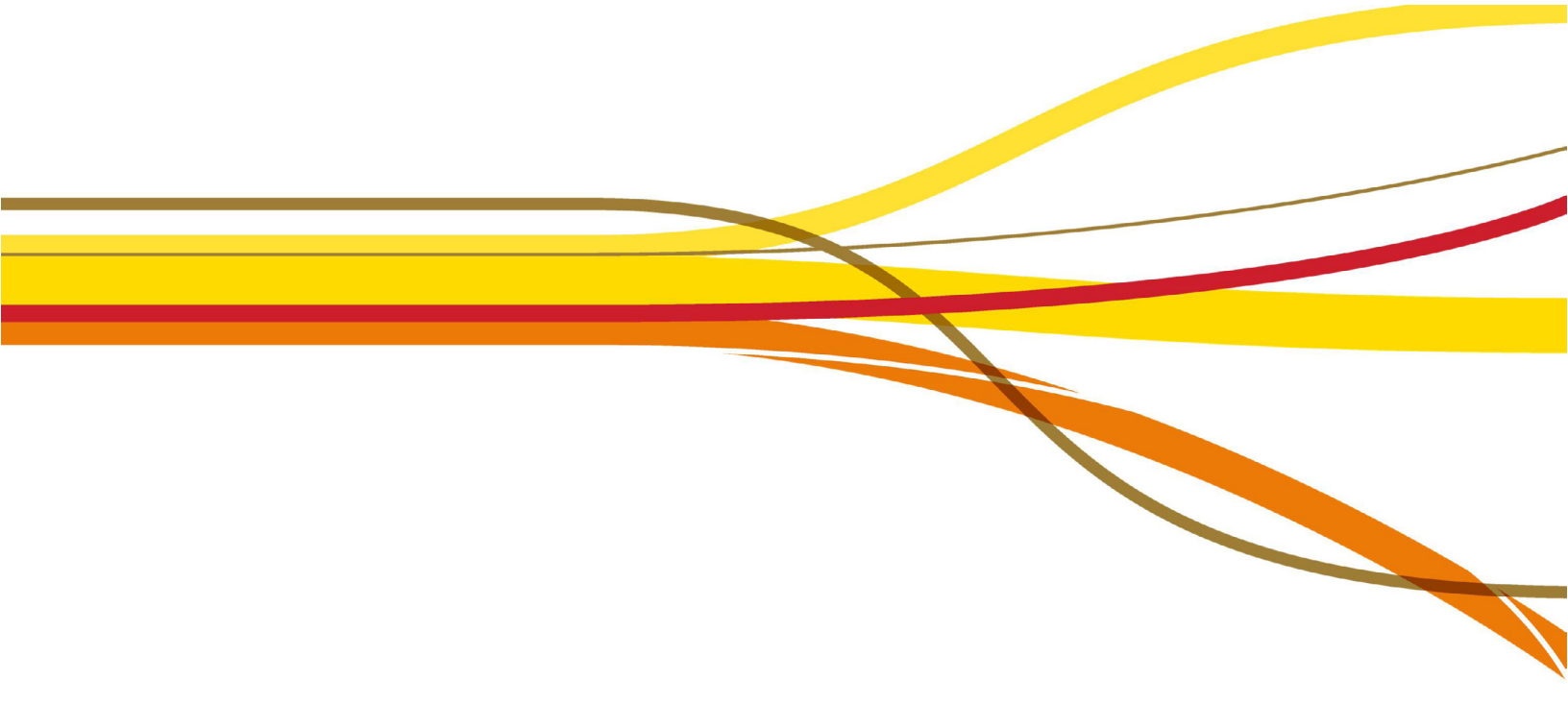
FY16 Annual Report

Clinical and Translational Science Institute



Office of Sponsored Programs

During FY16 a number of internal processes were examined and developed to address concerns and challenges impacting grant and contract activities. As a part of this assessment a new faculty online departure tool was developed to assist faculty, departments and central office staff in the transfer process. In addition, an electronic subaward processing tool was rolled out to both assist departmental staff in preparing the subcontract package and to decrease the turnaround time for issuing subcontracts.

Sponsored Programs processed more than 725 new awards in FY16 and approximately 450 subaward documents were issued to external collaborators. Both award set ups and subawards issued were increased over FY15. Proposal submissions remained consistent with FY15 with over 1,100 new proposals reviewed and submitted to external sponsors. Consistent with past years, NIH proposals account for the majority of the dollars requested.

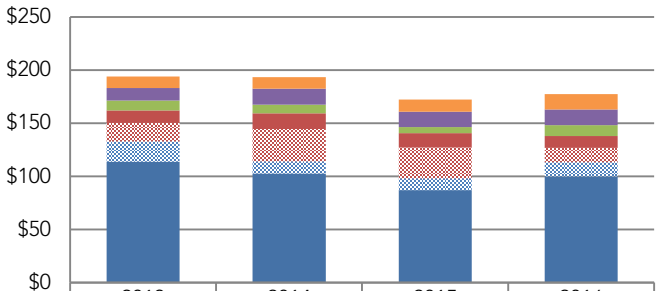
Additional highlights include:

- Increased use and functionality of PeopleSoft:
  - Activated the non-letter of credit (LOC) invoicing to make invoicing activity more transparent to departmental staff and assist in central office functions
  - Re-implemented combo rule functionality to ensure charges do not post to grants after the end date
  - Re-engineered HR retro functionality and effort reporting to accommodate Common Employer downstream impacts
- Upgraded InfoEd to handle and allow for more complex funding mechanisms, and
- Implemented a new proposal submission policy mandating a 3-day, 10am review deadline in advance of the sponsor deadline.

Extramural Funding Overview

Funding in FY16 showed an improvement over prior year, increasing $5.2 million, or 3%. Direct awards from NIH increased 15%. The increase in industry funding is primarily attributable to increased revenue collection due to improved accounts receivable processes and increased clinical trial enrollment in FY15. DOD decreases were primarily attributable to timing differences, with funds originally scheduled to be released in FY16 pulled forward by the DOD and issued in FY15.

