Office of Research Administration FY17 Annual Report (ORA)

Dr. David L. Wynes, Vice President for Research Administration
Melanie Lawrence, Chief Business Officer for Research Administration

FY17 Annual Report – Office of Sponsored Programs (OSP)

Holly Sommers, Directory for OSP, Assistant Vice President for ORA

Overview

After sustaining an increased level of sponsored awards in FY16, Emory once again saw a tremendous growth in award funding in FY17. Total awards received grew from $574.6m in FY16 to $624m in FY17, marking the first time in University history that sponsored awards topped the $600m mark. The number of awards processed similarly increased, from 2,931 in FY16 to 3,312 in FY17. An increase was also seen in the funding requested through sponsored proposals, with requested funding reaching $1.1b in requested funds in FY17. This is up from $1.0b in FY16. The number of proposals submitted increased from 3,959 in FY16 to 4,170 in FY17.

A major initiative of FY2017 was the support of the Compass Upgrade, upgrading the system from PeopleSoft 9.0 to 9.2. This was a major undertaking that was categorized more as a re-implementation than an upgrade. Much work had been done toward the design of the new system and accompanying new processes prior to FY2016 and that work continued into FY2017. During FY2017, all training materials to support the new systems and processes for OSP were finalized. One major aspect of preparation for the upgrade was cleaning up all proposals in workflow and preparing for the downtime of the system for several days immediately prior to the upgrade. OSP worked with several units, including all of the schools and OFSDA to ensure that all campus users were prepared for the upgrade and the system downtime associated with it. Operations during this downtime continued smoothly with no adverse impact to daily operations.

Part of the process change resulting from the Compass Upgrade was a change in the award set-up processes, including the shifting of certain activities from OSP to the newly configured Finance: Grants and Contracts (FGC) Post-Award Setup (PAS) team. Due to this transition, in the period immediately after the Upgrade, a backlog of award setups developed in FGC. Through the efforts of FGC leadership to identify the issues, and a commitment from Emory leadership to help clear the backlog, OSP staff shifted

resources internally to allow several staff members to re-focus their efforts for a concentrated period of time to address the problem. Through these efforts, OSP was able to assist in the project that fully-eliminated the backlog of award setups over a 2 week period. OSP continued throughout the year to partner with FGC by assisting with questions that came up on the award setup process.

OSP continued its support of the final stages of the RAS Transition and participated in numerous faculty feedback sessions to evaluate the work of both OSP and the RAS. Through these sessions, OSP identified areas in which to evaluate opportunities to streamline processes for more efficient operations.

In FY 17, Emory continued its participation in the Federal Demonstration Partnership's Expanded Clearinghouse pilot. Through this pilot, Emory participated in a demonstration which would decrease the administrative burden associated with the subrecipient monitoring requirements of the Uniform Guidance. OSP provided detailed metrics to the FDP as part of our participation. Through the participation of Emory and other universities, the

Status of Goals for 2016-2017

1. Support development of revised RAE Foundational training program. All materials for the program completed in FY17. All pre-award modules have been review and a plan for development of independent e-learning modules has been finalized. D e to departure of Education Director (who develops online modules), development of online modules has been delayed but will be completed in FY18.
2. Provided ability for RAS to enter comments in eGTS award tracking system. In an effort to build on the benefits provided by the automated data export from the eGTS award tracking system that was implemented in FY2016, OSP partnered with ORA-IT to develop a function whereby RAS staff members can enter information on a pending award directly in the system. Development of the system was conducted by ORA-IT, with OSP providing the business needs and rules, along with beta and QA testing for the system. The new function will allow information from the RAS to be entered directly in the system, so that both RAS and OSP staff can access current information in a single location.
3. Participate in the review and modification of Sponsored Projects Handbook. OSP has begun a comprehensive review of all pre-award sections of the sponsored projects handbook to ensure that all sections reference current processes which reflect any new

functionality in the Compass system. Completion is expected in FY18.

4. **Participate in FDP Pilot for Expanded Institutional Profile.** As a participant in the second cohort, Emory participated in an FDP pilot designed to reduce administrative burden. OSP is leading this initiative, liaising with the FDP on requirements, developing internal training and process documents, and communicating processes internally as well as to campus customers. Emory has participated as a full member of Cohort 2. As part of the pilot, OSP maintains the institutional profile, including having recently converted the profile to the new web-based system. OSP also provided the required reports (supplied every 4 months) documenting the outgoing subawards which have been issued under the streamlined processes made possible by the Clearinghouse. As a result of the pilot, including Emory's participation, the FDP approved the Expanded Clearinghouse to "graduate" from a pilot to an ongoing demonstration. OSP will continue to maintain the Emory profile in the Expanded Clearinghouse, which should reduce the number of detailed risk analysis profiles we are asked to provide.
5. **Continue final preparations and participate in launch of Compass upgrade. Provide post go-live support for grants-related issues that arise due to upgrade.** This included finalizing training manuals and process documents to support processes that will be new after the upgrade as well as communicating pertinent changes to all campus customers and developing materials to support all aspects of operations, from proposal routing, to award set-up and management, and reporting. The Compass upgrade was successfully implemented in November 2016. OSP staff completed all required training and provided necessary communication to campus customers describing changes effected by the upgrade. Successfully planned for and managed the several-day system downtime that occurred during the upgrade itself. Worked with OFSDA to address unexpected issues resulting from the upgrade, including developing manageable "workarounds" related to issues with EPEX proposal routing.

Other Notable Accomplishments

1. **Partnered with FGC Post-Award Set-up group to address backlog resulting following Compass Upgrade.** Assisted FGC with the redesign of their internal processes, and dedicated staff to a 2-week intensive clean-up project to process a significant backlog of award set-ups which was created by the Compass upgrade. The project was successful in removing the backlog and to allow OSP/FGC to achieve a "steady state" with respect to the timely processing of award set-ups.
2. **Updating OSP Policy and Procedures manual.** Currently in progress. Conducting a comprehensive review of the OSP Policy and Procedures manual to ensure that it reflects current policies and processes and is updated with new procedures related to the

Compass upgrade. Ongoing and will be completed in FY2018.

3. Updating outgoing subaward templates. Currently in progress. Worked with Office of General Counsel to finalize a standard template for use for outgoing subawards to international organizations on federally funded awards. Utilized updated language from this template to update standard outgoing subaward for domestic organizations on federally-funded awards. Currently in the process of updating standard subaward template for use on federal contracts and updating standard subaward template for use on awards funded from non-federal sources. Additional templates currently under review and completion expected in FY2018.

Goals for 2017-2018

1. Develop expanded/comprehensive internal training program for OSP: Review current development plan to evaluate opportunities now available to staff. Review status of training completion for all OSP staff members. Review current internal training process for OSP staff and determine how to best provide training to OSP staff (including development of online training modules).
2. Support revision of RAE Certification Program: Participate in the further development and completion of a revised, predominantly online certification program as well as the development of an expanded program with specialized certifications.
3. Develop policies and procedures for incoming service agreements that are routed through OSP: Research/benchmark other university policies and processes. Coordinate with other ORA departments to develop these policies and procedures.
4. Improvements to SAM Kiosk: Evaluate success of FY16 proof of concept moving SAM Kiosk (workflow management) to BPMS platform. Ensure electronic workflow is effective, improves current processes and evaluate reporting/metrics to ensure meets OSP needs. If yes, then work with LITS to move four remaining requests to BPMS platform. Evaluate whether other OSP processes (NDAs/CDAs) can be incorporated into SAM. If BPMS is not identified solution, evaluate alternatives.
5. Participate in updates of Sponsored Programs Manual and Investigator Guide: Review and edit all pre-award sections of these manuals to ensure they reflect current regulations, policies, procedures and institutional structure.

FY17 Annual Report – Office of Technology Transfer (OTT)

Todd Sherer, Executive Director for OTT, Associate Vice President for ORA

Introduction

Record Year

This past year brought many new milestones for Emory University. To begin with, Emory received a record high of $628M in sponsored research funding, with an all-time high of $63.63M coming from industry to support clinical trials and research, but that is just the beginning. Research funding continues to drive activity in the office and our inventors disclosed a record number of 245 new inventions to the office. As deal makers, we completed a grand total of 2,216 agreements between industry contracting and technology transfer, another record. Most of these are with our industry partners and lead to sponsored research funding and licensing new inventions.

Emory startups had an excellent year on a number of fronts. To begin with, Emory received a record high of $1,796,772 in translational funding to support future spin-out technologies while launching a record 8 new startups. Existing Emory startups raised $117M from venture capitalists and high-net-worth individuals, with $95M of that raised by Carrick Therapeutics based in Ireland. These startups also received some very noteworthy clinical/regulatory milestones this year including Clearside Biomedical's completion of Phase III patient enrollment, Accuitis' FDA clearance for its Phase II study and Cambium Medical Technologies' initiation of a Phase I/II dry eye study. We continue to work closely with all Emory licensees to help assure that our technology leads to new products that can benefit patients.

Behind the scenes, are many important activities that often go unnoticed but are critical to our success. For example, our technology scouting team alone met with 260 different faculty to inform, educate and find new invention disclosures. Our dedicated marketing team not only continued to build the office's brand through multiple social media campaigns, but also sent out a record 1,643 non-confidential summaries to prospective corporate partners. On top of that, the Emory Patent Group, our in-house patent firm, received a record number 41 issued patents this year.

We set up many new, innovative collaborations with industry that will help ensure a robust pipeline for the future. A great example of such a collaboration is the new multifaceted master research agreement put in place with Boston Scientific and which is targeted at sharing development and IP rights for promising new medical technologies. In addition, we continue to support the development of promising new therapies and medical devices through the execution of new sponsored clinical trial agreements that have resulted in approximately 1,804 active clinical research studies conducted by Emory faculty with approximately 17,070 participants.

I want to thank my staff for their hard work and dedication this past year. All of these records demonstrate your passion and commitment to Emory's success. Well done!

Highlights and Milestones

- Boston Scientific and Emory University enter into a joint development agreement to form an industry-academia partnership. Under this unique partnership, Boston Scientific engineers and Emory physicians will join force to develop device products and other solutions to meet unmet medical needs.
- Carrick Therapeutics Ltd. raises $95M in funding led by ARCH Venture Partners and Woodford Investment Management. Investors include Cambridge Enterprise, Evotec AG, Google Ventures, Lightstone Venture and Cambridge Innovation Capital.
- QUE Oncology receives $16M in Series A financing.

Company Milestones

- Cambium Medical Technologies receives an investment of $5M from a private investor in Taiwan. They have also submitted an IND to the FDA.
- Clearside Biomedical announces completion of patient enrollment in pivotal Phase III PEACHTREE clinical trial of CLS-TA for suprachoroidal administration in patients with macular edema associated with non-infectious uveitis.
- Accuitis raises $650,000, bringing the total equity raises of the company's preferred round to $1.85M. They also receive FDA clearance for its Phase II multi-center study of ACU-D1, a drug candidate for the treatment of Rosacea.
- Cambium Medical Technologies enters a Phase I/II GvHD Dry Eye study.
- Meissa Vaccines announces a seed round investment from FundRx, a New York based angel investor network. They also receive a $1.6M Fast Track SBIR grant to advance IND preparations for RSV vaccine candidate.
- Cocrystal Pharma, Inc. (OTCQB: COCP) closes on proceeds of $3M in a private placement offering of 12,5M shares of the Company's common stock at a purchase price of $0.24 per share.
- NeuroTrack receives a $500,000 grant from Johnson & Johnson Innovation and Janssen Research & Development for World Without Disease QuickFire Challenge and is offered residency at Johnson & Johnson Innovation.
- GeoVAX presents at the American Society for Microbiology conference a Zika virus vaccine that gives 100% protection in mice. They also raise $1M by selling shares to an unidentified investor in a private placement transaction.
- NeurOp receives a $3.5M award from the National Institute of Neurological Disorders and Stroke (NINDS) to begin clinical testing of drug candidate NP10679, for the prevention of ischemic damage during a stroke or subarachnoid hemorrhage (SAH).
- Metaclipse Therapeutics will receive a SBIR Phase II award for $1.5M to accelerate the company's IND filing and clinical trial. They also received a SBIR Phase 1 grant ($230,279) for a project on developing influenza vaccine for elderly using GPI-molecules as adjuvant.

Office Milestones

- Restructured technology scouting and translational support with the hire of a second staff member for this team. This will allow for the first ever full-time technology scout to "walk the halls."
- Implemented an intellectual property due diligence process for select technologies.
- Implemented programmatic improvements for industry contracting from the outside consultant review.

