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**Dear Colleagues,**

Fiscal year 2015 was a productive year for Biomedical Research Services and Administration (BRSA) with continued effort to evaluate and streamline processes and improve services to best support the work of our faculty and staff conducting research. While the funding environment continues to remain a challenge for investigators, our organization has made positive strides in our research mission and the BRSA organization will continue to strive to provide excellent service to support these initiatives. Below is a summary of FY15 activities.

- Successfully submitted the Clinical and Translational Science Award (CTSA).
- Clinical research enrollments increased by almost 25% compared to FY14 enrollments and a new Clinical Trials Office director was hired.
- Continued to provide quick turnaround times within the IRB with a 10% increase in review activity.
- The Human Subjects Research Protection Program participated in the Carolina Collaborative, a mutual reliance agreement that will enable faster study start-up for multi-site research involving data sharing.
- While our NIH funding base was slightly down from the previous year, proposal activity continues to be strong with a 9% increase in submissions compared to FY14.
- There was a 34% increase in the volume of industry supported research agreements, including clinical trial agreements.
- Extramural funding with an animal based research component increased by 4.5%.
- The Education Program developed six online research training modules.
- There was a 37% increase in REDCap users and projects and a significant increase in Translational Data Warehouse (TDW) activity with the launch of the Data Puller tool, which created a 96% increase in the number of direct TDW users.

FY16 is well underway and we continue to make great strides in our academic research mission. With the recently awarded CTSA grant, and many exciting new research initiatives on the horizon, we will continue to increase our ability to produce innovative and effective research. These exciting new initiatives will further strengthen our organization and support our ultimate goal of becoming a learning healthcare organization.

Sincerely,



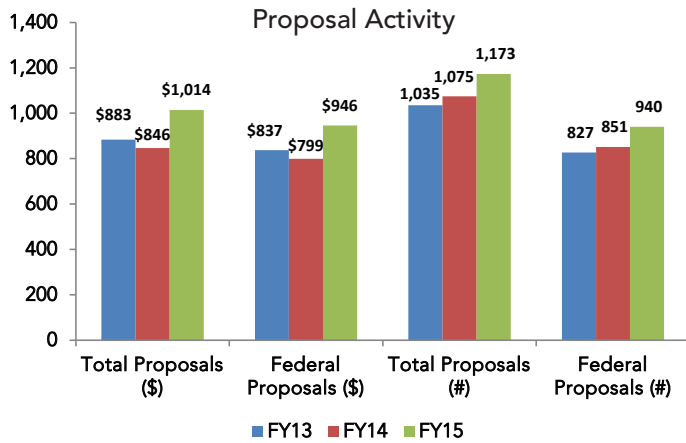
King Li, MD, MBA  
Senior Associate Dean, Clinical and Translational Research

## Office of Sponsored Programs

The Office of Sponsored Programs (OSP) continues on the path of self-examination for process improvements and ways to respond to issues and concerns related to the grants and contracts lifecycle. In FY15, procedures were examined to ensure consistency among staff for review of grants and contracts. We also focused on efficiencies for passing information both within OSP and with departmental staff. In addition, policies regarding cost share, cooperative groups and closeouts have been examined in response to national change. There has been significant focus on achieving the necessary changes to meet the new OMB guidance and NIH requirements for closeouts and drawing of funds. Implementation of a salary holding account, increased use of preaward and continuation forms and the addition of a closeout staff member have allowed us to plan appropriately to meet these challenges. We continue to actively close accounts and increased closeouts from 660 in FY14 to 875 in FY15.

### Yearly Proposal Activity

During FY15, OSP reviewed over 1,100 proposals for submission to all sponsors. This number represents a 9.1% increase over FY14. Along with the increase in volume was an increase of 20% in dollar value of submitted proposals.

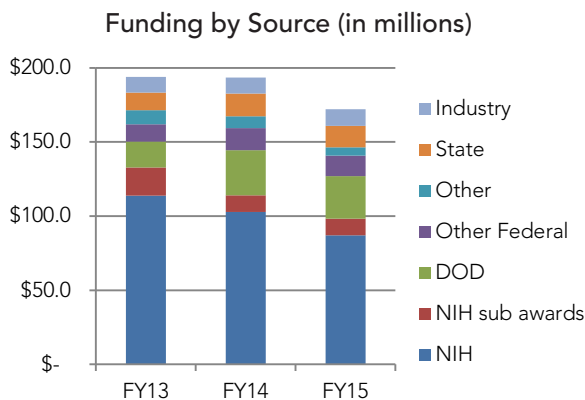


### Highlights

- » There was almost \$190M in annual expenditures on approximately 2,250 chartfields.
- » More than 675 new awards or new award years were processed during the fiscal year.
- » Over 400 subawards documents were issued to other collaborators.
- » OSP continues to work closely and collaboratively with Wake Forest Innovations (WFI) leadership toward the goal of increasing the volume of industry supported dollars.