Funding by Source ($ millions)



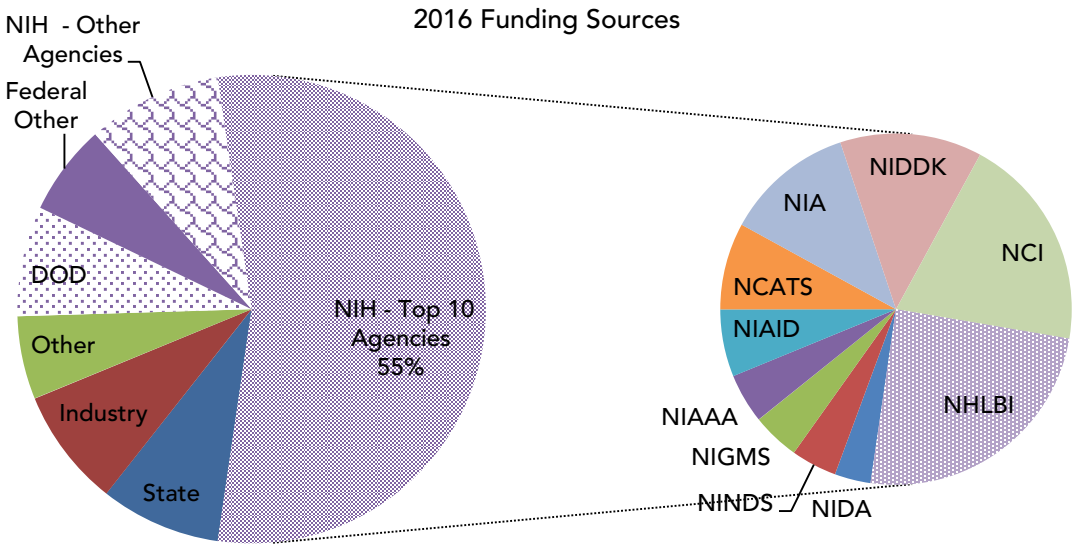
	2013	2014	2015	2016
Industry	$10.6	$10.7	$11.3	$14.5
State	$11.9	$15.2	$14.4	$14.7
Other	$9.4	$8.0	$5.7	$10.2
Other Federal	$11.6	$14.9	$13.6	$11.1
DOD	$17.6	$30.5	$28.9	$13.5
NIH sub awards	$19.0	$11.3	$11.1	$13.5
NIH	$113.8	$102.8	$87.1	$99.9
Total	$193.8	$193.4	$172.1	$177.3

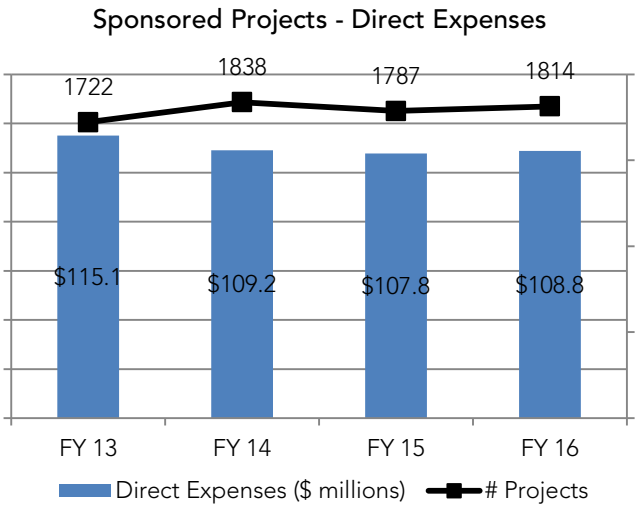
The increase in Direct NIH funding combined with the decrease in DOD funding impacted the funded portfolio mix in FY16, bringing Direct NIH funding to over 56% of the volume, a level not reached in the prior two fiscal years.

	FY13	FY14	FY15	FY16
NIH	58.7%	53.2%	50.6%	56.3%
Non-NIH	41.3%	46.8%	49.4%	43.7%

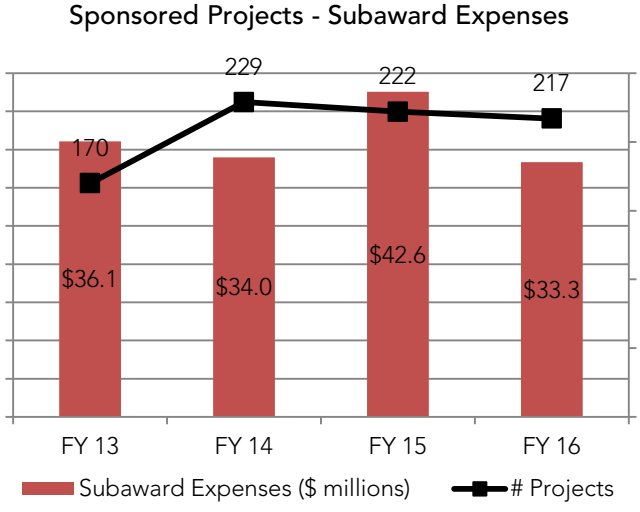
NIH Funding

Direct and flow through NIH funding comprised 64% of the FY16 funding. Our top 10 NIH funding agencies contributed 55% of total funding. Included in the top 10 agencies are those that closely correlate with our Strategic Research Focus Areas: National Cancer Institute (11%), National Institute of Diabetes and Digestive and Kidney Diseases (7%), National Institute on Aging (6%), and National Institute on Alcohol Abuse and Alcoholism and National Institute on Drug Abuse at 2% each.





Although new award dollar volume has decreased from FY13 levels, by almost $16 million, there has not been a commensurate decrease in project spending or the number of projects administered.

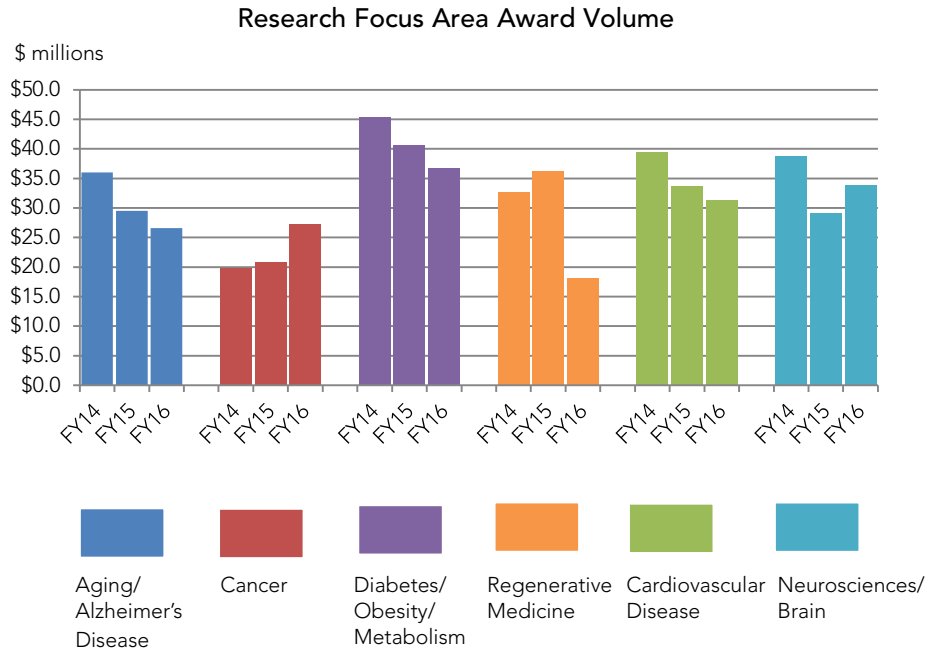


Collaborations with others have resulted in an increase in subawards since FY13 and appears to be remaining consistently about 1/3 or more of our overall expenses second only to salaries and fringe.

