COMPLIANCE FOR SMALL RESEARCH ADMINISTRATION OFFICES

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PHILADELPHIA COLLEGE OF OSTEOPATHIC MEDICINE

LEARNING OBJECTIVES

- Identify best practices for successfully running a small RA office

- Apply best practices to your RA office

ALL ABOUT ME…AND PCOM

- Almost 24 years at PCOM; 8 years in ORA at UMDNJ
  - IRB
  - IACUC
  - IEHSC
  - ORI
  - FCoI
  - SO, AOR
  - TTO
  - CITI admin
  - Miscellaneous other (more later)
- A *teaching* intensive institution, including HCCs for med ed in PA
  - Committees load

ABOUT PCOM – THEN AND NOW

1995

- About 260 FT & PT employees total, incl. 65 faculty
- One campus, 2 programs (DO program and fledgling MSBS program), student body 995
- 10 publications indexed in PubMed by
  - 2 faculty, 3 residents, 5 adjunct faculty

2019

- 630 employees total; about 200 faculty
- University status, 19 programs
  - Philadelphia campus (120 years old; 1,714 students)
  - Georgia campus (13 years old; 1,118 students)
  - South Georgia campus (opening August 2019; 55 DO students)
- 181 publications indexed in PubMed for 2018 (some by residents and adjunct faculty)
- Research and scholarly activity in 2018 by:
  - 51 faculty, 22 research support staff (lab techs), 10 residents, 123 students

MORE ABOUT PCOM – THEN AND NOW

1995

- 6 active grants totaling $689K ($180K research)
  - 3 Research
  - 3 Training
- No F&A rate
- 4 pending, 0 funded
- Sources
  - 3 Federal (one HRSA subcontract)
  - 1 State government
  - 2 Private
- Basic research + one clinical project
  - IRB met ad hoc (10 protocols)
  - IACUC met ~ monthly and took paper votes with signed ballots (10 protocols)

2019

- 14 active grants/subcontracts totaling >$1M
  - 10 Research
  - 3 Service
  - 1 Training (HRSA)
- 10 pending totaling >$10M
- Sources
  - 5 Federal (all as awardee institution)
  - 8 Private/VHO
- Basic, behavioral, medical education research (not much clinical YET)
  - ~300 IRB (80% exempt, expedited, full; average 70-80/year)
  - 29 IACUC (frequent amendments to add/subtract trainees)

THE PCOM FAMILY

- Social aspects (senior admin eat in caf, Appreciation Day, Holiday Luncheon, Recognition Luncheon)
  - Everybody knows just about everybody (for better or worse)
  - ORSP interacts with most programs, if not individuals within them

DIVISION OF RESEARCH

- Chief Research and Science Officer
- **Chief Research Operations Officer**
  - SRO, AO, FCoI officer, IRB, IACUC, TTO; IEHSC
- Research Officer, PCOM Georgia
- **Research Compliance Specialist**
- Resource Manager
- *Office Manager*
- Laboratory Coordinators and Oversight Staff (1 PA, 1 GA)
- Research Support Staff, including LAR (16 PA, 8 GA)

ABOUT PCOM ORSP

- 2.25 FTEs (up from 1.5 in 1995)
- Federal, local government, private agencies
- Research, training/education, service delivery
- Roles and responsibilities
- Now part of DOR
  - Safety Office moved to Legal Affairs

ONE-STOP SHOPPING

- *Everything* preaward
  - Regulatory
  - Budget
  - Proposal prep
  - Agreements/Contracts
  - Grantspersonship
  - Also TTO

- Postaward narrative progress reports and RPPR
  - I speak Preaward and Postaward

NOW TELL ME ABOUT YOU

- Years experience
- Central vs. departmental administrator
- Office size
- Purchased eRA system?
- Research intensity classification
- Level of responsibility vs. authority; staff vs. faculty appointment
  - IRB
  - IACUC
  - IBC
  - ORI
  - FCoI
  - SO, AOR, IO?
  - TTO?
  - Other?

