

"This research metrics document provides a 'look back' of research activity for FY14 and FY13. Despite the competition for a smaller pool of funds at a federal level, we were able to sustain our level of extramural funding for the past two years. Moving forward, we will continue to focus on the refinement of our strategic goals to help ensure priorities which we believe will better position the research enterprise for the future."

-Edward Abraham, MD
Dean, School of Medicine

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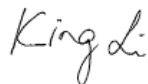
Dear Colleagues,

The fiscal year 2014 held many rewarding moments, as well as some challenges for our academic enterprise. Despite much transition, we have made solid progress in supporting high-quality research, including building strategic platforms for research services and support. Here is a summary of noteworthy accomplishments and goals achieved in FY14:

- Creation of an integrated research administration and service organization, Biomedical Research Services and Administration (BRSA), to better serve our research community.
- Began development of a comprehensive BRSA website consolidating multiple sources of information, to help faculty and research staff better locate information and navigate through available research resources and required processes.
- Continued focus on early-career faculty development, with selection of another cohort of 14 faculty for the Translational Research Academy.
- Continued expansion of our clinical research resources (e.g. study coordinator pool, Clinical Research Unit, and Clinical Trials Office); grants management support; and education and training resources to help faculty and staff successfully compete for extramural funding and execute high-quality research.
- Greater efficiencies within our IRB, increasing board review activity by adding four board meetings and reducing the overall number of protocol review days.
- 31% increase in data requests with a reduced wait time for processing, and increases in both the number of REDCap projects and number of active users by 42% and 35%, respectively.

Based on the rapidly changing environment in academic research and the scale and complexity of societal health issues we face, Wake Forest has an exciting opportunity to conduct research as part of a learning health care organization to more quickly and effectively impact patient health. With FY15 well under way, we have made great strides in this direction. We continue to focus and refine the research strategic plan, work with regional partners to develop a clinically integrated network, and place an increased emphasis on building our clinical trial capacity. These exciting new opportunities will further strengthen our organization and increase our ability to produce the most innovative and effective research to impact the health of our region and our nation.

Sincerely,



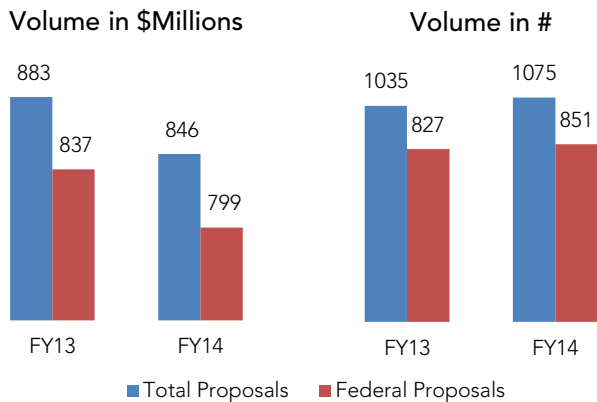
King Li, MD, MBA
Senior Associate Dean, Clinical and Translational Research

Office of Sponsored Programs

This past fiscal year, the Preadward and Postaward offices merged to establish the newly formed Office of Sponsored Programs (OSP). OSP is now responsible for the complete research lifecycle: proposal submission through award/contract closeout. This integration provides a one-stop shop for all sponsored program activities, resulting in new efficiencies and decreased redundancies. Noted improvements include some functional realignment of duties, cross-training of staff, and combining physical and computer files, allowing for seamless flow of information between sections.

Yearly Proposal Activity

During FY14, OSP reviewed over 1,000 proposals for submission to all sponsors. This number represents a 3.9% increase over FY13. Although proposal numbers show an increase from FY13 to FY14, proposal dollar amounts have had a decrease of 4.2% due to a variety of factors such as shorter project periods, an increase of modular awards, and more proposals to non profit sponsors.

