

Agenda
COMMISSION ON RESEARCH

November 14, 2018

130 Burruss Conference Room

3:30pm-5:00pm

COR Documents available to COR members in Team Drive: [COR FY2018-2019](#)

Attended:

Members: Virginia Pannabecker, Theresa Mayer, Marie Elisa Christie, Barry Miller (for Stefan Duma), Alan Michaels, Kevin McGuire, Deborah Milly, Nancy Dudek, Rajaram Bhagavathula, Brian Britt, John B. Phillips, Steve Nagle, Elizabeth Grant, R. Bruce Vogelaar, Zhen (Jason) He, Suzie Le, Uri Kahanovitch

OVPRI: Theresa Mayer, Diane Zielinski

Guests: Ken Miller, Kim Linkous

Presenters: Lisa M. Lee, Associate Vice President for Scholarly Integrity and Research Compliance; Bob Hickok, Chair, Commission on Faculty Affairs; Professor, Department of English

- I. Approval of the Agenda
 - A. Approved by vote
- II. Approval of October Minutes - approved by email
- III. Announcements
 - A. New member - Rajaram Bhagavathula, Senior Research Associate, Center for Infrastructure-Based Safety Systems joined COR as an elected representative for research faculty
 - B. Deadline Dec 7th - Submit nominations for the Alumni Award for Research Excellence. Awards are in two categories: science or engineering and social sciences, humanities, or arts with one award in each category and no more than one awardee from a single major unit (college or institute)
 - C. Deadline Dec 1st - Submit Intention to Participate Form for The Faculty Research Incentive Plan (FRIP)
- IV. Presentation by Lisa Lee, Associate Vice President for Scholarly Integrity and Research Compliance

A. See slides at the end of the minutes

B. New Division in October

1. Research Integrity and Consultation Program. Will include a research ethics consultation service - for researchers when ethical questions come up and they're not sure. This consultation can be before submitting a protocol.
2. Institutional Biosafety Committee Program
3. Animal Care and Use Program
4. Human Research Protection Program (HRPP)
 - a) Has received a great deal of attention; great increase in this type of research. Institutional Review Board (IRB) is required by federal law, 45 CFR 46, 21 CFR 56) and is part of HRPP. Conducted benchmarking and saw that VT HSP staff were low relative to comparative institutions; reviewed case load compared to research expenditures (included proposals not just awarded projects). By regulation have to touch each protocol each year to verify it is proceeding as approved; also have edits to protocols (about 3-5 per year on average); sometimes adverse events that require reporting beyond VT; currently have 4 staff (had 3).
 - b) HRPP staffing - HRPP Director search underway - this person will ensure compliance with regulations, including data management. HRPP Coordinators, search for 3 underway. Will provide bootcamp training in January for common training on process; then reallocation of workload to manage the bottleneck → part of this is ensuring researchers understand expectations; redesigning protocol submission forms ; collaborating with Statistical Applications and Innovations Group (SAIG) to analyze initial submissions. Will look at revision request letters to inform rolling out revised general and targeted training (by college or department). Rolling out research ethics consultation service (RECS) to encourage early engagement
 - c) New rules coming out in January - designed to decrease regulatory burden of human subjects research - these will be addressed in the January IRB bootcamp.
 - d) VT IRB - has too few members; only 6 members and 1 alternate compared to median 14 members and 13 alternates at peer institutions; looking to increase number and diversity of those serving on IRB; actively recruiting for 10 new members; bootcamp training scheduled; also working to improve recognition of this type of service; will reallocate designated reviewers to avoid and manage bottlenecks; looking at data of where protocols come from for targeted outreach.

- e) Developing an integrated Human Subjects Advisor corps within each department / college; facilitate implementation of changes to the IRB regulations (in effect Jan 2019); “dotted line” participation in HRPP (training); better initial protocol submission
- 5. Privacy & Research Data Protection Program
 - a) Secure Research Working Group: Proactive effort to build an integrated data framework to support world-class research. Started with data sharing and reuse group - IT, VTCRI, and others included; did assessment and some test projects. Phase 2 working group for integrated data framework to support all types of data security needs for a system wide approach
- 6. Conflict of Interest Program
 - a) Retirement of Linda Bucy; looking to restructure; create conflict of interest committee; Vicky Radcliffe = interim Conflict of Interest Officer; reorganization of this area is the next big project
- 7. Questions
 - a) Lisa Lee has provided tailored training for a class of students - what is the sustainability of that? Will be rolling out a new training in about 8 weeks; then after that more opportunities for all in HRPP to provide training as needed (one on one with researchers; and in the future there will be one position designated as a full time educator
 - b) How many proposals does full board review? Fewer than 100 per year go to the full board, but a huge chunk currently go to one designated reviewer, the Chair. As biomedical protocols increase, more will go to the full board - the more risk, the more likely it goes to the full board.
 - c) Is there legal exposure to those on the board? No; as long as institution meets requirements for board.
 - d) Is there a mechanism for protocols that are no risk, not funded, then renewed - faster review? Will be working on triage method at start and with more staff can route reviews by efficiency.
 - e) What is your short term advice, such as for graduate students - should we have them go to Western Institutional Review Board (WIRB) (<https://www.wirb.com/Pages/Default.aspx>) because it's faster or do something else? We (VT IRB) are about 4-6 weeks out on reviews now because of help from WIRB. WIRB is stronger in biomedical protocol review, less so in social sciences fields so consider that when you submit.
- C. Please send further comments and questions to Lisa Lee, Associate Vice President for Scholarly Integrity and Research Compliance