### Extramural Funding Overview

Business processes surrounding the recording and accounting of multiyear awards changed in FY14. Graphs presented below provide a 3 year comparison and will build to a 5-year trend over time.

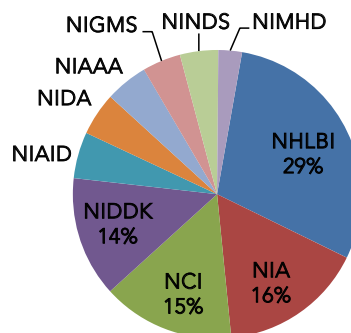


As shown in the graph above, a decrease in NIH funding was the primary cause of the overall decrease in FY15 funding. Direct funding from NIH decreased \$15.7 million (15.3%) from FY14. The decrease was driven by award volume with 72 fewer awards in FY15 compared to FY14.

	FY13	FY14	FY15
NIH	58.7%	53.2%	50.6%
Non-NIH	41.3%	46.8%	49.4%

NIH continues to be the largest funder at 50.6% in FY15. However, as securing NIH funding has become increasingly competitive the importance of portfolio diversification is magnified.

### Top 10 NIH Funding Agencies



Consistent with our strategic focus areas, NHLBI, NIA, NIDDK and NCI are the top four NIH institutes which accounted for 65% of our total NIH funding in FY15 for direct dollars and subcontracts.

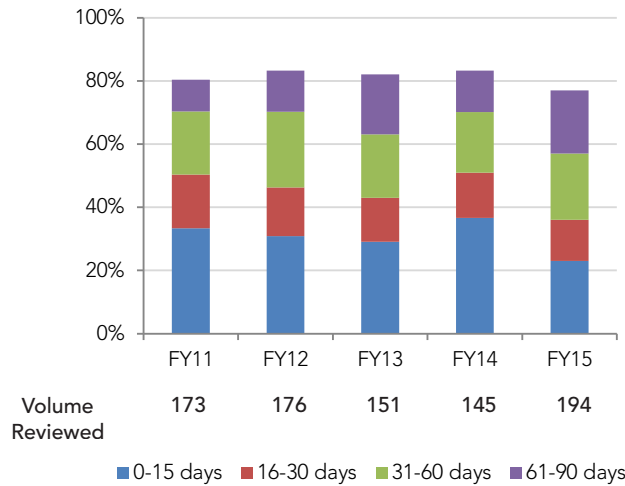
## Contract Negotiations

The Office of Sponsored Programs (OSP) handles all negotiation, execution and set up of all contractual sponsored agreements for the institution.

**Negotiation time** includes the number of calendar days it takes for the agreement to be fully negotiated, beginning from the receipt of the required routing package to OSP and ending when all legal terms are finalized.

The following graphs show a five-year comparison of volume and negotiation times for some of the different types of contractual agreements with our industry sponsors. All negotiation times for agreements are reviewed regularly to determine the causes of delays. Staff actively works to identify trends and solutions for delays.

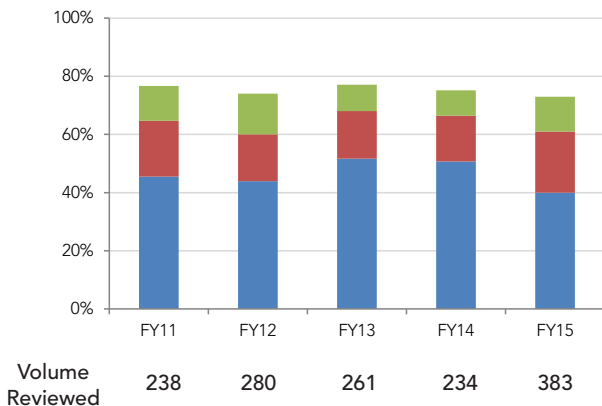
**Research Agreements  
Negotiation Time**



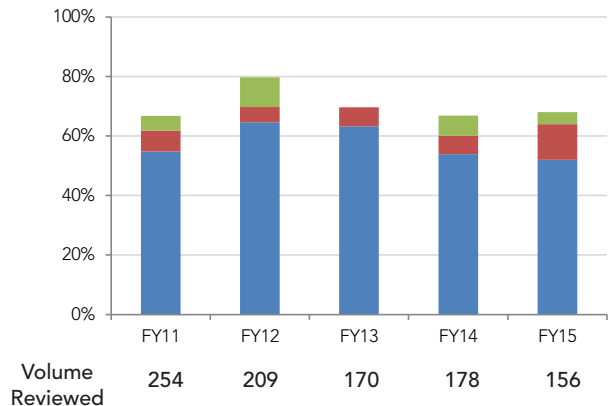
- There was an 18% year-over-year increase in overall volume for these agreements (Research, Confidentiality, and Material Transfer) from 621 in FY14 to 733 in FY15.
- There was a 34% increase in the volume of Industry-supported research agreements (including clinical trial agreements) in FY15, with the number completed rising from 145 in FY14 to 194 in FY15.
- 74% of the increase in research agreements (36 of 49 agreements) was attributable to an increase in clinical trial agreements.
- 77% of all research agreements were fully negotiated in 90 calendar days or less. This is consistent with the nationwide average.