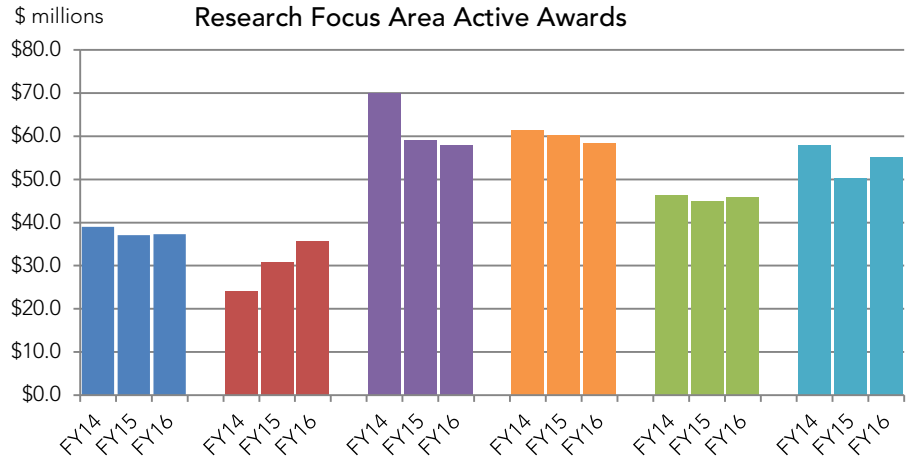
Strategic Research Focus Areas

In FY16 six themes were selected for inclusion in the Research Strategic Plan as shown below. Proposals and awards are included in each focus area based on the key codes selected or issuance by the relevant NIH Institute. Since multiple key codes may be selected, awards may be included in more than one research focus area. The Office of Sponsored Programs provides quarterly Research Focus Area metrics. Metrics include Award Volume, Active Awards, and Proposal Volume.

- Faculty played a key role in the Research Focus Areas with 342 of the 455 actively funded PIs represented in FY16 active focus area awards.
- New recruits in the past two fiscal years contributed $9.4 million to research focus area funding in FY16, of this $6.0 million was in the Cancer Focus Area.



Award volume measures projects with a funding period start date within the fiscal year (July-June).



Active awards are those with a funding period that spans the fiscal year end, regardless of start date.

Active awards in most focus areas have remained stable, reflecting the strong research base already established. Research Focus Area leaders will be challenged to continue to build these portfolios.

Strategic Research Focus Areas Initiatives

- In FY16 WFUHS applied for and was awarded (in FY17) a NIA-funded P30 Alzheimer's Disease Core Center (ADCC). There are 30 ADCCs nationally, and only 3 Centers in the 12-state Southeastern region, a region with the highest per capita prevalence of Alzheimer's disease.
- WFUHS has been awarded a 5-year, $7.86 million Program Project Grant from the National Institute of General Medical Sciences. The work funded by the award will focus on understanding, preventing, and treating chronic pain and disability after surgery. Research on pain is included in the Neurosciences Research Focus Area.
- Donald A. McClain, M.D., Ph.D., a nationally recognized leader in diabetes and obesity research, was named founding director of the new Center on Diabetes, Obesity and Metabolism.
- Two of the Strategic Research Focus Areas earned top-50 spots in the 2016-17 U.S. News & World Report's "Best Hospitals" rankings: Cancer –#19, and Diabetes – #36.

Industry Contract Activity

Executed agreements remained level at 1,007 in FY16. This continues the increased volume trend first seen in FY15 when agreements jumped 23% from the average of the prior three years. The institution's increased focus on clinical trial activity is a large driver of this increase.

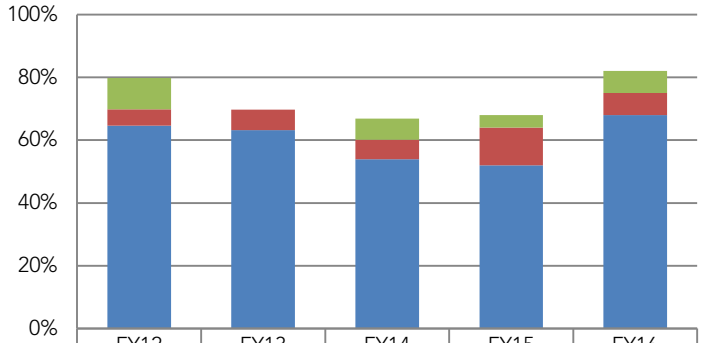
Agreement Type	FY12	FY13	FY14	FY15	FY16
Confidentiality	255	238	298	383	320
Material Transfer	192	155	178	156	215
Research	152	151	145	178	177
Amendment	177	135	172	159	185
Miscellaneous	45	49	80	93	86
Subcontracts	11	4	6	16	1
Indemnification Ltrs	12	3	8	24	23
Total Completed	**844**	**735**	**887**	**1009**	**1007**

Highlights

- OSP successfully completed negotiations on 11 Master Agreements during FY16 with seven of those being with pharmaceutical companies and related to clinical trials.
- In FY16 Wake Forest University Health Sciences took part in the ACTA (Accelerated Clinical Trial Agreement) initiative as a participating institution. The ACTA is a master agreement that was developed in conjunction with several leading academic institutions, as well as industry, to facilitate the negotiation process.

The following graphs show a five-year comparison of volume and negotiation times for three of the different types of contractual agreements that OSP negotiates with our industry sponsors. Negotiation times are reviewed regularly to determine the causes of delays.

