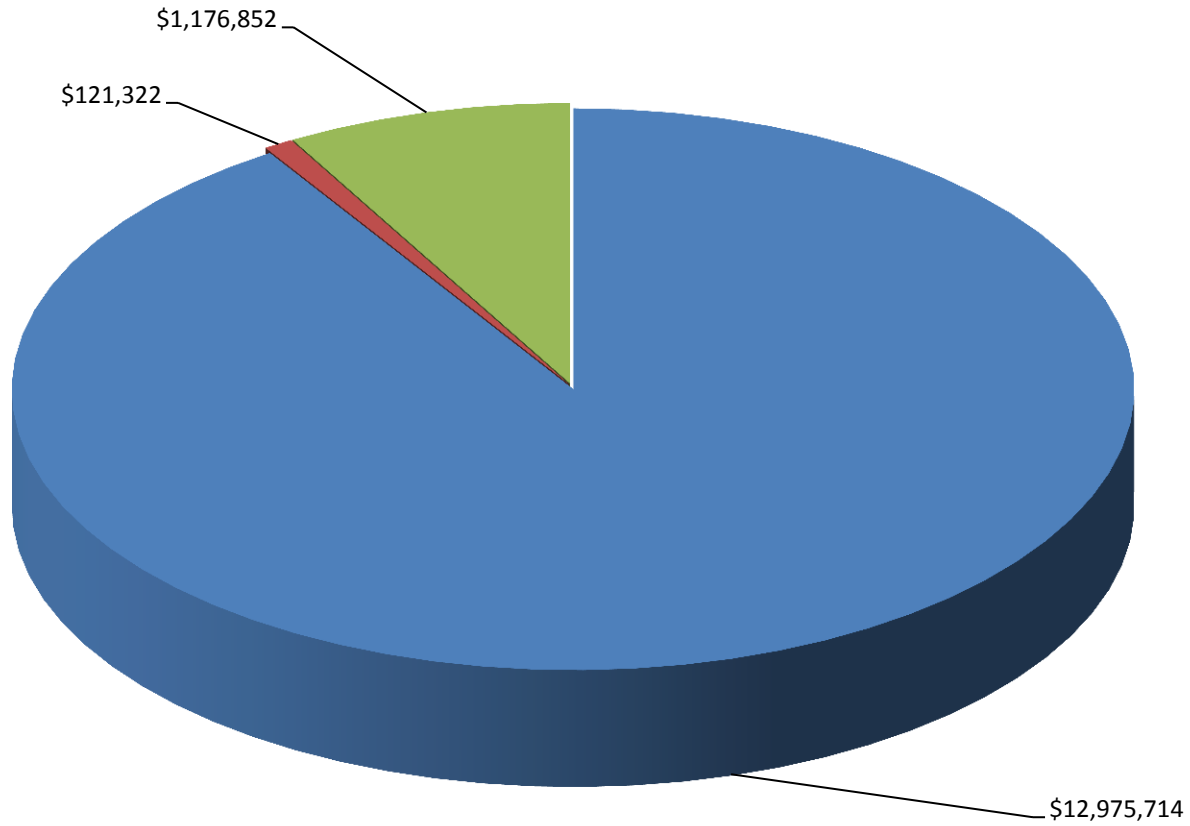


Vaccine Research Center \$22.8	Division of Microbiology & Immunology \$16.2	Director's Office \$10.2
Division of Dev & Cog Neuroscience \$6.2	Division of Neuroscience \$3.6	Ctr Trans Social NeuroSci \$2.0
Behav Neuro & Psych Dis \$1.5	Emory Inst Drug \$1.4	Sensory Motor Systems \$1.3
Pathology \$.60	Other \$.70	