- Most Confidentiality Agreements (61%) and Material Transfer Agreements (64%) continue to be negotiated in 10 days or less.
- 51% of Confidentiality Agreements were completed within 0-5 days, averaging 2.8 days.
- 54% of Material Transfer Agreements were completed within 0-5 days, averaging 1.1 days.

**Confidentiality Agreements  
Negotiation Time**



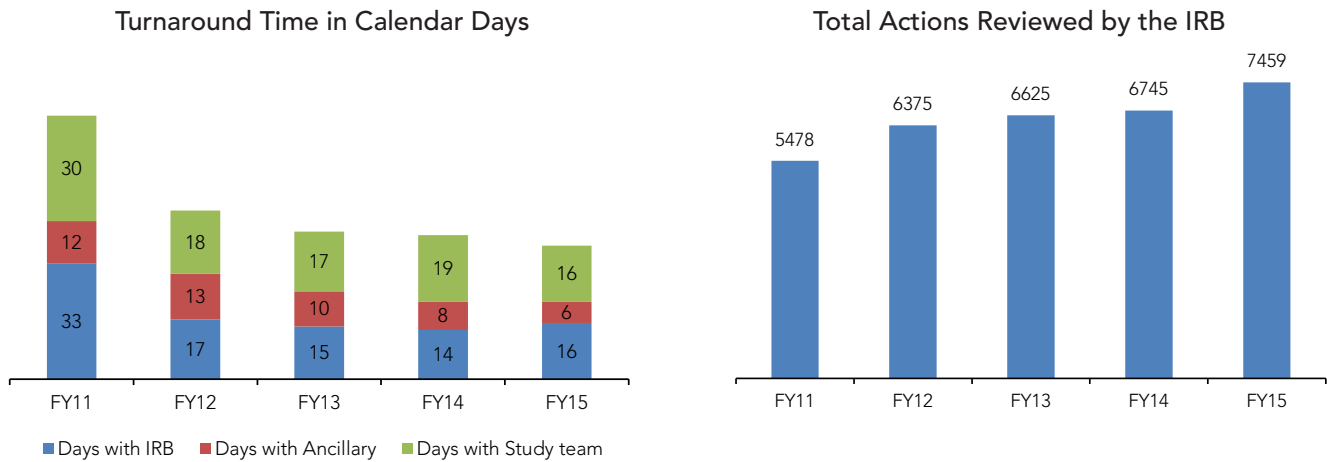
**Material Transfer Agreements  
Negotiation Time**



■ 0-5 days ■ 6-10 days ■ 11-15 days

## Human Research Protection Program (HRPP)

During the past year the Human Research Protection Program (HRPP) and Institutional Review Board (IRB) has maintained a high level of excellence in turn around times and quality of reviews. This efficient service was maintained even with a 10% increase since FY14 in the number of actions reviewed by the IRB. The number of actions have increased to 7459, 36% since FY11.



Additional HRPP activities included:

- Joined the national IRBShare initiative to help minimize duplicated efforts across institutions;
- Worked with the Carolinas Collaborative on a mutual reliance agreement that will enable faster start-up for multi-site research involving data sharing;
- Played a key role in the development of the Trial Innovation Center (TIC) grant to serve as lead review site for CTSA trials; and
- Assisted the BRSA Education Program in the development of human research educational modules.

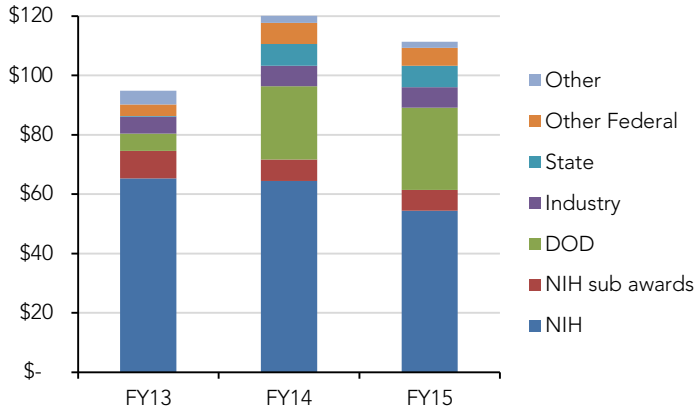
HRPP/IRB leaders presented on IRB related topics at 5 national conferences, 3 North Carolina-based conferences and lectures, and also participated in a national PCORNet group addressing pragmatic clinical trials.