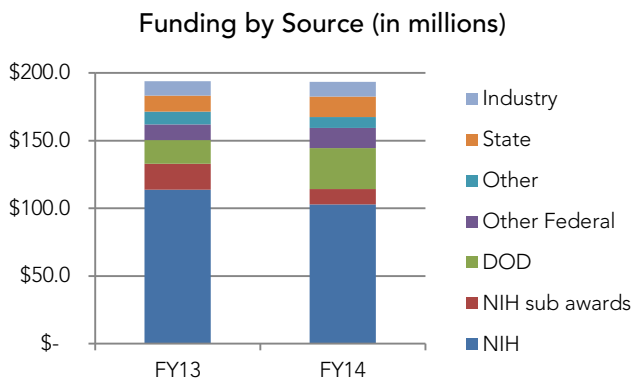


Highlights

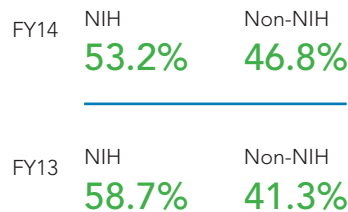
- » There was almost \$190M in annual expenditures on approximately 2,400 chartfields.
- » More than 675 new awards or new award years were processed during the fiscal year.
- » Over 400 subawards documents were issued to other collaborators.
- » OSP has worked closely and collaboratively with Wake Forest Innovations (WFI) leadership to streamline efforts and processes with the goal of increasing the volume of industry supported dollars.
- » There were approximately 40 new projects in collaboration with WFI involvement representing an approximately 50% increase in WFI projects from FY13.

Extramural Funding Overview

In FY14, business processes impacting the recording and accounting of multiyear awards were changed. Extramural data for FY13 has been restated to reflect this new practice; therefore, this annual report will only compare FY13 and FY14 data to ensure a comparable analysis of extramural funding for these past two years. Additionally, there is also focus on the 4 main areas of research focus from the Institution's Strategic Plan. The areas include: cancer, aging/Alzheimer's disease, diabetes/obesity/metabolism/related cardiovascular disease, and regenerative medicine.

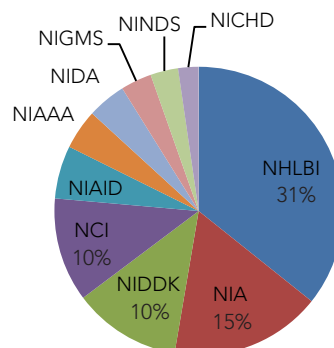


Extramural funding and sponsor diversification has remained relatively stable over the past two fiscal years but current funding trends are beginning to demonstrate small changes in the overall sponsor portfolio. As shown in the graph above, funding from NIH resulted in a small decrease relative to the overall total funding, 58.7% (FY13) vs. 53.2% (FY14), but is offset by a notable increase in funding from the DOD, \$30.5M in FY14 compared to \$17.6M in FY13.



NIH continues to be the largest direct sponsor of extramural funding to the institution which accounts for 53.2% (\$102.8M) of our total of \$193.4M funding in FY14.

Top 10 NIH Funding Agencies



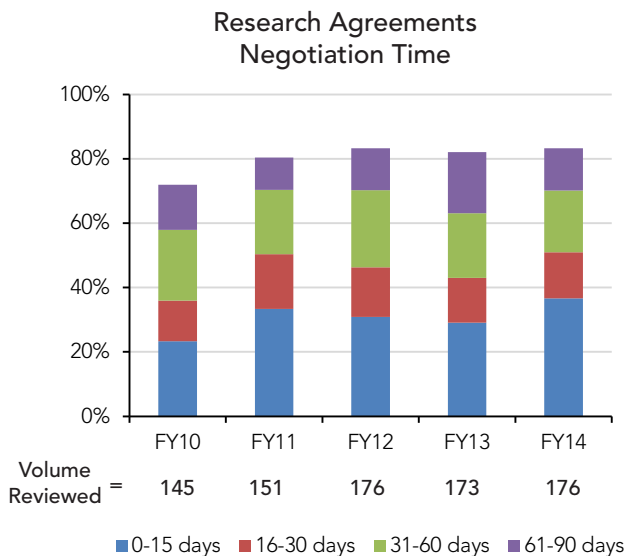
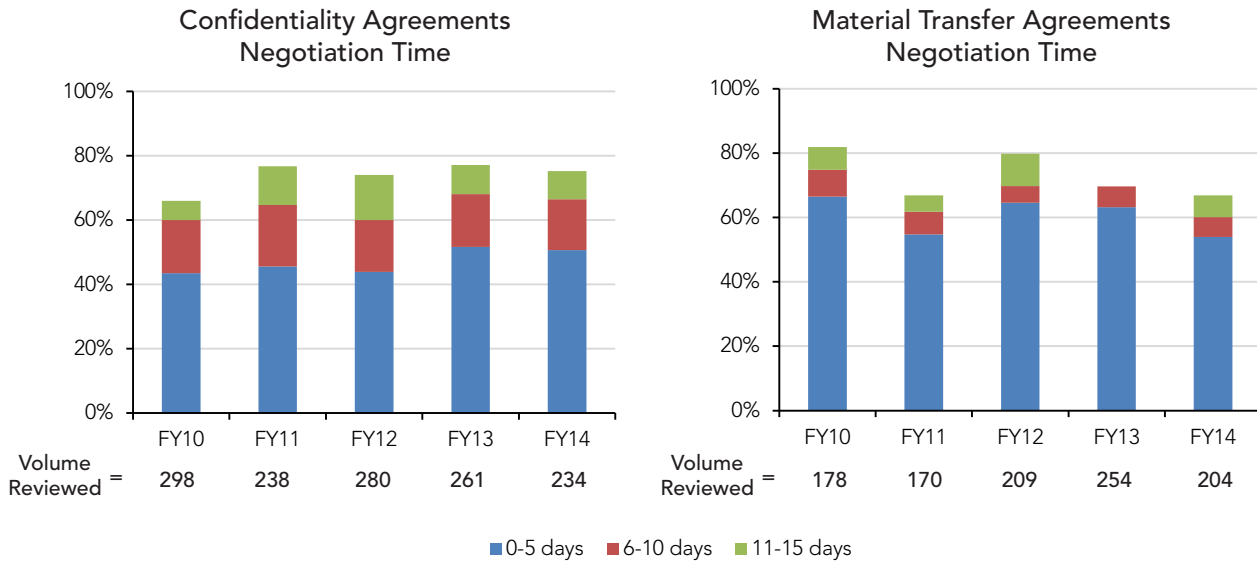
Consistent with our strategic areas of focus, NHLBI, NIA, NIDDK and NCI are the top four NIH institutes which account for 66% of our total NIH funding in FY14 both directly and via subcontracts.

