Statue of Senator Charles Sumner Outside Johnston Gate

RESEARCH ADMINISTRATION SERVICES

2014 ANNUAL REPORT
Dear Colleagues,

I am very pleased to present the Research Administration Services (RAS) Annual Report. The RAS mission is to support the research and scholarly activities of FAS faculty in collaboration with research and administrative staff. Our services range from finding funding and proposal development support to providing expertise and tools to efficiently manage the research enterprise. The services we provide are delivered by a highly motivated and talented team -- our aim is to provide excellent service that is responsive to faculty needs.

Our accomplishments of this past year align with our mission, the FAS mission, and our emphasis on excellent service. In FY14, the RAS team contributed to a number of outstanding initiatives and improvements in service delivery across a wide range of fronts, including an award of approximately $12M to establish an Energy Frontier Research Center directed by Professor Cynthia Friend, the first to be established at Harvard. Our Committee on the Use of Human Subjects (CUHS) and the IACUC Committee completed a successful transition to electronic based submission systems and CUHS saw an increase in submissions of 12% with a significant decrease in the average turnaround time. The IACUC was fully accredited with no suggestions for improvement. FAS also received a clean A-133 Audit report with no findings. RAS also played an active role in the redesign of the Harvard certificate program for research administrators, REACH. These accomplishments highlight only a few of the numerous ways we supported our faculty and researchers in FAS.

I would like to acknowledge Dean Michael Smith and Dean Leslie Kirwan for their continued support of RAS. Their advocacy for our work and their commitment to provide the necessary resources enable our staff to provide excellent service to the faculty and staff of the FAS.

I hope you find this report to be informative and the information presented helpful. Fiscal Year 2014 was a busy, and exciting time in RAS. We look forward to continued service to our faculty and staff and to furthering our partnerships across the FAS, other schools, and the University.

Sincerely,

Patrick Fitzgerald

Associate Dean for Research Administration
Executive Summary

Research Administration Services supports the research and scholarly activities of FAS faculty in collaboration with researchers and administrative staff.

Who We Are

RAS, formed in 2007 by the Faculty of Arts and Sciences, merged administrators from the FAS Office of Finance and the Science Center under one Associate Dean. The Associate Dean reports directly to the FAS Dean of Administration and Finance.

We facilitate research by partnering with departments, schools, and central offices to promote efficient and effective management of research and research funding. We protect FAS research by developing, interpreting, and administering research policy, resources, and procedures. Finally, we promote professional development of researchers and research administrators in an environment of continuous change.

RAS also represents the interests of FAS researchers and research administrators in discussions and negotiations with University central offices such as the Office for Sponsored Programs, the Office of the Vice Provost for Research, the Office of Technology Development, and Financial Systems Solutions. In addition, the Committee on the Use of Human Subjects (CUHS) reviews protocols for all human subjects research taking place at Cambridge- and Allston-based schools.

Functional Areas

Research Development works directly with faculty to identify funding sources and provides strategic advice for the pursuit of sponsored funding.

Divisional Support aids departments and divisions in the preparation of grant applications, reviews proposals to ensure adherence to FAS and Sponsor guidelines, provides post-award services as needed, and manages the FAS Temporary Research Administration Consulting (FASTRAC) program.

Research Finance supports the departments, labs, and centers of the Faculty of Arts and Sciences in the management and fiscal responsibility of sponsored funds.

Research Compliance advises researchers in areas such as research integrity, conflicts of interest, export controls, and biosafety in conjunction with the faculty Committees on Research Policy and Professional Conduct.

Institutional Animal Care and Use Committee (IACUC) Administration supports the faculty-led IACUC, helping researchers to follow a myriad of regulations designed to foster the most humane use and care of animals in research.

Committee on the Use of Human Subjects (CUHS) Administration supports the faculty-led Institutional Review Board (IRB) for the University-Area, ensuring that the basic ethical principles are followed when human subjects research is performed.

John Harvard Statue
Research Administration Services, a Department of the Faculty of Arts and Sciences, works with Central Offices (in Gray), and is Governed by the FAS Dean's Office, the Dean of Administration and Finance, and Faculty-led Committees (in Blue).