HRPP/IRB leaders wrote three articles that were published in peer-reviewed journals, 2 in the Journal of Clinical Research Best Practices and 1 in the Journal of Clinical Trials. Finally, HRPP/IRB leaders received funding from the Wake Forest University Center for Biotethics, Health, and Society to conduct a study on informed consent design. This study is ongoing and should contribute to the literature on improving informed consent comprehension.

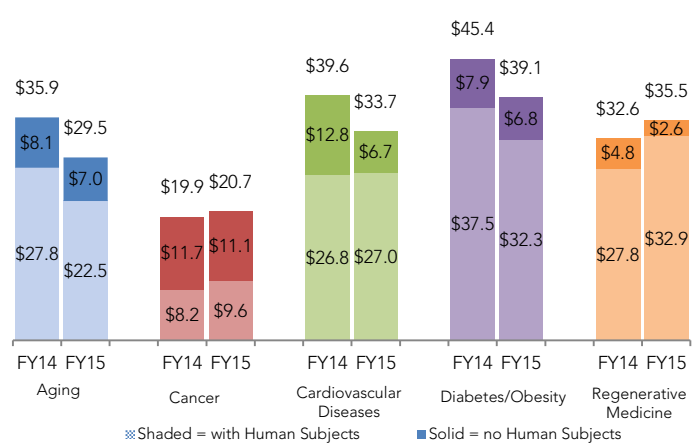
## Extramural Funding Supporting Human Research

The portfolio of extramural funding remains well diversified. This heterogeneity provides some degree of insulation from decreases in funding. Although overall funding for human subjects research decreased 7.3% in FY15, driven primarily by decreases in NIH and other federal dollars, DOD funding for human studies increased to 12.6% over FY14. The amount of industry and state funding remained largely unchanged. The figures below show the breakdown of funding sources for the overall human research portfolio and the strategic focus areas. Awards with potential for human subject research in our strategic focus areas saw a smaller decrease than the overall portfolio, down just 3% from FY14.

**Awards by Sponsor Supporting Human Subject Research (in millions)**



**Human Research in Strategic Focus Areas (in millions)**



The numbers reflected above are awards which are identified as having potential for human research. However, 100% of the awarded dollars might not be directly related to human subject work.

## Clinical Research Resources

The Clinical Research Resources services continued to expand in FY15. The Clinical Trials Office (CTO) team worked to further enhance the Clinical Research Management System by providing more training and guidance on budget development, managing study requirements, and participant flagging within WakeOne to ensure compliance. Throughout the year, 71 individuals received a CRMS training and/or consult. The CTO has also worked to increase and clarify the resources available to Wake faculty members through the Study Coordinator Pool, which includes but is not limited to the following: Budget Negotiations, IRB/Regulatory Submissions, Patient Eligibility Review, Consenting and Research Scheduling Support, Data Entry and Specimen Collection. Additionally, the Clinical Research Unit (CRU) has continued to see growth with an increase in the number of visits and studies supported.

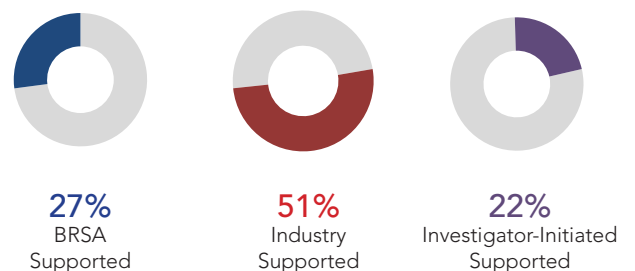
**Clinical Research Unit Visits by Type**

	Jul	Aug	Sep	Oct	Nov	Dec
Investigator Initiated	443	421	423	453	328	377
Industry	114	95	97	106	100	107
	Jan	Feb	Mar	Apr	May	Jun
Investigator Initiated	303	278	380	359	386	411
Industry	89	77	106	151	132	143

Total Visits: 5879 Studies: 88

The CRU had an active year in FY15 with a steady number of patient visits and increased activity for industry sponsored trials. The CRU supported 88 active trials for 146 principal and co-investigators.

**Study Coordinator Pool Support**



The Study Coordinator Pool supported a high volume of clinical trial activity in FY15. The pool supported 96 studies for 178 principal investigators across 52 different departments, including two departments from the Reynolda Campus.



## Faculty Research Awards

Providing Faculty Research Awards is an opportunity to increase awareness of the research endeavors pursued by faculty and recognize accomplishments. The Faculty Research Awards recognition honors investigators, mentors, and scientific teams that demonstrate outstanding scientific achievement. This program continues to excel every year, awarding our distinguished faculty for their excellence in research. Below is a list of the 2015 recipients.