ATTRIBUTES OF A SUCCESSFUL RA

- Knowledge, skills, attitudes and behaviors
- "Not a personality contest," but it really is (R. Branson)
  - Don't have to love me all the time, but do have to respect me
  - Can make or break
    - Bosses many faculty despised
    - IRB chair had to be removed
    - IACUC chair who loved discussions
      - Long meetings
      - Simultaneous conversations, hard to get accurate minutes

PRIORITY SETTING (LONG- AND SHORT-TERM)

- Grants vs. policy and other stuff
- Individualized attention and focus
- "Other related duties as required"
  - Ex officio on regulatory committees
  - Special committees
    - Disaster Recovery, Enterprise Risk Mgmt, Campus Climate Survey
  - Compliance Committee
  - Self-studies
  - Miscellaneous reports
   - Internal
    - External

FLEXIBILITY

- Internal deadlines
- Workload
- Not obstructionist
  - Help them get to Yes

PARTNERSHIP WITH PIs

- Approachable
- Available
- Indispensable resource
  - Deadlines, budgets, boilerplate, regs, forms
  - Focus on respective areas of expertise
- Brainstorming
- In this together
  - Not an us/them mentality
- Come TO us, not run and hide from us
  - Especially important for regulatory compliance
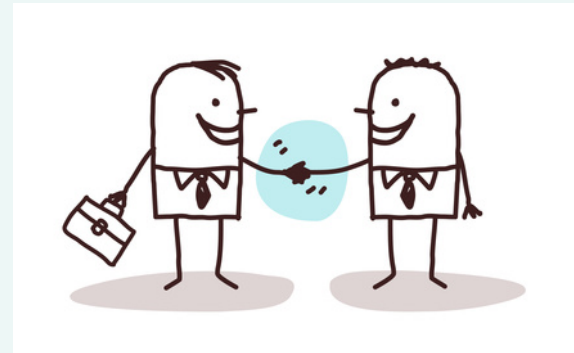
PARTNERSHIP WITH SENIOR ADMINISTRATION

- Manage upward
  - Working style, communication prefs, early warnings, etc.
- Trust
  - Two-way street
  - Be a resource – knowledge and tasks (e.g., SO/AOR); you're the expert!
  - Educate, inform, consult on big issues, e.g., continuing noncompliance
  - Comfort level in signing documents from you
  - Pull out big guns only when necessary
  - Help set tone at the top
- Keep things off bosses' desks
  - Problems (vs. solutions)
  - Issues below their pay grade
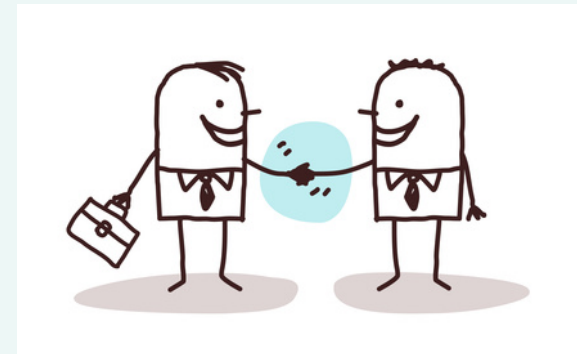
SETTING BOUNDARIES

- Nights, weekends, vacation, biz travel
    - Cell phone number sharing – or NOT
    - Out of cell phone range
    - E-mail
- Self-care!
    - "Brain sorbet" walks in the building
- May I *please*
    - Hang my coat up
    - Eat my lunch
    - Go to the bathroom
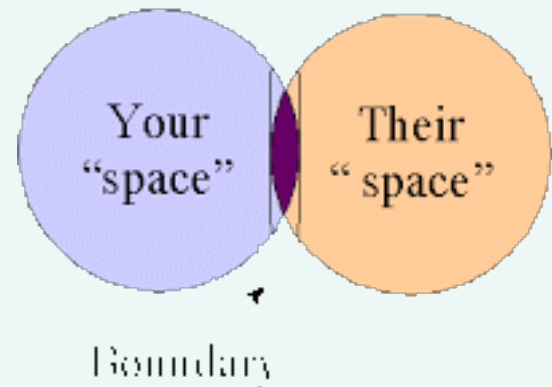
Thou Shalt Not

Call, E-Mail, Harass, Annoy, Irritate, Nettle, Disturb, Upset, Bother, Trouble, Worry, Agitate, Pester, Fluster, Ruffle, Hound, Nag, Torment, Distress, Bug, Hassle, Aggravate, Rile, or Otherwise Vex the Research Compliance Specialist

- Don't make me nag
  - Internal deadlines for e-grants; progress reports
- If I'm going to have the Provost mad at me, it's not going to be for this
- You don't get to get the institution in trouble with the feds

