

# OFFICE OF RESEARCH ADMINISTRATION NEWSLETTER

“Yale has a clear obligation to comply with all regulations pertaining to the administration of federal grants, and we will spare no effort to remedy any deficiencies in our practices.” President Rick Levin

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## Dr. “Andy” Rudczynski Retires from Yale

Effective June 30, 2015, Dr. Rudczynski will be retiring from Yale after nine years of dedicated service.

When he joined Yale in 2006, it was a challenging time for Yale and an opportunity for Andy to help Yale work through the investigation. It was also the beginning of Andy’s goal to create a more unified research enterprise. The Office of Research Administration, under Andy’s leadership, brought together GCA, GCFA, COI, IACUC, HRPP, ORCE, and OREO for the first time in Yale’s history. This integrated research organization better serves faculty and administrators as increased burdens continue to be placed on institutions of higher education.

Andy is widely recognized as a national leader in the research administration profession where he has been actively participating in efforts to reduce burdens associated with the conduct and administration of research. He is also recognized internationally as a leader in the profession and participates in the development of international collaborations. Having been both a researcher and a research administration professional, Andy has been in a unique position to provide a balanced approach to conducting research and recognizes the unnecessary regulations/burdens put upon faculty and staff. His voice supporting change at the national level will be sorely missed.

We appreciate and are grateful for Andy’s dedication and numerous contributions to Yale and the profession. Thank you for the time spent at Yale.

Bike on!

## Announcing The Office of Sponsored Projects (OSP)

The Offices of Grant and Contract Administration and Grant and Contract Financial Administration have joined to become a single office, the Office of Sponsored Projects. As in other major research-intensive universities, joining the pre and post functions under a single leadership is not uncommon. It is expected that this single organization will create a more synergistic and collaborative approach to the administration of research to better serve the faculty and department administrators.

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Briefly, OSP's senior level structure is as follows:

- *Executive Director* (**ALICE TANGREDI-HANNON** is currently interim)  
Reporting to the Executive Director are:
  - **CYNTHIA KANE** *Director, Business Operations*
  - **NANCY KENDRICK** *Director, Financial Operations*
  - **JEFF ALLEN** *Director, Clinical Agreements Management*
  - **DON DEYO** *Director Corporate Contracts and Export Control Licensing*
  - **CHERYL MAGOVENY** *Director, Award Management*
  - **AMY ELLIS** *Associate Director, Proposal Management*
  - **LAUREN PITE** *Associate Director, Subaward Management*

OSP will be hosting a Brown Bag at which each of the directors will have an opportunity to introduce their individual organizational structures and the functions performed. Brown Bag dates and times will be announced soon.

### ***Did you know that...***

***Adding a foreign component under an existing NIH grant requires Yale and NIH prior approval?***

***The performance of any significant scientific element or segment of a project outside of the United States, under a NIH award made to Yale, requires the prior approval of Yale and the NIH, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by Yale project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any Yale activity that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country.***

***Examples of other grant-related activities that may be significant are:***

- ***collaborations with investigators at a foreign site anticipated to result in co-authorship;***
- ***use of facilities or instrumentation at a foreign site; or***
- ***receipt of financial support or resources from a foreign entity.***

## **ORA Technology Projects — IACUC and HRPP**

A key component of ORA's strategy for improving Research Administration under the leadership of Andy Rudczynski has been to find innovative ways to use technology to reduce administrative burden on faculty and support staff. There are currently major projects underway in the IACUC Office (animal protocols) and the HRPP Office (human subjects protocols) to replace manual, paper-based protocol processes with a comprehensive system for the preparation, submission, approval, and modification of protocols. These systems will allow for:

- Automated routing of protocols including electronic signature and email alerts.
- System-based Q&A between PI's, their support staff, and central compliance offices.
- Smart form-based capture of critical protocol and compliance information.
- Reuse of protocol data so as to vastly streamline the modification and renewal processes.

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- In-line instructions and context-sensitive help for PI's and lab staff completing protocol applications.
- Automation of committee management functions.
- The use of tablets and even smart phones for many tasks required of PIs.
- Integration with other ORA systems to allow streamlining of the protocol-to-award congruency and COI processes.

These improvements are expected to save time and reduce mistakes throughout the process, resulting in less “back and forth” between PIs and compliance offices. In addition, the process for modifying and renewing protocols should be simplified.

### PROJECT STATUS

**The IACUC Electronic Protocol System project** was launched in late 2013. The system, developed with input from PIs, lab staff, IACUC Committee members, YARC veterinarians and IACUC Office personnel is ready for user testing, scheduled to begin in mid June. Testing is expected to continue through the summer with deployment scheduled to begin in late fall 2015.

**The HRPP Electronic Protocol System project** was launched in late 2014. Business requirements have been gathered and vendor selection is nearly complete. The design of the new protocol system is expected to continue into the fall of 2015, with development and testing scheduled through the spring of 2016. Deployment of the system is scheduled for summer, 2016.

For information on these initiatives please feel free to contact [bob.davis@yale.edu](mailto:bob.davis@yale.edu).