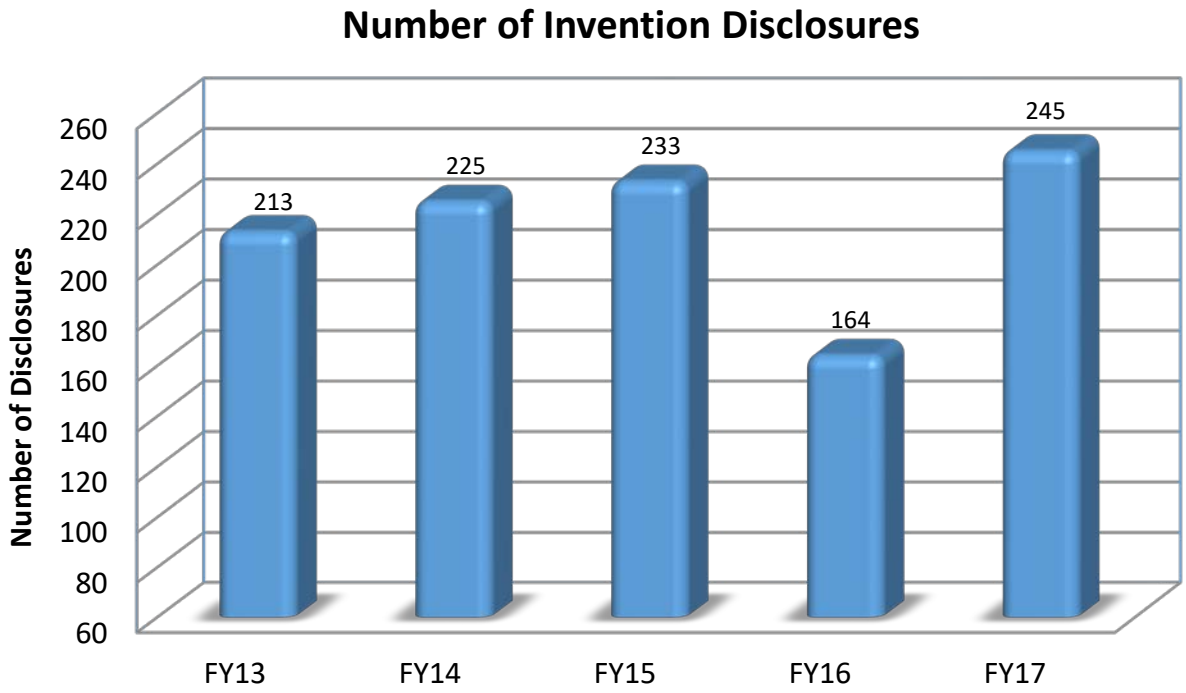
Statistical Milestones

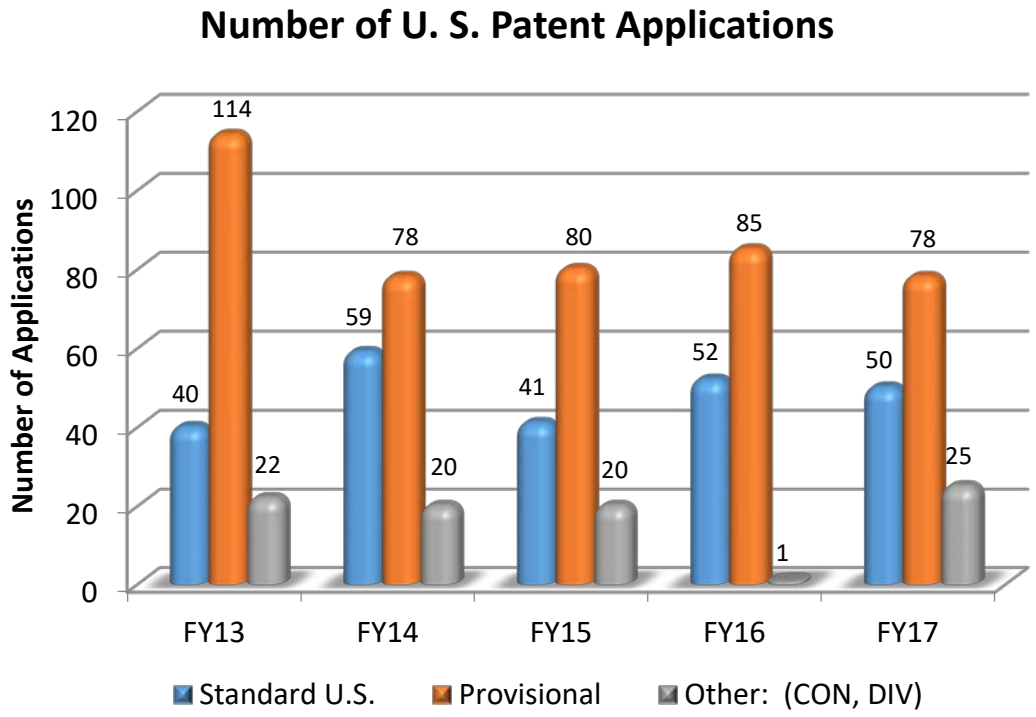
- The number of invention disclosures is 245 an all-time high.
- The number of AUTM reportable license licenses is 56 an all-time high.
- The number of startups is 8 an all-time high.
- Proof of principle funding was $1,796,772 an all-time high.
- The number of issued patents was 41 an all-time high.
- Corporate funding totaled $63,630,531 an all-time high.
- There were 1,643 non-confidential summaries sent to prospective licensees an all-time high.
- Of this year's 260 faculty scouting meetings a record 193 were with new faculty.

Staff Acknowledgements

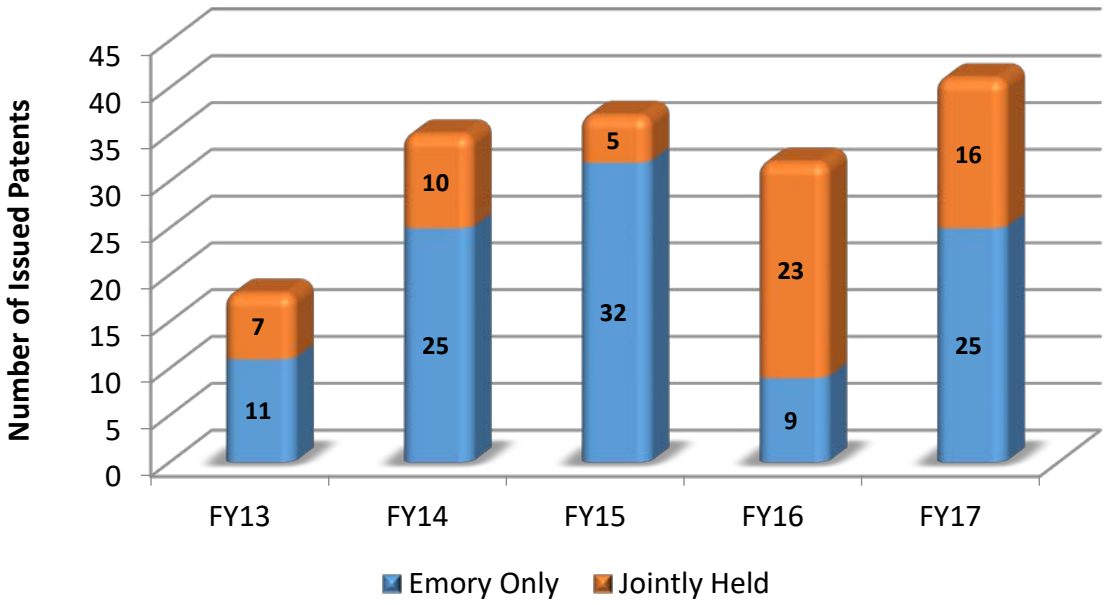
- Tammie Bain hired as Assistant Director, Industry Contracting
- Justin Burns promoted to Licensing Associate
- Kae Eppley hired as contract specialist
- Hyeon (Sean) Kim hired as Licensing Associate
- Patrick Reynolds hired as Assistant Director, Faculty & Startup Services
- Laura Fritts is named a Corporate IP Star for the third year in a row
- Cliff Michaels receives Certified Licensing Professional(CLP) designation
- Linda Kesselring receives Registered Technology Transfer Professional (RTTP) designation
- Professional Volunteering
    - Laura Fritts is a member of Atlanta IP Inn of Court's Chair of Special Events
    - Cliff Michaels is a member of AUTM's Strategic Communications Committee
    - Linda Kesselring joined AUTM's Program and Website Committees
    - Patrick Reynolds was promoted to co-chair of AUTM's Better World Project
    - Todd Sherer is currently chair of SEBIO
    - Quentin Thomas is a member of AUTM's Marketing Course Committee