- V. [4:15pm - 25 min] T&R Faculty P&T Guidelines Changes by Bob Hickok, Chair, Commission on Faculty Affairs; Professor, Department of English
- A. Discussion of Faculty Handbook Promotion and Tenure Guidelines revisions in process by Commission on Faculty Affairs. A full revisions document plus an update for section 3.4.4, 'General expectations for promotion and tenure.'
 - B. Bob Hickok provided an overview of the revisions process, noted some key changes, including reviewing the 3.4.4 most recent update. COR members provided comments and asked questions.
 - 1. Notes: Expectations documents required for each department. Use of metrics is a topic of great interest - primarily leaving this to departments. Interest was expressed regarding institutional policy or approach, or some other method of standardization. Goal for sending the new revisions through for approval is June, but waiting to time with completion of department expectations documents. Revisions must also be in sync with provost guidelines for promotion and tenure. For those going up for promotion or tenure this year, reference the current guidelines. Question about how to ensure recognition of work towards diversity and inclusion? Recommendation is to look to include in department expectations documents. Language in handbook guidelines moving away from qualified terms such as 'outstanding' towards concepts of 'impact' and scope 'national,' 'international.' Please send further questions or comments to Bob Hickok, Chair of Commission on Faculty Affairs.
- VI. [4:40pm] Unfinished Business
- A. Report of Ongoing Activities
 - 1. Committee on Research Competitiveness – B. Miller for S. Duma
 - a) The Committee on research competitiveness has continued benchmarking other universities to compile best practices relative to increasing large scale funding as well as diversifying the portfolio. We continue to target Spring 2019 to complete our report.
 - 2. University Library Committee – V. Pannabecker
 - a) The ULC met on October 30th. The Committee discussed membership, space issues, new library systems in relationship to identifying objectives for the coming year. Edward Becker (CAUS) volunteered to facilitate the next meeting. The next meeting is planned for December but, due to scheduling conflicts, the date has not been set yet.
 - 3. Faculty Senate – B. Vogelaar or B. Britt
 - a) Met 6 times; 2 issues recently include: How visas are handled in hiring faculty from outside the U.S.: need more people to review these for better efficiency; and Faculty Handbook Promotion &

Tenure guidelines review discussion - find ways to reward faculty service.

4. Update to Policy 13005 – A. Michaels
 - a) Have a completed draft; inviting anyone interested to help review; it's now out to Stefan Duma to review; will send to others as well.
5. Open Access Policy update – K. McGuire
 - a) Meeting this Friday with an enhanced committee. In response to earlier feedback to include more teaching and research faculty from more areas: added Cayelan Carey from Biological Sciences, Tom Sanchez from School of Public and International Affairs. Updating presentation. Elements system is an easy method to submit articles to the VTechWorks institutional repository and provides guidance on journal-specific posting policies as well as an embargo option all within the system.
6. Software Review Backlogs update
 - a) Commission on University Support discussion addressing this issue is planned for CUS meeting on Nov 15th, 2:00pm, Burruss 130.

B. OVPRI Update - T. Mayer

1. Trudy Riley, the new associate vice president for research and innovation, Sponsored Programs, just announced in VT News. Riley was previously at University of Delaware; most recently executive director of the Office of Sponsored Programs at Georgia Tech. Brings a strong understanding of integrity and compliance; has overseen research portfolios for institutions, large portfolios of research. Begins January 7th.
2. Also beginning on January 7th - David Schabdach will begin as an associate vice president for research and innovation, serving as the Attending Veterinarian and directing the university program for laboratory animal resources.
3. News regarding new innovation campus in Alexandria. Virginia has made a tremendous commitment to Virginia Tech as part of supporting this new campus. Funds will go towards faculty to support enrollment growth in Blacksburg as well as in northern Virginia. Diversification of economy is a priority for the commonwealth and representatives in the Virginia legislature understand the importance of higher education and are looking to support it.

VII. [4:55] New Business

A. Center Updates

1. CREATE - Notification of change to center bylaws.
2. Center for Watershed Studies requested to close as it is no longer active and the request was approved by OVPRI who is working with them to manage administrative tasks for closing.