Sources of Yerkes National Research Primate Center Funding

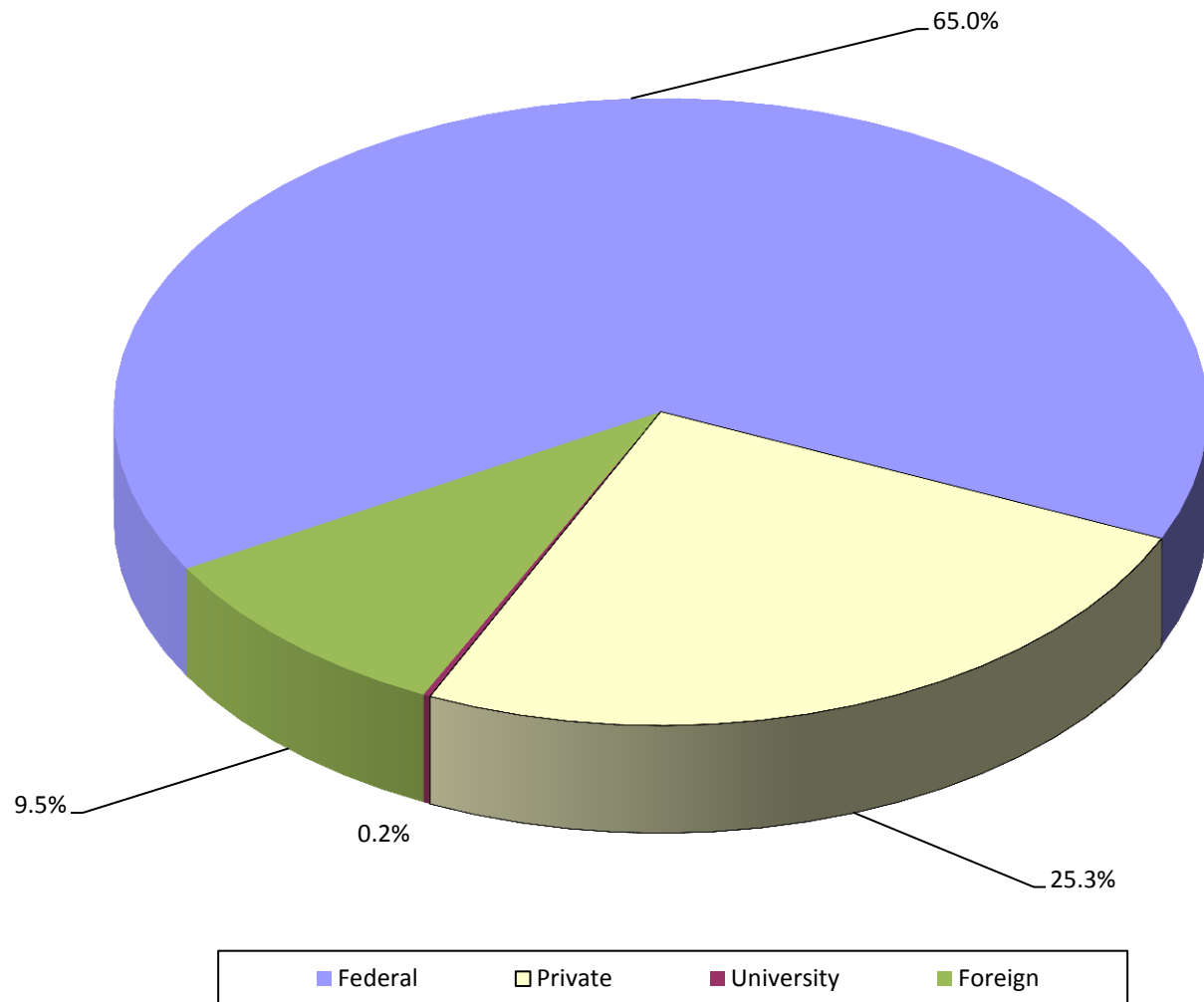


Nell Hodgson Woodruff School of Nursing Total Research Awards \$14,273,888

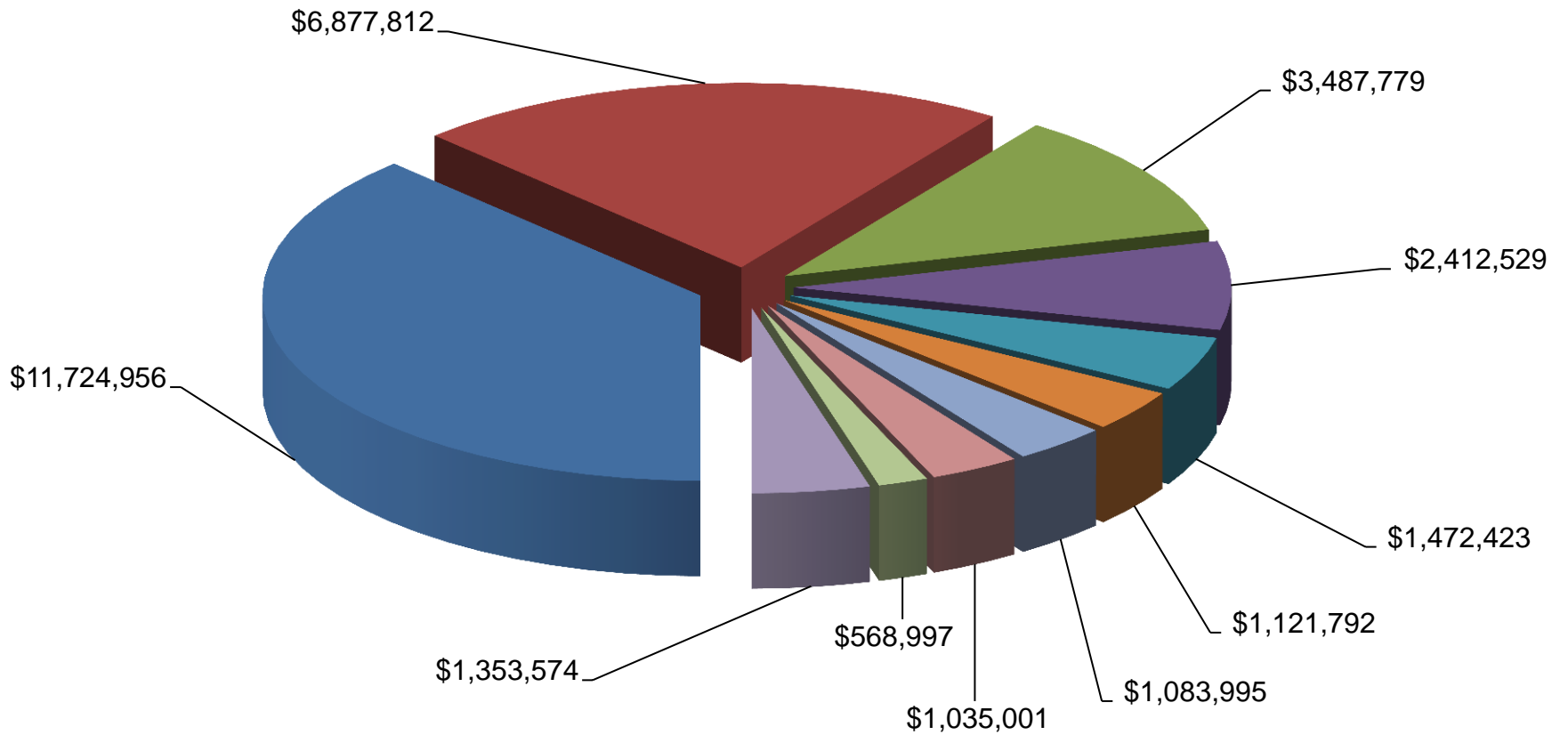


■ Adult and Elder Health \$12.9	■ Deans Office \$.1	■ Office of Academic Advancement \$1.2
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Sources of Nell Hodgson Woodruff School of Nursing Funding