### Early Career Basic Sciences – Raghunatha R. Yammani, PhD; Molecular Medicine

“Targeting Unfolded Protein Response (UPR) Signaling Pathway for Osteoarthritis Therapeutics”

### Mid-Career Basic Sciences – Emilio Salinas, PhD; Neurobiology & Anatomy

“What Simple, Rapid Choices Tell Us About Decision Making Mechanisms”

### Mid-Career Clinical Sciences – Carlos J. Rodriguez, MD, MPH; Epidemiology & Prevention

“Cardiovascular Disease Disparities in Hispanics/Latinos and the Echocardiographic Study of Latinos (ECHO-SOL)”

### Established Basic Sciences – Beth A. Reboussin, PhD; Biostatistical Sciences

“Searching for Hidden Subpopulations: Moving Beyond Diagnostic Classification Systems”

### Established Clinical Sciences – Dalane W. Kitzman, MD; Cardiology

“Heart Failure in the Elderly: the Old, the New, and the Unknown”

## Special Awards

### Mentoring Award

Sally Shumaker, PhD; Public Health Sciences, Social Sciences & Health Policy

### Team Science Award

National Cancer Institute (NCI) Community Oncology Research Program (NCORP)

## Oversight and Outreach Program

Oversight and Outreach specialists work closely with the IRB and IACUC where problems, deviations and safety events are discussed and plans for remediation are recommended. In FY15 the Oversight and Outreach (O&O) Program for Animal Research conducted 64 Post Approval Monitoring Reviews. In addition, the Quality Assurance Task Force (QATF), an ad-hoc subcommittee of the Institutional Animal Care and Use Committee (IACUC), performed in-depth post approval reviews of 4 targeted protocols. A new, QATF pre-approval review was initiated this year to help preempt adverse events, improve research design and identify potential problems and corrective actions that can be put into place prior to the start of a study. The QATF also conducted 4 pre-approval reviews of high risk studies.

An equally important component of the program is training and education. Educational programs in compliance objectives, best research practices and changes in regulations are provided several times throughout the year. Training is recommended for faculty, study teams and lab managers. In FY15, O&O for Human Research worked with the CTO to develop study coordinator modules. The Study Coordinator 101 and 102 educational classes utilized the “world cafe” theme which was very well received. In addition, specific training sessions were offered to summer research interns regarding the informed consent process and provided guidance documents and templates. The O&O for Animal Research provided education on changes in the USDA inspection and reporting practices, humane endpoints, and housing requirements for USDA - regulated animals. A best practice, team-based communication program, modeled after behaviors and methods used in human operating rooms, was piloted and implemented using direct interaction and real time coaching.

### Human Subjects Protection Program Random Site Visits, Cause Site Visits, & IRB Review Process Audits

FY15	<b>64</b>	FY14	33
		FY13	20
		FY12	29
		FY11	25

26 random site visits, 5 for cause site visits, and 33 audits of the IRB review process for new protocol submissions.

### Animal Welfare Program Post Approval Monitoring & Quality Assurance Task Force Reviews

FY15	<b>72</b>	FY14	72
		FY13	66
		FY12	51
		FY11	29

64 post approval monitoring reviews and 8 quality assurance task force reviews.

## Animal Welfare Program & Institutional Animal Care and Use Committee (IACUC)

The Animal Welfare Program has been fully accredited by the Association for the Accreditation and Assessment of Laboratory Animals (AAALAC) since 1966 and was most recently re-accredited in 2014.

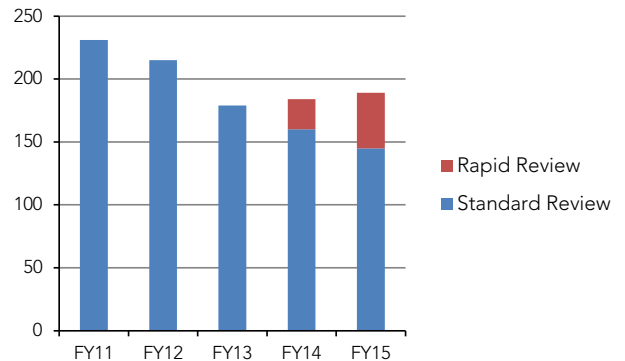
This past year, 135 faculty members managed about 425 IACUC protocols across 17 organizational units including 19 different types of animals used in research projects.

Mice and rats accounted for 92% of the animals used in research, which is fairly typical for animal research in the U.S. Notably, nonhuman primates were the 3rd most common animal used at Wake Forest School of Medicine, and various other USDA-regulated animals (which exclude rats, mice, and birds) were routinely engaged as animal models.