Contract Negotiations

The Office of Sponsored Programs handles all negotiations, 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. While the volume of all types of agreements has remained steady or increased over time, the average time to fully negotiate these types of agreements has remained steady and/or decreased this past fiscal year. Most Confidentiality Agreements (66%) and Material Transfer Agreements (60%) are negotiated in 10 days or less.



There has been a notable increase in the number of Industry-supported research agreements (including clinical trial agreements) completed within 30 days or less from 43% in FY13 to 51% in FY14. Current academic medical center average negotiation time with industry-supported contracts is 90 calendar days.

- 84% of all research agreements were fully negotiated in 90 calendar days or less (up from 82% in FY13)
- 5% of research agreements were negotiated between 90 and 95 days
- 11% of agreements negotiated fell within the 95-110 calendar day ranges.

All negotiation times for agreements are reviewed regularly to determine the causes of delays, and staff actively work to identify trends and solutions.

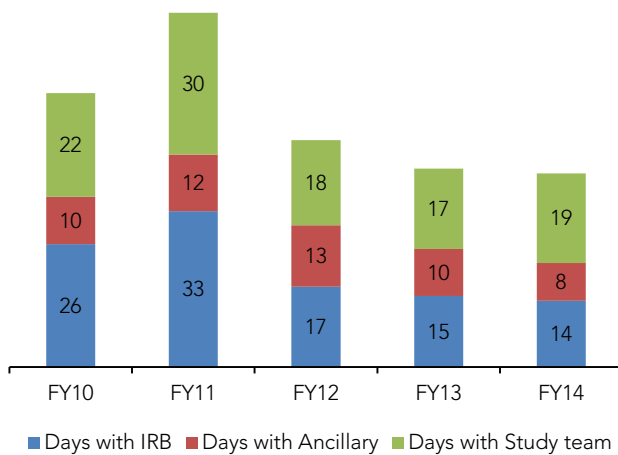
Human Research Protection Program (HRPP)

In June 2014 the HRPP achieved a five year renewal of its full-accreditation status from the Association for the Accreditation of Human Research Protection Programs (AAHRPP). This designation signifies that the Wake Forest School of Medicine's Institutional Review Board (IRB) continues to meet the highest standards in review, quality and compliance with regulatory requirements.

Innovative Improvements to IRB Processes

As a result of the ongoing self-assessment of the IRB, a new model was implemented that increased the number of boards and meetings. In FY14 this new model demonstrated an increased quality of protocol review and a 50% decrease in approval turn-around times, which has been maintained since implementation.