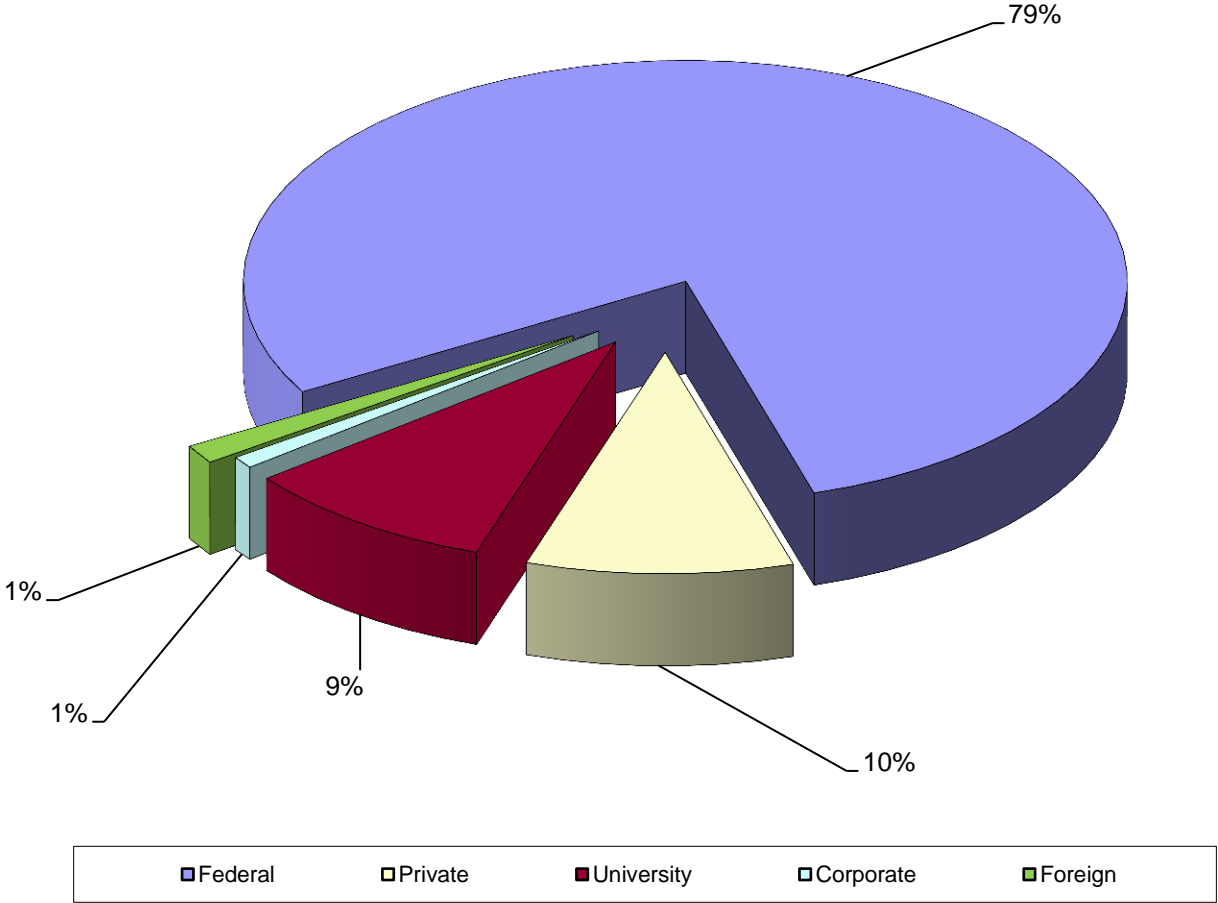


Emory College Total Research Awards \$ 31,138,858

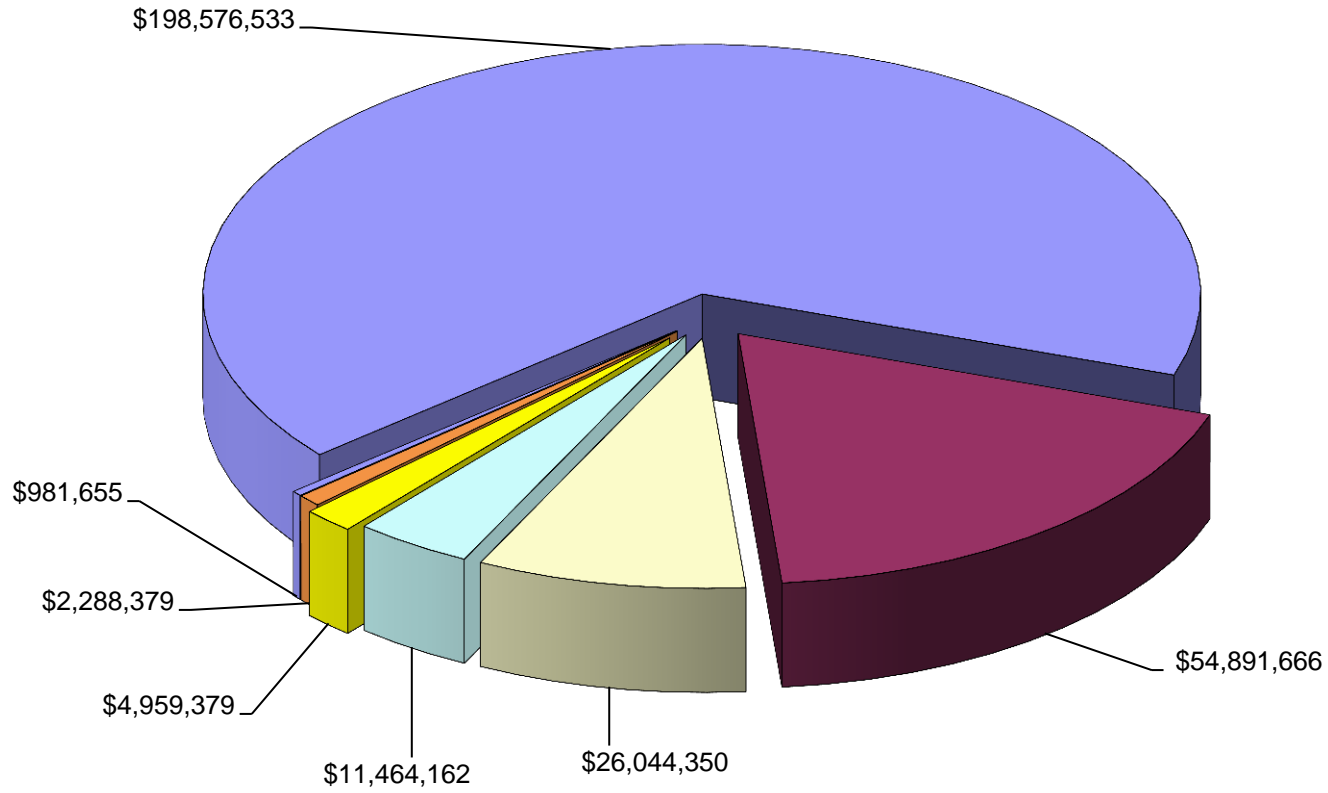


■ Chemistry \$11.7	■ Biology \$6.9	■ Psychology \$3.5
■ Mathematics & Computer Science \$2.4	■ Physics \$1.5	■ Environmental Studies \$1.1
■ Anthropology \$1.1	■ Emory Tibet Partnership \$1.0	■ Economics \$.60
■ All Others \$1.4		