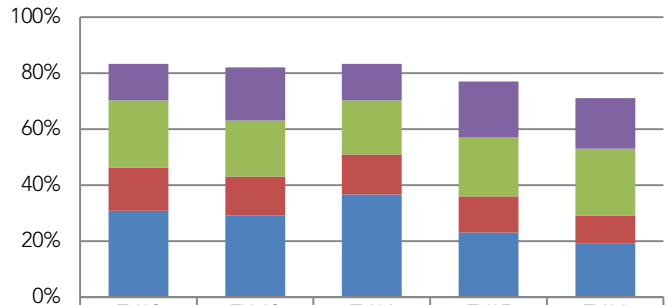
Negotiation Time - Material Transfer Agreements
% completed within



	FY12	FY13	FY14	FY15	FY16
11-15 days	10%	0%	7%	4%	7%
6-10 days	5%	6%	6%	12%	7%
0-5 days	65%	63%	54%	52%	68%
Volume	209	170	178	156	215

- Material Transfer Agreements (MTA) volume grew by 38% in FY16, from 156 to 215. Much of this increase was attributable to faculty recruitment, particularly in the Cancer Research Focus Area.
- Along with the increased volume of MTAs, improvement was achieved in negotiation times with the amount of MTAs completed within 5 days increasing to 68% of the total submitted to OSP in FY16, up from 52%.

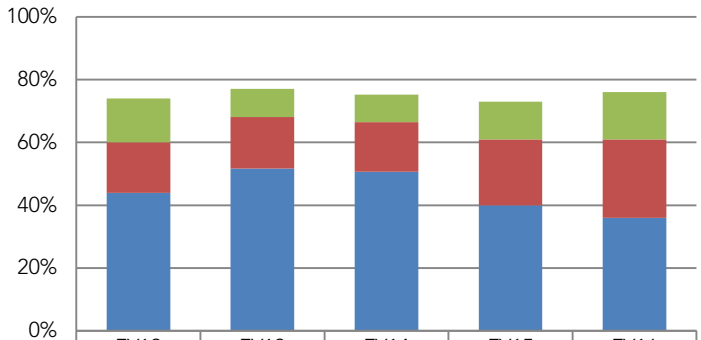
Negotiation Time - Research Agreements
% completed within



	FY12	FY 13	FY14	FY15	FY16
61-90 days	13%	19%	13%	20%	18%
31-60 days	24%	20%	19%	21%	24%
16-30 days	15%	14%	14%	13%	10%
15 days or less	31%	29%	37%	23%	19%
Volume	176	151	145	194	178

88% of the Research Agreements completed in FY16 were clinical in nature, a 9% increase from the prior year.

Negotiation Time - Confidentiality Agreements
% completed within



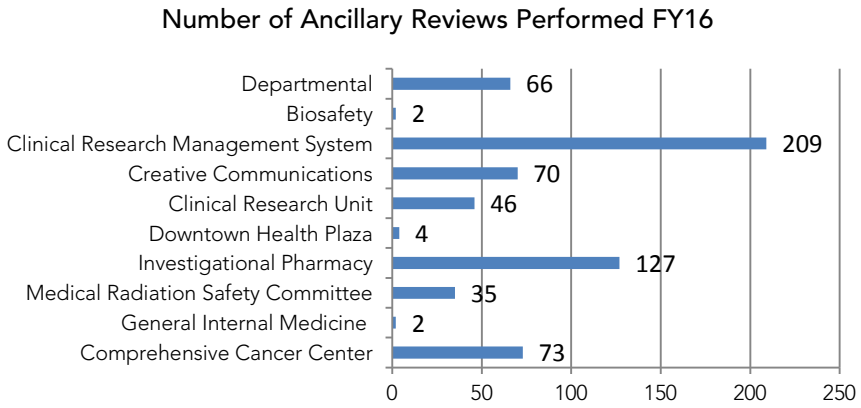
	FY12	FY13	FY14	FY15	FY16
11-15 days	14%	9%	9%	12%	15%
6-10 days	16%	16%	16%	21%	25%
0-5 days	44%	52%	51%	40%	36%
Volume	280	238	298	383	320

Confidentiality Agreements completed within 10 days remained level at 61% and those completed within 15 days increased slightly to 76%.

Human Research Protection Program (HRPP)

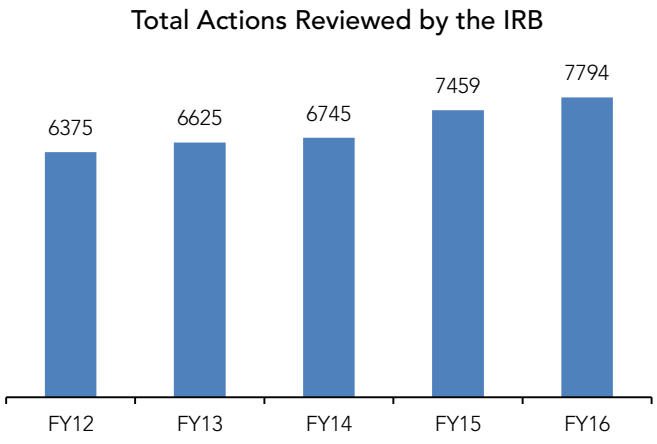
The purpose of the Human Research Protection Program (HRPP) is to protect the safety, rights and welfare of human subjects, who are participants in research, with special attention to vulnerable subjects, including prisoners, pregnant women, and children. The HRPP is guided by the ethical principles for the protection of human research participants as set forth in the Belmont Report and is comprised of the Institutional Review Board (IRB) and all other subject safety components that make up the review and approval process. The groups, who review studies for compliance with laws and best practices in areas such as biosafety and radiation safety, prior to IRB review, are collectively referred to as ancillary committees of the HRPP. The ancillary reviews also incorporate institutional needs. For example, all human research studies are evaluated for billing risks by the Office of Clinical Research and all research involving recruitment advertisements or other branded public-facing material flows through Creative Communications for approval by the Brand Champion prior to IRB approval. Reviews by the ancillary components of the HRPP are illustrated by the graph below.

During FY16, the HRPP as a whole reviewed 7794 actions. As a part of those reviews, the ancillary components were engaged, when applicable, 825 times upon initial review during FY16. The work of the HRPP positively affects participants, the research enterprise, and the community by assisting with the implementation and oversight of ethically appropriate and scientifically valid human research that advances medical knowledge.