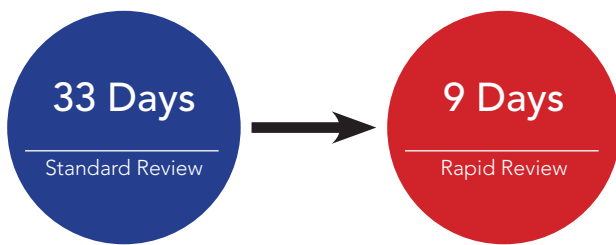
### Innovations to the IACUC

In the past year, regulatory agencies relaxed rules to allow certain amendments to IACUC protocols that involved clinical drugs, or other aspects of veterinary care, to be approved by Animal Resource Program veterinarians instead of the full IACUC. Dubbed Veterinary Verification Consultation (VVC), these amendment reviews typically turnaround within 24 to 48 hours. For the second year, the IACUC used a **rapid review process** that resulted in reduced average turnaround times from approximately one month to one week, about 1/4 of the national average for academic institutions. In the past year, the eligibility for rapid review was expanded and applied to 23% of all protocols (44/189 protocols).

### Total Protocols Reviewed



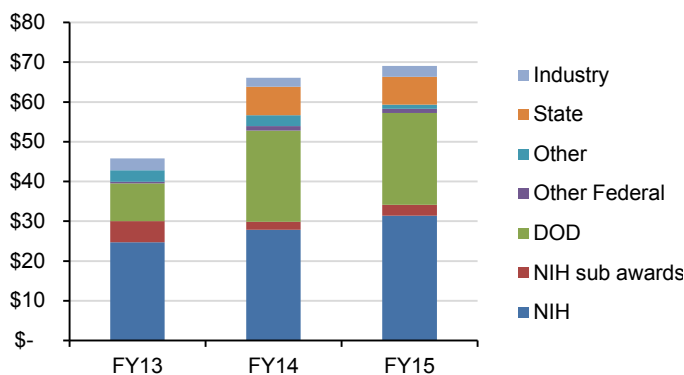
As shown by the graph above, the number of new animal protocols began to slowly rise in FY13 through FY15, and the number of rapid review protocols increased to 23% of total.



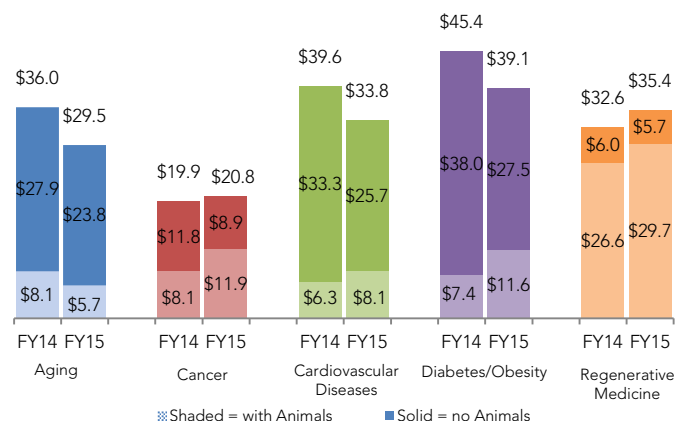
### Extramural Funding Supporting Animal Research

Sponsored research funding that included animal research remained a significant part of the overall institutional research portfolio, rising from \$66 million in FY14 to \$69 million in FY15. The majority of animal research funding was sponsored by the NIH (\$34.1M) and the Department of Defense (\$23.1M). Within the strategic research focus areas, the percentage of animal-based support rose in all but one area over the past year.

### Awards by Sponsor Supporting Animal Subject Research (in millions)



### Animal Research in Strategic Focus Areas (in millions)



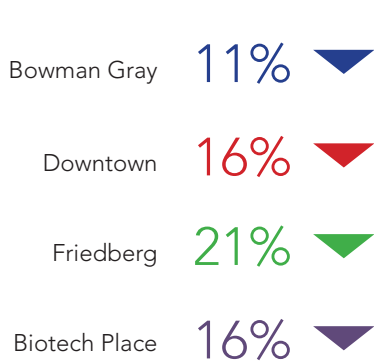
The numbers reflected above are awards which are identified as having potential for animal research. However, 100% of the awarded dollars might not be directly related to animal subject work.

## Animal Resources Program (ARP)

The ARP is responsible for procuring and caring for all animals used in research and teaching and for providing scientific and technical assistance regarding animal care and use. The ARP works closely with the IACUC and other institutional services to provide a comprehensive program and works to assure regulatory compliance with the United States Department of Agriculture (USDA), the Public Health Service Policy and the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) accreditation.

The ARP oversees 228,823 square feet of animal facilities on four campuses. Annually the ARP provides husbandry and medical care for about 35,000 animals (17 different species). The FY15 annual operating budget for the ARP was approximately \$9.2M with 60-65% of operating expenses recovered via per diem income.