Sources of Emory College Funding

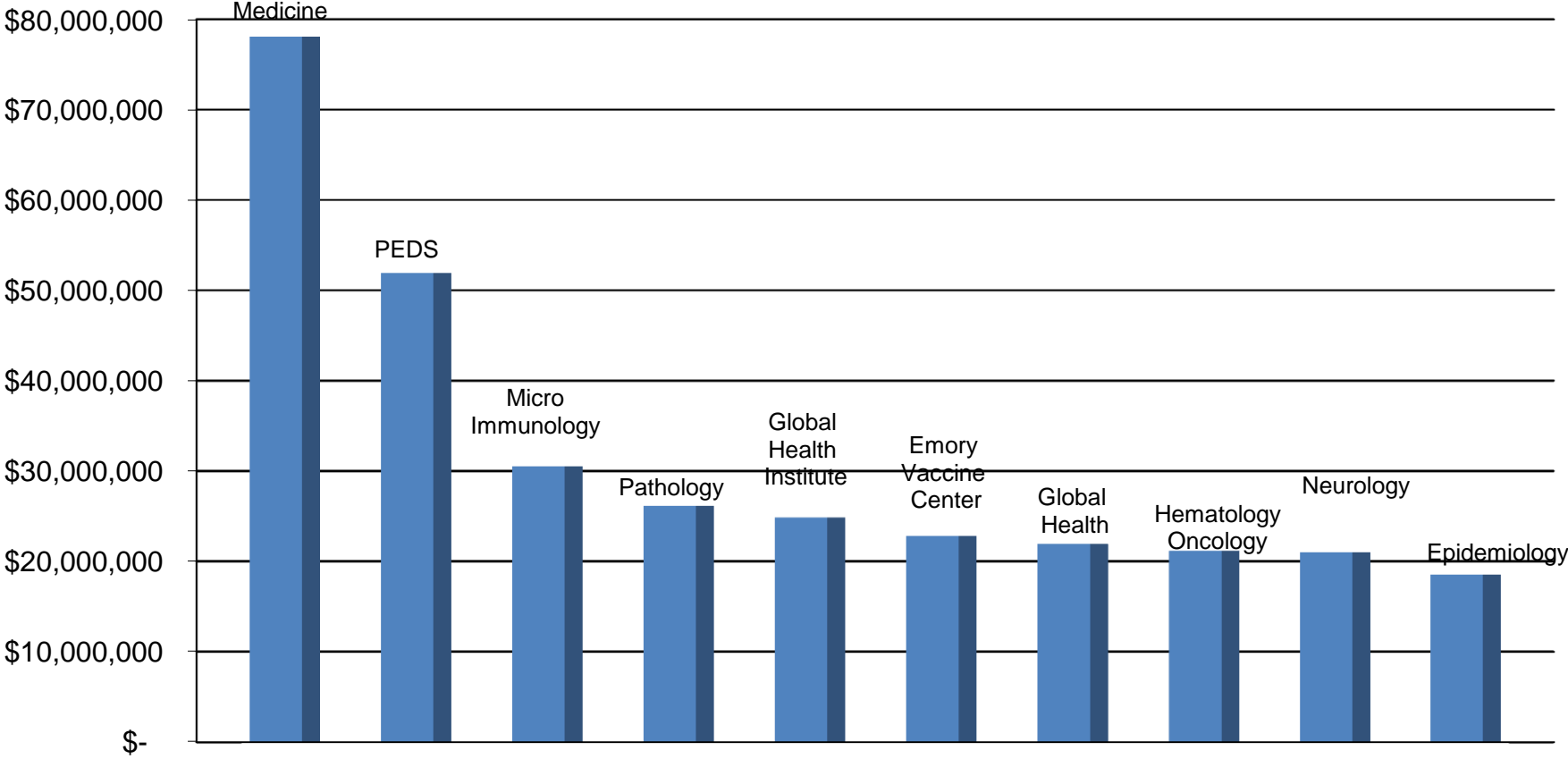


National Institutes of Health \$299,206,124

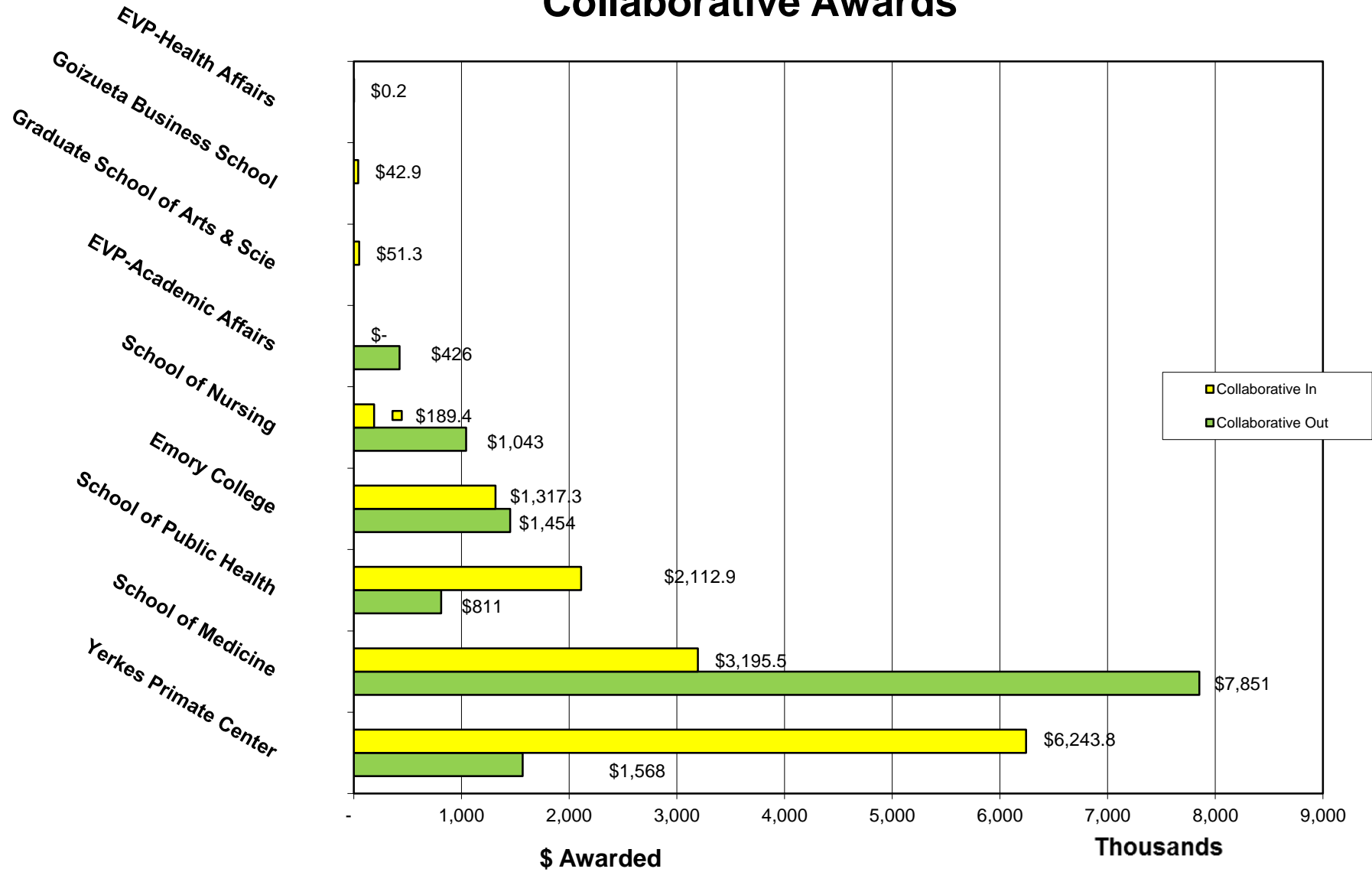


■ School of Medicine - \$198.6	■ Yerkes Primate Center - \$54.9	□ School of Public Health - \$26.0
□ Emory College - \$11.5	■ School of Nursing - \$5.0	■ Office of VP for Health Affairs - \$2.3