- B. Lisa Lee presentation (see above)
- C. Bob Hickock presentation (see above)

V. Adjournment

*Please take note of the following upcoming meetings which will all take place in Burruss 130 from 3:30pm-5:00pm unless otherwise noted:

12 December 2018

9 January 2019

13 February 2019

13 March 2019

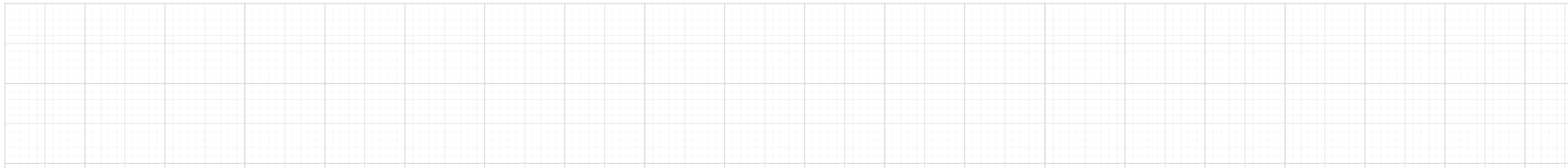
10 April 2019

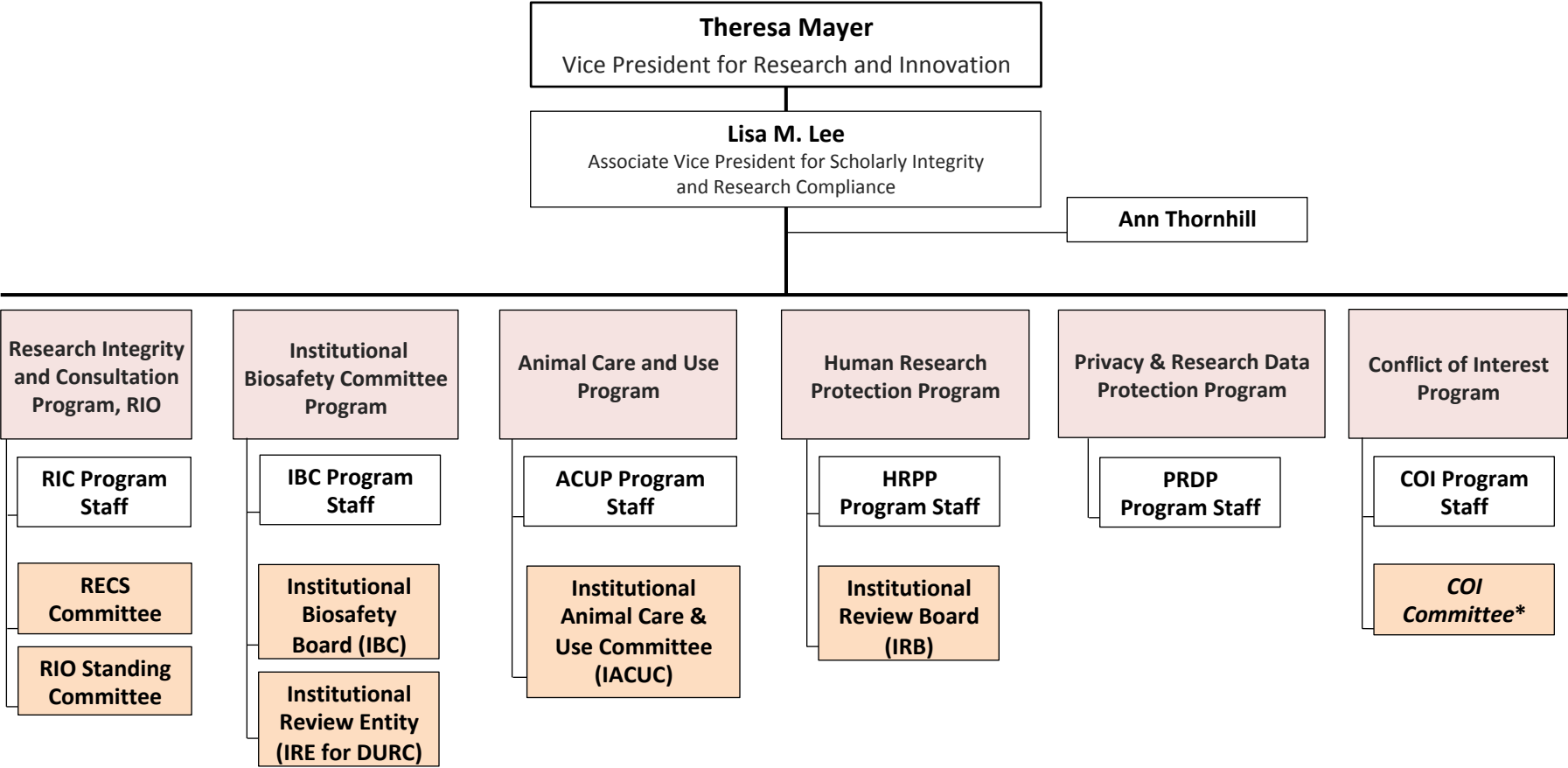