By the Numbers

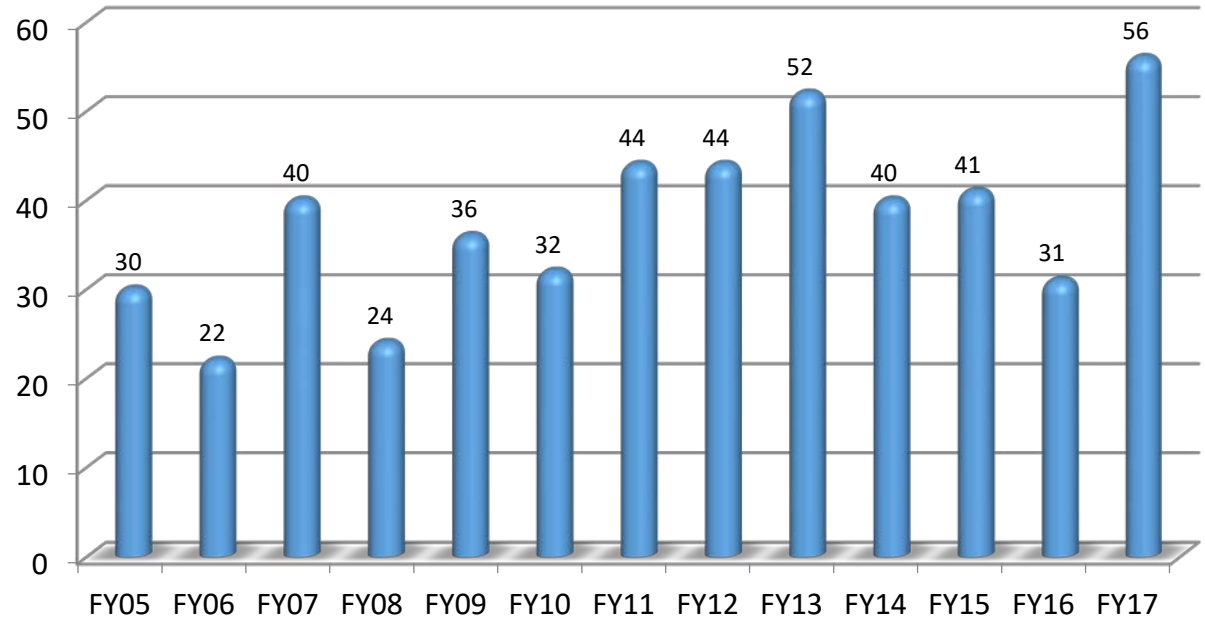


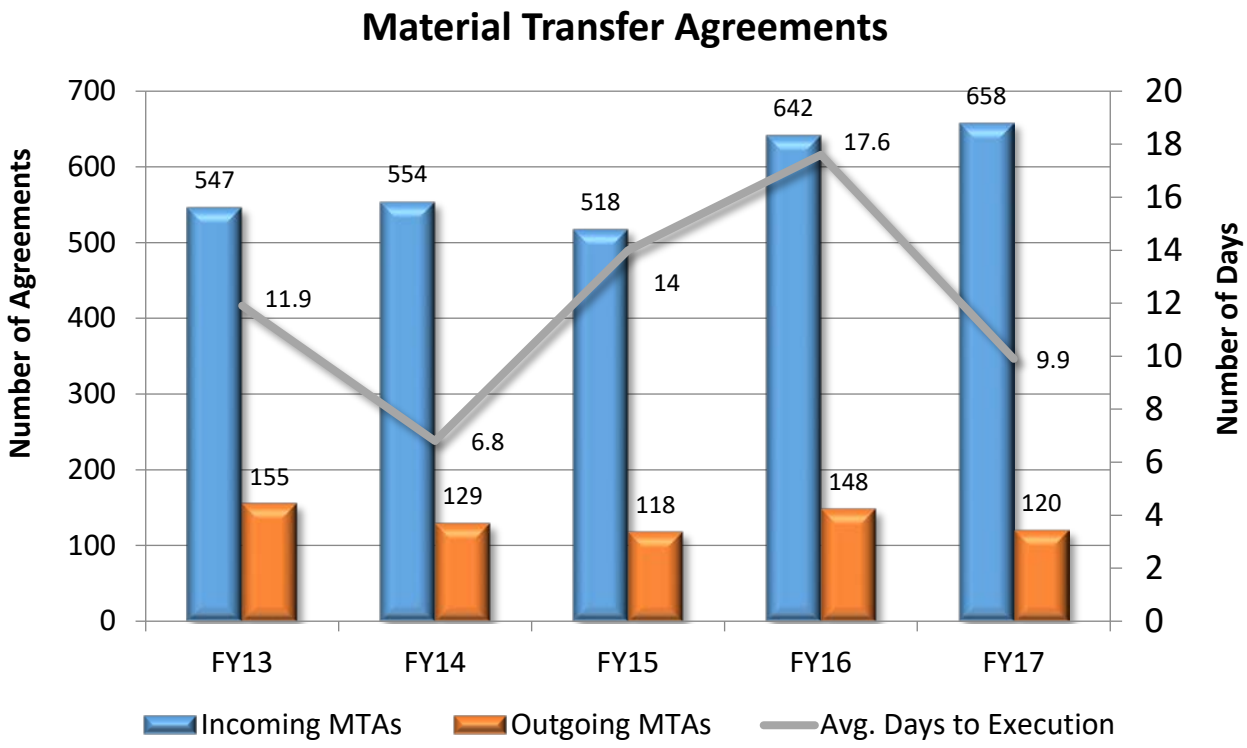


Number of U.S. Issued Patents

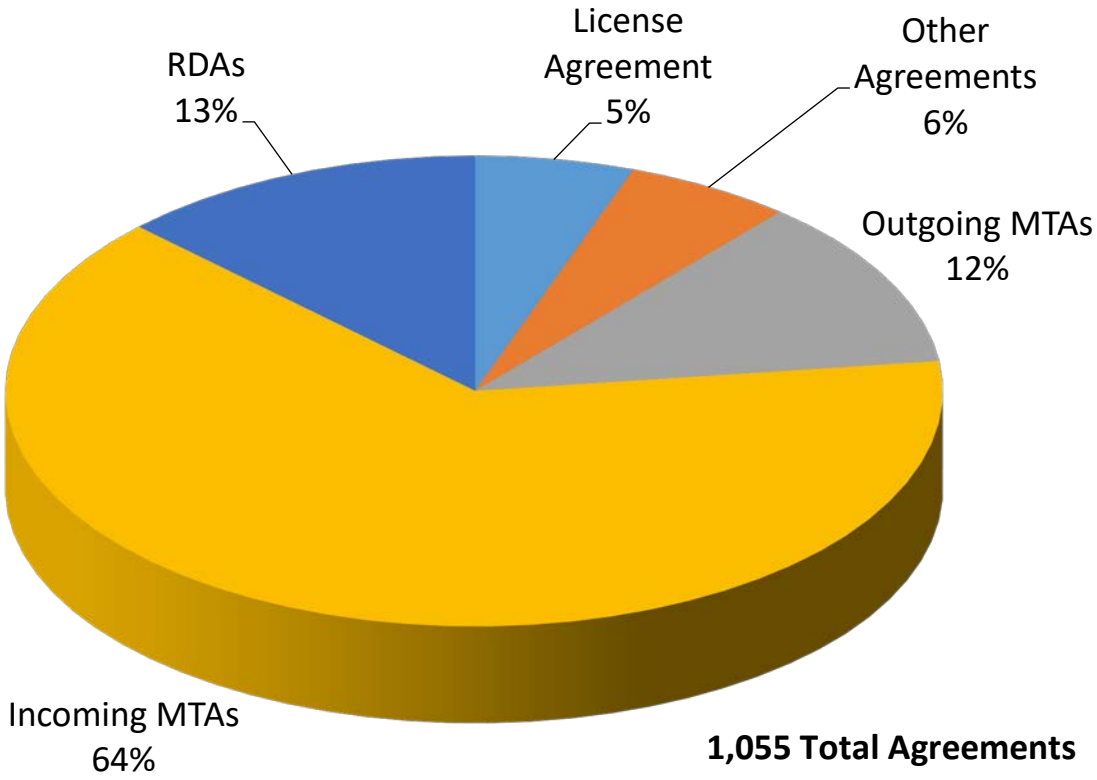


AUTM Reportable Agreements

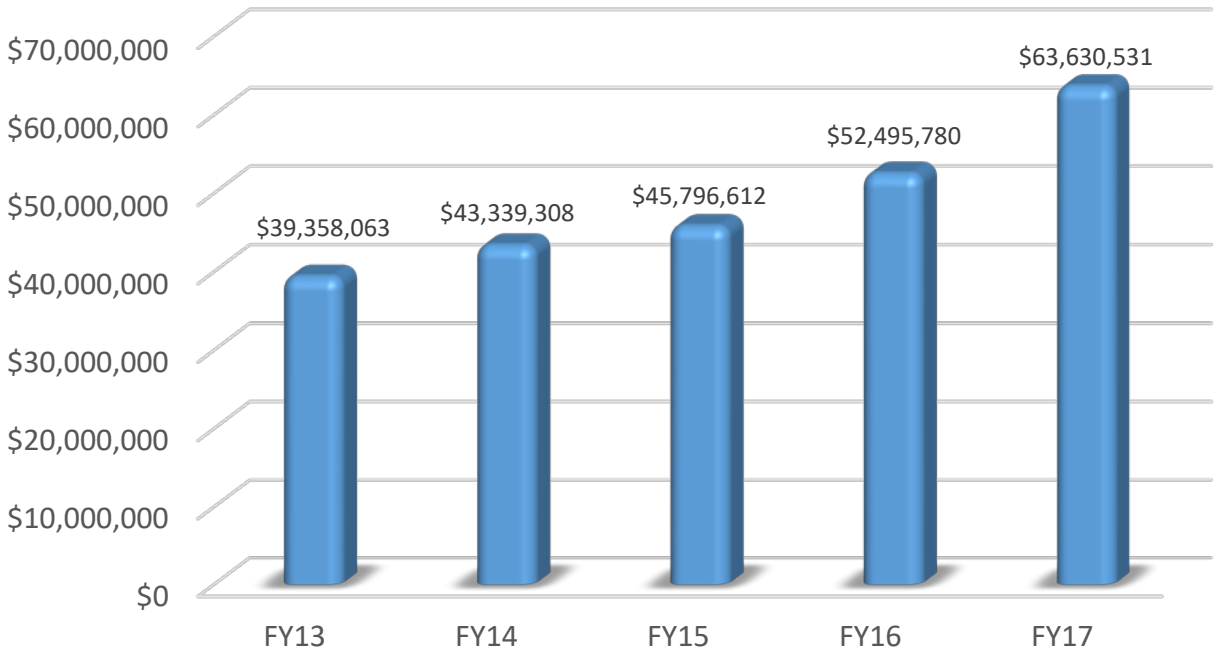



Material Transfer Agreements
Number of Agreements
Number of Days
700
600
500
400
300
200
100
0
20
18
16
14
12
10
8
6
4
2
0
547
554
518
642
658
155
129
118
148
120
11.9
6.8
14
17.6
9.9
FY13
FY14
FY15
FY16
FY17
Incoming MTAs
Outgoing MTAs
Avg. Days to Execution

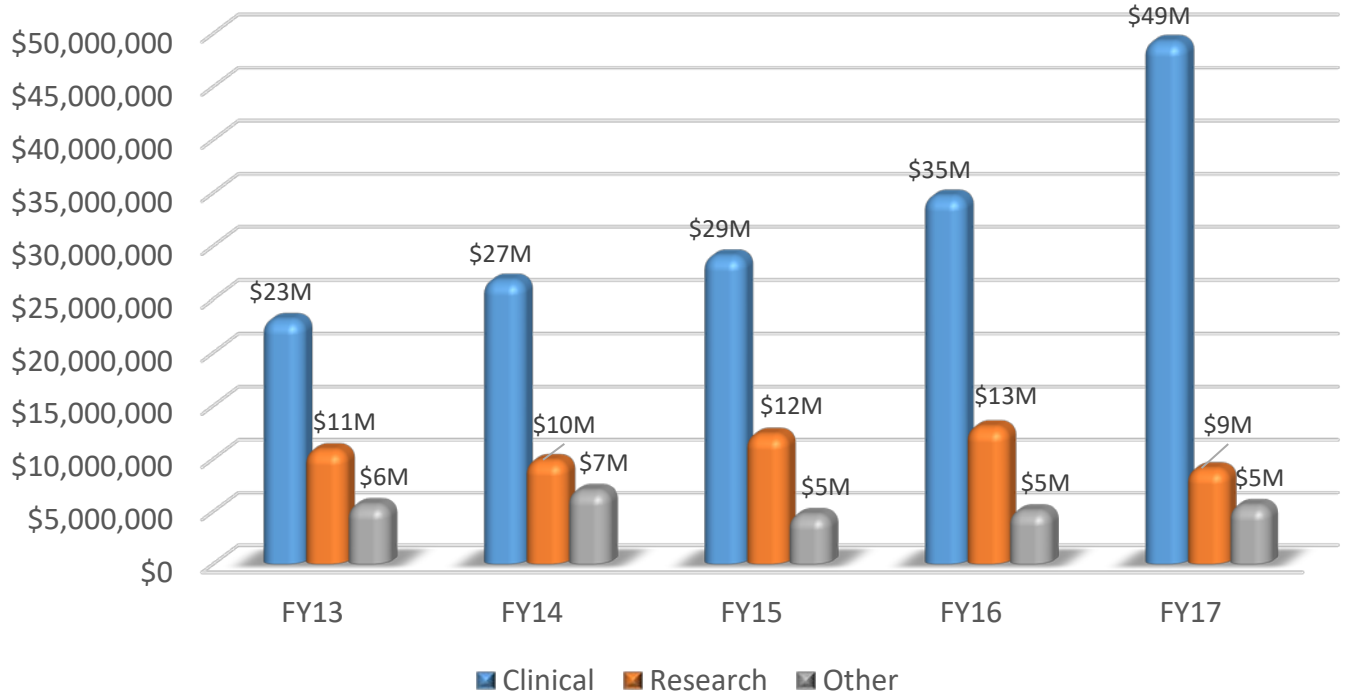
Network of Technology Agreements



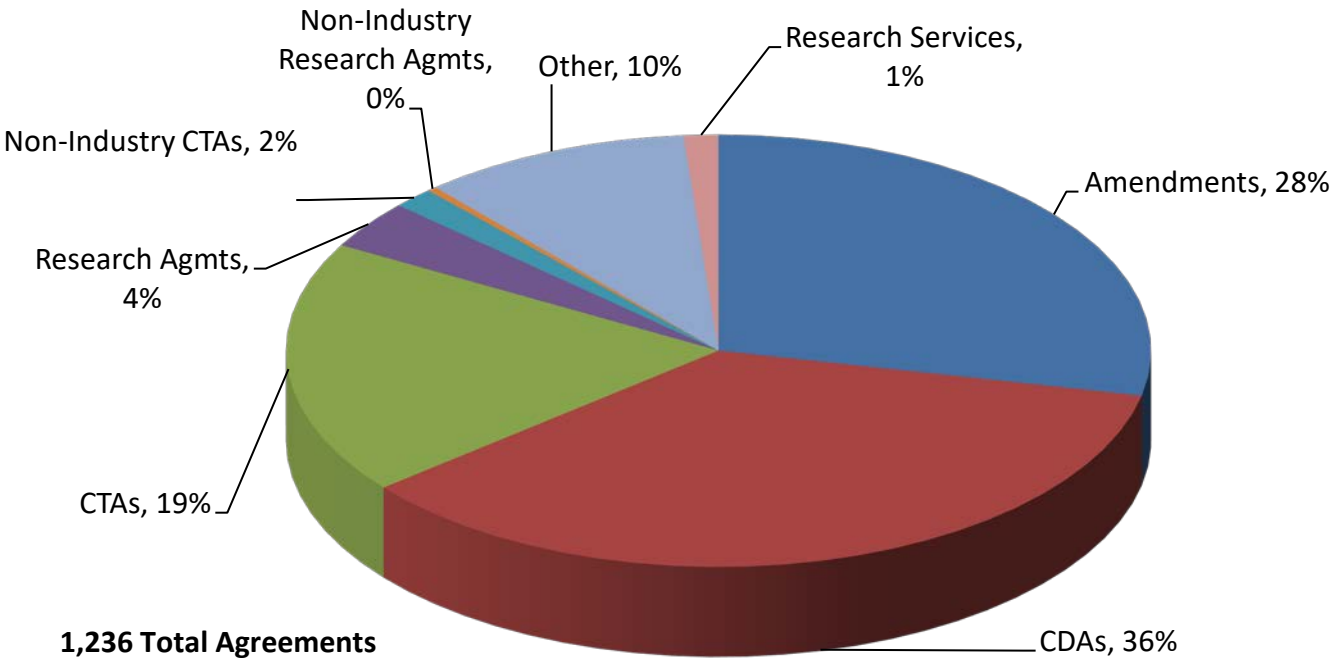
Corporate Funding



Corporate Funding by Type



Network of Outgoing Corporate Agreements



1,236 Total 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 - 2002	$(22,719,712.39)	$8,419,656.32	$145,248.51	$74,998797.53	$60,843,989.97
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	($3,472,688.33)	$1,849,685.53	$127,178.28	$14,382,136.46	$12,886,311.94
2011	($3,359,364.75)	$2,409,734.70	$167,126.17	$15,899,106.74	$15,116,602.86
2012	($3,373,606.44)	$2,095,020.52	$208,089.82	$25,630,179.86	$24,559,683.76
2013	($2,657,200.88)	$1,372,763.95	$54,508.61	$4,124,414.34	$2.894,486.02
2014	($2,664,210.72)	$1,311,112.08	$83,103.49	$9,816,203.06	$8,546,207.91
2015	($2,343,656.91)	$952.215.22	$87,580.91	$7,948,858.99	$6,644,998.21
2016	($2,236,162.05)	$860,029.87	$274,979.23	$6,589,923.16	$5,488,770.21
2017	($2,165,647.99)	$760,918.04	$131,407.24	$7,936,913.79	$6,663,591.08
Total	($39,919,270)	$16,168,740	$2,073,304	$867,737,331	$833,163,194

* 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 FY17

Directly to PI'S	$3,052,581.57
PI Labs	$1,232,393.39

College	$ 36,351.43
College Departments	$ 113,961.72
Chemistry	$ 113,961.72

School of Medicine	$ 666,106.21
School of Medicine Departments	$ 651,022.92
SOM Department Breakout	
Biochemistry	$ 2,000.68
Cardiology	$ 234,893.13
Cell Biology	$ 4,071.09
Dermatology	$ 2,801.70
Emergency Med	$ .00
Genetics	$ 19,970.39
Hematology	$ 479.47
Dept. of Medicine	$ 2,310.00
Microbiology	$ 10,524.92
Pathology	$ 240.02
Neurosurgery	$ 1,355.40

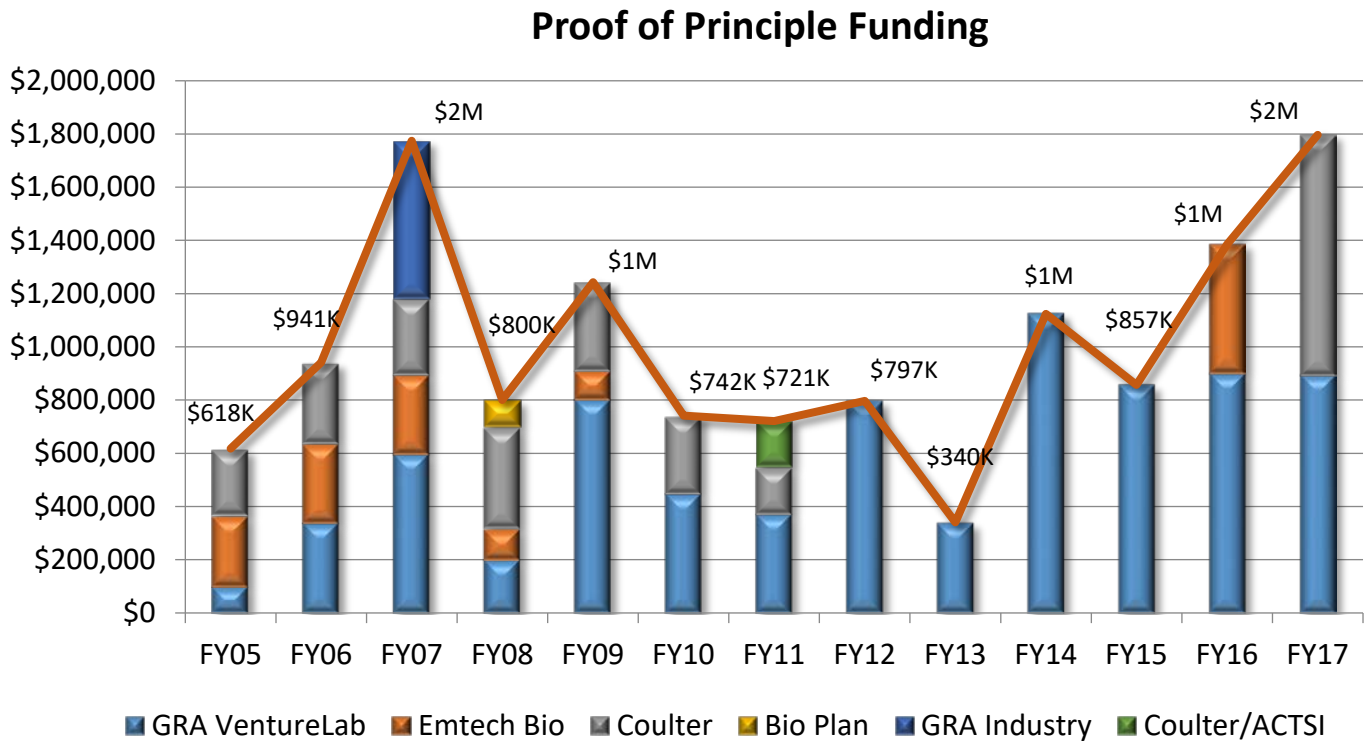
Yerkes	$2,941.69
Yerkes Departments	$668.25
Yerkes Department Breakout	
Microbiology	$ 668.25
General University Share	$1,464,522.14
Legal Expenses	$ .00
Misc. Expenses	$ .00
Coursera Reimbursement	$ 2,297.38