■ Laney Graduate School - \$1.0		

Sponsored Research Awards 10 Largest Departments

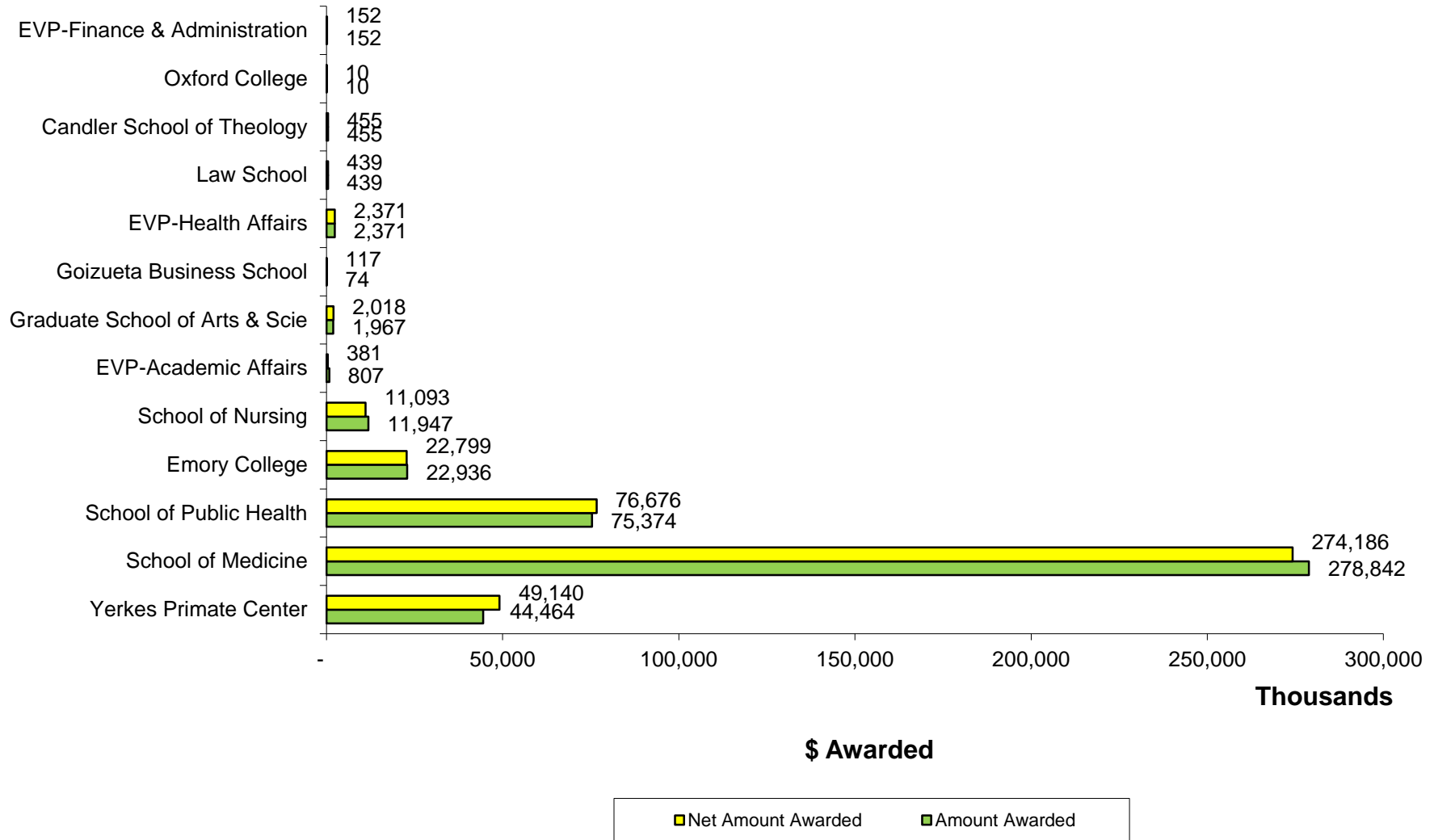


Collaborative Awards



Total Awarded vs. Net Awarded Dollars

Net Awarded Dollars = Total Awarded Dollars +/- Collaborative Award Dollars



Top Sponsors (\$1 million or more)