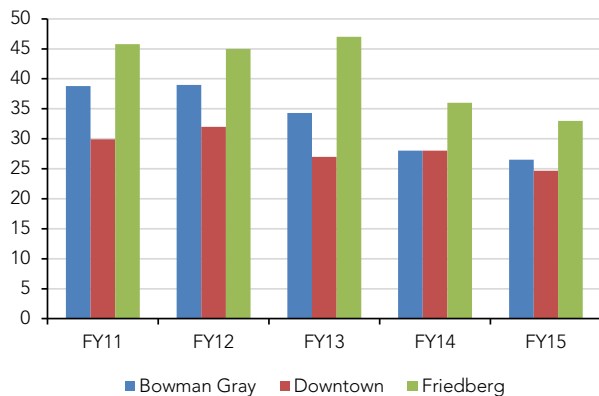
This past year Wake Forest School of Medicine continued the development of Scientific Neighborhoods to promote synergy among scientists. The Scientific Neighborhood concept is to optimize the performance of highly innovative and impactful research through locating investigative teams with common interests in adjacent space that is also proximate to frequently used cores and infrastructure. The primary goal of this initiative is to create vibrant and interactive scientific communities that will enhance discovery and optimize the productivity and innovation of our investigative faculty. Aligning with this goal, the ARP has begun to reorganize animal housing locations to accommodate the relocation of investigators participating in a Scientific Neighborhood and their study animals.



### Animal Care Days

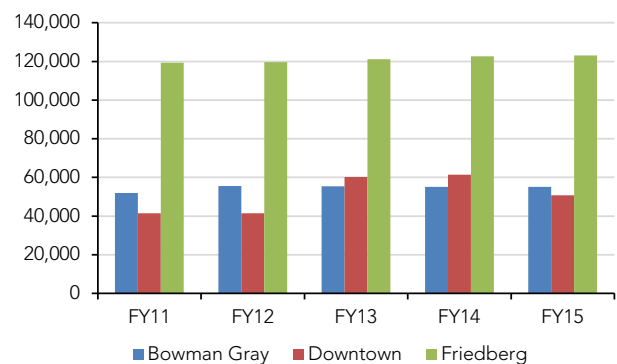
As described, Wake Forest School of Medicine has focused areas of research as part of the institution's Strategic Plan. The decrease in Animal Care Days (ACD) is partly due to faculty departures, reduced sponsor funding, and realignment with the Strategic Plan. Between FY14 and FY15, the ARP experienced an actual net decrease of 280,937 (-15%) animal care days over all campuses. This reduction was due to a net decrease in care days of all categories of animals; rodents (-15%), non-rodent/non-primate (-24%) and non-human primate (-15%) populations. There are anticipated future increases in current rodent ACD in the areas of diabetes and cancer.

Total FTEs by Campus



The ARP has adjusted staffing in response to the reduction in animal census to fit current and projected needs. For FY15, the ARP was supported by approximately 103 full- or part-time employees. This was a 5% decrease from FY14 and a 18% decrease from FY13 in total FTE.

ARP Space by Campus (sq. ft)



The changes in ARP space for FY15 reflect a net decrease in vivarium space on the Downtown Campus. ARP space was consolidated with the closure of the animal housing facility in the A1a Building at the end of FY15. Research activities and animals were transfer to other Downtown ARP facilities.

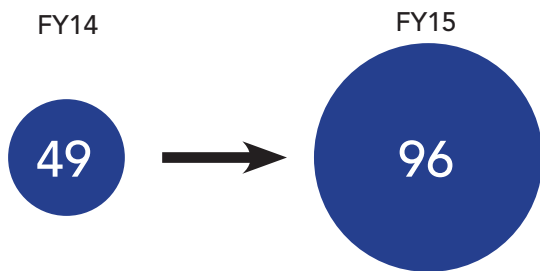


## Biomedical Informatics

BRSA fosters the development of innovative solutions to conducting effective research. Our Biomedical Informatics tools and services provide access to enterprise clinical and research data, expertise and customized software tools to assist investigators with data collection and management.

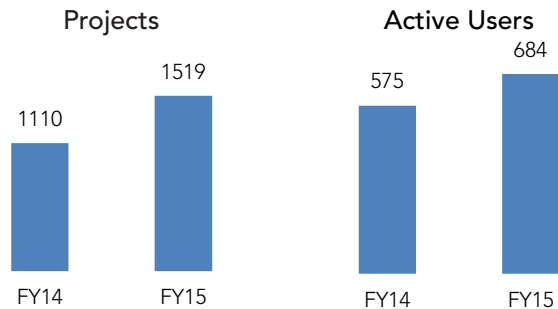
### Data Access

Over the past fiscal year, the Data Access Team continued to enhance the data available within our Translational Data Warehouse (TDW), how the data can be searched, and how the data is accessed. In May of 2015, the Data Puller tool was released, which allows investigators and study teams on approved IRB protocols to extract their own clinical data for an identified patient population. This prompted a 96% increase in number of direct TDW users, as shown below.



### REDCap

The REDCap system has shown consistent growth in the number of projects and users compared to FY14. There has been a 37% increase in the number of projects and a 19% increase in active users. Additionally, training sessions were implemented to support increased activity and provide individuals with hands-on instruction.