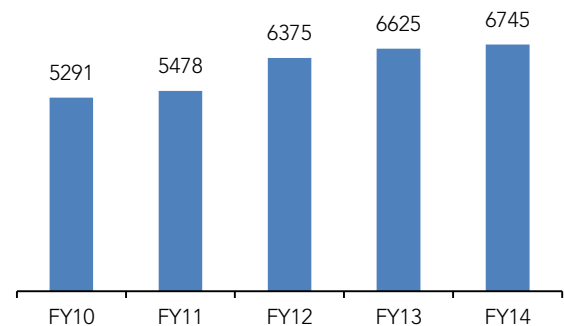
Turnaround Time in Calendar Days



Four manuscripts outlining the new model for IRB review have been published by the HRPP leadership team. Additional activity included two presentations at national and regional conferences, a national teleconference, and an interview by a staff writer for *IRB Advisor*. These publications and presentations have had a direct impact on best practices and standards at a national level.

This past year, the IRB undertook a ground-up assessment and redesign of the electronic IRB submission system, eIRB. This redesign included a new application that requires investigators to only complete questions that apply to their study. The application is now significantly shorter, requiring less time for faculty and study team members to complete and easier for IRB members to review.

Total Actions Reviewed by the IRB



As shown in the graph above, there has been a 27% increase in IRB activity since 2010. Even with the steady increase in activity, turnaround times continue to decrease.

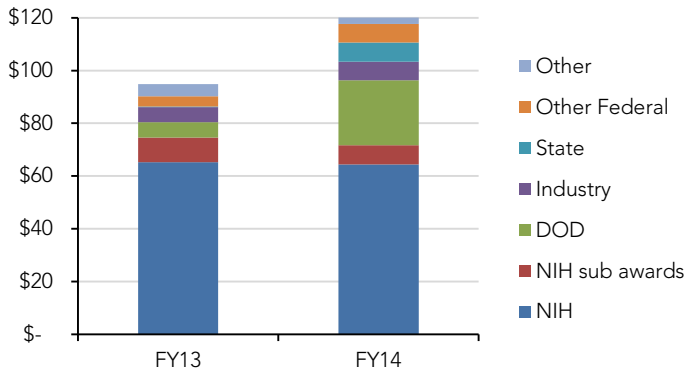
The increase in IRB activity coincides with an overall increase in clinical trial funding. The data below illustrates the increase in clinical trial funding over the past fiscal year.



Extramural Funding Supporting Human Research

Extramural funding for human research increased 27% from FY13 to FY14, to over \$120M. This increase correlates with the rise in the number of actions reviewed by the IRB in FY14. Two sizable awards, one from the state of North Carolina and the other from the U.S. Department of Defense, contributed substantially to the growth in human research funding for 2014. The figure below illustrates the current diversification of the human research funding portfolio.

Awards by Sponsor Supporting Human Subject Research (in millions)



Human Research in Strategic Focus Areas

Human research was funded in each of the 5 strategic research focus areas during 2014.

- » 85% of **Regenerative Medicine** research was for human participants (\$27.8M of \$32.7M)
- » 77% of **Aging** research (\$27.8M of \$36M)
- » 74% of **Cardiovascular disease** research (\$26.8M of \$36.1M)
- » 83% of **Diabetes/Obesity** research (\$37.5M of \$45.4M)
- » 41% of **Cancer** research (\$8.2M of \$19.9M)

Clinical Research Resources

The Clinical Research Resources services continued to expand for clinical research in FY14. The Clinical Trials Office (CTO) team worked to further implement the Clinical Research Management System providing more training and guidance on budget development, managing study requirements, and participant flagging within WakeOne to ensure compliance.

Additionally, the Clinical Research Unit (CRU) and Study Coordinator Pool provided early-career and established researchers with service to support clinical studies including space, patient care, bionutrition, laboratory, and coordinator support.

Clinical Research Unit Visits by Type

	Jul	Aug	Sep	Oct	Nov	Dec
Investigator Initiated	495	447	388	478	456	423
Industry	59	31	53	82	38	22
	Jan	Feb	Mar	Apr	May	Jun
Investigator Initiated	443	436	430	416	389	406
Industry	40	44	35	65	92	92

Total Visits: 5860

The CRU had an active year in FY14 with a steady number of patient visits and increased activity for industry sponsored trials. The CRU supported **84** active trials for **161** principal and co-investigators.