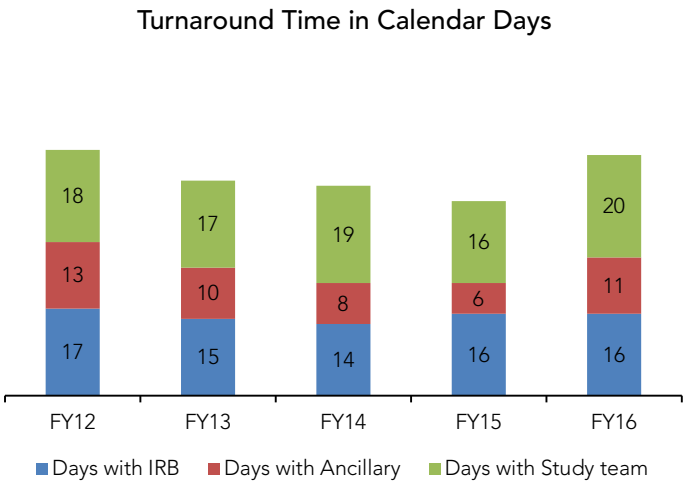


Institutional Review Board (IRB)

The Institutional Review Board (IRB) is comprised of eight panels that each meet every other week. During FY16 the IRB maintained the high level of efficiency first realized in FY12 with the introduction of several process changes in FY10 and FY11. According to the latest figures published by our accrediting body, the Association for the Accreditation of Human Research Protection Programs (AAHRPP), our IRB was again significantly more efficient that the median throughput time reported by accredited academic IRBs. The median time from submission to approval by a convened board at accredited IRBs reported by AAHRPP in 2015 is 43 days. The median number of days from submission to approval by a convened board at our IRB was 30 days, which is 30% faster than the throughput time of our peers. In addition to superior throughput, the IRB has maintained the quality of reviews and compliance with regulatory requirements that are fundamental to its primary mission of protecting human subject safety and welfare. A routine inspection by the Food and Drug Administration (FDA) of IRB compliance in February 2016 showed excellent compliance practices with no need for any corrective actions.



As the graph above shows, there was an 18% increase in the number of actions reviewed over the past five years.



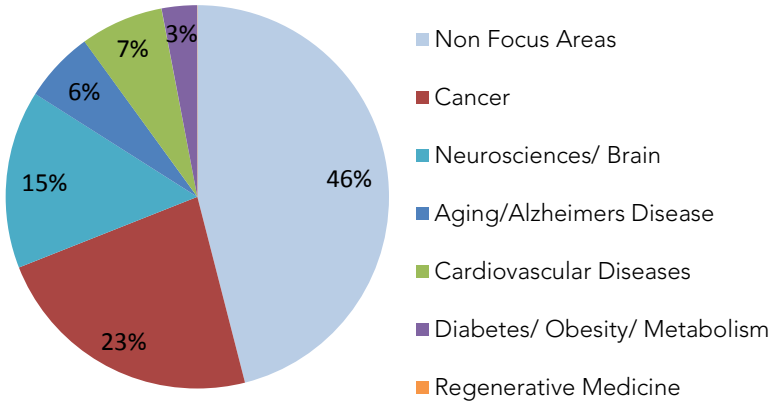
The bars in the graph above show both the overall time from submission to study approval by the IRB, and the time required by the review components and study team. While overall time increased slightly in FY16, time in the hands of the IRB is unchanged from FY15 at 16 calendar days.

Additional HRPP/IRB activities included:

- Serving as the IRB of record for approximately 25 hospitals across the state, making the implementation and conduct of the COMprehensive Post-Acute Stroke Services (COMPASS) study possible.
- Implementation of detailed metrics to meet NCATS reporting requirements.
- Created the IND/IDE Navigation program with the addition of an IND/IDE Navigator successfully underwent routine FDA inspection in February 2016 with no corrective actions required.
- Development and piloting of the Novel Executive summary and Appendix Template (NEAT) consent form. A larger trial being conducted with the Arthrosclerosis Risk in Communities (ARIC) study was developed for launch in FY17.
- Served as part of the site visit interviewee team for the Comprehensive Cancer Center grant renewal effort
- Presented at 2016 Model Agreements & Guidelines International (MAGI) conference and participated in a National Center for Advancing Translational Sciences cross-site processes planning meeting.

Strategic Focus Areas Full Board Studies Approved in FY16

The pie chart to the right illustrates the proportion of new studies approved by the IRB in FY16 that fall into the strategic focus areas for research. We expect the number that fall outside of the strategic areas to decrease with further alignment of research efforts in future years.



Oversight and Outreach Program for Human Research

The Oversight and Outreach (O&O) Program for Human Research monitors regulatory, procedural and protocol compliance on the approval and conduct of human subjects research. Oversight and Outreach specialists work closely with study teams and with the IRB to identify and review deviations, non-compliance, corrective action plans and unanticipated problems. In FY16, 78 safety events required Full Board review, including 16 unanticipated problems, 51 protocol deviations, and 11 other reports that required IRB assessment of risk to human subjects. Also, In FY16 the O&O Program for Human Research conducted group and one-to-one educational sessions and assisted the CTSI with the development of online modules for study coordinator training.

Oversight and Outreach (O&O) Program for Human Research Random Site Visits and IRB Review Process Audits

FY16

81

64 FY15
33 FY14
20 FY13
29 FY12

40 random site visits, 5 for-cause site visits, and 36 audits of IRB review process for new protocol submissions.

Oversight and Outreach taught monthly "lunch and learn" sessions covering the following topics:

- The informed consent process
- The importance of ensuring & documenting subjects meet eligibility criteria for enrollment
- The dos and don'ts of IRB submissions
- How to read a protocol from a coordinator perspective
- The importance of following the protocol as written
- Changes requiring prior approval from the IRB before implementation
- Seven day reporting criteria for unanticipated problems and major protocol deviations
- Best practices in documentation to evidence the protocol was followed as written

Oversight & Outreach continued the practice of assisting study teams individually during site audits by providing valuable services such as helping coordinators create/complete regulatory binders, creating protocol specific study tools for use in investigator initiated and unsponsored studies, and serving as a resource for finding answers to a variety of individual study related questions. O&O also helped to facilitate the implementation of the new Medical Records Documentation policy that requires clinically relevant information discovered during the course of the research to be entered into a research subject's medical record.