Neurology	$	24,761.85		
Pediatrics	$	170,772.06		
Pharmacology	$	1,178.11	Total Distributed	$ 7,222,846.70
Psychiatry	$	250.00		
Radiation Oncology	$	22,755.00		
Radiology	$	152,659.10		
Surgery	$	.00		

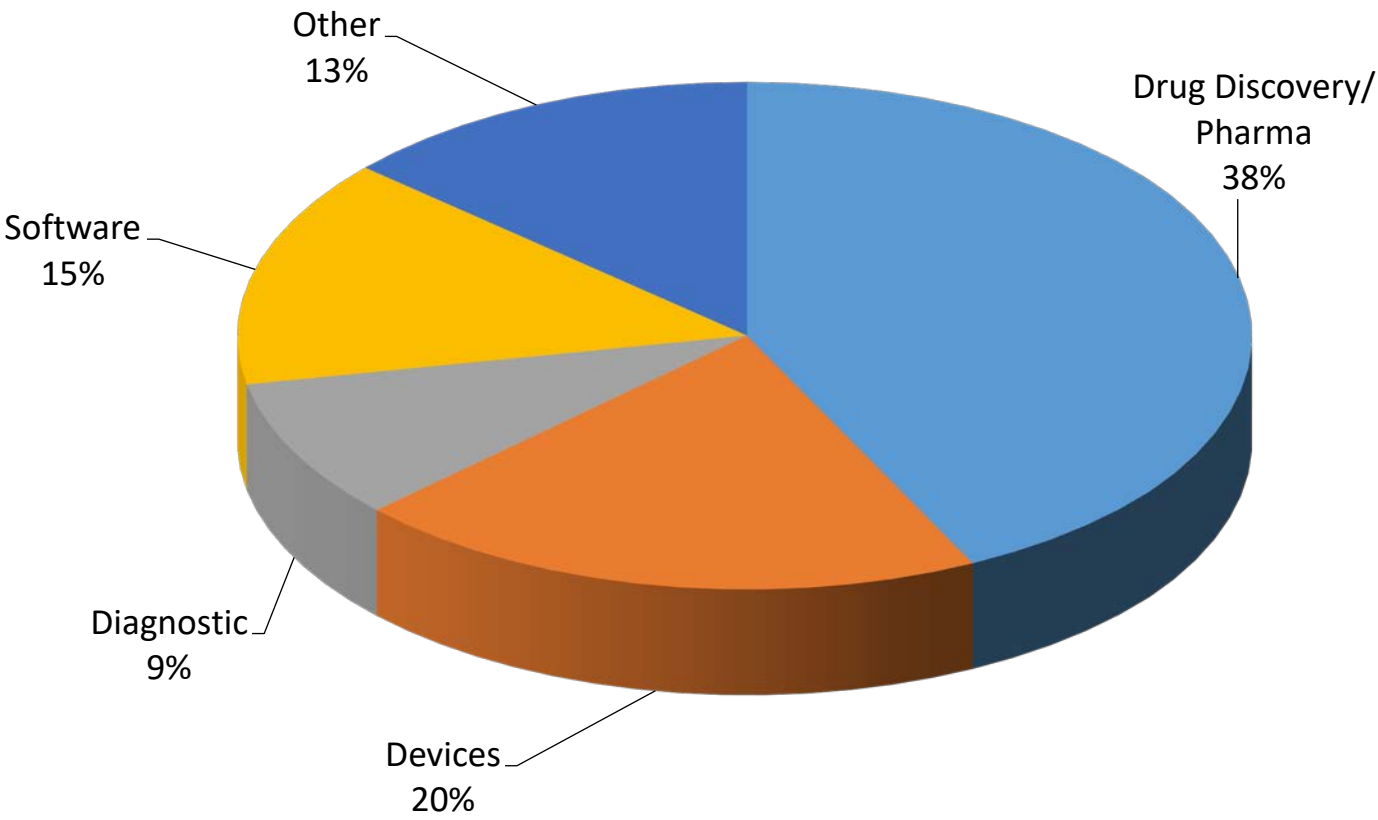
Industry Contracts
Turnaround Targets vs Actual FY17
OTT-ICG: Median Contract Processing Times in Business Days

Agreement Type	PHASE 1: Received by ICG to 1st Revision		PHASE 2: 1st Revision to Negotiation Complete		PHASE 3: Negotiation Complete to Fully Executed*		Total Time For All Steps	
	Target	Actual	Target	Actual	Target	Actual	Target	Actual
Industry CTAs	4	8	20	28	5	3	29	39
Industry Research Agmt.	5	11	20	31	5	5	30	47
Research Services Agmt.	5	11	20	27	5	4	30	42
Confidentiality Agmt.	3	5	10	5	5	2	18	12
Amendments	3	2	5	1	5	5	13	8
Other	4	1	5	1	5	6	14	8

* Calculated from the date the partially-executed agreement is sent to sponsor until the fully-executed agreement is received back from sponsor.


Proof of Principle Funding
$2,000,000
$1,800,000
$1,600,000
$1,400,000
$1,200,000
$1,000,000
$800,000
$600,000
$400,000
$200,000
$0
$618K
$941K
$2M
$800K
$1M
$742K
$721K
$797K
$340K
$1M
$857K
$1M
$2M
FY05
FY06
FY07
FY08
FY09
FY10
FY11
FY12
FY13
FY14
FY15
FY16
FY17
GRA VentureLab
Emtech Bio
Coulter
Bio Plan
GRA Industry
Coulter/ACTSI

Start-up by Field



89 Start-up Companies

FY17 Annual Report - Research Administration Services (RAS)
Kathleen Bienkowski, Executive Director for RAS, Associate Vice President for ORA

FY17 has been a challenging but productive year for RAS. We began the fiscal year having just launched the last two of nine RAS units a couple months prior, and still had Phase 2 of the CAPS RAS launch to complete (i.e., integrating the remaining schools, Oxford College and executive office), which has since been completed. As had been the case in the past, the units are in various stages of maturity, so each unit has been addressing different challenges, issues and opportunities. From a RAS Central perspective, FY17 started with a key position vacant as the former Assistant Director, RAS Operations resigned in August. Denise Ehlen, Director – RAS Operations and Special Projects, was hired in December 2017 to replace that role. Denise brings extensive research administration experience to Emory. As such, she has been able to hit the ground running, and quickly become a valuable resource to RAS Central.

The RAS training position was also vacant at the start of FY17 (note: we had reduced headcount in this area from two FTE down to one FTE during FY16). At the time, the Finance: Grants and Contracts (FGC) team also had an open position for a training resource. The AVP FGC and AVP RAS made the decision to combine training resources i.e., have two resources jointly supporting RAS and FGC, as there was a lot of crossover in training priorities, e.g., post-award tools training, customer service, etc. The shared RAS/FGC training staff were hired in Oct/Nov timeframe. This was also the time leading up to the Compass Upgrade (scheduled for November 14th), so there was a great deal of activity around identifying the training needed for the RAS and ensuring RAS staff were registered for, and completed, the training – which was completed successfully. The two training resources were both new to Emory and to research administration. As such, there was a learning curve, so, from the RAS perspective, progress on training development was slow. However, in addition to the completion of the Compass training for RAS and the corresponding updates to job aids, etc., we did launch the new approach to RAS new hire orientation in October, which has gone well. In March, 2017, one of the trainers resigned, so RAS took the opportunity to again change the approach/structure of the RAS training position, and, in the fall of 2017, hired a RAS Training Specialist, Kim Caroline, who reports into RAS Central. Kim joined RAS Central from the CAPS RAS and brings many years of research administration experience to the training role. While we believe this is the right path forward to ensure a nimble, responsive training approach for RAS, progress has gone slow in this area as we made the decision to second Kim to the Basic Sciences RAS unit for several months in early 2018 to support pre-award work there as there were a number vacancies and new staff members in that unit. RAS

Central developed strategic training priorities based on input from a variety of stakeholders (faculty, the RAS Improved Study Work and Faculty Advisory Groups, CBOs, and RAS staff). Training goals include 1. Develop a comprehensive and strategic RAS training plan and 2. Develop, deliver, and assess priority training to address customer and RAS needs. The 2018-2019 priority training topics / themes fall into four primary categories: 1. Emory-specific research administration, 2. General research administration, 3. Leadership and professional development, and 4. Other new training and/or development opportunities (including a revised RAS onboarding strategy). Finally, we also launched an online training repository to facilitate sharing of training resources across RAS units.

An additional transition early in FY17 was that of the Recruiter in HR who was responsible for filling all RAS positions. The Recruiter assigned to RAS for much of FY16 was not a good fit, and HR assigned a new recruiter to support RAS in October. While this was a net positive , RAS leadership spent a great deal of time helping to get the new Recruiter up-to-speed on RAS and the types of people/skills needed to be successful, etc. There was definitely a steep learning curve and ramp-up time. While the new Recruiter was working out well, she was abruptly terminated by HR after six months (in April 2017) and RAS was assigned yet another Recruiter, who has now been in the role for just about 12 months. This is a critical function to RAS, as, based on the size of the organization, at any time we typically have 4-8 positions open across RAS.

Another big area of impact to RAS in FY17 was the release of the University Faculty Council RAS Task Force Report that was sent to Executive Leadership in September. The report detailed recommended changes to the RAS model from the Faculty RAS Task Force. In response, the interim Provost initiated several meetings in the December 2016/January 2017 timeframe with the RAS Task Force and ORA/RAS leadership. These meetings ultimately resulted in the creation of a RAS Task Force Improvement Study, in which a cross-functional Working Group and a Faculty Advisory Group were created and assigned to identify and implement changes addressing recommendations from the report in two selected RAS units. The Improvement Study ran from March 2017 through March 2018, and culminated in a report which included study findings and additional recommendations which was submitted to the Provost at the end of March 2018. The RAS AVP and the RAS Director, Operations and Projects both served on the Working Group, which met bi-weekly. In response to the Working Group report, the Provost has engaged a consulting firm to analyze the entire sponsored awards lifecycle to identify improvement opportunities and make recommendations. We expect to hear more about this initiative in the coming months.

Another key area of success for RAS in FY17 has been the work completed over the past year with the EBI team to develop a consolidated, automated, user-friendly reporting tool (a.k.a. FORT – Financial Outlook Reporting Tool) which provides visibility into faculty's sponsored and non-sponsored research portfolios, while at the same time eliminating manual (i.e., data entry) effort for the RAS, and enabling an easier, more accurate way to forecast spending/burn rates on awards. Although this initiative was incorporated as a deliverable into the Task Force Improvement Study, it was a work in progress well before the Task Force report was published in September 2016. The tool was initially launched to the two RAS units participating in the Improvement Study in the fall of 2017. While there are still critical enhancements needed to achieve the full benefit of the FORT tool, feedback on the tool has been positive thus far. The current tool will be launched to the remaining seven RAS units in June 2018. We anticipate this tool will be a game-changer for faculty and the RAS in understanding and managing Emory's research funding. Another potentially transformative development was the launch of phase I of the Sponsored Projects Dashboard (SPD), in collaboration with the EBI team. SPD was designed to provide customizable sponsored projects reporting to a variety of stakeholders providing meaningful lifecycle data and eliminating manual management reports previously developed and routed by RAS Central.

One of the last remaining pieces of the full implementation of the RAS model was eliminating redundancy in FSR reviews between RAS and FGC. The two groups worked through the details of the transition to the future state which included collaborating on the development of the FGC FSR QA process which is a key component of the future state model. The new process launched in May 2018. Other work related to FSRs has been done this year as well, including improving the existing ART tool (Award Review Tool) and creating additional versions for various sponsors and working toward the development of a new FSR tool that will ultimately be automatically generated in EBI.

Amidst the challenges, HR transitions and special projects during FY17, RAS continued to successfully execute on its mission to support Emory's sponsored research. In addition, solid progress has been made toward the specific goals we set forth to accomplish this year as outlined below.

Goals for 2017-2018

1. Maintain/Improve RAS Operations

Goal	Status
Participate in Faculty Focus Groups and the development and execution of resulting action plans to improve faculty satisfaction and effectiveness of research administration at Emory.	RAS co-hosted faculty focus groups in Cancer and Imaging and Basic Sciences. Action plans were developed based on faculty/administrator input and assigned to the relevant RAS Directors for implementation.
Continue to refine and implement RAS KPIs: Implement FinPro tool to track Reconciliation metric; Obtain reporting from OSP to launch proposal quality metric; Refine FSR metric to reflect new process.	RAS Central collaborated with OSP to explore the pilot "Return to RAS" data to support a proposal quality metric. We hosted focus groups with RAS staff to generate recommendations to improve the data, which were shared with OSP. OSP and RAS will collaborate in 2018-2019 to refine data collection with a goal to launch the proposal quality KPI in 2019. We began the pilot Financial Outlook Report Tool (FORT) launch with DOM and BSCI in August of 2017. RAS Central began work with the FinPro consultants, RAS post-award administrators, and the EBI Team to develop an engagement tracker. The tracker will be integrated with the FORT to automate collection of the reconciliation data. These data will be loaded into the data warehouse to allow reporting on the reconciliation metric at the department, RAS unit, school, and/or individual analyst level. The new tool will also allow the reconciliation schedule to be customized based on the faculty member's needs. The reconciliation metric will be based on an engagement schedule developed in collaboration with the PI, department/division administrator and/or chair, and RAS staff. Launch of the new metric is scheduled for 2019.

	The FSR transition began in July 2017 and was scheduled to be completed by March 2018. Lessons learned from the transition will guide launch of a refined FSR metric (reflecting the new process) in 20182019.
Complete transition of final FSR reviews from FGC to RAS.	The FSR transition was initially scheduled to be completed in March 2018. The schedule was modified due to transition challenges. The transition of FSR reviews from FGC to RAS will be completed in May 2018.
Maintain pre-review for 95% of effort certifications	Pre-review for effort certification was 99% on 4/2/2018. The deadline for the current effort reporting cycle is 5/31/2018.
CRM Plan - develop for RAS Central and each RAS unit and launch; (partially imbedded in FinPro project)	RAS Central completed the majority of data collection for the CRM. The final CRM will be released in May/June 2018. The faculty engagement component (for award/project reconciliations) will be integrated into the FORT. Pilot data will be available in EBI in July/August 2018.
Migrate RAS Blackboard to new restricted RAS website	Complete. The RAS Blackboard portal was decommissioned prior to the termination of Emory's Blackboard contract. RAS-specific resources are now available in a secure intranet (called RASnet) from the RAS website.
Support R&R projects led by ORA (T-awards, Industry Contracts, Clinical Trials)	RAS continued to support the R&R projects. The DOM RAS assumed a leadership role in testing a revised T award process; testing will continue in 2017-2018. RAS staff participated in the industry contracts R&R project, which was completed.