NOTE: The organization chart above is simplified and does not represent actual reporting relationships within RAS.
RESEARCH ADMINISTRATION SERVICES ANNUAL REPORT FY 2014

Major Accomplishments

In FY14, RAS contributed to the following initiatives:

- Deployment of the electronic effort certification reporting system ("eCERT"), resulting in four successful consecutive quarters of timely certifications
- Enhancement of systems for human subjects research ("ESTR") and animal subjects research ("eProtocol") resulting in significant improvements in service and turnaround time
- Establishment of Harvard's first Energy Frontier Research Center (EFRC) at Harvard, resulting from receipt of a $12M Department of Energy award to Professor Cynthia Friend
- Our first overhaul of the RAS website since 2007, the year RAS was established, providing a new RAS web presence with a customer-centric focus
- Redesign of the curriculum for the "Research Excellence in Administration Certificate at Harvard" (REACH) Foundations professional development program, resulting in new and enhanced training for research administrators

RAS staff garnered many individual honors:

- Dean's Distinction award winner: Erin Cromack
- Four Impact Award Winners: Mandy Ellenwood, Charlotte Gallant, Ann Janik, and Denise Moody
- Two staff, Ellyn Lane and Kathy Meunier, earned the title "Certified Professional IACUC Administrator"

Four RAS staff members received promotions this past year:

- Betsy Draper, Assistant Director of IRB Administration
- Nuala McGowan, Director of Research Finance and Compliance
- Steve Crowley, IACUC Administrator
- Julie McCarthy, IACUC Coordinator

Finally, RAS staff presented at professional conferences and workshops across the country, including the National Council of University Research Administrators (NCURA) and the National Organization of Research Development Professionals (NORDP).
Goals for Next Year

- Increase Awareness of RAS Services and Support (externally)
  - Communicate our mission of service to faculty and administrators in print and via the web
  - Provide metrics/measurable accomplishments to University and FAS senior administrators
- Increase Awareness of the reach of RAS Services and Support across each functional area (internally)
  - Topical brown bags
  - Shadowing program
- Provide proactive training and outreach to RAS customers (faculty, researchers, and administrators) to reduce administrative burden, increase service and prevent non-compliance
  - Provide localized outreach efforts
  - Drop-in sessions

### Sponsored Expenses FY10-FY14, Including ARRA and Financial Aid

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<tr>
<th>Year</th>
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<th>Non-Federal</th>
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Research Development

Purpose

Research Development provides strategic advice and support for all FAS faculty who are seeking internal or external grant funding from public or private sponsors. We help faculty identify appropriate funding opportunities and provide support for proposal development and submission for a wide range of projects. These include individual investigator grants and large-scale center grants, early career awards, sabbatical and fellowship funding, book projects, exhibitions, outreach programs, curriculum development, and travel to conferences or archives.

The team assists with the development of non-disciplinary proposal components like management plans, broader impact plans, program evaluation plans, postdoctoral mentoring plans, outreach plans and data management plans. The team also developed additional resources and templates to aid with proposal development. In FY14 we responded to over 319 requests for support, an increase of 39% over FY13.

We work in close partnership with colleagues Mandy Ellenwood and Samantha Schwartz and with FAS administrators. We also help connect faculty with Harvard resources and services that can offer additional support. We partner closely with divisional leadership to ensure that we provide services and resources that are responsive to faculty and divisional needs and priorities. All of these services, coupled with the robust resources we created, provide valuable support to researchers who face an increasingly competitive funding environment and diminishing resources for external funding.

Award Highlights

In FY14, Research Development was pleased to aid in the creation of many successful proposals that led to exciting new research initiatives. A sample of these awards are highlighted below:

- **Amgen Scholars Program ($850K), Harvard College.** Beginning in the summer of 2015, this establishes the first Amgen Scholars program at Harvard, a highly selective initiative that provides 20 undergraduate students nationwide with the opportunity to engage in a hands-on summer research experience with the world’s leading scientists. Harvard joins MIT, CalTech, Berkeley, Columbia and other leading institutions as a participating host institution.

- **NIH Early Independence Award, Alison Hill, a postdoctoral fellow at the Program for Evolutionary Dynamics ($2.5).** Dr. Hill was the second FAS postdoctoral scholar to receive the National Institutes of Health (NIH) prestigious Early Independence Award (EIA); she will use this funding to add graduate students to her research team and develop mathematical and statistical tools to help predict and interpret new curative strategies for HIV.

- **NIH New Innovator Award, Professor Ethan Garner, Assistant Professor, Department of Molecular and Cellular Biology, ($2.5M).** Established in 2007, the New Innovator Award supports exceptionally creative early career investigators pursuing pioneering, potentially high-impact research ideas in biomedical and behavioral science.
FAS early career faculty garnered approximately $6M in prestigious early career and scholar awards, including the Packard Fellowship for Science and Engineering, the Sloan Fellowship (6 awards), the Smith Family Award for Biomedical Research, the NSF Faculty Early Career award and others. Internal funding increased, with eleven (11) Milton Fund grants awarded to FAS faculty ($440K). Every FAS division received multiple Milton awards. Total awards to FAS faculty increased 57% in FY14.