Study Coordinator Pool Support



27%
BRSA
Supported

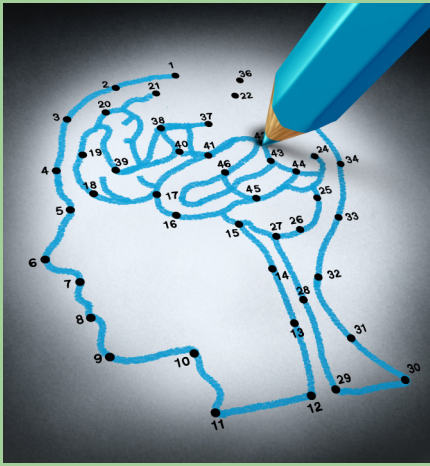


50%
Industry
Supported



23%
Investigator-Initiated
Supported

The Study Coordinator Pool supported a high volume of clinical trial activity in FY14. The pool supported **60** studies for **114** principal and co-investigators across **36** different departments, including two departments from the Reynolda Campus.



Research Focus: Alzheimer's Disease Prevention Program

In October 2012, Dr. Suzanne Craft, an internationally renowned scientist in the field of Alzheimer's disease (AD), aging and dementia research, was brought to Wake Forest, along with a colleague, Dr. Laura Baker, and several members of their research team from the University of Washington. They came to expand AD research at Wake Health and to establish what is known today as the Alzheimer's Disease Prevention Program (ADPP).

To further this mission, in fiscal year 2014, the ADPP expanded personnel, increased trials and project volume, and successfully submitted a P30 center grant application. The team has made great strides over the past year to establish infrastructure to support research in the prevention and treatment of AD. Currently, the ADPP has eight open and actively-enrolling AD-related trials, with three more slated to open in the next three months. The ADPP also serves as the coordinating center for two national, multi-site AD prevention clinical trials, the SNIFF and EXERT studies, and is a participant site for a third multi-site study, the A4 Study.

This past year, Dr. Craft recruited two new members to her team, Dr. Tao Ma, Assistant Professor of Neuroscience from Mount Sinai School of Medicine, and Nora Shively, Program Manager, who previously served as the Director of Life Sciences Research at NC A&T State University. Dr. Ma's research focuses on novel molecular mechanisms underlying the pathophysiology of AD and identifying potential therapeutic targets and biomarkers for AD. Ms. Shively brings over two decades of experience in research administration, program development and community outreach, providing the fiscal and managerial expertise.

The ADPP has partnered with BRSA utilizing the Clinical Research Unit and working closely with the Clinical Trials Office for study start-up and management procedures within the CRMS. This partnership will continue in FY15 and has been an integral part of supporting the ADPP's goals. In the future, the ADPP will continue to build partnerships with the other departments, centers and institutes, to work collaboratively to provide specialized resources to accelerate research investigating the role of metabolic and vascular factors in the cause of AD. The ADPP established a pilot program to foster multi-disciplinary collaborations and access to large data and specimen repositories of well-characterized study participants. The ADPP will continue to build a successful research program and further its mission of providing preventions and cures for AD.

Oversight and Outreach Program

The purpose of the Oversight and Outreach Program is to ensure compliance with institutional, state and federal guidelines and regulations and to encourage "good" science by identifying support and educational needs. A primary activity of the Oversight and Outreach Program is to conduct Post Approval Monitoring to ensure both human subjects' rights and animal care and well being are held to the highest standards. As a result of post monitoring activities, institution-wide improvements have been initiated to increase the safety of human research subjects and improve the safety and quality of animal research activities. Over 2,000 safety and adverse events are reviewed by the outreach specialists yearly which are reviewed and reported to the Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC), respectively.

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.

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 FY14 a number of Post Approval Monitoring visits were conducted by the Human Subjects Protection and Animal Welfare Programs.

Human Subjects Protection Program Post Approval Monitoring



There was a 39% increase of reviews over last year.

Animal Welfare Program Post Approval Monitoring



There was a 9% increase of reviews over last year.

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

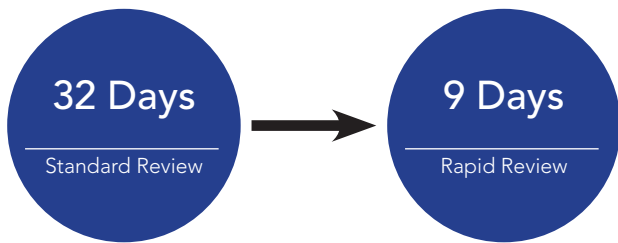
The Animal Welfare Program has been fully accredited by the Association for the Accreditation and Assessment of Laboratory Animals (AAALAC) since 1966. AAALAC conducted a triennial site visit of Wake Forest School of Medicine in March 2014 and reissued our full accreditation in May.