Sponsor	Number Awarded	Dollars Awarded
NIH	758	\$299,206,124
BILL AND MELINDA GATES FOUNDATION	14	\$25,067,101
CENTERS FOR DISEASE CONTROL	99	\$23,891,728
NATL SCIENCE FOUNDATION	50	\$15,564,058
DEFENSE ADVANCED RESEARCH PROJECT AGENCY	4	\$10,606,122
PATIENT CENTERED OUTCOMES RESEARCH INSTI	10	\$8,228,391
HEALTH RESOURCES AND SERVICES ADMIN	22	\$7,002,062
INTL AIDS VACCINE INITIATIVE	11	\$5,398,622
ASST SECTY FOR PREPAR. & RESPONSE BARDA	1	\$4,242,396
GEORGIA INSTITUTE OF TECHNOLOGY	37	\$3,666,332
HEMOPHILIA OF GEORGIA	8	\$3,166,432
US DEPT OF VETERAN AFFAIRS	34	\$2,569,092
GEORGIA STATE UNIVERSITY	31	\$2,521,614
NASA	8	\$2,424,984
ASSOC OF SCHOOLS OF PUBLIC HEALTH	3	\$2,412,306
GAVI ALLIANCE	1	\$2,292,141
US DEPT OF VETERANS AFFAIRS	55	\$2,265,542
Department for International Development	1	\$2,121,574
GILEAD SCIENCES	13	\$1,924,503
DUKE UNIVERSITY	34	\$1,896,252
HENRY M JACKSON FOUNDATION	9	\$1,884,071
GEORGIA DEPARTMENT OF BEHAVIORAL HEALTH	6	\$1,833,115
BRISTOL MYERS SQUIBB	14	\$1,670,474

Top Sponsors (\$1 million or more)

ROYAL COMMONWEALTH SOCIETY FOR THE BLIND	2	\$1,600,535
CYSTIC FIBROSIS FOUNDATION	16	\$1,595,881
EDWARDS LIFESCIENCES	1	\$1,581,891
LEIDOS BIOMEDICAL RESEARCH	15	\$1,556,029
JOHNS HOPKINS UNIVERSITY	20	\$1,542,043
GEORGIA DEPT OF PUBLIC HEALTH	9	\$1,528,490
UNIVERSITY OF CALIFORNIA LOS ANGELES	8	\$1,487,883
AMER HEART ASSOCIATION	26	\$1,480,586
ATLANTA RESEARCH AND EDUCATION FDTN	15	\$1,409,859
BRIGHAM AND WOMENS HOSPITAL	15	\$1,373,164
MICRONUTRIENT INITIATIVE	3	\$1,361,488
UNIVERSITY OF MICHIGAN	32	\$1,351,861
EMMES CORPORATION	2	\$1,339,780
CHILDRENS HEALTHCARE OF ATLANTA	22	\$1,306,079
US DEPARTMENT OF DEFENSE	5	\$1,248,429
UNIVERSITY OF GEORGIA	15	\$1,227,347
GE Foundation	1	\$1,220,232
UNIVERSITY OF CALIFORNIA SAN FRANCISCO	16	\$1,186,661
MICHAEL J FOX FDTN FOR PARKINSONS RES	12	\$1,160,126
McCormick Foundation	1	\$1,150,000
UNIVERSITY OF PENNSYLVANIA	14	\$1,129,548
JOHN TEMPLETON FOUNDATION	3	\$1,115,570
UNIVERSITY OF CALIFORNIA DAVIS	7	\$1,106,952
NEW YORK UNIVERSITY	12	\$1,092,693
MEDTRONIC	9	\$1,080,569
W M KECK FOUNDATION	1	\$1,000,000

Top Researchers (\$1 million or more)

Rank	Researcher	Total
1	Koplan, Jeffrey P.	\$24,485,222
2	Ahmed, Rafi	\$17,404,025
3	Caughman, Stewart Wright	\$10,233,594
4	Allen, Susan	\$8,372,302
5	Mulligan, Mark Joseph	\$8,214,277
6	Hunter, Eric	\$6,969,923
7	Stephens, David Samuel	\$6,634,841
8	Warren, Stephen Theodore	\$6,516,479
9	Levey, Allan I	\$6,282,515
10	Pulendran, Bali	\$5,693,835
11	Ribner, Bruce S	\$5,161,208
12	Krishnamurti, Lakshmanan	\$5,051,941
13	Eaton, Douglas Charles	\$4,842,679
14	Blumberg, Henry Michael	\$4,741,367
15	Del Rio, Carlos	\$4,734,626
16	Orenstein, Walter A	\$4,570,068
17	Sullivan, Patrick Sean	\$4,503,109
18	Silvestri, Guido	\$4,156,783
19	Breiman, Robert F	\$4,143,144
20	Roback, John Donald	\$4,047,501
21	Galinski, Mary R	\$3,701,599
22	Larsen, Christian	\$3,604,011
23	Quyyumi, Arshed Ali	\$3,586,024
24	Davies, Huw M.L	\$3,349,557
25	Omer, Saad Bin	\$3,241,349
26	Ofotokun, Ighoverha	\$3,175,405
27	Wilson, Mark Edward	\$3,120,748

Top Researchers (\$1 million or more)

Rank	Researcher	Total
28	Ramalingam,Suresh Sakkarai	\$2,888,393
29	Amara,Rama Rao	\$2,842,838
30	Lim,Sung Sam	\$2,838,220
31	Klin,Ami	\$2,826,966
32	Moe,Christine Lorraine	\$2,737,428
33	Villinger,Francois J	\$2,671,148
34	Altman,John D	\$2,667,821
35	Paiardini,Mirko	\$2,581,323
36	Ward,Kevin C	\$2,572,173
37	Haddad,Danny	\$2,571,947
38	Taylor,Kathy Griendling	\$2,530,370
39	Buchman,Timothy	\$2,488,458
40	Mayberg,Helen Susan	\$2,450,368
41	Young,Larry J	\$2,430,204
42	Lollar III,John Sherman	\$2,426,239
43	Rogers,Martha F	\$2,412,306
44	Compans,Richard W	\$2,367,201
45	Ressler,Kerry	\$2,281,595
46	Jones,Dean P	\$2,249,499
47	Miller,Gary W	\$2,247,608
48	Antia,Rustom N	\$2,211,312
49	Kugathasan,Subramaniam	\$2,182,396
50	Lennox,Jeffrey L	\$2,154,026
51	Cummings,Richard Dale	\$2,148,297
52	Fu,Haian	\$2,123,810
53	Umpierrez,Guillermo E	\$2,112,091
54	Glass,Jonathan D	\$2,096,949

Top Researchers (\$1 million or more)