8 May 2019

Scholarly Integrity & Research Compliance

COMMISSION ON RESEARCH
LISA M LEE, PHD, MA, MS

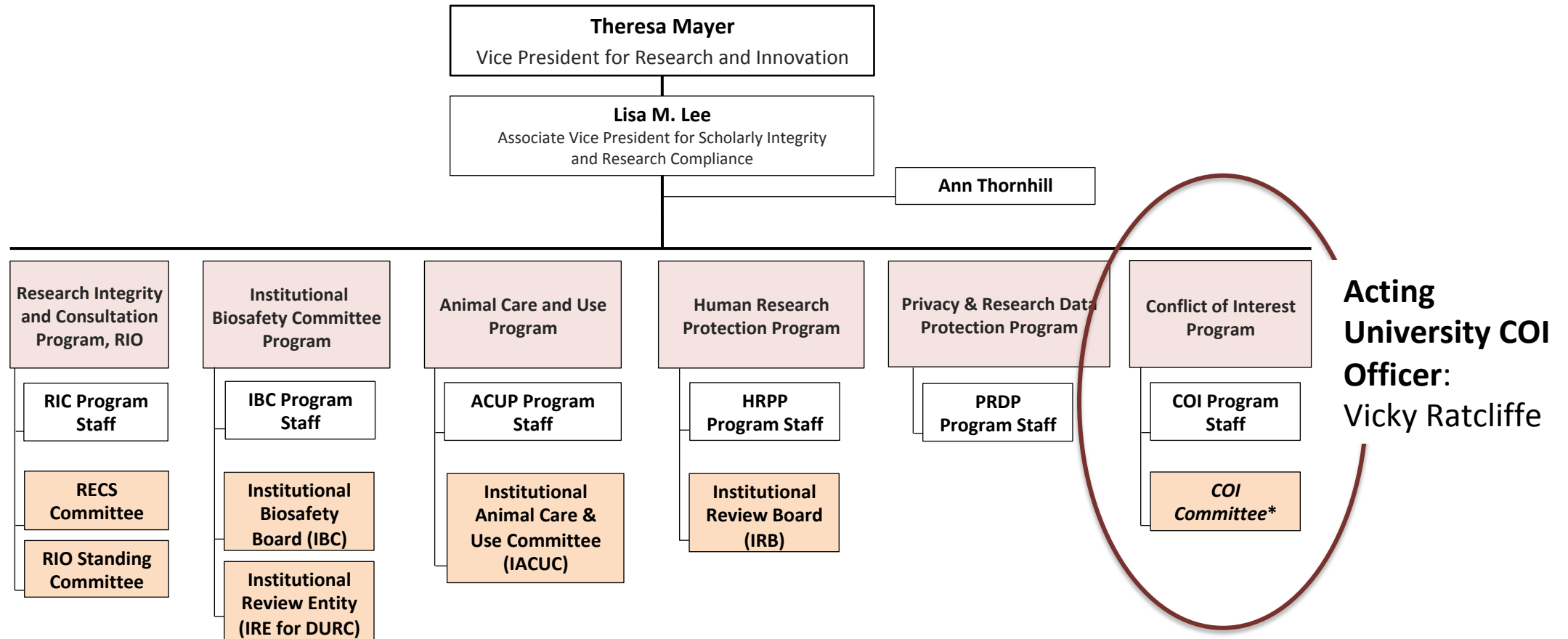
NOVEMBER 14, 2018





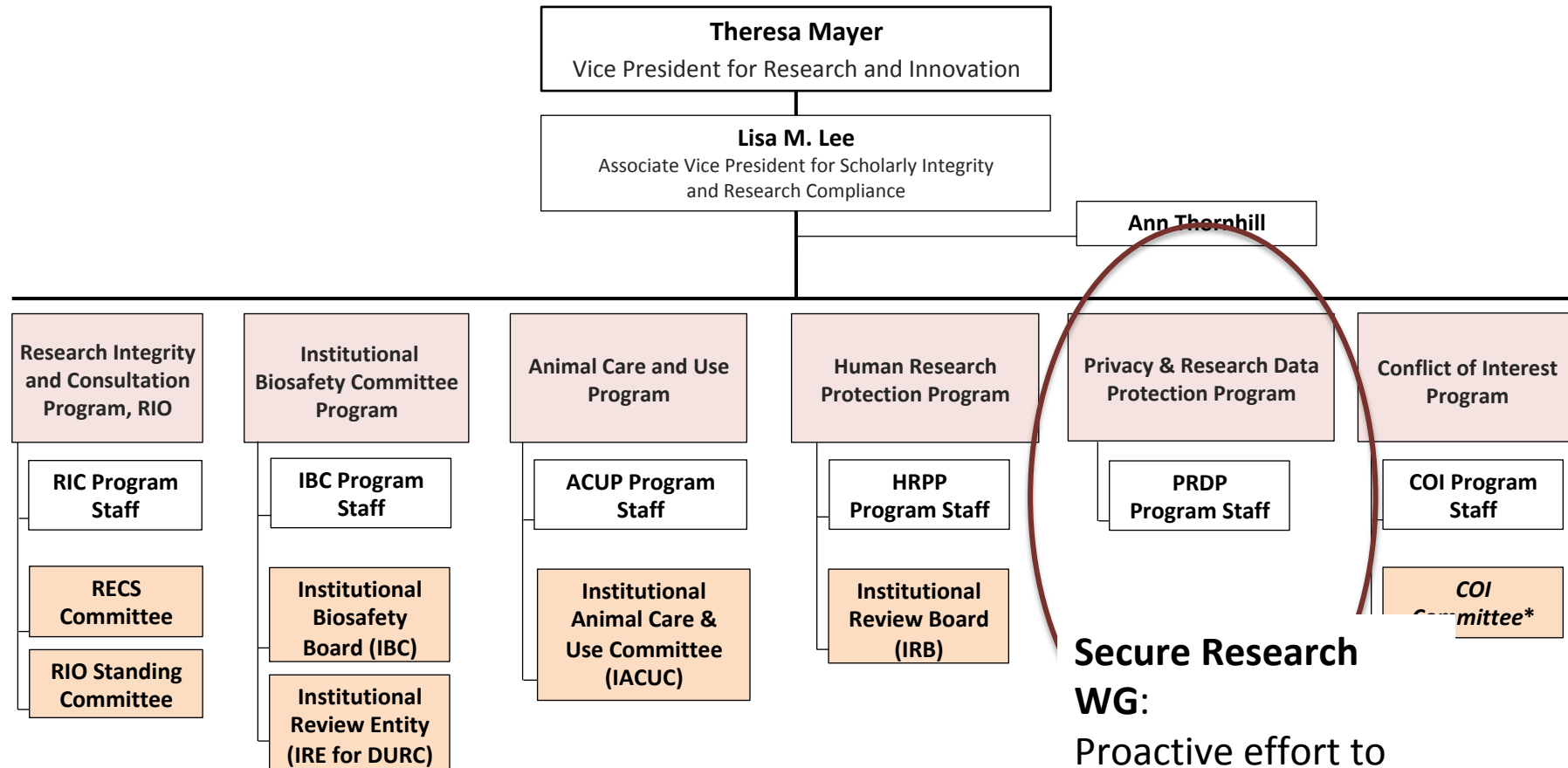
The division of *Scholarly Integrity and Research Compliance* facilitates scholarly excellence by fostering ethical decision-making and ensuring research regulatory compliance.