On June 18, 2014, the Department of Energy announced an award of approximately $12 million to establish an Energy Frontier Research Center (EFRC) at Harvard, to be directed by Professor Cynthia Friend. This Center, Integrated Materials for Sustainable Catalysis (IMASC) is the first to be established at Harvard and one of ten new centers nationwide. Harvard’s new center will integrate collaborative work from CCB and SEAS with Lawrence Livermore National Laboratory, Lawrence Berkeley National Laboratory, Brookhaven National Laboratory, University of Notre Dame, Tufts University, the Fritz Haber Institute in Berlin and the National Research Council of Italy. Student and postdoctoral scientists working at IMASC will tackle some of the most important energy challenges facing the nation, and receive exposure to cutting-edge experimental and computational tools in an environment that cuts across traditional disciplines.

National Endowment for the Humanities, The Giza Project: Consolidated Archaeological Reference Database ($300K), Professor Peter Der Manuelian. This award supports the creation of an integrated database of archaeological data from excavations at the Egyptian site of Giza, distributed across ten institutions in the United States, Europe, and Egypt, and representing some 170,000 digital files.

National Endowment for the Humanities, Professor Jeffrey Hamburger, ($40K). This award will support the planning phase of a Boston-area exhibition, a catalog, a website, educational programs, and an international conference on illuminated manuscripts dating from the 9th to the 16th century.

**Outreach and Programming Highlights**

In addition to outreach meetings with all new faculty across FAS, we offered or participated in the following outreach activities and programs in FY14:

- History of Art & Architecture, 3/11/14
- Anthropology, 9/10/13
- Harvard Center for Astrophysics, CfA: 12/12/13, Finding Funding Workshop
- Arts and Humanities, Department Chairs meeting
- Social Science New Faculty Luncheon
- Social Science Council
- Science Council
- Science Division, Faculty Scientific Management Series
- Science Division, New Faculty Reception
- Marc Ruppel, Division of Public Programs, National Endowment for the Humanities, Campus Visit
- Krastan Blagoev, Program Director, National Science Foundation, Campus Visit, The Brain Initiative
New Resources

- In FY14, Erin Cromack played the lead role in the launch of the new University-wide electronic system for managing the limited submissions and internal grants process, the Harvard University Funding Portal (HUFP).
- Caitlin McDermott-Murphy, in collaboration with Sarah Elwell, division of science, developed a new online resource for science faculty, Facilities and Resources Descriptions. This resource includes descriptions and templates for use in applications to external funders.
- Jennifer Corby monitored funding trends related to the BRAIN (Brain Research through Advancing Innovative Neurotechnologies Initiative) and disseminated these funding opportunities via a newly created Brain Initiative listserv designed for faculty affiliates of the Center for Brain Science, and the Mind, Brain and Behavior Initiative. In September 2014, two groups of FAS researchers became the first researchers nationwide to receive BRAIN Initiative funding; they will receive $8M over the next three years.

Praise from Faculty, Researchers, and Staff

I am so very grateful that you took the time to put together this incredibly useful funding search for me. I’ve had a chance to review it briefly, though shall certainly plan to be back in touch with you with any additional queries. In the meantime, my sincerest thanks for all of your hard work on my behalf.

...[this responsiveness review for my NSF Career award] looks AMAZING! Thank you so much!!! This really surpassed my expectations. I look forward to being in touch soon. Again, thanks a million; this is a HUGE help.

I’d like to take this opportunity to say how much the OVPR has appreciated [your] commitment to improving the LSO process, finding and contracting with a vendor, and implementing the new software system. I am personally grateful for the immense amount of time [you] spent over the summer getting the LSO system off the ground.

Thank you again for ...conducting an incredibly helpful and productive [finding funding] workshop. I received very positive feedback afterwards from every person at the workshop. One investigator wrote, “This was one of the most effective sessions of the kind I’ve ever attended. Not only did I learn much but I came away empowered!”

...this new Facilities and Resources Descriptions resource... is awesome! Excellent to have all of this easily accessible and online. It is just really good to have them all in one place. You should advertise this resource to everyone in the sciences, because there is always a “resources” description required, and this will help a lot....

I can’t thank you enough…I can detect all the time and effort that went into this. It provides exactly the kind of targeted prospects and logistical information that we need to be able to move forward.

...When she came to our faculty chairs meeting a month ago, she immediately grasped the questions that were raised and was able to respond in a smart and generous way, explaining what FAS RAS can do and also what it can’t. She comes across as knowledgeable and smart but not condescending and that is exactly what our faculty need to see if they are to reach out to RAS.
Divisional Support

Purpose

Divisional Support sponsored research administrative staff support faculty and administrators across the three FAS divisions. The DS team works with divisional and departmental leadership to support all sponsored research needs as they arise across a variety of sponsored research issues.

Two positions are dedicated to pre- and post-award support in the Arts and Humanities and Social Science Divisions. In addition, the FAS Temporary Research Administration Consulting (FASTRAC) program provides direct support to FAS departments and centers for short term vacancy needs and project-based consulting services.