Rank	Researcher	Total
55	Taylor,W Robert	\$2,080,635
56	Jin,Peng	\$2,045,952
57	Remais,Justin Victor	\$2,034,871
58	Spearman,Paul William	\$2,000,728
59	Wang,Ya	\$1,993,350
60	Miner,Kathleen Rae	\$1,980,634
61	Rothbaum,Barbara O	\$1,974,366
62	Eaton,Molly Ellen	\$1,936,313
63	Joiner,Clinton	\$1,931,456
64	Ortlund,Eric A.	\$1,816,054
65	Druss,Benjamin G	\$1,814,303
66	Sullivan,Patrick	\$1,811,289
67	Kempton,Christine Luise	\$1,775,105
68	Gross,Robert Elkan	\$1,756,886
69	Ansari,Aftab Ahmed	\$1,723,486
70	Curran Jr,Walter J	\$1,712,435
71	Venkat Narayan,Kabayam M.	\$1,706,317
72	Kottke,Melissa Jo	\$1,650,500
73	Guidot,David M	\$1,639,163
74	English,Arthur W	\$1,602,191
75	Waldrop-Valverde,Drenna	\$1,548,770
76	Dyer,Richard Brian	\$1,503,207
77	McNabb,Scott J	\$1,492,153
78	Johnson,Robert Paul	\$1,486,868
79	Spencer,Harold Trent	\$1,478,761
80	Kegler,Michelle Crozier	\$1,444,635
81	Wang,Baozhong	\$1,437,275

Top Researchers (\$1 million or more)

Rank	Researcher	Total
82	Cooper,Hannah L.F.	\$1,434,982
83	Boss,Jeremy M	\$1,423,159
84	Kalman,Daniel	\$1,416,735
85	Babaliaros,Vasilis C.	\$1,405,166
86	Xiong,Li	\$1,403,751
87	Blais,Linelle Marie	\$1,403,453
88	Iuvone,Paul Michael	\$1,398,326
89	Sanchez,Maria del Mar	\$1,389,854
90	Bassell,Gary J	\$1,388,827
91	Loring,David William	\$1,388,491
92	Sanz,Ignacio	\$1,385,136
93	Pavlath,Grace K	\$1,382,855
94	Keilholz,Shella Dawn	\$1,365,800
95	Heaven,Michael C	\$1,364,133
96	Sibley,Lynn M	\$1,361,488
97	Hall,Randy A.	\$1,343,995
98	Edupuganti,Srilatha	\$1,321,495
99	Coles,Claire D	\$1,317,802
100	Nie,Shuming	\$1,294,859
101	Kaufman,Jonathan Lyle	\$1,291,001
102	Kahn,Richard A	\$1,285,165
103	Shim,Hyunsuk	\$1,281,885
104	Neish,Andrew S	\$1,274,783
105	Flowers,Christopher Robert	\$1,273,223
106	Kowalczyk,Andrew Patrick	\$1,268,991
107	Chan,Anthony Wing Sang	\$1,263,307
108	Corwin,Elizabeth J	\$1,255,235

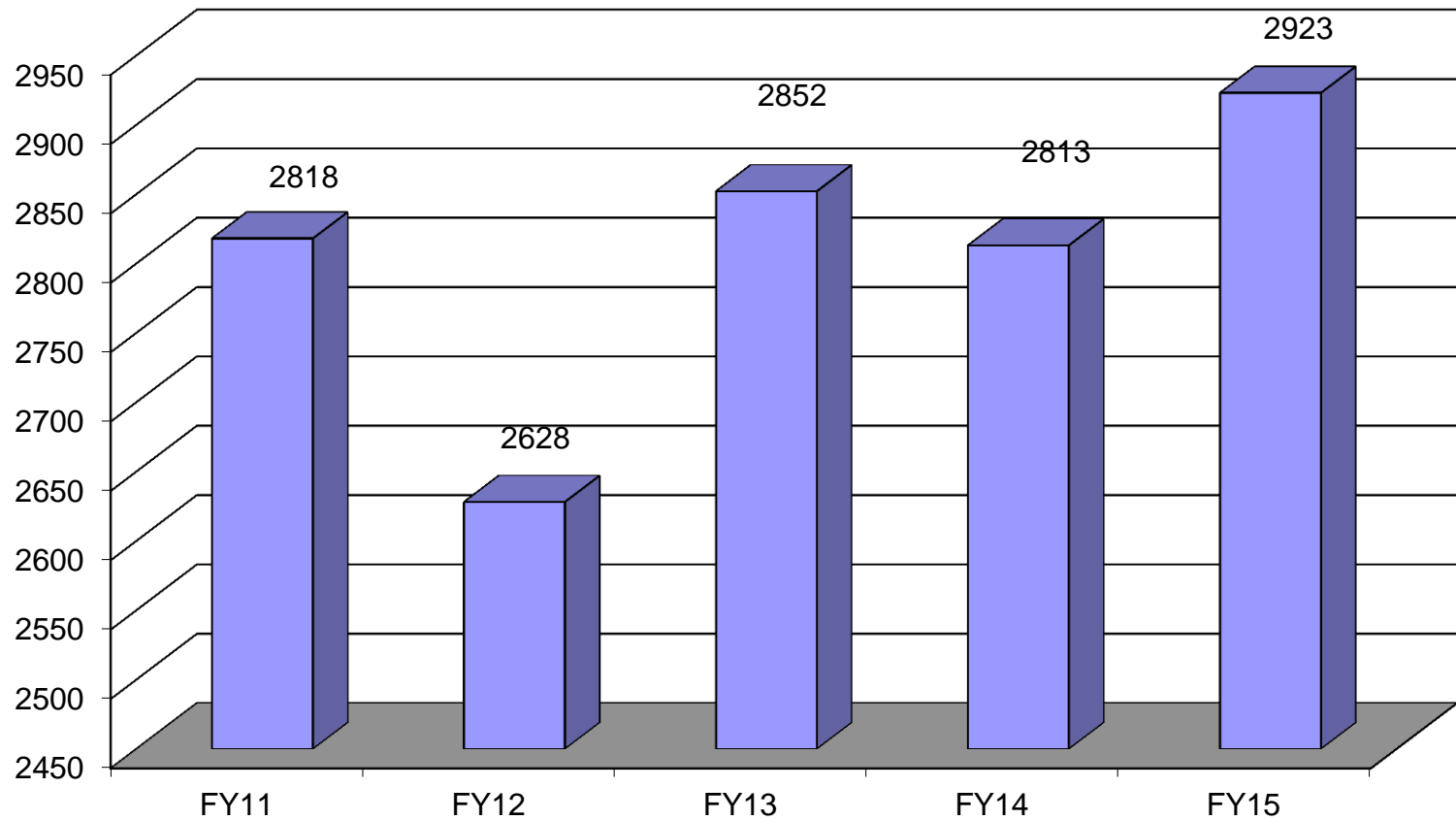
Top Researchers (\$1 million or more)