*Proposed



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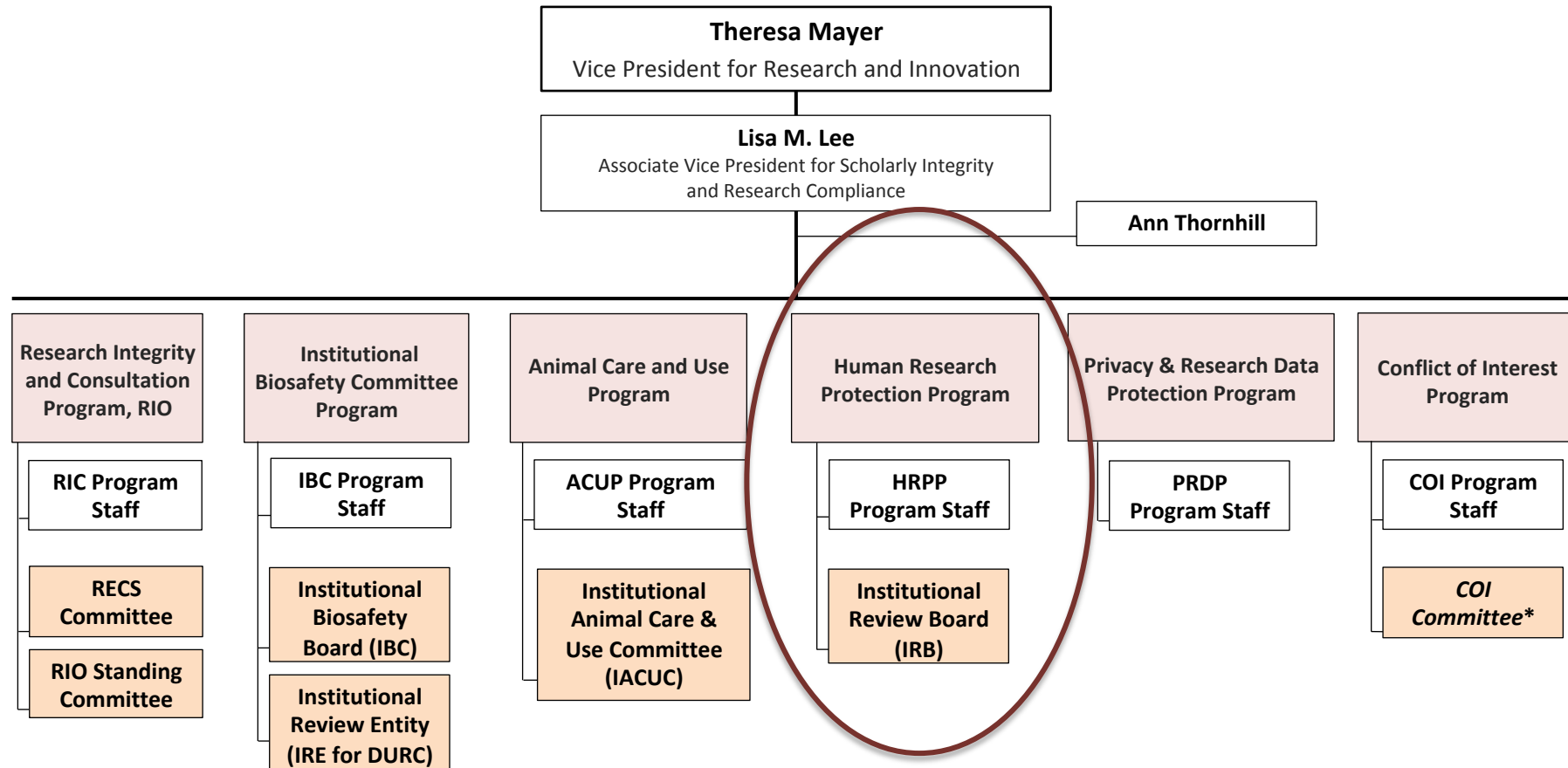