IND/IDE Navigation Program

The CTSI offers regulatory support and assistance navigating FDA regulations for Investigational New Drug (IND) and Investigational Device Exemption (IDE) applications. Some of the FY16 accomplishments for this program include:

- Developed a close working relationship with Wake Forest Innovations and Conflicts of Interest Office to bring these two key groups into discussions early to ensure that inventor-investigators are given appropriate advice from the beginning of the process.
- Collaborated with UNC, RTI and Duke to develop the Regulatory Guidance for Academic Research of Drugs and Devices (REGARDD) and website.
- Provided consultations and ongoing guidance to faculty from departments across the Institution (see list below).

FY16 IND/IDE Consultations by Department

Anesthesiology (2)
Cancer Biology (2)
Dermatology (1)
Gastroenterology (2)
Gerontology/Geriatrics (1)
Hematology/Oncology (6)
Internal Medicine & Public Health Sciences (1)
Neruobiology & Anatomy (1)
Neurology (1)
Nursing Research (1)
Obstetrics/Gynecology (1)
Opthamology (1)
Orthopaedics (1)
Otolaryngolgy (1)
Pediatrics/ Neonatology (1)
Surgery, Plasic & Reconstructive (1)
Urology (2)
Wake Forest Innovations (6)

Other IND/IDE Services

- Providing a centralized resource of information and support related to addressing regulatory requirements, obligations, and responsibilities that govern the conduct of clinical research studies under investigator-sponsored INDs and IDEs
- Assisting WFBMC researchers in the preparation or review of initial IND or IDE applications, annual progress reports, and preparing responses to the FDA
- Ensuring appropriate institutional oversight of commitments made under investigator-sponsored INDs and IDE

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 2016 recipients.

Early Career Basic Sciences – Kylie Kavanagh, VMS, MVS, MPH; Comparative Medicine

Early Career Clinical Sciences – Sabina Gesell, PhD; Social Sciences & Health Policy

Mid-Career Basic Sciences – Jasmin Divers, PhD; Biostatistical Sciences

Mid-Career Clinical Sciences – Jamy Ard, MD; Epidemiology & Prevention

Established Basic Sciences – Floyd (Ski) Chilton, III, PhD; Physiology & Pharmacology

Established Clinical Sciences – Ralph B. D'Agostino, Jr., PhD, FASA; Biostatistical Sciences

Clinical Investigator – Joseph Skelton, MD, MS; Pediatrics

Special Awards

Mentoring Award
Elsayed Z. Soliman, MD, Msc, MS

Team Science Award
Multi-Ethnic Study of Atherosclerosis (MESA)

Clinical Research Resources: Clinical Trials Office and Clinical Research Unit

The Clinical Research Resources services continued to expand in FY16. A new Clinical Trials Office Director joined the CTSI at the beginning of FY16. In the first quarter of the FY, after receiving the CTSA, a number of new clinical research services/programs were developed to help provide new and innovative support to clinical research being conducted at WFBMC, adding to the existing services, the clinical research unit, study coordinator pool, and study administration.

Study Coordinator Pool Support

42% BRSA Supported

39% Industry Supported

19% Investigator-Initiated Supported

The Study Coordinator Pool supported a high volume of clinical trial activity in FY16. The pool supported 97 studies for 192 principal investigators across 61different departments.

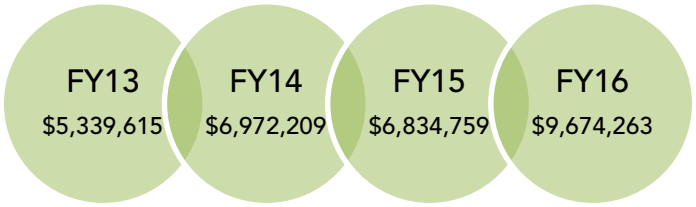
Clinical Research Unit Visits by Type

	Jul	Aug	Sep	Oct	Nov	Dec
Investigator Initiated	323	341	367	382	363	295
Industry	142	105	125	115	105	98
	Jan	Feb	Mar	Apr	May	Jun
Investigator Initiated	316	337	372	263	348	396
Industry	111	105	112	101	111	103

Total Visits: 5436 Studies: 93

The CRU had an active year in FY16 with a steady number of patient visits and increased activity for industry sponsored trials. The CRU supported 93 active trials for 126 principal and co-investigators.

Industry Sponsored Clinical Research Revenue:



The Clinical Trials Office saw a 42% increase in FY16 industry clinical research revenue compared to FY15. A portion of this increase can be tied to improved accounts receivable (A/R) processes.

New Clinical Research Services FY16:

Integrating Special Populations

- ISP Research Navigation Services
- ISP Recruitment Consultation
- Language Services (Document Translation and On-Site Interpretation)
- Voucher Program Funding

Recruitment Unit

- Feasibility Analysis
- Recruitment Consultations
- BeInvolved/Social Media Support
- Accrual Monitoring

Research Subject Advocacy

- ClinicalTrials.gov liaison
- WF I-DSMB support
- Research Participant Hotline

Network Research

- Clinical Research Training
- Study Start-Up Activities
- IRB and Regulatory Submissions
- Assistance with Investigational Drug Receipt, Inventory, Dispensation and Accountability
- Eligibility Review, Consenting, Registration of Participants on Open Clinical Research Studies
- Participant Visit Scheduling and Management
- Data Entry and Query Resolution
- Study Close Out Activities

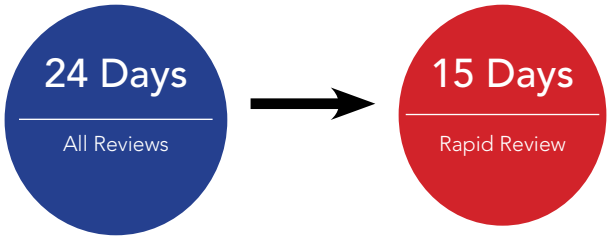
Animal Welfare Program & Institutional Animal Care and Use Committee (IACUC)

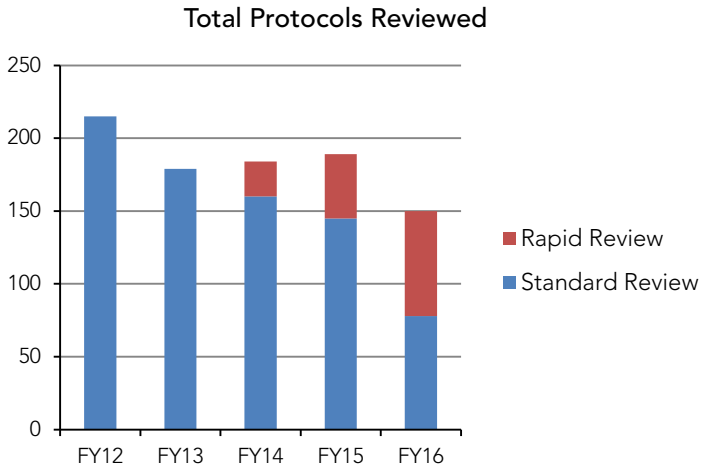
The Animal Welfare Program has been fully accredited by AAALAC International since 1966 and was most recently re-accredited in 2014. Wake Forest is assured by Public Health Sciences (NIH) for animal research and holds a research registration from the U.S. Department of Agriculture.