Rank	Researcher	Total
109	Yang,Lily	\$1,234,718
110	Kim,Baek	\$1,231,872
111	Meador,Kimford Jay	\$1,229,423
112	Walker,Elaine	\$1,221,975
113	Coopersmith,Craig	\$1,216,800
114	Fitzpatrick,Anne Mentro	\$1,213,529
115	Gutman,David A	\$1,211,601
116	Dickert Jr,Neal Workman	\$1,180,762
117	McCauley,Linda A	\$1,176,852
118	Chen,Jing	\$1,151,160
119	Trumbower,Randy D	\$1,138,996
120	Van Meir,Erwin G	\$1,137,987
121	Fei,Baowei	\$1,130,900
122	Jo,Hanjoong	\$1,116,343
123	Cubells,Joseph Faustino	\$1,110,833
124	Painter,George R	\$1,085,529
125	Cooper,Max Dale	\$1,077,122
126	Traynelis,Stephen F	\$1,075,594
127	Gambello,Michael J	\$1,069,599
128	Weiss,David Strum	\$1,064,576
129	Howell,Leonard Lee	\$1,057,988
130	Thurman,Sandra	\$1,042,568
131	Goodman,Michael	\$1,041,327
132	Tansey,MariadeLourdes Gamez	\$1,039,384
133	Shaw,Leslee J.	\$1,036,146
134	Negi,Satya Dev	\$1,035,001
135	Ford,Mandy Leigh	\$1,034,107

**Top Researchers
(\$1 million or more)**

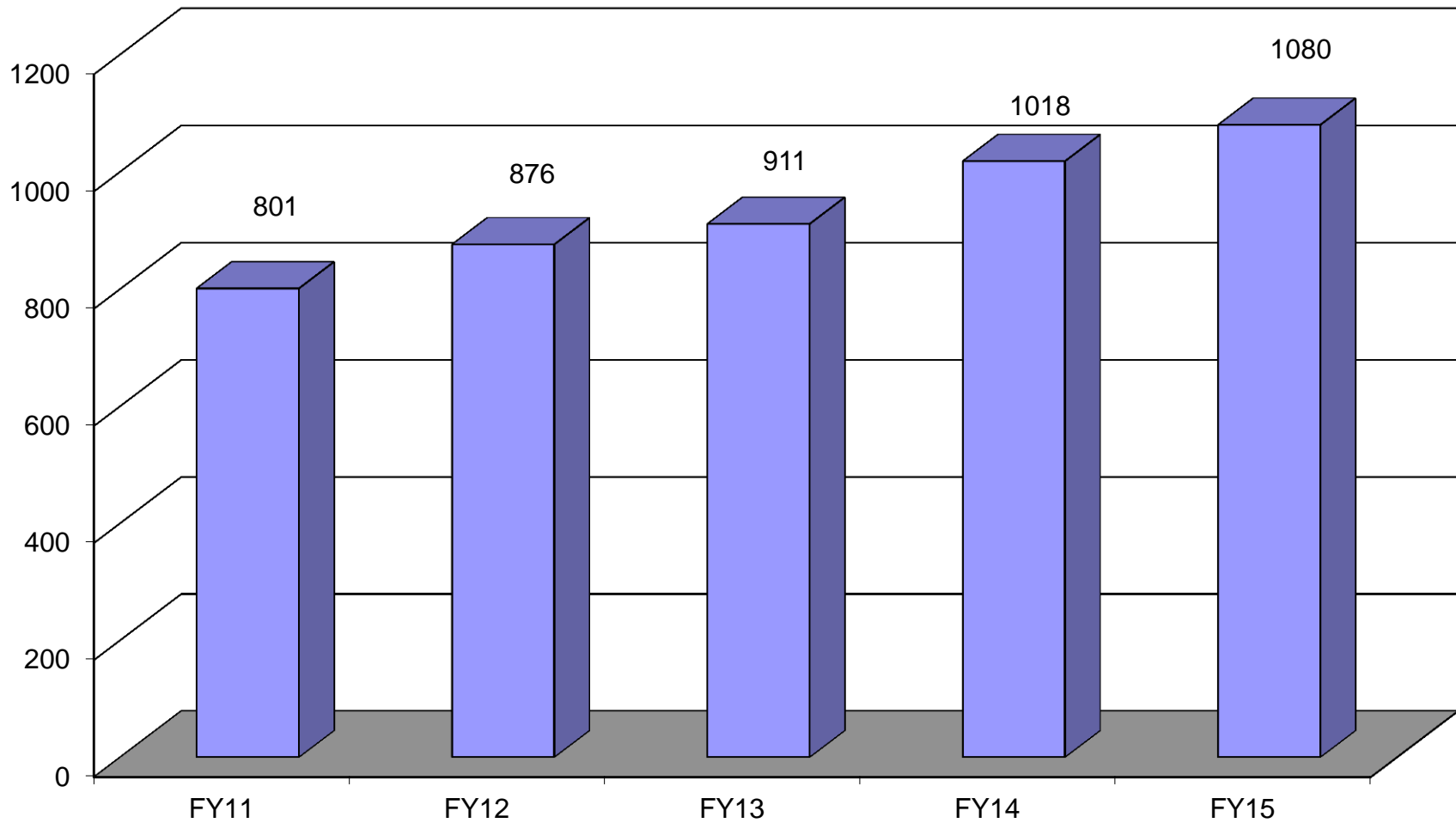
Rank	Researcher	Total
136	Karpen, Saul	\$1,033,402
137	Wright, David W.	\$1,030,664
138	Stein, Aryeh D.	\$1,018,762
139	Mao, Hui	\$1,011,896
140	Chahroudi, Ann M.	\$1,003,686
141	Patzer, Rachel Elizabeth	\$1,001,543

Awards (Processing Totals)



Note: The method of how the University accounts for the total number of awards received was changed in fiscal year 2013. Previous reports included the number of all award actions on clinical trials, which resulted in individual clinical trials being included multiple times. The reports have been changed to provide a more accurate count of awards received by the University, with each clinical trial now counted only once.

Subcontracts Issued by Emory Totals by Fiscal Year



GrantForward (formerly IRIS) Searches