This past year, 141 faculty members managed 437 IACUC protocols across 17 organizational units including 15 different types of animals used in research projects.

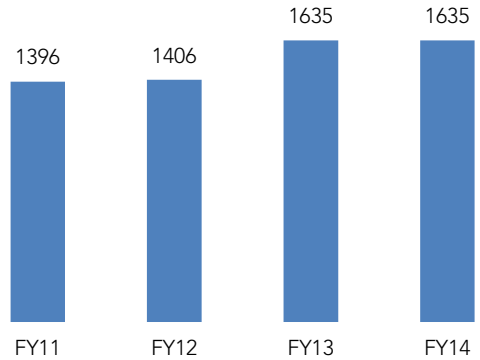
Mice and rats accounted for 91% of the animals used in research, which is fairly typical for animal research in the U.S. Notably, nonhuman primates were the 4th most common animal used at Wake Forest School of Medicine, and various other USDA-regulated animals were routinely engaged as animal models.

Innovations to the IACUC

This past year, the IACUC piloted and successfully implemented 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. This was accomplished by administratively triaging protocols on the front end, requiring prior clearance by other ancillary committees, e.g., Institutional Biosafety Board and employing key committee members to review protocols outside of monthly committee meetings.



Total Actions Reviewed by the IACUC

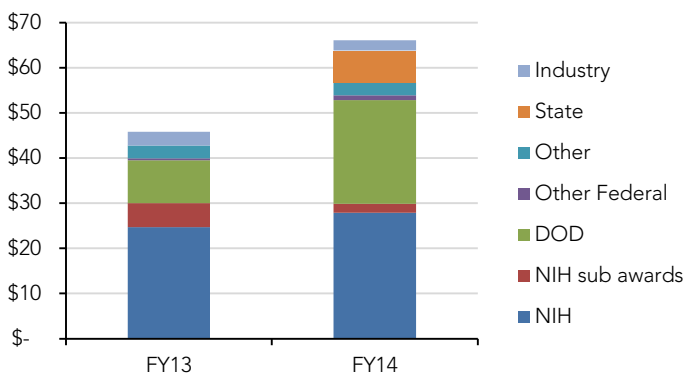


As shown by the graph above, overall activity rose slightly since FY11. IACUC activity has remained stable in FY13 and FY14, with an increase in the number of amendments completed.

Extramural Funding Supporting Animal Research

Sponsored research funding that included animal research remained a significant part of the overall institutional research portfolio. Extramural funding with an animal-based research component rose significantly 44% from FY13 to FY14, topping \$66M, or 1/3 of total sponsored research awards in 2014. This increase was based chiefly on two major awards from the state of North Carolina and the U.S. Department of Defense (DOD). Historically the majority of animal research funding has come from the National Institutes of Health, and this trend was in fact sustained from FY13 to FY14 at about \$30M per year.

Awards by Sponsor Supporting Animal Subject Research (in millions)



Animal Research in Strategic Focus Areas

Each of the 5 strategic research focus areas employed animal models in FY14.

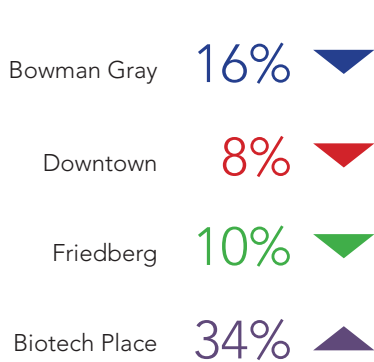
- » 81% of **Regenerative Medicine** research included animal models (\$26.6M of \$32.7M)
- » 51% of **Cancer** research (\$10.1M of \$19.9M)
- » 22% of **Aging** research (\$8.1M of \$36M)
- » 17% of **Cardiovascular disease** research (\$6.3M of \$36.1M)
- » 16% of **Diabetes/Obesity** research (\$7.4M of \$45.4M)

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 239,034 square feet of animal facilities on four campuses. Annually the ARP provides husbandry and medical care for about 42,000 animals (17 different species). The FY14 annual operating budget for the ARP was approximately \$9.4M with 60-65% of operating expenses recovered via per diem income.