DS staff duties include preparation, development, and/or review of non-disciplinary components of proposals to enhance proposal competitiveness. Staff also reviews and approves FAS research proposal submissions on behalf of the Dean to ensure compliance with sponsor and University guidelines and policies, as well as sponsor terms and conditions.

The DS team members also manage sponsored awards for financial monitoring and compliance. They provide interpretive support on sponsor requirements and University policy and provide advice to divisional and departmental leadership and administration on a variety of sponsored research related issues.

Major Accomplishments

- Formation of the RAS Council, a cross department and division sponsored leadership group that vets, advises and collaborates on policies, initiatives and activities impacting the sponsored research community.
- Formation of the RAS Coffee Club, a bi-monthly small group drop-in session around topics of interest and importance to the departments and the faculty they serve.
- Review and revision of the FAS/RAS/OSP Roles and Responsibilities Matrix to streamline procedures and provide ease and clarity throughout the proposal review process.
- Increase in scope of Mandy Ellenwood’s existing role in the Social Science (SS) division to include proposal review and sign off, allowing for in depth review and support of SS division proposals and one main point of contact in RAS. In addition, Mandy received approximately fifty requests from SS departments and faculty this past year.
- Active in the leadership and facilitation of the University Research Administration Training Team which:
  - coordinates the University-wide REACH program, Harvard’s certificate program in research administration.
  - created an online module called “Financial Oversight of Sponsored Projects: What Researchers Need to Know.”
- RAS Sponsored Research Administrators also provide support and leadership for a variety of outreach activities formal and informal, including: RAS Council, RAS Friday Monthly Meetings, RAS Coffee Club, Divisional Faculty, Chairs, and Department Administrator meetings and forums—frequently in partnership with the RAS Research Development team—FAS Department Administrators meetings as needed.

<table>
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<th>Number of Unique Sponsors Funding FAS Projects</th>
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<td>Federal</td>
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<td>Foundations</td>
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<td>Subcontracts (to distinct primes)</td>
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<tr>
<td>Corporate</td>
</tr>
<tr>
<td>Foreign Other</td>
</tr>
<tr>
<td>Local, state and foreign governments</td>
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<td><strong>Total</strong></td>
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• Samantha Schwartz provided direct service to the Arts and Humanities division by fielding 38 requests in FY14. This total includes new sponsored proposals, support for intricate no-cost extension and rebudget requests, sabbatical/fellowship proposals, and non-sponsored proposals.

• The FASTRAC program was active July through November 2013. During this time, they assisted five departments with two maternity leaves, two vacancies, and one medical leave. In August, we were able to refill one position and we are working to hire another consultant soon.

### Praise from Faculty, Researchers and Staff

... I have to tell you that [she] went so far above and beyond the call of duty with our last grant submission, a small gesture of thanks was the least we could do. She was truly a rock star, and we could not have done it without her. Suffice it to say, we were very grateful for her help (and, it should be said, for all the great support RAS has provided over the last year!). You’ve really got an outstanding team.

You have our deepest gratitude... for getting us through a crazy period of transition. Your professionalism and expertise are a great asset, and I’m so glad you spent the past several months with us. Our doors are always open to you!

Just a brief note, to say thank you, for a very thorough quality review of the recent Physics proposals. Staff at the department have commented how they really appreciate working with such a great quality review team.

Just finished an NSF...and I have to say she was MOST helpful with catching some of the nuances in the solicitation that I missed. I thanked her for her great work and really did appreciate the help.

I am extremely pleased to have [her] as a colleague and partner in supporting FAS Arts and Humanities clients.

### Proposals Reviewed and Approved by RAS

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<td><strong>Total Reviewed</strong></td>
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Research Finance

Purpose

In collaboration with researchers, department administrators, the Office for Sponsored Programs, and central administration, we provide advice and assistance to ensure financial compliance and reporting of sponsored funds. Our team offers guidance on Post Award policies and procedures relating to cost-sharing, cost transfers, effort reporting, service centers, sub-recipient monitoring, award closeout and spending sponsored funds. We also provide audit support, such as the annual A-133 audit, and are responsible for assisting in the development of the University-Area Facilities and Administrative (F&A) cost rate.

Major Accomplishments

eCRT Effort Reporting System - Rollout and Implementation

In the Fall of 2013, Harvard implemented an electronic University-wide Effort Reporting and Salary Certification System (eCRT), which captures faculty and non-faculty salaries charged directly to federal awards. Effort (salary and wages) can represent more than sixty percent of total grant costs and is heavily scrutinized by the federal government. Transitioning to an electronic system was challenging but it afforded Harvard the opportunity to streamline 12 different school policies into one University-wide policy. We replaced a manual monthly paper process for non-faculty with an electronic quarterly process, decreasing the number of effort statements overall for our PIs. We have had four successful consecutive quarters of timely certifications, as demonstrated in the graphs on this page.