2. Support RAS Task Force Improvement Study (Basic Sciences and DOM are pilot units) – Completed.

3. Training/HR Activities: Continue to develop RAS staff professional and technical competencies (hard and soft skills); Team-building across RAS; Finalize and Formalize RAS New Hire Onboarding and Orientation Process

Goal	Status
Develop/launch training modules based on topics identified by RAS/RAS leadership during professional development planning and the Improvement Study Surveys (of faculty, administrators, and RAS staff).	RAS Central released the 2018-2019 Training Priorities. Development of new modules has been delayed due to training staff transitions in RAS Central. RAS Central began work to develop a comprehensive and strategic training plan. A tool has been developed to map job description competencies to training (to include existing training, new training, and web-based training in Lynda.com). This work supports RAS Central's goals to offer comprehensive training aligned with competencies, to ensure RAS staff understand competencies and have access to training to develop competencies, and to ensure RAS Central reviews and maintains competencies and training long-term.
Develop quarterly "town hall" meetings to share best practices, offer RAS-wide training, and build a culture of collaboration.	RAS hosted the first quarterly Town Hall meeting in December 2017. We identify and select topics and speakers to support the goal of the meetings to share best practices, offer RAS-wide training, and build a culture of collaboration.
RAS Directors will complete the L&OD Development series: 5 Behaviors of a Cohesive Team	Completed at RAS Directors' retreat in October 2017.
Build Presentation Library to promote best-practice sharing and employee development; provide opportunities for RAS team members to give or attend presentations by other RAS team members.	RAS Central launched the training library in fall 2017, which includes presentations. The library currently contains twelve resources, which have been vetted for quality and accuracy. We plan to expand the library in 2018-2019.
Review current onboarding and orientation process, develop improvements (as/if	RAS Central completed a preliminary mapping of the onboarding and orientation process. We

necessary) based on best practices and feedback from RAS leadership and SMEs.	also hosted two onboarding focus groups with RAS Directors and Managers. A new onboarding and orientation process will be launched in 2018-2019 based on input from RAS leaders/SMEs and grounded in best practices.

4. Finalize and Launch Award Complexity Tool as input for RAS capacity analyses and School resource decisions
    - Collected and disseminated pilot (2016-2017) complexity data. Developed process recommendations for 2017-2018 data collection.
    - Finalized and launched capacity analysis.

5. Reduce redundant efforts related to proposal reviews across RAS and OSP via continuous improvement in proposal quality enabled by OSP feedback to RAS.
    - Launched pilot "Return to RAS" feature in EPEX to collect data on common errors to drive RAS-wide and local training and development. This important work will allow us to complete an analysis of risk and develop strategies to manage risk as/if appropriate.
    - We hosted focus groups with RAS staff to generate recommendations to improve the data, which were shared with OSP. OSP and RAS will collaborate in 2018-2019 to refine data collection with a goal to launch the proposal quality KPI in 2019.

FY17 Annual Report – Environmental Health & Safety Office (EHSO)
Patricia Olinger, Executive Director for EHSO, Assistant Vice President for ORA

What we do…

Our mission is to provide and support comprehensive environmental, health and safety programs and services in support of the University's mission to create, preserve, teach and apply knowledge in the service of humanity. We also support Emory Healthcare's mission to serve humanity by improving health through integration of education, discovery and health care delivery. To do this, EHSO offers the following:

- Guidance for the use, storage and disposal of materials used in research, clinical, academic and operational activities.

- Tools and resources that empower your team to: control occupational exposures, understand OSHA, EPA, GA DNR & other regulatory requirements, and maintain regulatory compliance.
- Assistance when you need environmental, health and safety information or training; experience an occupational incident; notice potential hazards; have safety concerns.

EHSO provides support through six specialties and functions, detailed in the following.

FY17 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. An example of how this is applied is the progress made with Emory Healthcare during FY17 to assess the scope of EHSO services within the entire Emory Healthcare enterprise and identify any potential gaps. The Training and Communication programs are responsible for providing educational and outreach resources to educate and assist the Emory community in EHS matters. These components are a critical support structure to the other EHS programs.

Accomplishments

- Conducted a comprehensive process review of our inspection program to improve efficiency and effectiveness.
- Created an internal Executive Dashboard to visually display status of key performance indicators.
- Simplified internal documentation, including streamlining of required documentation.
- Updated 108 core documents. The majority of these were format conversion to a more web readable template.
- EHSO program areas completed 13 Objectives and Targets and developed action plans for 23 new ones.
- Content and instructional design updates to 15 online and classroom trainings.
- iPads integrated into classroom training.
- Over 18,000 student and employee training completions in the area of EHS occurred.
- LinkedIn page launched.
- Over 100 webpage updates to provide most current information.

- Monthly safety campaign calendar implemented.
- 10 safety campaigns launched that included the creation of print and visual designs created (videos, posters, newsletters, presentations, magnets).
    - EHSO Visibility Campaign "Do You Know EHSO?"
    - LiveSafe
    - Slips, Trips and Falls Campaign
    - Emergency Preparedness Campaign (including Hurricane Irma alerts)
    - Hearing Protection Campaign
    - Eclipse Safety Campaign
    - Biosafety Campaign
- Research Safety Communications transitioned into digital version using MailChimp (Lab Rat Newsletter, Monthly Reminders)

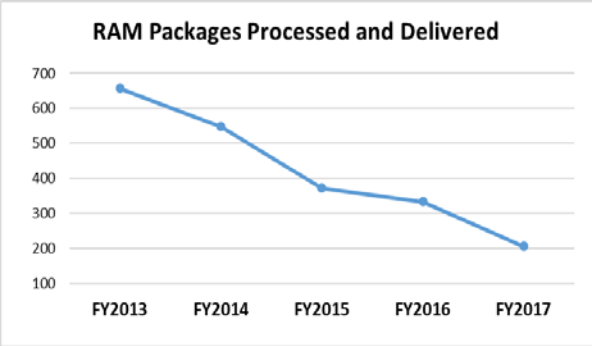
Environmental Compliance

The Environmental Compliance Program (ECP) provides compliance assistance with environmental regulatory requirements to the Emory Enterprise. This program evaluates environmental regulatory requirements, implements regulatory programs, and manages the environmental outcomes of Emory operations with the goal of maintaining compliance and minimizing environmental impact of Emory operations. Personnel conduct regulatory compliance inspections covering numerous environmental regulations; assist Emory personnel with collecting, storing, managing, and shipping regulated waste; permit reviews and due diligence; HSRA projects; regulatory reporting requirements; management of oil storage (underground storage and above ground tank management); and records retention; all with the goal of being "audit ready" should state or federal regulators visit Emory. ECP provides internal logistics of Radioactive Material (RAM) management including receiving, processing and delivering incoming isotopes for Healthcare and research, as well as management of RAM waste. ECP leads the Spill Response Team for spills and releases of regulated substances, and team members are trained in emergency preparedness and response. The ECP collaborates with Emory's Sustainability initiatives to serve as a technical resource for environmental.

Accomplishments

- Hazardous Waste Management
    - 2482 Hazardous Waste Collections
    - 138,811 lbs. Hazardous Waste disposed
    - 23,256 lbs. Waste Reduction efforts
    - 26,906 lbs. Universal Waste collected
        - 22,500 lbs. Spent fluorescent lamps recycled
        - 4,406 lbs. Batteries recycled (plus 1,400 lbs. non-regulated batteries)
- Radioactive Material (RAM) Management

    - 311 Packages procured and delivered (value of over $240,741)
    - 149 Radioactive waste collections
    - 2,670 lbs. Radioactive waste disposed
    - 3,213 lbs. Waste decayed on site
- Regularly conducted audits for Underground Storage Tanks, Above Ground Storage Tanks, pesticide use, stream management, hazardous waste storage areas, silver recovery units, eye-wash stations, and general mechanical areas.
- The GA EPD conducted an Underground Storage Tank regulatory inspection at Emory University Orthopedic and Spine Hospital; Emory was in full compliance.
- The groundwater remediation project at 1984 North Decatur Road was removed from the Hazardous Site Response Act, Hazardous Site Index; has been ongoing since 1996.
- Implemented an on-line system for requesting and tracking regulated chemical waste.
- Responded to 23 hazardous materials releases.
- Submitted Tier II Reports for 8 Emory properties, assessing 683 chemicals.
- Conducted 13 NPDES inspections.
- Incorporated GIS and AutoCAD applications to support and enhance environmental operations, addressing storm water management and RCRA Contingency Plan updates.
- Reduced negative compliance findings for used lamps from 24% of audits to 8%.
- Conducted SEC inspections of 316 spaces in 61 buildings.
- Assessed and organized online Emory utility data to meet the Atlanta Energy Ordinance requirements and prepare for Atlanta annexation of Emory properties.
- Expanded support and services to Emory Healthcare: Assessed RCRA requirements at EUHM, EUOSH, ESJH, and EJCH; and began assisting them with their hazardous waste management and disposal regulatory requirements.
- Provided subject-matter expertise as a member of the university committee that established Emory's most comprehensive electronic waste management initiative.
- Analyzed approximately 12,300 swipe samples to survey for potential radioactive contamination in multiple facilities as required under Emory's Broad Scope License.



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

- Disposed 124 sealed sources.
- Hired a Medical Physicist to support Emory's Quality CT Program.

- Hired a Director of EHSO to support Emory's EHSO Radiation Safety Program.
- Reviewed and approved 197 radiation protocol applications and amendments.
- Conducted and serviced 244 x-ray machines.
- Completed 61 clinical audits.
- Created 8 shielding plans, performed 11 shielding integrity surveys and 8 radiation scatter surveys at Emory Orthopaedics and Spine Center, EUH Tower, EUH Cardiac Cath Lab, EUH Radiology, Emory Sports Medicine Center, EUHM EP Lab, EUHM Radiology, EUHM Radiation Oncology, Emory Smyrna Orthopaedics, Emory at Belmont, and Yerkes National Primate Research Center.
- Provided health physics support for the new Georgia Proton Treatment Center.
- Commenced the Radiation Module of BioRAFT.
- Conducted 157 leak tests and inventoried 416 sealed sources.
- Improved radiation badge return rate as indicated below:

Research/Biosafety

Customer service and compliance assistance are integral parts of the Research Safety (RS) Office mission. We provide support to all Emory University researchers on matters relating to biosafety, chemical safety, research radiation safety, and laser safety. These support efforts are conducted through consulting services including risk assessments, training programs (to include Bloodborne Pathogen, Biosafety, Laser Safety, Laboratory Safety, Shipping of Infectious and Biological Substances, and Radiation Safety), review of protocols (to include the use of recombinant DNA, biological toxins, infectious agents, highly hazardous chemicals, etc.), accident/incident investigations, laboratory inspections, equipment decontamination using TOMI SteraMist system, and lab decommissioning.

Accomplishments

- Risk and Hazard Assessments: 6 lab specific assessments; 7 laser hazard assessments.
- Training Programs: 8,916 trainings were taken online or in a classroom setting.
- Review of Protocols:
    - Biosafety protocols – 1,446 reviewed; 634 involving recombinant DNA
    - Chemical Safety protocols – 200 reviewed
- Three new electronic forms created (eliminating paper forms): Highly Hazardous Chemicals Survey, Chemicals in Animals Form, and Chemical Safety Form.
- Accident/Incident Investigations: 46 investigations reported from both research labs and the Division of Animal Resources (DAR); 3 involving recombinant DNA.
- Laboratory Inspections: 26 of 44 departments inspected; 251 of 450 Principal Investigators.
- Decontaminations using TOMI SteraMist System: conducted 6 research equipment decons.
- Lab Decommissioning: 5 laboratory spaces; 46 inactive radioactive materials permit closures.
- Equipment Certifications/Calibrations: 758 Biological Safety Cabinets certified annually; 875 Chemical Fume Hoods certified semi-annually; 134 Geiger meters calibrated annually.
- Mercury Thermometer Initiative: 171 mercury thermometers replaced by alcohol filled alternatives reducing mercury hazards in laboratories.
- Led formation of a Working Group to generate a frame of work for handling hazardous drugs across the Emory Enterprise (Research and Healthcare).

Safety and Industrial Hygiene Group

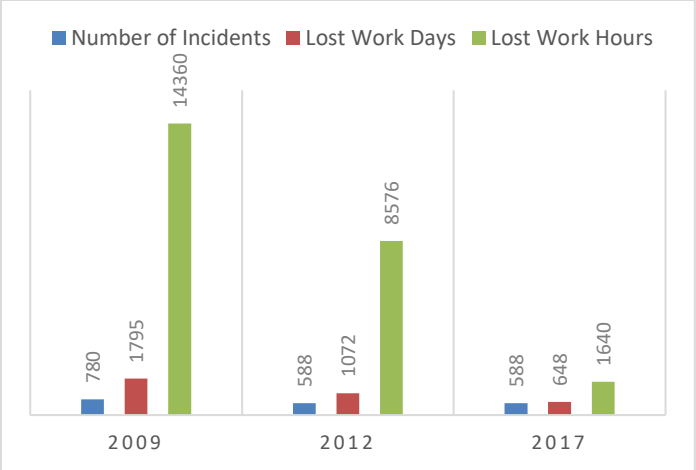
The Safety and Industrial Hygiene staff assists the Emory community in maintaining a workplace that is as free as practical of known safety and health hazards. Our Indoor Air Quality (IAQ) professionals are called upon to investigate various customer concerns ranging from foul odors and stagnant air 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 and safety audits, and develop and implement safety programs and procedures for all of Emory. Our staff works closely with Campus Services, Healthcare, 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 to evaluate and establish control strategies. We conduct safety audits and assessments to measure compliance.

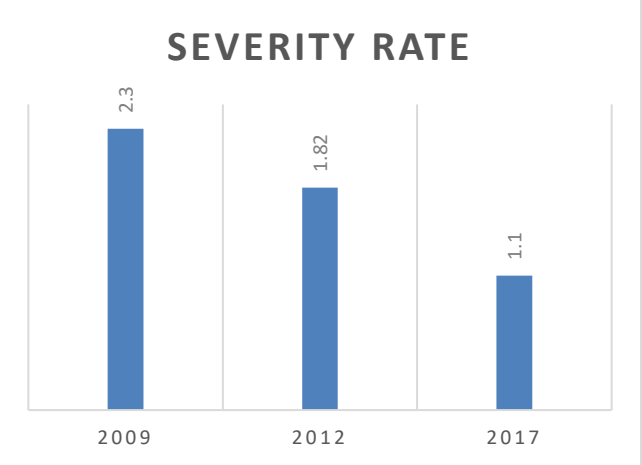
General Safety

Accomplishments

- Continuous reduction of time away from work due to injury.
    - A steady decrease in the number of recordable incidents can be observed, while there is a continuous increase in the number of non-recordable incidents 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 1.1 in 2017.
    - Our top three accidents this year are contact with blood (SOM), slip/trips/falls and sprains/strains.