Institutional Animal Care and Use Committee (IACUC)

This past year, 135 faculty members managed about 450 IACUC protocols across 21 organizational units with 19 different types of animals. The IACUC is comprised of 22 voting members, including 19 faculty, and supported by 5 IACUC staff.

Mice and rats accounted for 92% of the animals used in research at Wake Forest, which is fairly typical for animal research in the U.S. that averages about 95%. Notably, nonhuman primates were the third 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. This emphasis on larger mammals distinguishes the Wake Forest translational research programs from other regional schools. For the third year, the IACUC expanded its use of the 'rapid' review process to nearly half of all new protocols (72 of 150) with a median turnaround time of 15 days. All protocol review turnaround decreased from 27 days to 24 days during the past year.





Oversight and Outreach

The Oversight and Outreach for Animal Research, comprised of two staff, while independent of the IACUC, works in tandem with the IACUC to ensure compliance with federal regulations governing animal research and to promote an environment in which research is conducted according to the highest standards. The primary responsibilities are quality assurance, post-approval monitoring reviews of IACUC protocol activity, management of adverse events and investigations of noncompliance incidents.

In FY16, 98 post-approval monitoring (PAMs) reviews were conducted. In addition, the Quality Assurance Task Force (QATF), an ad-hoc subcommittee of the IACUC, performed in depth pre-IACUC approval reviews of two high risk studies and post-IACUC approval reviews of three targeted protocols. One-on-one and individual research team training has been a focus of PAM reviews and has been extremely effective in increasing compliance. It has also helped to standardize operations across campuses and between research labs. In conjunction with IACUC staff, guidance was given. The Oversight and Outreach leader and the Institutional Official led a workshop on "Responsible Animal Research: Creating a Culture of Care, Integrity and Responsibility" at the SRA Regional meeting.

Laboratory Animal Training for Research Staff

The program, initiated in 2010, is run by a dedicated trainer who teaches research staff basic animal handling and methodology and manages a dedicated Laboratory Animal Training Facility. Training is available for users of all species, but is mandatory for rodent users. Training includes handling, restraint, injections, blood collection, IV catheter placement, anesthesia, euthanasia, pain assessment and scoring, general recordkeeping, and aseptic surgical technique. In FY16, 394 staff received formal training – up from 167 in FY15 - with an overall satisfaction rating of 4.9 out of 5.

Wake Forest Laboratory Animal Training Facility

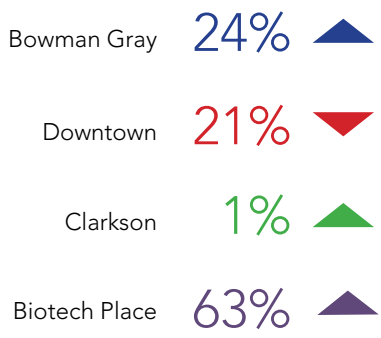
Animal Resources Program (ARP)

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 31,000 animals (17 different species). The FY16 annual operating budget for the ARP was approximately $8.4M with 60-65% of operating expenses recovered via per diem income.

This past year the ARP has been working through a required large system upgrade to our financial management software from Granite/Topaz Enterprise to Topaz Elements. Topaz Elements is a suite of scalable web-based software applications designed to meet specific research management needs. This upgrade also requires electronic census, which will move the ARP from paper-based manual counting of animals to bar code and RFID census collection.

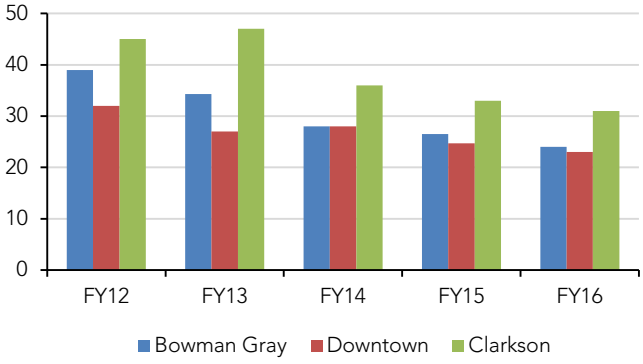
The ARP continues to assist Wake Forest School of Medicine's development of Scientific Neighborhoods to promote synergy among scientists. Aligning with this goal, the ARP has begun to reorganize animal housing locations to accommodate the relocation of investigators participating in a Scientific Neighborhood and their study animals.



Animal Care Days

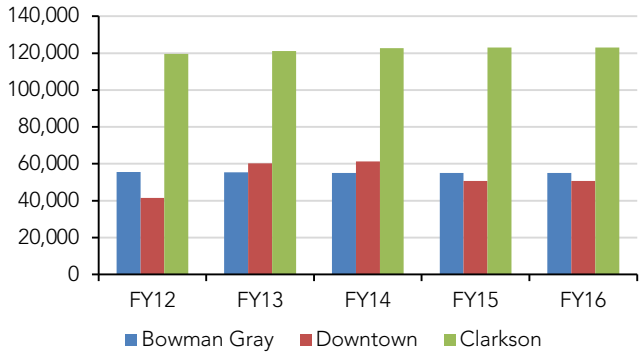
Wake Forest School of Medicine has focused areas of research as part of the Institution's Strategic Plan. The upswing in Animal Care Days (ACD) on the Bowman Gray campus is partly due to successful faculty recruitment in response to the realignment with the Strategic Plan. The increase in ACD at the Biotech Place Building and the decrease on the Downtown campus is likely due to relocations of laboratories and animals to Biotech Place. Between FY15 and FY16, the ARP experienced an actual net increase of 103,132 (6%) animal care days over all campuses. This rise was due to a net increase in care days of all categories of animals; rodents (+3%), non-rodent/non-primate (+156%) and non-human primate (-1%) populations. There continues to be anticipated future increases in current rodent ACD in the areas of diabetes and cancer. The Reynolda Campus is not represented in this ACD data due to low census.