Clean Audit Reports - A-133 external audit and RMAS Service Center Audit

- A-133 Audit: Our team successfully managed the annual A-133 Audit process this past year, and provided the resources necessary to assist departments to obtain, review and submit the appropriate supporting documentation to PricewaterhouseCoopers on time. We received a clean A-133 Audit report with no findings noted for the FAS.

- RMAS Service Center Audit: The FAS currently has 21 academic service centers with annual operating expenses of $13 million dollars operating in 10 departments. We had two facilities selected for an Internal Audit, both of which performed very well. RMAS noted that the approval process and key controls were deficient in the other Harvard Schools.
The FAS was identified as the only school that displayed evidence of a solid annual approval process for our Service Center rates, a new policy requirement. The auditors also noted that our process in the FAS should be “modeled” University-wide.

ARRA Reporting

The American Recovery and Reinvestment Act of 2009 brought approximately $45 Million dollars of funding to the FAS between 2009 and 2014, creating over 35 jobs. The FAS received 76 awards, spanning 18 departments, from several federal agencies (illustrated in the graph below). The Research Finance team managed and monitored the federal reporting requirements and delivered 18 consecutive quarters of successful reports on time. We continue to play an active role as the funding winds down and created closeout procedures for finalizing the ARRA reporting process.

ARRA Awards by Sponsor, $ in Millions, %

DOE, 4.5, 10%
NSF, 16.7, 37%
NIH, 22.5, 50%
NIST, 1.35, 3%

Indirect Cost Rate (IDC) - Extension

The Research Finance team is responsible for assisting in the development of the University-Area indirect cost (IDC) rate, also known as the Facilities and Administrative (F&A) cost rate. Our IDC rate is calculated approximately every four years. This process involves significant resources and expertise, and our calculations undergo extreme scrutiny by the Cost Allocation Services (CAS) of DHHS. The University-Area was scheduled to calculate the IDC rate this year; however, RAS acquired information that positioned us to seek a “one-time” extension to our current negotiated rate from the federal government. This extension will result in significant savings in time and resources for the FAS. Even though the University-Area is not undergoing a full rate proposal, the Research Finance team is working with 9 departments, representing 90% of the FAS research dollars, in performing a “space survey” to functionalize their space.

Oracle Fixed Assets Rollout and Transition

The Research Finance team managed and monitored the equipment management process in the FAS until recently, when it transitioned to Oracle fixed assets in July 2014. The FAS has approximately 6,000 assets with a gross value of over $222 Million dollars, with biennial audit reporting requirements. The team played a major role in preparing the quality and accuracy of the data for the transition to the new Oracle system, which will be managed by the FAS finance office.

Praise from Faculty, Researchers, and Staff

I know that outstanding result [of the audit] is attributable to the efforts of all of you, in partnership, and just want to pass along sincere thanks for your hard work – not just when there is an audit coming, but day in and day out, in support of the faculty and students.

Just a quick note to express my appreciation for your contributions to the FAS in such a short time. Your skills and willingness to embrace and tackle new assignments are noticed and appreciated!

Thank you for your diligence on this. We are very appreciative for the support RAS gives us and the University.

Thank you for preparing and sending the report and letting us know the status of the grant and the expectation of what is to come, this is very helpful.
Research Compliance

Purpose

The Research Compliance team provides independent oversight of the FAS research compliance programs, activities, and processes. Our commitment to compliance includes the development of general and specific training, policies, and appropriate oversight and monitoring to assist members of the FAS community in conducting research activities. The University is committed to responsible research through regulatory compliance in the key areas of Conflicts of Interest, Research Integrity, Export Controls, and the Responsible Conduct of Research.

Conflicts of Interest

Under the FAS conflicts of interest (COI) policy, all faculty members and holders of a teaching appointment, except any senior non-ladder or non-ladder individual whose FAS appointment is less than 50 percent, as well as any Investigator on a National Science Foundation (NSF), Public Health Service (PHS), or sponsor who follows PHS conflict of interest regulations (PHS+) must submit a financial disclosure at least once annually. Therefore, the total number of participants required to report based on University and Sponsor policies is 1,424 (includes 703 Investigators).

Nearly 20% of the financial disclosures result in a “needs review” status, which may include a significant financial interest, a fiduciary or management role, or receipt of royalties on intellectual property. Most of the disclosures result in “no conflict”. However, the FAS has six (6) active conflict management plans in place that relate to sponsored funding.