Figure 1: Incidents





- Developed Drone Safety Policy for the university.
- Implement the LiveSafe App for reporting near misses.
- Created the Slip/Trip/Fall campaign to assist in reducing the number of injuries resulting from slips, trips, and falls.
- This year we implemented the following changes to the SEC Inspections:
    - Cross trained our inspectors so that each inspector can conduct a comprehensive safety and environmental inspection.
    - We increased our number of inspection teams from 3 (2 inspectors/inspection) to 7 (individual inspectors/inspection).
- In addition, the Safety Team Conducted:
    - 925 SEC Inspections, an increase of 41% from FY2016.
    - 124 Accident Investigations, an increase of 49% from FY2016.
    - 89 Safety Assessments, an increase of 10% from 2016.

Industrial Hygiene

Accomplishments

- Conducted a building wide Indoor Air Quality survey in WMB.
- Revamped the Formaldehyde Qualitative Exposure Assessment process for the laboratories.
- In addition, the industrial group conducted:
    - 147 Industrial Hygiene Projects as opposed to 12 from FY2016.
    - 71 IAQ projects, an increase of 180% from FY 2016.
    - 137 Asbestos/Lead/Mold projects.

Yerkes Safety Office

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. The Yerkes Environmental Health and Safety Office (YSO) is committed to providing an environment that is as hazard-free as possible and that reduces the risk of human injuries. The YSO is responsible for ongoing monitoring and implementation and oversight for the occupational health and safety programs at the Center. The YSO has 5 dedicated professional team members: Training Coordinator, Containment Manager, Administrative Manager, Hazardous Waste Specialist and the Yerkes Safety Officer. The Yerkes Safety Officer is also a member of the Emory University's Environmental Health and Safety Office (EHSO).

Accomplishments:

- Successful AAALAC triannual site review, no recommendations for EHSO.
- Continued with Zika work, agent specific training and occupational health consults. Nonhuman primate work colluded in fall of 2017.
- Reviewed/ Revised/Published 22 Yerkes Standard Operating Procedures (SOP).
- Collaborated with Malaria Researchers, Animal Resources and Facilities Management for the construction and opening of the Yerkes Arthropod Containment level 2 mosquito insectary at Yerkes. Facility opened in November 2017
    - Working with Malaria Researchers, Animal Resources and Facilities Management to develop insectary SOPs, access and security plans.
    - Established safety office inspection schedule. Containment Manager to conduct weekly inspections for the first 3 months and then move to monthly if deemed appropriate.
- Coordinated and completed decontamination, shut down and maintenance of second and third floor Vaccine Research Center BSL-3 laboratories.
- The Yerkes Safety Committee met quarterly in 2017.
    - Reviewed injury/illness/exposure reports, safety training, SOP reviews, lab inspections and near miss safety events.
    - Conducted/reviewed fire drills, utility outages and conducted animal escape drills.
    - Developed Flood Disaster plan currently in review.
- Conducted weekly safety inspections of (4) BSL-3 labs, (1) ABSL-3 rodent facility and (1) NHP ABSL 2+ facilities.
- Yerkes Biosafety level 3 containment subcommittee for BSL-3 laboratory users, met in 2017.
    - The subcommittee is reviewing mentoring and training requirements as well as reviewing inspection reports.
- Conducted onsite weekly Heath Assessments.
    - New employee health assessment, respirator medical clearance, ABSL-3/BSL-3 medical clearance and immunization updates.
- Placed, read and documented greater than 700 TB tests, include TST and T-spot.
- Conducted 187 new employee/ contractor Orientations.
- Conducted greater than 3000 training sessions for Yerkes personnel.
- Worked with Yerkes IT and PeopleSoft IT to address transitioning online training and training records to ELMS. Added Yerkes specific training to ELMS.

Staff Participation and Professional Development

- Conferences where EHSO staff represented Emory through presentations (national and international)
    - American Association of Laboratory Animal Science
    - American Biological Safety Association
    - CDC International Symposium on Biosafety
    - NIH Health and Safety Consortium
    - Preventing Biological Exposure Colloquium
    - Southeast Biological Safety Association

- Industry Leadership Positions held by EHSO staff
    - CDC 15th International Symposium on Biosafety Steering Committee
    - Chair, National Primate Research Center Occupational Health and Safety Consortium
    - CSHEMA Board Member
    - CSHEMA Co-Chair of Environmental Community of Practice
    - CSHEMA Past President
    - Deputy Convener for the development of the ISO Biorisk Management Standard – ISO 35001
    - Emory University Senate Committee on the Environment Member
    - Occupational Health Colloquium: Preventing and Treating Biological Exposures Steering Committee
    - Technical writing team, ISO Biorisk Management Standard – ISO 35001

- Professional Memberships maintained
    - AIHA
    - Alliance of Hazardous Materials Professionals
    - American Biological Safety Association (ABSA)
    - American Chemical Society (ACS)
    - ARMA
    - ASSE
    - Association for Talent Development (Training & Development)
    - Campus Safety Health and Environmental Management Association (CSHEMA)
    - Health Physics Society
    - International Association of Administrative Professionals
    - National Association of Environmental Managers
    - SHRM
    - Southeast Biological Safety Association (SEBSA)
    - Women in Safety Engineering (WISE)

- Continuing Education
    - 1 Staff member obtained the Associate Safety Professional designation
    - 1 Staff member obtained the Certified Safety Professional designation
    - 1 Staff member completed requirements to obtain certification in Occupational Health Nursing (COHN-S)
    - 2 Staff member achieved Registered Biosafety Professional designation

- Professional Development courses and seminars attended by EHSO Staff
    - 1 Staff members completed Emory's Administrative Professionals Program
    - Numerous industry trainings and webinars (Lab Safety, Asbestos, OSHA, Environmental, Hazardous materials transportation, Training, Management Systems, etc.)

FY17 Challenges

- Keeping up with growing demands with current staffing levels.
    - Healthcare growth, expectations and needs.
    - Growing needs and support of Campus Services.
- Deficiencies in Learning Management System requires extensive staff hours to troubleshoot and overcome.

On the Horizon for EHSO-Goals for FY18

- Continue to evaluate and define our roles and responsibilities within EHC, TEC, and ESA.
- Work towards improving our overall Safety Culture.
    - Review our overall safety committee structures;
    - Improve EHSO communications;
    - Evaluate and improve our EHS electronic interfaces.
    - EHS Support to new lab construction.
- Continued support for EHS-Management System for quality and process improvement.
    - Integrate new regulations and standards to include ISO 45001 and ISO 35001 (once approved) and RCRA Hazardous Waste rules;
    - Evaluate our current overall EHS committee structures and make recommendations and implement improvements where appropriate;
    - Continue to implement a "corporate audit" component where applicable;

- Continually evaluate and improve efficiency and effectiveness of EHSO processes.

- Training and Development
  - Implement BioRaft training module;
  - Continue to develop a Training Needs Assessment for learners;
  - Continue to develop staff into world class personnel;
  - Conduct targeted training to faculty and staff based on results of identified trends from inspection findings.

FY 2017 Annual Report - Institutional Review Board (IRB)
Rebecca Rousselle, Director for 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 90 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. Ten of our staff are Certified IRB Professionals, the standard certification for our field.

As we moved into FY 2018, the IRB and the research community prepared for new NIH mandates, including the requirement for single-IRB review of multisite studies, application of Certificates of Confidentiality to all NIH-funded human research, and an expanded definition of "clinical trial." We continued to await the roll out of the significantly revised "Common Rule" (DHHS's human subjects research regulations), which was finalized but still uncertain as to effective date.

Our Numbers

Number of active studies that undergo expedited review (as of June 2017):	2,471
Number of active studies that undergo full board review (as of June 2017):	1,559
Total active non-exempt studies reviewed by Emory IRB: (compared with 4,075 in FY15)	4,030

Number of new…

Sociobehavioral protocols submitted to the Emory IRB in FY17: (compared with 342 in FY16)	366

Biomedical protocols submitted to the Emory IRB in FY17: (compared to 827 in FY16)	752
Total new study submissions in FY17 (all inclusive): (compared to 1,389 in FY16, and 1,355 in FY15)	1,428
Total new study submissions without WIRB/CIRB/XIRB:	1,288

New studies received during FY17

That required full board review:[1] (compared to 267 in FY16)	211
That were reviewed via expedited procedure: (compared to 698 in FY16)	632

Submissions of exempt studies: (compared to 192 in FY16, 169 in FY15, 107 in FY14 and 157 in FY13)	158

Median number of calendar days between receipt of complete submission by IRB and[2]:

Full board approval:	47 calendar days
Expedited approval:	12 calendar days
Exemption determination:	20 calendar days

Number of amendments submitted to the IRB: (compared with 4,027 in FY16)	4,201
Number continuing review applications submitted to the IRB: (compared to 3,216 in FY16)	3,365
Number of reports submitted to IRB (potential noncompliance and/or unanticipated problems): (compared to 609 in FY16, and 694 in FY15; and of which 345 were handled via administrative review only, as not potential UPs or serious/continuing noncompliance)	686
Number of cases of noncompliance and/or unanticipated problems full board: 39 (compared with 54 in FY16, 96 in FY15 and 54 in FY14)	
Number of those that were determined to be serious or continuing noncompliance: (compared with 4 in FY16, 7 in FY15 and 8 in FY14)	6
Number of those that were determined to represent an Unanticipated Problem Involving Risks to Subjects Or Others: (compared with 35 in FY16, 30 in FY15, and 22 in FY14)	21
• Number of education/outreach presentations and monthly webinars:	~30

[1] Only studies that were already in approved state at time of report can be counted; others might have gone on to full-board or expedited review later.

Accomplishments

- Created a new paradigm for tracking studies being reviewed by external IRB's, in anticipation of increased reliance on such IRB's under the upcoming NIH single-IRB mandate
- Implemented a new continuing education program for IRB members
- Worked with the Emory Office for Clinical Research (OCR) to incorporate the Office of Quality-related forms into eIRB, to streamline the work of researchers
- Completed projects to clean up departments listed in eIRB, to simplify the Departmental Review requirement, and to minimize the number of possible user roles in eIRB, thus speeding up the software.
- Revamped the IRB's workflow to reassign continuing review submissions to junior analysts, freeing up more senior analysts to focus on amendments and new studies.
- Our overall customer satisfaction rate is 4.4 out of 5 on our online survey, slightly higher than FY16 (previously 4.35). Satisfaction with IRB staff interactions is at 4.68 out of 5, higher than last year.
- Our monthly webinars have continued to be well-attended, and are archived on our website.
- The HIPAA structure underwent a major change between FY16 and FY17, and the IRB facilitated adjustments to research studies; burden related to HIPAA was reduced.
- The IRB has focused on the compliance areas of IRB reliance, HIPAA waivers, expanded access changes with the FDA, and mobile medical apps.

Goals for FY18

1. Select and start implementing a new electronic submission system. The IRB will work with ORA-IT and LITS to develop a contract and scope of work for implementing a new system. The current system is no longer supported.
2. Revise our IRB Policies and Procedures, website, tools, and guidance to align with the revised Common Rule, which was scheduled to go into effect on January 19, 2018. The IRB created a working group of IRB staff, leadership, and other ORA/Compliance colleagues as needed to identify all items that need revision and to assign tasks. The IRB administration laid the groundwork to redesign our electronic submission system to align with revised Common Rule, and to do the extensive needed revisions to our Policies and Procedures.
3. Continue to adapt to increased Use of Central IRB's and evaluate whether the IRB can reduce the number of Chairs and Committees with increased reliance on central IRBs. We will build into the new electronic system a workflow for studies reviewed by other IRB's, which avoids unnecessary data entry yet facilitates capturing what is normally required by the central IRB and our colleagues in other research administration offices. The IRB

has been asked to help educate researchers on the requirements for each central IRB they use, and to provide that information on our website for reference. We shall also educate the researcher community about the need to discuss the appropriateness of reliance prior to signing agreements. To help accomplish this goal, we shall employ a Reliance Specialist on staff to manage external IRB processes. A benefit of increased reliance is expected to be a reduction in the number of full board IRB panels. We must determine the volume of new full-board submissions, amendments, and renewals that would result in reduction of an IRB panel, and monitor volume on a quarterly basis.

4. Work with our close partner institutions (e.g. CHOA and Saint Joseph's/Johns Creek Hospitals) and the Georgia CTSA to ensure accurate agreements are in place to provide IRB oversight by a single IRB when possible, and to ensure clear communication around human subjects research.

FY17 Annual Report – Institutional for Animal Care and Use Committee (IACUC)
David Martin, Director for IACUC

The IACUC office underwent a number of changes in FY2017, which will be continuing into FY2018. Most significantly, in August of 2016, the IACUC transitioned protocol submission and approval from The TOPAZ web P&R system (Enterprise) into an updated version, Topaz Elements. In addition to the software systems change, the format of the protocol submission form was significantly altered in response to both changes from the 8th edition of *"The Guide for the Care and Use of Laboratory Animals*" as well as in response to community concerns and feedback. Prior to campus-wide rollout, all approved IACUC protocols were partially converted from Topaz Enterprise to Topaz Elements. Upon rollout in August of 2016 all new protocols and three year renewals were initiated and approved in Elements. It was decided that subsequent amendments to currently approved but partially converted protocols (from Elements to Enterprise) could be reviewed in the new system using the PDF of the previously approved Enterprise version of the protocol. This was in lieu of complete conversion of the entire protocol into Elements by the individual PI's. Unfortunately, the new software suffered from a number of technical issues leading to poor efficiency of transition and significant pushback from the user community. This lead to the decision in January of 2017 to determine that Topaz Elements was a "failed launch" and to roll back all protocols possible into the Enterprise version. This placed a heavy burden upon the IACUC office staff who were tasked with taking partially converted protocols with subsequent amendments and reverting them back into Enterprise, or partially converted protocols with significant amendments and completing the full conversion to Elements for the time being. These significant issues, coupled with the software's continued reliance upon Silverlight, led to a decision to cut ties with the company and to seek a new vendor in April of 2017. That process was led by Dr. Martin, who was then the Associate Director under

Dr. Larry Iten. Huron was identified as the new vendor and the process of implementation of the new software solution was initiated in July of 2017. That process continues into FY2018 with an expected soft launch of 1/26/18 and a full roll out by the first of March 2018.