Total FTEs by Campus



For FY16, the ARP was supported by approximately 99 full- or part-time employees. This was a 6% decrease from FY15 and a 10% decrease from FY14 in total FTE. The ARP has adjusted staffing by campus in response to the increase in animal census to fit current and projected needs. The Downtown Campus includes Biotech Place in this chart.

ARP Space by Campus (sq. ft.)



Space on all campuses has remained stable for FY16. Proposed research activities and animal transfers from Bowman Gray to Downtown ARP facilities have been delayed. The Downtown Campus includes Biotech Place in this chart.

Community Engagement

The Program in Community Engagement (PCE) enjoyed a great deal of growth in FY16, furthering 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 to provide guidance to the PCE and offer space for community connections. One example of that collaboration was that the hours of operation of the Hazardous Household Waste facility were changed to extend Saturday hours due to concern from the community that the constrained hours were causing environmental health issues. The PCE provided scientific information about the public health implications associated with improper disposal of hazardous household waste and worked with local officials on addressing the community's concerns.

Program initiatives included collaborating with Speas Global Elementary School on the 2015 Science Fair Workshops and conducting a community tour for faculty and staff from across the medical center. The tour offered an expanded cultural understanding of the local community, including the history influencing current health disparities; the barriers to effective health care delivery and participation in research studies; and the impact of patients' environments on their health. The PCE also initiated the Assessing Barriers to Cycling Diversity (ABCD) project, gaining insight into barriers African America face in riding a bicycle. ABCD methods include in-depth interviews and systematic observations of greenways by citizen scientists.

In addition, the PCE engaged a Community Intern, who partners with community groups to create a network of coordinated care for immigrant children in Forsyth County, and an Academic Intern, who focuses on program evaluation for non-profit organizations. The Academic Intern collaborated with the PCE on the Youth Perspectives on Violence Photovoice Project, the findings for which were publically presented at Biotech Place on June 22, 2016.

The PCE contracted two Community Research Associates (CRAs) who work closely with the violence as a health disparity work group, helped to increase the program's social media presence, engaged citizen scientists, and planed workshops.

The Community Engagement Affinity Group currently has 59 members and continues to foster information sharing among faculty and staff that share common interest in community-engaged research.

Public presentation of youth photovoice research project at Biotech Place on June 22, 2016

Education and Training Program

Over the past year, the Education and Training Program, working with a wide range of faculty and staff, has enhanced its program infrastructure and planned and implemented a broad cross-section of educational activities for varied constituencies across the institution. Selected highlights are described below.

Translational Science Education Coordinating Committee

In December 2015, the Translational Science Education Coordinating Committee (TSECC), comprised of representatives from diverse research education stakeholders across the institution, was established. The TSECC's goals are to a) align educational activities to promote integration and synergies; b) review educational programs' performance and provide guidance to increase their success; and c) identify opportunities to reduce administrative burden and achieve economies of scale.

Faculty Career Development

- To promote the research careers of promising early career investigators, the Education Program managed two important initiatives, the KL2 Mentored Career Development Program and the Translational Research Academy. After an extensive review process, three early career faculty members were selected as KL2 Scholars for 2016-2018, receiving significant salary support, funding to implement their educational and research plans, and comprehensive support services. A fifth cohort of 19 early career faculty was selected for the 2016-2018 Translational Research Academy, a research education and networking program.

- A new Mentor Academy was planned and implemented this year. Twelve mid-career and senior faculty participated in a formal, evidence-based 6-months long didactic and experiential training program to enhance their knowledge and skills in both research and career-related mentoring. Participant evaluations were overwhelmingly positive with all indicating that Mentor Academy was a valuable use of their time and that they were very likely or likely to recommend the training to a colleague.

- The CTSI Clinical Informatics Affinity Group and Education Program collaborated to sponsor a new 16-hour short course entitled Introduction to Clinical Informatics: Data Acquisition, Analyses, and Applications. Thirty-nine faculty and staff members participated in the program to enhance their understanding of the flow of data and information in the health system, clinical data standards, decision science, and statistical methods and ethical issues in using electronic health record data.

Research Staff Education

The Clinical Study Staff Orientation online modules were completed this year. This competency-based orientation program was designed to ensure that clinical study staff team members receive consistent and comprehensive education to enable them to fulfill their major job responsibilities. Fifteen modules are available, 11 of which were released in FY16. Topics cover the gamut from study start-up to study closeout, informed consent, working with the IRB, quality assurance, recruiting and working with participants, documentation, and clinical research billing. Completion of the modules is voluntary, but 120 participants have completed one or more modules during FY16.

Administrative and Financial Staff

The Education Program collaborated with the Office of Sponsored Programs to revamp the Research Administration Certificate (RAC) Program into a cohort model. The Certificate program requires 11 courses: 8 are required and 3 electives enable participants to focus on Grants Management, Contracts Management, or Financial Management. The goals of the cohort model were to enable participants to complete program requirements in a more concentrated time frame and to have enhanced networking opportunities. The initial RAC cohort began in spring 2016 with 26 participants; 9 have completed all RAC requirements and 5 are completing electives. Scheduling changes increased access for participants and course attendance increased markedly.

Research Education for Trainees

At the initial TSECC meeting, enhanced education, programs, and services to support scholarly activity for residents and fellows was identified as a high-priority area for integration. In April 2016, the CTSI sponsored a retreat for Residency and Fellowship Program Directors, ACGME leaders, and leaders of the Graduate School, translational science graduate programs, and the CTSI Education leadership team. The highest priority was given to developing a core curriculum in research education that Program Directors could access for their trainees. Building upon the existing research education curriculum sponsored by the Department of Internal Medicine, we established a plan and timeline to record a series of fourteen lectures, make them available online, and develop supplemental learning materials that could be used in small groups in individual departments, at the discretion of the Program Directors. The modules of the Research Curriculum for Residents and Fellows will be released as available, with the entire curriculum available by spring 2017.

We managed the long-standing Medical Student Research Program (MSRP) providing a nine-week summer research experience with a faculty mentor; observational experiences with the IRB or IACUC; training in responsible conduct of research, scientific communication, and discussing clinical research with patients. Thirty-one students participated in 2015; and 37 participated in 2016. We also sponsored the annual Medical Student Research Day in late September 2015, with 51 students participating. The event included a keynote speaker, a poster session of student projects, and awards for students with outstanding research projects. We also successfully competed for the renewal of our NIH NIDDK Short-term Research Training Grant. Funding for the MSRP comes from the NIH T35 grant, institutional funds, and endowment funds.