Research Integrity

Under the procedures to respond to allegations of misconduct in research, the Research Integrity Officer is responsible for working with the Committee on Professional Conduct, an FAS faculty-led group, to reply to all allegations of research misconduct in the FAS. FAS receives approximately twenty (20) to twenty four (24) allegations of research misconduct in a given year. Of these, three (3) to four (4) cases move to the inquiry phase and subsequently one (1) to two (2) go to a full investigation. A full investigation can take from six weeks to six months but on rare occasions up to two years depending on the complexity of the case.

Export Controls

The FAS is responsible for ensuring that all faculty and departments are in full compliance with all export control regulations as issued by the federal government. Under various regulations instituted between 2013 and 2014, the FAS investigated and approved a total of seventy five applications for H1B1 visas sixty material transfer agreements. In addition, we analyzed fifteen proposals and research agreements to ensure the proposed export control language was acceptable to the FAS. For sixty eight scientific research proposals, we offered guidance to faculty in making a determination as to what specific export regulations applied and, where necessary, provided assistance to acquire licenses from the appropriate regulatory agency.

Responsible Conduct of Research (RCR)

RAS sponsored two RCR classes last year, attracting a diverse group of Harvard-Affiliated researchers. RCR is a highly recommended “best practices” course for those desiring to deepen their knowledge of ethical research and responsible conduct. It is also an excellent professional opportunity for anyone interested in furthering a career in research. Praise from student evaluations included:

Important information was delivered directly and concisely. Very well-organized structure for the entire course. The online material was very useful and informative. I felt that this was the BEST responsible conduct of research course that I have ever taken (and I have taken a few others).
Purpose

The Institutional Animal Care and Use Committee (IACUC) administrative staff are responsible for the following functions for the FAS as well as the School of Engineering and Applied Sciences:

- Support IACUC functions as promulgated by federal, state, and local animal care and use rules and regulations
- Oversight and application of the occupational health program for (1) personnel working with or near animals, (2) research personnel training program for the use of animals, and (3) noncompliance tracking and corrective measure program
- Vetting of sponsored research proposals against approved IACUC protocols and confirmation of IACUC approval to funding agencies
- Maintenance of institutional assurance, accreditation, registration, and license documents for the use of vertebrate species.
- Annual reporting to federal, state, and city agencies

Major Accomplishments

- The IACUC program received full accreditation with no suggestions for improvement from the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) (site visit completed January 2014; accreditation letter received July 2014)
- Both the USDA and the City of Cambridge reported no findings during their annual inspections (June-July 2014 and October 2013, respectively)
- We achieved 100% compliance with active users who require re-assessment on a triennial basis in the occupational health program
- We completely migrated Word-version protocol documents to the online eProtocol system by May 2014, including 122 protocols during the FY14 time period
- The number of full committee meetings increased from 2-3 per year to 11 total for FY14
- We on-boarded and trained seven (7) new committee members in FY14
- As of January 2014, the IACUC administration is completely paperless
Training and Outreach

The IACUC administration significantly increased the training and outreach offered throughout the year and collaborated with partners such as the Office of Animal Resources (OAR), Stem Cell and Regenerative Biology (SCRB), and Molecular and Cellular Biology. We provided the following training opportunities:

- eProtocol Editor Systems Training: 10 training classes (47 participants from 26 different labs)
- Responsible Conduct of Research IACUC Module: 2 FAS sessions and 2 HSPH sessions
- Humane Care and Use of Animals: 3 researcher sessions and 4 student sessions (SCRB 160, 162, 175, DRB Bootcamp)
- Individual Lab Trainings on IACUC/Non-Compliance: 5 training classes (3 labs)
- SCRB Lab Manager Meetings: IACUC update: 2 meetings
- OAR New Researcher Orientation: IACUC section: 24 sessions

Protocol Metrics

In FY14, we processed the following protocol applications:

- Brand-new protocols: 14
- Administratively-approved amendments: 115
- Committee-approved amendments (full and designated member): 72
- Annual renewals: 85
- Third year renewals (review of full protocol): 16
- Protocol closures: 11

Policy, Procedure, and Guideline Revisions

We reviewed and updated all policies, procedures, and guidelines during the FY14 period. In addition, we consolidated many previously delineated policies and procedures in order to be more easily accessed by the users. The resulting number of revisions are as follows:

- Policies: 24
- Procedures: 1
- Guidelines: 5

Praise from Faculty, Researchers and Staff

I truly appreciate the efforts that have been made recently to increase communication and response time. I also appreciate the engagement of the IACUC and veterinary staff in our studies, and their thoughtful consideration of our experiments. This is having a very real, positive impact on our science and I cannot thank you enough!

You are such a pleasure to work with – I really appreciate the status updates and fast response.

Thank you so much for the extremely rapid turn-around. I really appreciate it!

Efficiency begets efficiency. Everyone in the group who has dealt with you has commented on how efficient and downright awesome you are.