Secure Research WG:

Proactive effort to build an integrated data framework to support world- class research

The division of *Scholarly Integrity and Research Compliance* facilitates scholarly excellence by fostering ethical decision-making and ensuring research regulatory compliance.

**Proposed*



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**Proposed*



HRPP Structure

Structure to support IRB regulatory requirements



HRPP Staff

Number and qualifications



IRB Membership

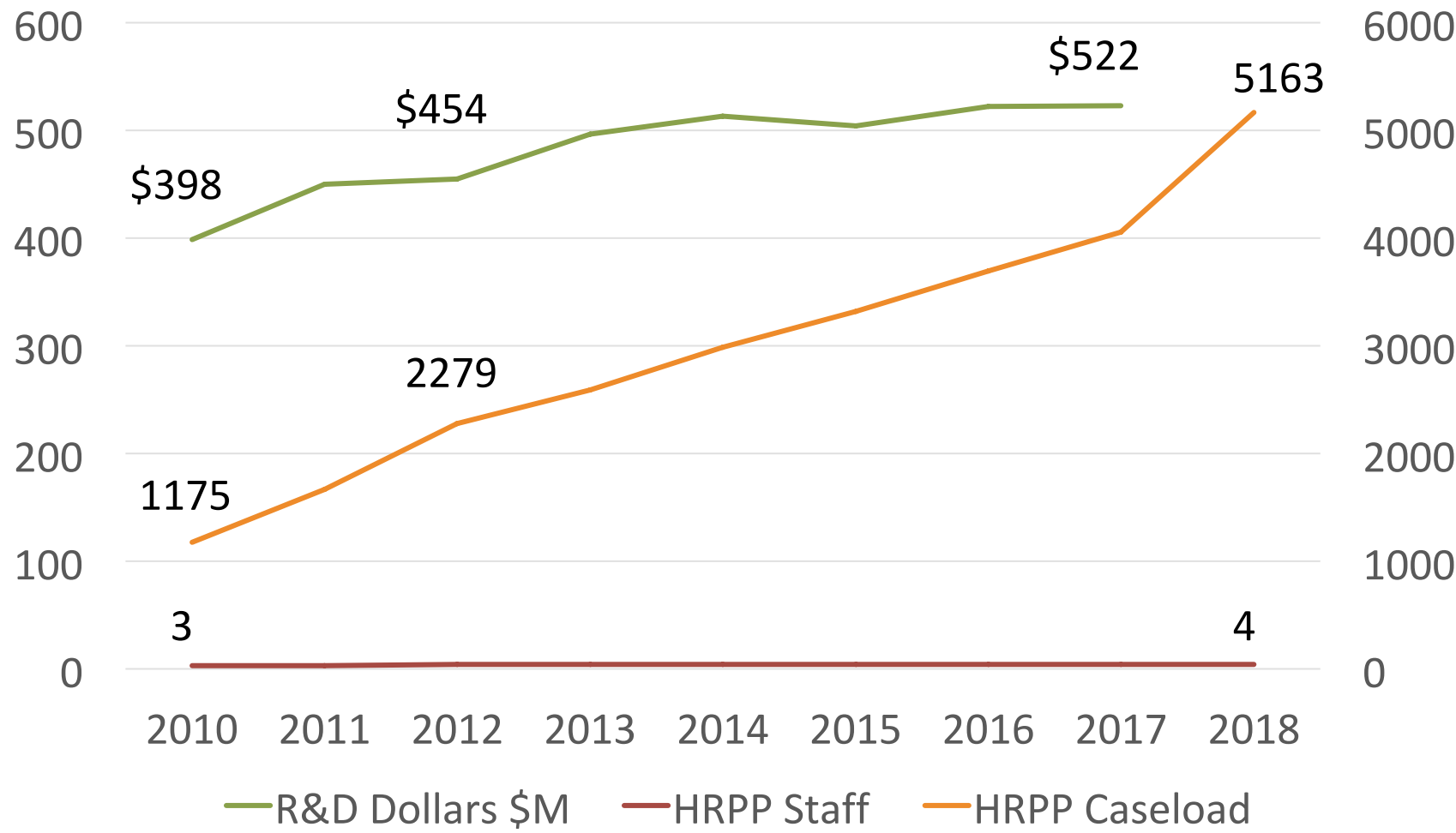
Members and alternates

IRB: Board of
research
peers

HRPP: HSP
professionals
assisting
researchers
and IRB

- IRB: Institutional Review Board
 - Required by federal law (45 CFR 46, 21 CFR 56)
 - Protect rights & welfare of human research participants
 - Concerned with ethical protections for participants
 - Review research protocol & monitor research activities
- HRPP: Human Research Protection Program
 - Median # Human Subjects Protection professionals:
3–4 times Virginia Tech's current staffing