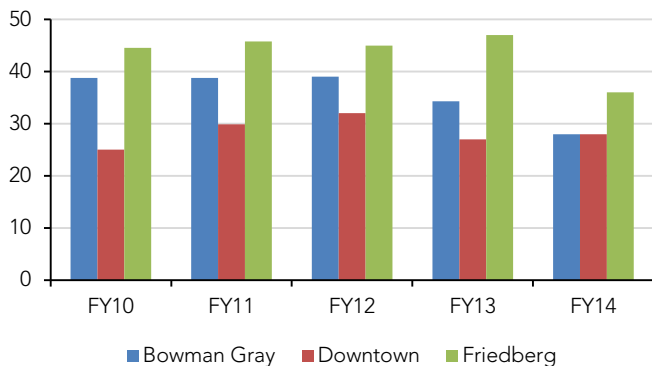
This past year Wake Forest School of Medicine began the development of Scientific Neighborhoods to promote synergy among scientists. Scientific Neighborhood concept is to optimize the performance of highly innovative and impactful research through locating investigative teams with common interests in 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

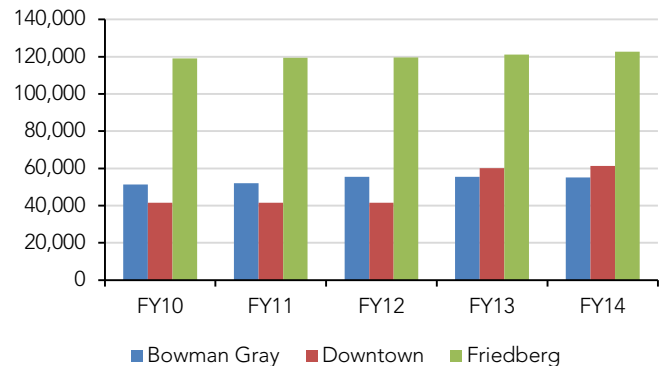
As described, Wake Forest School of Medicine has focused areas of research as part of the institution's Strategic Plan. The decrease in Animal Care Days (ACD) is partly due to faculty departures, reduced sponsor funding, and realignment with the Strategic Plan. Between FY13 and FY14, the ARP experienced an actual net decrease of 176,317 (-9%) animal care days over all campuses. This reduction was due to a net decrease in care days of all categories of animals; rodents (-8%), non-rodent/non-primate (-12%) and non-human primate (-10%) 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 FY14, the ARP was supported by approximately 103 full- or part-time employees. This was a 14% decrease from FY13 and a 20% decrease from FY12.

ARP Space by Campus (sq. ft.)



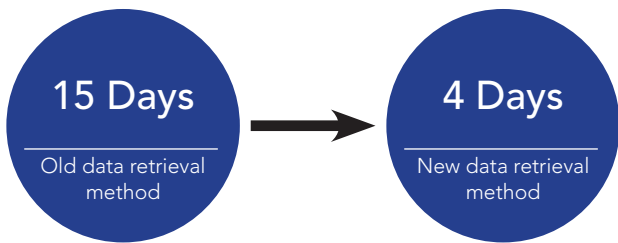
Increases in space for FY13 reflect the addition of the Biotech Place vivarium included in the Downtown Campus data. In accord with the Strategic Plan and the formation of Scientific Neighborhoods, future ARP space will be consolidated with the closure of older buildings and the transfer of animal activities to new modern 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.

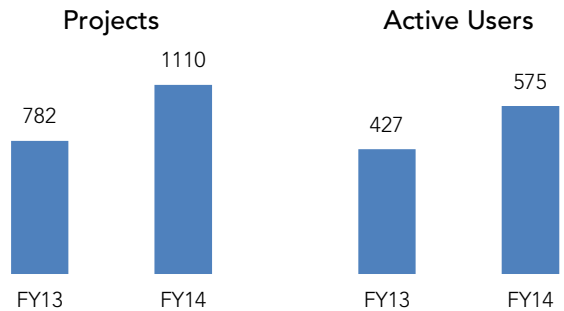
Data Access

Over the past fiscal year, the Data Access Team has been remodeling the way investigators access data for research purposes. This included handling all data requests in house and ensuring migration of WakeOne data was performed in an accurate and timely manner. In FY14, there was a 31% increase from the prior year in the number of data requests received.



REDCap

The REDCap system has showed consistent growth in the number of projects and users compared to FY13. There has been a 42% increase in the number of projects and a 35% increase in active users. Additionally, training sessions were implemented to support increased activity and provide individuals with hands-on instruction.