Based upon the volatility of the protocol review and approval process during the entirety of FY2017, accurate metrics are difficult if not basically impossible to provide in regard to protocol review activity. This is further complicated by the fact that a significant portion of the protocol activity was either to simply migrate/convert protocols (both to and back from Elements) or to do so in conjunction with an amendment. On 9/1/2016 there were 581 approved protocols in the electronic system. As of 9/1/17 there were 557. At the writing of this report there were 177 protocols approved in the Elements software and 330 in Enterprise.

The IACUC office is currently staffed with 5 full-time employees including the IACUC Director. A sixth position is being filled currently. In spite of the difficulties with protocol reviews, the IACUC office assisted in a successful reaccreditation from AAALAC in February 0f 2017. All other program activities including program review and semiannual inspections were completed on time and the semiannual reports to the IO as well as all regulatory reports to USDA and OLAW have been completed on time and without an incident.

The primary goal for FY18 is to complete the process of protocol transition into the new eIACUC solution. The goal is to have all protocols migrated to the new solution no later than October 31, 2018. In addition, data from other program activities including meeting minutes, program reviews, and semiannual site inspections are being transitioned into the new system so that all reporting data is in a single source. It will also be critical to leverage the new system to begin generating protocol review metrics data for analysis of review efficiency. Finally, the IACUC is working diligently to develop standard descriptions for common procedures both through internal generation as well as through promotion of investigator generated “team” procedures. This will aid greatly in both consistency of approach in the labs, as well as in efficiency of protocol review and approval.

FY17 Annual Report - Office for Clinical Research (OCR)
Robin Ginn, Executive Director for OCR, Assistant Vice President for ORA

With the increasing demands and oversight in the clinical research environment, the complexity and requirements for conducting research are continuously evolving. Academic institutions must effectively manage the changing regulatory and compliance obligations by also advancing in order to meet these requirements - including increasing costs, growing competition and the continuing expansion of oversight and scrutiny associated with conducting clinical research. To

support Emory University in its research endeavors, Emory's Office for Clinical Research (OCR) offers many services to support the clinical research enterprise through six functionally distinct teams: education and outreach, pre-award, data integration and integrity, clinicaltrials.gov, clinical research support services and clinical research financial management. These teams accomplish many functions across the clinical trials life cycle ensuring adherence to high standards for patient safety, research billing compliance, clinicaltrials.gov compliance and financial accountability on behalf of Emory. These teams collaborate with colleagues across Emory University, Emory Healthcare (EHC), and our affiliate institutions to support the clinical research enterprise at Emory.

Our mission is to organize and enhance operational processes that support the efforts of the clinical research team and 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 customer service, high quality, efficiency, communication and transparency as evidenced in our accomplishments.

OCR: 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 (CRCs). The training includes regulations for human research protections, good clinical practice, research billing compliance and institutional policies. The team offers training for all investigators and coordinators including those new to Emory or new to research, and will consult with existing departments as needed or requested.

Accomplishments

- Conducted 77 educational seminars/courses with 1,428 attendees who were awarded 4,824 total CMEs/CEUs. 1,753 investigators and 1,088 clinical research coordinators completed mandatory training.
- Facilitated Shibboleth project in conjunction with LITS and IRB to assist clinical research community with single sign-on for CITI mandatory training across Emory.
- Piloted intermediate level, case-based curriculum for clinical trial financial management and research billing compliance requested by Clinical Research Coordinator Advisory Committee.
- Implemented internal OCR data-driven quality improvement process across all OCR teams.

Goals for FY18

- Continue to provide/conduct mandatory clinical trials training, Emory Research Management System (ERMS) training, AHA Basic Life Support Healthcare Provider certification/recertification and facilitate Research Matters seminar series.
- Facilitate expansion of non-invasive, non-medication order entry to all Emory unlicensed clinical research coordinators and development of training course.
- Implement enhancements to eCREST (Emory Collaborative Research Training) designed to track clinical research training and competency-based learning for clinical research staff across a collaborative academic enterprise. Collaborate with LITS to incorporate data from CITI for mandatory training. Data cleanup in process before download to eCREST. Plan to include Grady and VA next.

Opportunities

- No formalized process for identifying learners that require mandatory training before IRB submission.
- Lack of robust educational and IT infrastructure for better reporting of clinical research learners.

OCR: 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. This is completed for any human subjects' research by an Emory investigator that includes EHC or Grady billable items and services. In addition, study budgets are developed for non-federal studies in conjunction with the research team to ensure the sponsor's budgets cover Emory's costs.

Accomplishments

- Completed 463 PRAs and 271 budgets with median of 15 days (mean of 20) in FY17 from receipt to submission in the EPEX routing system for non-federally funded studies including time spent by the OCR, sponsor and investigator. *Target = 20 days*
- Negotiated higher budgets than the sponsor's initial offer by a median of 23% (mean of 36%), equating to an additional $15,563,105 if target enrollment met.
- Aegis Compliance reviewed a sample of PRAs for quality and expressed they were "some of the best he'd ever seen." Held full day training session for staff and created customized QA tool for management. Watershed Associates provided customized negotiation training for staff.

- Refined process for negotiating and invoicing for withdrawn studies to compensate study for effort expended to cover administrative fees. Facilitated invoicing of $240,490 for withdrawn studies.

Goals for FY18

- Continue to provide high quality and efficient PRAs and budgets for all studies with EHC/Grady billables with a median turnaround time of 20 days for nonfederal studies and 13 days for all studies, exploring process improvement initiatives to ensure high quality PRAs and budgets that cover costs.

Opportunities

- Transition the pre-award access database into ERMS to eliminate redundancy, increase consistency and improve workflow.
- Collaborate with research partners to facilitate the pre-award budget process and decrease protracted budget negotiations.
- Continued delays since study team has not determined how they are going to operationalize the study prior to submission to OCR and submissions without required documents needed to negotiate the budget with the sponsor.
- Challenging budget negotiations with academic health centers for their PI-initiated studies with industry funding to be conducted at Emory.

OCR: 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. They upload the active clinical trials and study level documents to EeMR including the PRA, "Clinical Research Key Points" with 24-hour contact information and "Investigational Drug Data Sheet" for side effects and drug interactions. When a research participant is enrolled, the team flags them in EeMR as participating in a clinical trial and uploads the signed informed consent document. This flag triggers a 100% bill hold for these research participants until all charges are reviewed and adjudicated by the EHC Clinical Trials Billing Department.

Accomplishments

- As of September 8, 2017, there were 1,808 active clinical trials (per the NIH definition) conducted by Emory faculty with 17,773 research participants flagged as on-study.
- During FY17, 8,498 new participants were entered and flagged in EeMR as participating in a clinical trial; 6,719 signed informed consent documents (new and amended) were uploaded to EeMR, 476 PRAs (new and revised), 307 "Clinical Research Key Points" and

178 “Investigational Drug Data Sheets”. These study level documents were uploaded within 24-48 hours of notification of award to provide clinically relevant information at the point of service to support patient safety.

- Facilitated timely ERMS enrollment of each research participant 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 patient safety and research billing compliance.

Goals for FY18

- Upon notification of an award by FGC, continue to enter studies and study level documents in EeMR within 24-48 hours.
- Upon ERMS notification by CRC, continue to enter research participants into EeMR on same day, which triggers 100% bill hold.

Opportunities

- Collaborate with EHC IT to allow NCT# from clinicaltrials.gov to be viewable for financial counselors to pre-certify patient insurance for clinical trial services.
- Implementation of new eIRB system may impact access to information used for internal controls.
- Need better communication across ORA departments and FGC to communicate to each other studies that are closing in a timely manner.

OCR: ClinicalTrials.Gov Team

Function

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

Accomplishments

- Transitioned Access database to ERMS for tracking ClinicalTrials.gov studies to ensure maintenance of ClinicalTrials.gov requirements on behalf of Emory responsible parties.
- In FY17, the ClinicalTrials.gov team-initiated registration for 71 studies, updated 510 study records (new and amended), addressed 14 NIH QA Review Comments, and entered results for 25 studies.

- As of August 31, 2017, Emory was listed as the sponsor in ClinicalTrials.gov for 852 studies (280 active studies) with outstanding queries in 33 of these studies, significantly reducing the number of study records for Emory-owned studies requiring attention.
- Proactively reviewed eIRB database for health science studies approved by the IRB to determine if entered into ClinicalTrials.gov as required by FDAAA, NIH and ICMJE.
- Implemented recharge center model to assist faculty with meeting new FDA and NIH reporting requirements through ClinicalTrials.gov, incorporating a service center fee.

Goals for FY18

- Continue PRS Administrator role for ClinicalTrials.gov to assist PIs for Emory-owned studies with registration, updates and results reporting in ClinicalTrials.gov to maintain compliance with FDAAA, NIH and ICMJE.
- Continue to update ClinicalTrials.gov number for all Emory studies in ERMS (required on Medicare claims) and update IRB number in ClinicalTrials.gov.
- Incorporate notification of first patient, first visit to ClinicalTrials.gov team to facilitate required federal updates and data element completion in real time.
- Develop a quarterly report of all active PI-initiated studies to include: sponsor-investigator, lead PI of multi-center study, coordinating center, IND/IDE holder, responsible party per ct.gov, sponsor, funder, phase 1, NIH or ACT definition of clinical trial.

Opportunities

- Biostatistician support would enhance reporting of results data in ClinicalTrials.gov.
- Keeping current with the frequently changing FDA/NIH rules and understanding the changing dynamics of the requirements within the ClinicalTrials.gov website and data element fields.
- Lack of streamlined process for notification to OCR of investigator-initiated clinical trials conducted at Emory, as well as NIH-funded clinical trials.

OCR: Clinical Research Support Services Team

Function

The OCR Clinical Research Support Services program assists 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. The team will prioritize need based on whether faculty are new to research, new to Emory, junior faculty, investigators without coordinators or whether the research is PI-initiated or Phase 1.

Accomplishments

- Cultivated relationships with industry sponsors and CROs to facilitate the pre-award approval process, improve performance metrics, increase the pipeline of clinical trials and scientific collaboration with Emory including BMS, Quintiles, Celgene, Covance, Novartis, Medtronic, St. Jude, WIRB and more.
- Developed clinical trial tracking tool with data downloaded from departmental systems instead of manually. Expanded to include GaCTSA partners from Morehouse and UGA.
- Developed format and implemented electronic scorecard (daily, monthly and year to date) with performance metrics for ORA departments. Available on OCR website.
- Designed and tested on-line application for new Investigator's Guide.
- Collaborated with EML Leadership to streamline EML approval process, including training. Created newly, revised EML Checklist to eliminate review of routine labs, thereby significantly reducing the workload.
- Developed infrastructure to support GaCTSA Quality and Efficiency and Liaison to Trial Innovation Center sections. Facilitated relationship with all GaCTSA navigators (including regulatory and recruitment) across partner institutions (Morehouse, UGA, Georgia Tech).

Goals for FY18

- Phase-in facilitation and follow-up of pre-award approvals for federally funded clinical trials to identify gaps and trends related to the pre-award process.
- Facilitate update of content for new Investigator's Guide with ORA/other departments and fully implement with research community. Expand to Morehouse and UGA.
- Communicate and implement new EML Checklist process across the research enterprise.
- Continue to enhance the Clinical Trials Automation Workflow Tool to include an Investigator Dashboard and escalation reports.

Opportunities

- The ability to make a difference in clinical trial workflow and maximize efficiency through study facilitation by clinical research navigators.
- Development of new relationships with GaCTSA partner institutions to reduce intra- and inter-institutional barriers to implementing multi-site clinical trials.

OCR: Clinical Research Financial Management Team

Function

The OCR Clinical Research Financial Management team standardizes invoicing, accounts receivable and accounts payable processes for industry supported clinical trials. The team invoices the sponsor per the PRA; tracks payments owed by the sponsor for invoiceable and 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 $158,737,324 to date across all departments since its inception in 2009 for a total of 1,615 study accounts reviewed to date.

Accomplishments

- During FY17, reviewed 962 total studies, 3,457 total research participants with invoicing activity, and 19,293 research visits with a 97.51% reconciliation rate. Received a total of $34,708,531 owed from clinical trials during FY17 with another $12,676,688 not yet received from outstanding non-federal invoices, non-invoiceable visits and monies withheld as of 8/31/2017. Also, paid $3,219,979 in study expenses.
- Reconciled clinic and hospital charges for assigned grant accounts per the PRA utilizing the EHC clinical data warehouse.

Goals for FY18

- Continue baseline performance measures and random QA audits monthly for all departments to ensure 95% of all assigned studies are reviewed and reconciled within a 30-day cycle.
- Implement PeopleSoft software enhancement to download accounts receivable information (non-invoiceables) nightly from the invoicing database into PeopleSoft as receivable information is not currently recorded in PeopleSoft until a payment is received.
- Design, test and transition the current Invoicing database from Access to ERMS with an SQL server to handle volume and improve functionality and reporting capabilities.

Opportunities

- Remote access of Invoicing database causing system to crash—each employee has laptop and CPU—will be resolved when Access database transitioned to ERMS.
- Exploring mechanism to differentiate between OCR, RAS and FGC management of clinical trials within EPEX.
- No awareness if funds deposited into wrong account until study financials reconciled.

Annual OCR Scorecard for Fiscal Year 2017

As of September 8, 2017, there were 1,808 total **active clinical research studies** conducted by Emory faculty with 17,773 **participants** on-study (of which, 159 active research studies at **Grady** with 3,114 participants on-study).