VT HRPP Caseload & Staffing, 2010-2018



HRPP* Solutions

*Human Research
Protection
Program

- HRPP: Staffing Improvements In Progress

HRPP Director search underway

HRPP Coordinators (n=3) search underway

Bootcamp training in January

Reallocation of workload to manage bottlenecks

Number of Protocols Submitted to HRPP and Number in Need of Revision, Jan, Apr, Jul 2018



HRPP* Solutions

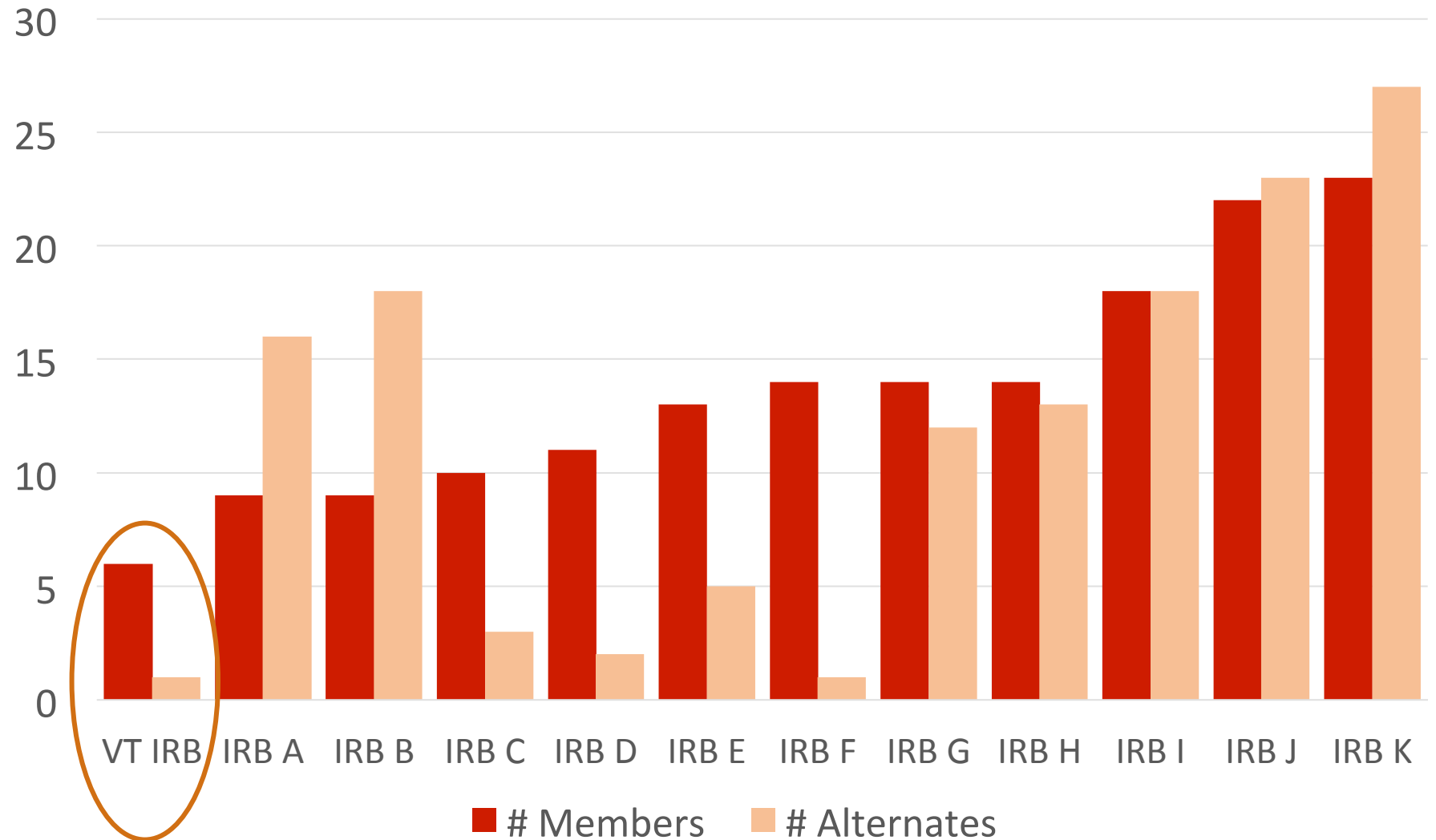
*Human Research
Protection
Program

- HRPP: Protocol Submission Improvements In Progress
 - Redesigning protocol submission forms for next PM release
 - Collaborating with SAIG to analyze initial submissions
 - Rolling out revised general and targeted training (by college or department)
 - Rolling out Research Ethics Consultation Service (RECS) to encourage early engagement