Education, Training and Other Research Support

The formation of the BRSA organization also included research Education and Training, a Grant Management Core and Proposal and Manuscript Editing services which continued to be active in FY14.

The Grant Management Core service added two new departments to its portfolio assisting select departments with overall financial support including reporting on postaward monthly grant and other account activity, progress reports, projections and effort reporting.

Education and training is a critical component of the BRSA organization and continues to expand to provide faculty and staff with the necessary training support needed to conduct research. Training includes the Responsible Conduct of Research courses, the Research Administration Certificate Program, and Animal Laboratory Training. In FY14, a total of 103 classes were offered through BRSA.

The TSI 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 FY14, an additional cohort of 14 faculty were added to the program. Over a two-year period scholars will focus on building career and leadership development skills and navigating the research process.

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 the BRSA. A total of 79 grants were funded including 22 small award "Ignition" grants and 10 co-funded institution partner grants.

Pilot Investment Tracking

Return **\$43.7M**

Investment **\$2.6M**

KL2 Investment Tracking

Return **\$9.7M**

Investment **\$2.3M**

Grant & Manuscript Editing

Proposals **115**

Manuscripts **62**

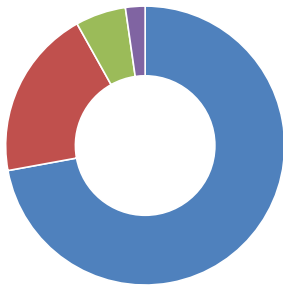
Research Institutes, Centers, and Shared Services Administration

The Research Institutes, Centers, and Shared Services Administration office was established during FY12, and in its first two years has set up a structure for the centers and cores peer review application and annual review process, standardized pricing guidelines, surveyed and prioritized requests for capital equipment and infrastructure/services, established regular communications and advertising for the services through monthly InterAc meetings, and connected appropriate directors with Wake Forest Innovations for marketing services to external industry partners.

In FY14, institutional operational investment for the centers and cores total \$3.7M; consisting of Center support of \$2.88M (\$2.66M operations and \$216k administration) and Core support of \$813k (\$729k operations and \$84k administration).

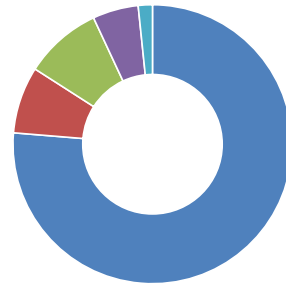
In the research cores, the overall activity in FY14 was \$5.1M with \$3.9M (76%) coming from fees, \$396k (8%) in direct grant support for the infrastructure from the Comprehensive Cancer Center extramural funds, and \$813k (16%) from institutional resources.

Actual Investments in Research Centers and Cores



■ Research Centers Operational Support	\$2,661,142
■ Research Cores Operational Support	\$728,875
■ Research Center Administration	\$215,827
■ Research Cores Administration	\$83,668

Research Cores Sources of Funds



■ User Fee-for-Service Revenue	\$3,891,273
■ Direct Support CCC Grants/Contracts	\$395,675
■ CCC Institutional Support	\$458,449
■ Direct Institutional Support	\$270,426
■ Research Cores Administration	\$83,668

Community Engagement

In FY14, the Program in Community Engagement (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. A major program initiative was the formation of the Gun Violence as a Health Disparity workgroup. Project activities included a summer film series on gun violence which featured community collaborators and Wake Forest faculty coming together to explore the disparate impact of gun violence on the health of African Americans in our community.

Additionally, four opportunities were offered in a campaign to raise awareness of these issues and promote collaboration with community organizations. Workshop topics included:

- What is a Health Disparity? And What Does that Have to do with Gun Violence?
- The Health Impact of Male Gun Ownership on Intimate Partner Violence
- Mental Health and Gun Violence
- Gun Violence: A Campus and Community Discussion

The PCE also continued work in the Farm Fresh Healthy Living Program, engaging individuals from lower income households to learn about local healthy food options available to them and how to prepare nutritious recipes using these foods. The activity includes a partnership with a local grower and local agencies such as El Buen Pastor Latino Community Services. An additional initiative included the Parent/Child Interaction workgroup to raise awareness of the unique needs of infants and small children for healthy brain development. The PCE continued to work with organizations to receive critical feedback on health issues that truly impact our community.