### New Director and Name for the Institutional Animal Care and Use Committee

After a nationwide search, and in consultation with academic leadership and faculty researchers, effective March 30, 2015, Troy Hallman, MS, VMD, DACLAM joined Yale as the Director of the Institutional Animal Care and Use Committee (IACUC) Office. Troy also brings with him his experience as a laboratory animal medicine diplomat, a consulting attending veterinarian at several Philadelphia area institutions, and as an ad hoc specialist and site visitor for AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care), the accrediting agency for Yale's animal care program. Troy joined us from the University of Pennsylvania where he served for the past seven years as the Director of Animal Welfare in Penn's IACUC Office. During his time at Penn, he helped transform Penn's IACUC Office into one that focused on supporting the principal investigators, both with the IACUC review process and with post-approval compliance issues. It is this researcher-focused approach, among other things, that Troy brings to Yale.

The transformation of the Yale IACUC Office begins with a simple name change. The IACUC will now be known as the Yale Office for Animal Research Support (OARS). It will focus on reducing regulatory burden for investigators studying biomedical and biological animal models. OARS will accomplish this primary responsibility by providing support for the investigators in protocol development, shepherding IACUC submissions through the review process, education and training in topics related to animal research, and assisting in resolution development in case of adverse events or compliance concerns. Much of the burden is transferred to the dedicated OARS staff who serve as liaisons to and advocates for the animal research investigators.

A significant enhancement to the office will be the new responsibilities of the Protocol Liaisons. Their primary role will be to conduct a robust, transparent, content-oriented, and timely pre-review of protocols and modifications. They will pair-up with a compliance support specialist to serve as your primary contact with the Office and serve as an intermediary between the IACUC and PI during the review process and for resolving any compliance issues.

Dr. Hallman may be reached at [troy.hallman@yale.edu](mailto:troy.hallman@yale.edu) or 203-737-5236 for any questions, comments or concerns.

## Did you know that...

*Faculty supported by a NSF award can receive more than 2 months salary in a fiscal year?*

*As a general policy, NSF limits the salary compensation requested in the proposal budget for senior personnel to no more than two months of their regular salary in any one year (define by Yale as fiscal year). This limit includes salary compensation received from all NSF-funded grants.*

*If anticipated, any compensation for such personnel in excess of two months must be disclosed in the proposal budget, justified in the budget justification, and must be specifically approved by NSF in the award notice budget. Under normal rebudgeting authority, Yale can internally approve\* an increase or decrease in person months devoted to the project after an award is made, even if doing so results in salary support for senior personnel exceeding the two month salary policy. No prior approval from NSF is necessary as long as that change would not cause the objective or scope of the project to change. NSF prior approval is necessary if the objective or scope of the project changes.*

*\*Approval is obtained through the Provost's Office.*

## New Fee Schedule for IRB Reviews

Effective July 1, 2015, the Human Research Protections Program is changing its IRB review fee schedule for protocols supported by **non-federal** awards. The changes to the fees are due to increased volume, the need for better software to manage documentation of studies and IRB review, and need to increase staff to support the volume. This fee structure is not dissimilar to that of other major research institutions.

The schedule of fees is as follows:

- Initial review of protocol by Yale's IRB (includes associated material) \$3,000.00
- Yale's administrative review of a protocol if originally reviewed externally \$2,000.00
- Amendment reviewed by Yale's IRB (full board) \$700.00
- Amendment reviewed by Yale's IRB (expedited) \$500.00
- Yale's administrative review of an amendment reviewed externally \$600.00
- Continuing Review by Yale's IRB IRB \$1,500.00
- Yale's administrative review of continuing review reviewed externally \$750.00
- Protocol closure by Yale's IRB \$250.00
- Yale's administrative review of a protocol closure reviewed externally \$100.00

The increases in fees are to strengthen the Yale IRB by providing additional resources to manage future growth. Additional information and updates will be provided on the Yale HIC/HSC website.

Please refer to IRB Policy 110 *Institutional Review Board Review Fees* for additional guidance.

Currently, Yale is considering outsourcing some portion, yet to be decided, of its research portfolio to an independent or commercial IRB. These independent IRBs are governed by the same U.S. federal regulations as the Yale IRB and have been in existence for more than 40 years.

If an independent IRB is selected to partner with Yale for outsourced review, administrative functions must still be completed by Yale's HRPP office in order to facilitate the review conducted by the outside entity. For

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example, designated HRPP staff will review the submissions to ensure that the studies meet the required criteria approved for outsourcing, that the studies do not include vulnerable populations that Yale may wish the local IRB to review, and for other issues such as open PI compliance issues, COI concerns, training, and as well as ensuring other Yale required Committee approvals are obtained.

The Yale's HRPP staff will track the initial submission in its software system as an outsourced study. All subsequent submissions will be made to the IRB of record or outsourced partner but the Yale IRB will retain a placeholder for the study in the local software system.

**OFFICE OF RESEARCH ADMINISTRATION MISSION STATEMENT**

To coordinate the activities of the various University offices providing support to faculty, staff and students on sponsored projects, to assure that service provided by those offices is of the highest caliber and professionalism, and to serve as an effective representative for the research enterprise.