IRB Membership: VT Peers, 2018

Median # **Members**: 14
Median # **Alternates**: 13

VT # **Members**: 6
• 3 faculty
• 3 non-faculty
VT # **Alternates**: 1



IRB* Solutions

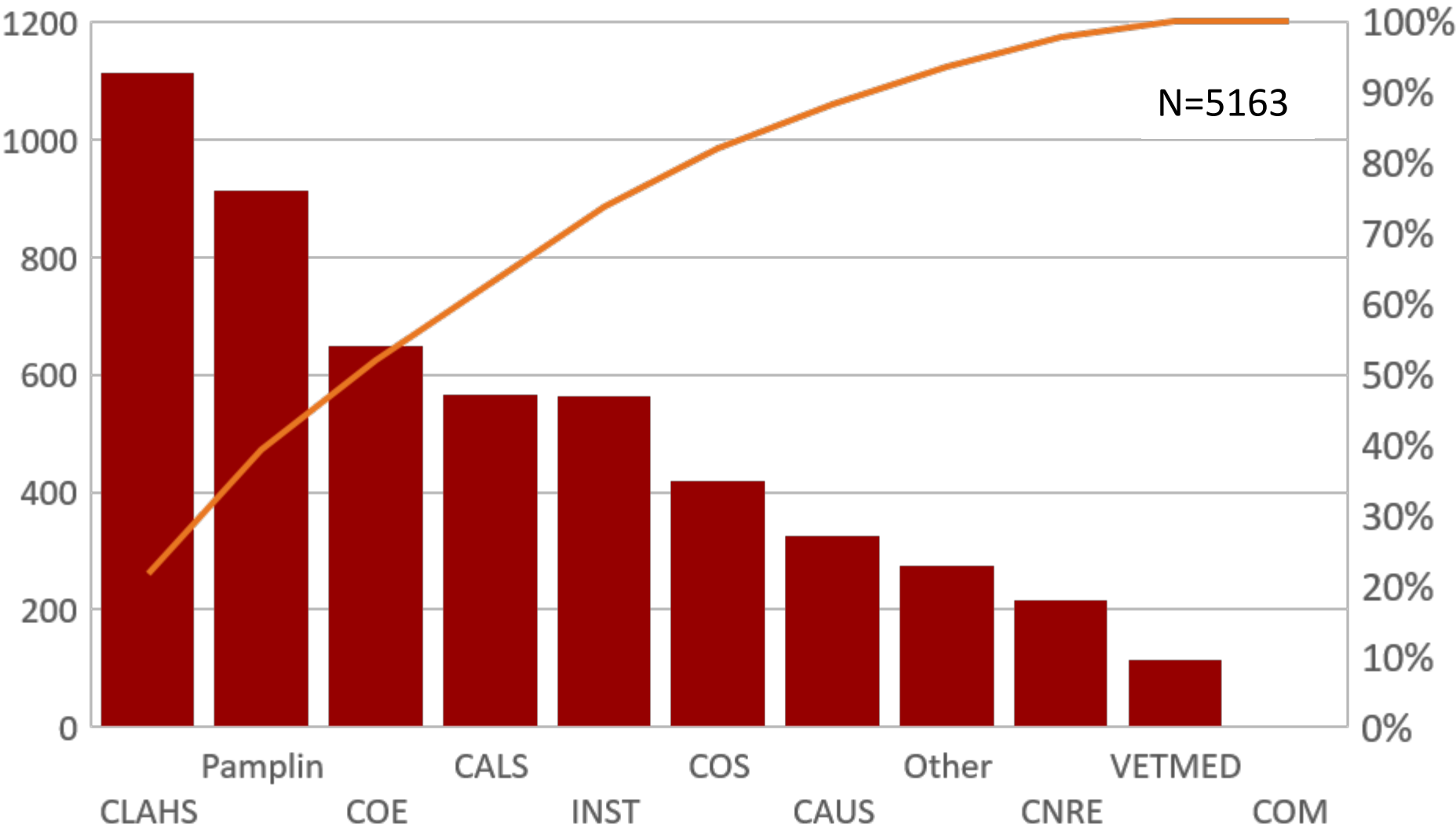
*Institutional
Review Board

- IRB: Board Improvements In Progress
 - Actively recruiting 10 members, 5 alternates
 - Recognition of service in tenure and promotion
 - Bootcamp training scheduled
 - Reallocation of Designated Reviewers to avoid and manage bottlenecks

3 VT Faculty IRB
Members:

- CALS (HNFE)
- INST (VTTI)
- COS (Psych)

Number of Active IRB Protocols, by College, Virginia Tech, 2018



Combined Academic & HRPP Solutions

- Academic : HRPP Interface
 - Developing an integrated Human Subjects Advisor corps
 - Facilitate implementation of changes to the IRB regulations (in effect Jan 2019)
 - “Dotted line” participation in HRPP (training, etc.)
 - Better initial protocol submission = more efficient review



Achieving Success

- SIRC
 - HRPP staffing, training
 - IRB composition, expertise
 - Clarify expectations
- Research Community
 - IRB service
 - Infusion of dual-expertise
 - Recognition of investigator duty