...It was wonderful working with [you] and I am so very happy that [you are] a part of the IACUC team. [You] clearly know the ins and outs of working with eProtocol and having [you] on board was extremely helpful... You have a great team over there.
Committee on the Use of Human Subjects

Purpose

The FAS Faculty Standing Committee on the Use of Human Subjects (CUHS) retains a staff of nine personnel housed administratively in Research Administration Services. CUHS serves the Faculty of Arts & Sciences, the Graduate School of Education, the Graduate School of Design, the Harvard Kennedy School, Harvard Business School, the Divinity School, the School of Engineering and Applied Sciences, Harvard Law School, and University Health Services.

The Committee provides human subjects protections by applying the Belmont Report, the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Ethical Principles and Guidelines for the Protection of Human Subjects of Research). The minimum standard is set by the Department of Health and Human Services regulations at 45 CFR 46 (the “Common Rule”). CUHS applies additional University policies beyond the regulations, which help to establish the highest expectations for performance and oversight by investigators, Institutional Review Boards (IRBs), and the University. For more information, please see the Statement of Policies and Procedures Governing the Use of Human Subjects in Research at Harvard University, as voted by the President and Fellows of Harvard College, September 22, 2003.

Major Accomplishments

ESTR (Electronic Submission, Tracking and Reporting)

CUHS made a successful transition to an electronic-based submission system, ESTR, completing its first full year of implementation. CUHS staff assisted FSS with training researchers throughout the year, contributed to the decision-making process on upgrades and modifications to the system on a continual basis, and provided “walk-through” support to users, as needed.

Education and Continuous Improvement

CUHS implemented a planned strategy to increase outreach to the research community to improve the quality of submissions and turn-around times. We implemented bi-monthly drop-in hours in February 2014, and established learning opportunities with the Reach program, Psychology Department, History, Economics, Anthropology and Undergraduate Studies. Leadership met with the Law School and Kennedy School to develop guidelines for Master’s level student projects. Staff meetings occur one to two times each week in order to maintain internal consistency in reviews, provide continuing education, and discuss current events that impact human subjects reviews. The investment in outreach has impacted the number of submissions through ESTR; consistently, CUHS is experiencing a 20% increase in submissions as supported by statistical reports comparing trends over 16 months.

Average Turnaround Time (Days) June 2013-July 2014
Operations Metrics

- Received submissions: 3,498
- Completed actions: 3,511
- Average turn-around time: 12.25 days
- Drop-in Sessions (implemented January 2014): 11 sessions, 54 clients served
- Outreach classes: 13
- CITI Ethics Certifications: 1514
- Continuing Education (internal): 4 webinars, 2 major conferences, weekly staff meetings cover current relevant topics
- Committee CUHS representation: ESCRO (observer), HarvardX Research Committee (observer), Harvard Catalyst IT Subcommittee, Harvard Catalyst Social and Behavioral Subcommittee

Praise from Faculty, Researchers and Staff

*I was super happy with the IRB process…. The person who helped us was super efficient.*

Many thanks to you, and your fine colleagues for your thoughtful review, and for the fast turnaround. Your judgment on this issue seems completely reasonable and appropriate. Thanks very much, also, for offering to provide a letter...

Firstly, I wanted to thank you so much for coming to talk with Anthro 161 on Monday. The talk really resonated with students, and a lot of them have expressed to me that they now feel more comfortable approaching the IRB, ethical issues, and the early research processes. Coming from someone who has some IRB training, I really appreciated the talk and some of the clarifications you offered. We’re really lucky to have such good people working with students, professors, and TFs.