Education & Outreach Team:

- 77 educational seminars/courses with 1,428 attendees (312 attendees on-line & 1,116 attendees in-person) awarded 4,823.5 total CMEs/CEUs
- 1,753 of 1,779 investigators completed "Key Concepts in Clinical Research" or "CITI GCP" course
- 1,088 of 1,195 CRCs/other key personnel completed "Introduction to Clinical Research at Emory" or "CITI CRC" course (both incorporate "CITI GCP" course as pre-requisite)
- Help Desk inquiries processed: 1,810
- Internal QA projects completed: 1 (Clinical Research Finance Management)

Pre-award Team *(metrics based on completion date)*:

- New studies submitted to OCR for review: 679
- Pre-award review completed (budget, PRA, OCR review needed and/or LOI): 651 studies
- PRAs completed: 463
- Business days from receipt to submission for 365 externally funded studies[1] (all effort): 20 mean; 15 median
- Business days from receipt to submission for 651 all studies[2] (all effort): 17 mean; 12 median
- Total $ and % difference between OCR-negotiated sponsor budget & sponsor initial offer for 271 studies: $15,563,105; 36% mean; 23% median

[1]*Externally funded studies include those industry or federally funded studies submitted through EPEX*

[2]*All studies include externally funded, non-negotiable studies, no OCR review needed, & LOIs (letters of intent for industry studies)*

Data Integration and Integrity Team:

- Clinical Research Studies: 397 activated in ERMS & PowerTrials
- On-Study Subjects: 8,498 added to PowerTrials; Off-Study Subjects: 6,966 removed from PowerTrials

- Signed Informed Consent Documents (ICD): 5,671 uploaded to PowerChart; Amended Signed ICDs: 1,048 uploaded to PowerChart
- Clinical Research Key Points: 307 uploaded to EeMR; 98.5% compliant (average/year)
- IDS Drug Data Sheets: 178 uploaded to EeMR; 93.25% compliant (average/year)
- PRAs: 279 uploaded to EeMR; Revised/Amended PRAs: 197 uploaded to EeMR
- Total eIRB Studies Reviewed: 313; Total Ad Hoc Studies Reviewed: 46
- As of August 31, 2017, Emory listed as sponsor in clinicaltrials.gov for 852 studies (280 active studies)
    - Clinicaltrials.gov inquiries: 1,187; ERMS review for NCT numbers required for billing compliance: 305
    - OCR-initiated study registration for 71 studies, updated 503 study records, addressed 14 NIH QA Review Comments *(Q3 & Q4 only)*, updated records for 7 amendments *(Q3 & Q4 only)*, & entered results for 25 studies

Clinical Research Financial Management Team (as of August 31, 2017):

- Active Studies: 962; Active Research Participants w/Invoicing Activity: 3,457; Research Visits Reviewed: 19,293; Reconciliation Rate: 97.51%
- Outstanding Non-Federal Invoices: $4,404,559
- Outstanding Non-Invoiceable Visits & Monies Withheld: $8,272,129
- Federal Encumbrances: $243,212
- Actual Received & Reconciled: $30,924,345
- Received NOT Reconciled: $3,784,186
- Expenses Paid: $3,219,979

FY17 Annual Report – Conflict of Interest Office (COI)
Brenda Seiton, Assistant Vice President for ORA

Accomplishments

Develop a triage system within eCOI to reduce the number of forms faculty must complete for research grant and contract proposals. Continue to evaluate vendor provided COI software programs.

The Emory eCOI software program is an enterprise software application that was developed within Emory University in 2008-2010. It is supported by Emory LITS. We encountered a few bugs within the system during the fall, which caused a delay in beginning the eCOI triage project.

Our data indicated that many faculty members do not have any financial interests

related to their institutional responsibilities. Our eCOI In FY2016, we worked closely with ORA-IT to develop and test an algorithm to query the data tables in order to identify investigators who have financial interests. During this past year, we developed the business case and project charter. LITS has taken the algorithm developed by ORA-IT to begin coding. We plan to complete testing in the summer and implement by fall.

Revise University COI Procedures based upon changes in federal policy and regulations and changes in the eCOI software.

No new federal policies have been executed or implemented that address investigator financial interests in research. We have worked closely with the Deans' Offices and Finance when potential conflicts of interest in procurement have arisen.

Once the eCOI triage patch has been tested and finalized, we will revise our procedures as needed. We do not expect that the policy will be changed. We will engage all departments to ensure that faculty complete the Annual Disclosure Report and keep their external activity/consulting agreement information up to date.

Continue to provide training and expand as needed to meet campus needs and to ensure research staff as well as faculty understands their responsibilities in reporting financial interests related to research.

So far this year, we have provided 18 training programs that reached more than 397 faculty and staff members. As noted above, we will be providing additional training when the eCOI triage patch is ready.

Work with IRB on developing standards for reliance on Central IRBs and developing a process for reviewing Central IRB agreements.

Joi Mindingall and Brenda Seiton continue to work with Rebecca Rousselle in reviewing IRB Authorization Agreements. As the Single IRB directive from NIH will be implemented this fall, Brenda will work with Rebecca in designing decision flows and procedures to ensure that Emory research is thoroughly reviewed and protected when another institution becomes the IRB of record.

Goals 2017-2018

1. Transition COI Review Office to new administrative leadership.
2. Work with other compliance units within ORA to find a suitable replacement for the eCOI system.
3. Continue training faculty and staff on conflicts of interest in research, targeting

new procedures for the eCOI system once the triage software patch is deployed.

4. Continue to work with IRB to develop and coordinate COI reviews under the single IRB mandate.

Year	2016-2017	2015-2016	2014-2015	2013-2014	2012-2013
Transactional Disclosures	22,785	18,616	20,308	18,315	18,356
No Conflict	22,537	18,389	20,116	17,644	17,626
Sent to COI	248	217	188	164	143
Individuals to COI review	88	99	81	84	73
Consulting Agreements	1,049	1,017	1,044	1,054	1186
Individuals reporting	535	493	500	493	570
Agreements Sent to COI	75	64	79	71	45
Individuals to COI review	57	55	57	59	41
Total Managed Cases	159	166	154	150	145
PHS	46	35	38	43	57
Total New Cases	48	84	56	64	
Individuals	27	39	36	37	68
PHS Cases	10	18	16	10	
FCOI Reports	5 New (1 subcontract) 19 Annual (8 subcontracts	19 New (14 subcontracts) 14 Annual (12 subcontracts)	6 New 17 Annual	7 New 33 Annual	36 (includes 5 subcontractors)
FCOI Individuals	16 (includes 6 subcontractors)	14	12	22	19 (plus 3 subcontractors)

Training Presentations	25	27	19		30

FY17 Annual Report – Information Technology (ORAIT)

Wil Brown, Director for ORAIT

Research Administration Information Technology (ORA-IT) serves as a technology facilitator, intermediary, and project liaison on behalf of ORA departments with the University's central IT division (LITS) and various third-party vendors. ORA-IT also negotiates and monitors the ORA service level agreements with LITS and third-party vendors for all ORA departments. Staff work in close collaboration with each ORA unit to understand their day-to-day activities, and long-term objectives. In addition, the team provides tiered application support and management for each of ORA's Enterprise-class IT applications. Likewise, ORA-IT works in close collaboration with the ORA units to establish IT procurement, management, and support priorities and requirements. ORA's suite of Enterprise-class IT applications include commercial systems such as Huron/Click for IRB and IACUC operations, along with University developed systems for Conflict of Interest (eCOI) and divisional services.

Status of FY17 Goals

- Any ORA Data, Any Where, Any Time, On Any Platform, SECURELY
    - Ongoing objective
- Identify and start the implementation of a New eIRB and eCOI SaaS solution(s)
- Explore importation of training data into Elements (1st iteration)
- Elements upgrade for remaining IACUC features
- Partner with SOM: DAR and IACUC in the development of IACUC reports
    - Elements was upgraded and did not successfully address performance issues
    - Due to Elements issues, the focus turned to stabilizing and identifying a new IACUC solution causing the identification of a eCOI SaaS solution to be delayed
    - Importation of training data into Elements was not pursued
- eCOI Triage implementation
    - Triage was implemented reducing administrative burden for Researchers
- Implementation of new BioRAFT modules
    - Chemical module fully implemented
- Explore importation of ELMS data into BioRAFT

    - ELMS training data feed into BioRAFT speeds the process of training review within BioRAFT
- Stabilize DocAccell
- Partner with LITS, OSP, RAS, and FGC in migrating DocAccel to OnBase
    - Delays with LITS: Client Services has negatively impacted moving this objective in a positive direction
- Partner with LITS and ORA units in the migration of ORA Network data storage to cloud-based storage
    - Emory Box has been embraced by a few ORA units
- Partner with LITS and EHSO in the migration from Blackboard to Canvas for EHSO Radiation Safety committees
    - After exploring solutions, a division web service was crafted and implemented
- Improve communications with units
    - ORA Sr Staff meetings and retreats have provided the opportunity for units to share goals and objectives
- Improve IT ordering and IT inventory
    - ORA met with LITS: Client Services in the effort to improve IT ordering and created standard bundles
- Partner with LITS and EHSO in supporting the implementation of BioRAFT modules
    - Chemical module implemented
- Partner with LITS and OTT in moving OTT documents to OnBase
    - Ongoing objective and was not achieved due to other pressing ORA issues
- Partner with LITS and OSP to evaluate the replacement of SAM Kiosk (POC in BPMS)
    - LITS Proof of Concept was presented and other solutions are being evaluated

Other Accomplishments

- CITI Shibboleth
- Onboarding for eIACUC (business processes review and training opportunities)
- ORA Active Directory clean-up
- eCOI issues
- eIRB product evaluation
- eIRB ESB Service analysis
- eIRB Roles clean-up
- eIRB Platform upgrade
- Topaz Elements platform updates (three total)
- SAM Kiosk issues
- Built and modified several eIRB reports for IRB

- ORA Roadmap Strategy
- eCTS and eGTS data in EBI
- FGC and DMG data transitioned from ORA data storage
- Patricia upgrades
- ORA Network Storage moved to updated infrastructure
- Network printing fully-implemented
- eIRB Common Rule
- Content Managers lectures and Q&A sessions
- *Served on ORA Web Content Managers committee, Research Administration governance committee, Topaz Elements executive committee, OnBase steering committee, and IT Advisory committee*

Strategic Challenges

While demand for ResAdmin IT oversight, assistance, and support continues to increase within the Division, limited ORA-IT staffing resources continue to create the need to prioritize initiatives.

The increasing paradigm shift to device independent, vendor provided, cloud-based applications, continues to emphasize the need for management practices and strategic plans which actively embrace these trends and the benefits they embody. One specific area where innovation and planning are critical is in the purchase and delivery of business applications. SaaS, Software as a Service model, should be leveraged where appropriate. An increasing desire to merge and aggregate operational data from various systems and present the resultant combined data in a device independent manner, continues to challenge the ORA-IT group. With the many disparate systems that currently comprise the ORA IT portfolio, a concerted effort, comprised of both technological and non-technological components, needs to be actively undertaken in order to successfully aggregate ORA data for management purposes. As always, much of ORA's technology success hinges on the appropriate mix of internal and vendor-based applications and services. ORA-IT continually evaluates the blend in an effort to determine its appropriateness for addressing the demanding and changing business needs of ORA. Vendors represent key partners and ORA-IT continues to evaluate new and existing vendors to determine if the products and service offerings are kept current with technology trends, are appropriately priced, fit within Emory's and ORA's technology architecture, and meet both current and future ORA operational needs. The top three items of strategic challenges are: Topaz Technologies, LITS: Application Development and LITS: Client Services.

Goals for FY18

- Any ORA Data, Any Where, Any Time, On Any Platform, SECURELY
- Partner with LITS, OSP, RAS, and FGC in migrating DocAccel to OnBase
- Partner with LITS and ORA units in the migration of ORA Network data storage to cloud-based storage
- Improve IT ordering and IT inventory
- Introduce new video services solution (Microsoft Stream)
- Introduce new form services solution (Microsoft Forms)

FY17 ORA Annual Report Highlights

- A total of $628.0 million was awarded from all extramural sources of sponsored research and training in FY17, which reflected a 9.3 % increase from FY16.

- Of that total, $475.7 million (75.74%) and $152.3 million (24.3%) were awarded in direct and indirect costs, respectively. FY16 reflected a 75%-to-25% split.

- The School of Medicine received $356.0 million reflecting approximately 56.7% of the total dollars awarded. The total for the School of Medicine represents a 2.29% increase from FY16. Of this total, $190.9 million was awarded from the National Institutes of Health, reflecting a 9.5% decrease from FY16 in NIH Funding received by the School of Medicine.

- The Rollins School of Public Health received $131 million reflecting approximately 20.9% of the total dollars awarded. This total represents an increase of 38.20% from FY16.

- The Yerkes National Primate Research Center received $79.1 million reflecting approximately 12.6% of the total dollars awarded. This total represents a decrease of 0.04% from FY16.

- Emory College received $35.6 million reflecting approximately 5.68% of the total dollars awarded. This total represents an increase of 24.22% from FY16.

- The Nell Hodgson Woodruff School of Nursing received $14.9 million reflecting 2.39% of the total dollars awarded. This total represents a decrease of .89% from FY16.

- The total funding in the Woodruff Health Sciences Center was $584.5 million reflecting 93.1% of the total $628.0 million awarded to the University.

- The federal government, Emory's largest sponsor, awarded $384.1 million reflecting 61.16% of total dollars awarded. This was a 1.44% decrease from FY16.

- The private sector, Emory's second largest sponsor, funded $117.9 million in research (18.8% of the total dollars awarded). This reflected a 40.04% increase from FY16.

- Third in providing research support was funding from corporations which granted $60.0 million (9.6% of total). Corporate sponsored funding increased 26.14% from FY16.

- Of the federal agencies, the National Institutes of Health (NIH) was again Emory's largest sponsor of research awards. NIH awarded $320.7 million (3.71% decrease from FY16). The NIH support accounted for 83.49% of total federal dollars obligated to Emory and 51.06% of all funding received.

- Since FY09, Emory has grown from $484.3 million in FY09 to $628.0 million in FY17; this represents an increase of 29.69%.

- The ten departments that with the highest level of awards received $361.3 million or 57.54% of the total dollars awarded.

    - Department of Medicine with $91.3 million (increased 6.08%)
    - Department of Pediatrics with $51.2 million (increased 4.45%)
    - Yerkes, Emory Vaccine Center with $29.8 million (decreased 14.72%)
    - Department of Neurology with $26.0 million (increased 10.33%)
    - Department of Hematology/Oncology with $31.4 million (increased 34.85%)
    - Department of Global Health Institute with $38.1 million (increased 77.20%)
    - Department of Global Health with $29.5 million (increased 42.49%)
    - Department of Epidemiology with $24.1 million (increased 16.5%)
    - Department of Surgery with $20.1 million (increased 13.93%)
    - Department of Environmental Health with $19.9 million (increased 33.74%)

- The total number of proposals submitted to all sponsors was 4,170 reflecting a 5.33% increase from FY16. The total dollars requested increased in FY17 to $1,100.3 million, reflecting an 8.48% increase from FY16 ($1014.3 million).

- Of the $1,100.3 million in proposal requested during FY17, $742.4 million (67%) was requested from federal sources.

- A total of 1,227 subcontracts were issued by Emory on research grants and contracts during FY17. This was an increase of 11.14% from the amount issued in FY16 (1104) and an increase of 53% since FY11 (801).