## Community Engagement

Fiscal year 2015 was another productive year for the Program in Community Engagement (PCE). The PCE supported several initiatives to further its mission of working with local community organizations to identify health concerns and seek solutions through partnership and collaboration. The Stakeholder Advisory Committee met quarterly, providing space for community connections and discussion of emerging research interests. Three presenters spoke about active transportation via bicycling at the February meeting. Because of community interest, the PCE convened a working group to write a research proposal entitled "Assessing Barriers to Cycling Diversity."

Representatives of the PCE attended a national conference on Citizen Science to learn more about engaging community members in research. The PCE Speakers Bureau program facilitated 61 presentations in the community. The presentations given by faculty and staff educated and translated recent research findings so that community members were able to access current health information.

The PCE project, Farm Fresh Healthy Living Program, entered its fourth year. The program engages individuals from low-income households in a community support agriculture (CSA) program in which they purchase a box of locally-grown produce at a reduced price weekly for 14 weeks, learn how to prepare nutritious recipes using these foods, and learn about local healthy food options available to them. The activity includes a partnership with a local grower, Harmony Ridge Farms, and with three local agencies: El Buen Pastor Latino Community Services, Imprints Cares, and the YWCA.

An additional initiative included the Parent/Child Interaction workgroup, made up of collaborators from our institution, UNCG and community based organizations. This workgroup completed several workshops for parents to raise awareness of the unique needs of infants and small children for healthy brain development.

Faculty and staff from across the Medical Center involved in community-engaged research were invited to a one-day conference at Graylyn International Conference Center to discuss common concerns and shared interest in this work. The conference accomplished its purpose of establishing the Community Engagement Affinity Group. The PCE continues to form productive research collaborations across the Medical Center and the community.

## Education, Training and Other Research Support

BRSA also provides a well-developed educational program and proposal and manuscript editing services. The numbers of proposals and manuscripts have both increased from FY14, and are 116 and 64, respectively.

Education and training is a critical component of the BRSA organization and continues to expand to provide faculty and staff with the necessary training needed to conduct research. Online and in-person training includes courses in the Responsible Conduct of Research, Research Administration Certificate Program, Financial Research Compliance, and Animal Laboratory Training. An online Clinical Research Study Staff Orientation program was initiated in FY15, with six online modules currently available and more being developed.

BRSA provides administrative oversight of the Medical Student Research Program, a 9-week, full-time summer research experience for rising second year Wake Forest medical students. Thirty-one students participated in the program in 2015. BRSA also coordinates an annual Medical Student Research Day each fall so that all medical students can showcase their research projects and develop their scientific communication skills.

The Translational Research Academy, an elite education and research support program for promising early-career faculty, provides a forum for Academy Scholars to network, learn from experienced investigators, and have designated time to focus on career and research goals. In FY15, our fourth cohort of 14 faculty continued in the two-year long program, focusing on navigating the research process and enhancing their career and leadership development skills.

Investments made in both pilot funds and through the KL2 scholar program provided by the Translational Science Institute (TSI) over the course of previous fiscal years continue to be tracked for progress through BRSA. A total of 90 grants were funded including 22 small award "Ignition" grants and 15 co-funded institution partner grants.

### Pilot Investment Tracking

Return **\$45.6M**

Investment **\$2.6M**

### KL2 Investment Tracking

Return **\$10.5M**

Investment **\$2.3M**

### Grant & Manuscript Editing

Proposals **116**

Manuscripts **64**

## Research Institutes, Centers, and Shared Services Administration

The Research Institutes, Centers, and Shared Services Administration office was established during FY12. The office and the Centers and Cores Advisory Committee (CCAC) is responsible for peer reviews for the institutional Centers and Cores that apply for financial subsidies to achieve their goals. The oversight ensures that these activities are aligned with the strategic direction of WFBMC, and that funds are allocated to help achieve specific research goals. The budget for support of the operations and administration for the centers and cores is \$3.35M, consisting of \$2.4M for center operations, \$637k for core operations, and \$274k for faculty administrative support. Much of the center operational funds are allocated to support pilot funding and grow new areas of science. In FY14 and FY15, budgeted pilot funds accounted for \$380k and \$460k, respectively. In addition, CCAC recommendations from the faculty Needs Assessment Survey, and the Core Applications lead to purchases of capital equipment to support the research infrastructure in FY15 and FY16 of \$850k and \$1.4M, respectively.

Other goals of the office include promoting the utilization of the core/shared resource services. In the past year, there were advancements in the CTSI and core website information, a Research Core Symposium was held with 136 participants, and the InterAC Forum expanded to be an open meeting for all interested faculty and staff. Enhancements targeted for FY16 include the activation of Eagle-i and REACHNC.org software search engines, and the installation of the first 10 shared resources on the iLab Solutions Software laboratory management system that will promote efficiency and standardization across the fee-for-service lab operations.