Wow! These edits are really wonderful! Thanks for taking so much time to help me!
<table>
<thead>
<tr>
<th>Name</th>
<th>Functional Area</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pam Baker-Webber</td>
<td>Divisional Support</td>
<td>617-495-9840</td>
<td><a href="mailto:bakerwebber@fas.harvard.edu">bakerwebber@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Thomas Bourgeois</td>
<td>Research Finance</td>
<td>617-495-1488</td>
<td><a href="mailto:tbourgeois@fas.harvard.edu">tbourgeois@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Monica Busch</td>
<td>RAS</td>
<td>-</td>
<td><a href="mailto:monicabusch@fas.harvard.edu">monicabusch@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Jen Corby</td>
<td>Research Development</td>
<td>617-495-1590</td>
<td><a href="mailto:jcorby@fas.harvard.edu">jcorby@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Cattie Coyle</td>
<td>CUHS</td>
<td>617-496-6087</td>
<td><a href="mailto:ccoyle@fas.harvard.edu">ccoyle@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Erin Cromack</td>
<td>Research Development</td>
<td>617-496-5252</td>
<td><a href="mailto:cromack@fas.harvard.edu">cromack@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Steve Crowley</td>
<td>IACUC</td>
<td>617-495-3589</td>
<td><a href="mailto:scrowley@fas.harvard.edu">scrowley@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Betsy Draper</td>
<td>CUHS</td>
<td>617-496-3137</td>
<td><a href="mailto:bdraper@fas.harvard.edu">bdraper@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Mandy Ellenwood</td>
<td>Divisional Support</td>
<td>617-496-3627</td>
<td><a href="mailto:mellenwood@fas.harvard.edu">mellenwood@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Fanny Ennever</td>
<td>CUHS</td>
<td>617-495-1775</td>
<td><a href="mailto:fennever@fas.harvard.edu">fennever@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Pat Fitzgerald</td>
<td>RAS</td>
<td>617-495-4083</td>
<td><a href="mailto:pwf@fas.harvard.edu">pwf@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Charlotte Gallant</td>
<td>Research Finance</td>
<td>857-998-2051</td>
<td><a href="mailto:cgallant@fas.harvard.edu">cgallant@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Susan Gomes</td>
<td>Research Development</td>
<td>617-496-9448</td>
<td><a href="mailto:susan_gomes@harvard.edu">susan_gomes@harvard.edu</a></td>
</tr>
<tr>
<td>Gearoid &quot;Griff&quot; Griffin</td>
<td>Research Integrity</td>
<td>617-495-9204</td>
<td><a href="mailto:gearoid_griffin@harvard.edu">gearoid_griffin@harvard.edu</a></td>
</tr>
<tr>
<td>Rebecca Holmes-Farley</td>
<td>CUHS</td>
<td>617-496-1185</td>
<td><a href="mailto:rholmesfarley@fas.harvard.edu">rholmesfarley@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Ann Janik</td>
<td>RAS</td>
<td>617-496-6535</td>
<td><a href="mailto:ajanik@fas.harvard.edu">ajanik@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Ellyn Lane</td>
<td>IACUC</td>
<td>617-495-1510</td>
<td><a href="mailto:lane@fas.harvard.edu">lane@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Elizabeth Lennox</td>
<td>RAS</td>
<td>617-496-2491</td>
<td><a href="mailto:lennox@fas.harvard.edu">lennox@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Karen Woodward Massey</td>
<td>RAS</td>
<td>617-496-1261</td>
<td><a href="mailto:kwmassey@fas.harvard.edu">kwmassey@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Julie McCarthy</td>
<td>IACUC</td>
<td>617-495-4234</td>
<td><a href="mailto:julie_mccarthy@fas.harvard.edu">julie_mccarthy@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Caitlin McDermott-Murphy</td>
<td>Research Development</td>
<td>617-496-2618</td>
<td><a href="mailto:cmcdermottmurphy@fas.harvard.edu">cmcdermottmurphy@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Nuala McGowan</td>
<td>Research Finance</td>
<td>617-495-7681</td>
<td><a href="mailto:nmcgowan@fas.harvard.edu">nmcgowan@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Kathy Meunier</td>
<td>IACUC</td>
<td>617-496-4678</td>
<td><a href="mailto:kmeunier01@fas.harvard.edu">kmeunier01@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Denise Moody</td>
<td>RAS</td>
<td>617-496-3090</td>
<td><a href="mailto:denisemoody@fas.harvard.edu">denisemoody@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Andres Orco</td>
<td>RAS</td>
<td>617-495-3705</td>
<td><a href="mailto:aorco@fas.harvard.edu">aorco@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Heather Pixley</td>
<td>CUHS</td>
<td>617-496-5593</td>
<td><a href="mailto:hpxley@fas.harvard.edu">hpxley@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Rady Rogers</td>
<td>Divisional Support</td>
<td>781-697-9215</td>
<td><a href="mailto:rrogers@fas.harvard.edu">rrogers@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Olga Sachs</td>
<td>CUHS</td>
<td>617-496-2146</td>
<td><a href="mailto:osachs@fas.harvard.edu">osachs@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Sam Schwartz</td>
<td>Divisional Support</td>
<td>617-496-6216</td>
<td><a href="mailto:sschwartz@fas.harvard.edu">sschwartz@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Damema Spragens</td>
<td>IACUC</td>
<td>-</td>
<td><a href="mailto:spragens@fas.harvard.edu">spragens@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Alison Wellman Smith</td>
<td>Research Finance</td>
<td>617-496-0974</td>
<td><a href="mailto:awellmansmith@fas.harvard.edu">awellmansmith@fas.harvard.edu</a></td>
</tr>
<tr>
<td>Diana Weld</td>
<td>CUHS</td>
<td>617-495-5459</td>
<td><a href="mailto:dweld@fas.harvard.edu">dweld@fas.harvard.edu</a></td>
</tr>
</tbody>
</table>