TIME MANAGEMENT

1. Know your goals
2. Prioritize wisely
   a. Important and urgent first
   b. "Busy work" last
3. Just say no
4. Plan ahead
5. Eliminate distractions
6. Delegate or outsource
7. Watch what (time) you spend
8. Take care of yourself

https://quickbooks.intuit.com/r/employees/8-tips-for-effective-time-management/

THE PAPER CHASE

- About 100K pieces of paper/year for IRB and IACUC
- Set calendar reminders and clean out files periodically
- Scan everything completed > 3 years ago (general federal retention rule)
  – Work study students, with training and supervision
- Scan handwritten meeting/conference notes
- Buy a smart notebook that links to the cloud
- My desk may look like this, especially at grant time, but never this

TOOLS

- Funding search subscription
- Grants.gov e-mails
- Private sponsor e-mails
- Course/organization management system
- Purchased eRA system?
- E-mails tailored to groups/individuals
- Tickler calendar with alarms
- Lists/Checklists, calendar reminders
  - Jane, the Ultra Organized
- Color coded jackets and folders
- Database + Google Drive for IACUC health & safety
- ASSIST
- Contracts management system
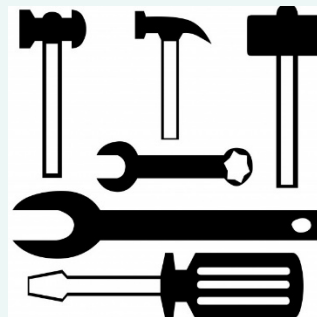
RESOURCES

- Prof'l orgs like SRA, PRIMR
  - Policies to "recycle"
  - News
  - Discussion groups
  - Publications
  - Training and education
  - Professional assessment of research administration office
- Funding agency staff
- Regulatory agency staff
- Research Committee
- IRB, IACUC, IBC, etc.
  - Subcommittees for policies…

RESOURCES

- Grant accountants
- Legal department
  - New tiers for review greatly expedite approvals
- Department and faculty meetings
  - FAQs, P&P, new regs
- Internal auditors
  - Best practices
  - Interdepartmental communication
  - Holes in the cheese (R drive)
- "Inside the Beltway" and state capitol consultants for upcoming grants
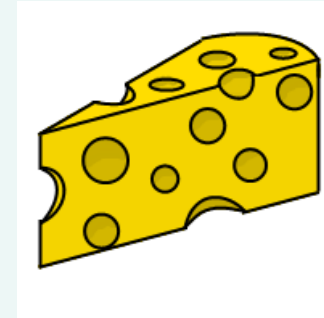
- Successful federal inspections

TALES FROM THE TRENCHES

- Priority Setting
  - "Get…out of my office"
- Flexibility
  - Special dispensation to extend internal deadline
- Partnership With PIs
  - Excel so we can try different scenarios, e.g., % effort
  - Psych faculty consults in advance and when BBB discovered
  - Education about new Common Rule, esp. exemptions
- Partnership With Senior Administration
  - Subject line for Provost e-mails
  - "The F Word" story
  - Comfort level in signing documents from you (not accepting from faculty)
  - The RIGHT way to administer IRB and IACUC

TALES FROM THE TRENCHES

- Setting Boundaries
  - Boss gave my cell phone number to a "repeat offender" while I was at a conference
- Enforcing Policies & Procedures
  - Faculty and esp. students calling afternoon of IRB/IACUC meeting to ask status
  - All contacts from faculty
    - Captain of ship and trained researcher
    - Train the trainer vs. having a zillion people calling and e-mailing
    - Students with selective hearing and/or memory and PI not in loop
  - Yes, you have to complete the application
    - No, I'm not creating a special form just for you
  - You owe me a LOT of chocolate

TALES FROM THE TRENCHES

- Time Management
  - Daily priority setting
    - Take 10 minutes beginning/end of each day
    - Focus on these and avoid distractions, including self-interruptions
    - Just say No (or Not now)
  - Auto e-mail reply when super busy
    - Then DON'T LOOK at e-mails
  - Hide when necessary
    - Close office door, if you have one
    - Work in someone else's office (PI/PD)
    - Reserve a conference room
    - University library
  - Telecommute when necessary
    - Home, local library, ?another institution
    - Black tie optional ;-)

TALES FROM THE TRENCHES

- – Are you a lark or an owl?
- – Single tasking
- Recalcitrant researcher who wouldn't submit progress reports; advice from OHRP
- Exemption category opinion from OHRP for student records research
- Asked demanding USDA inspector why
- Contacted OLAW for help with proposed exotic species
- I'm not a doctor and I don't play one on TV, so I have to run this by
  - – Legal department, Dean, Safety Officer, HR, etc.
- It usually takes __ business days
- I'm also not a bench researcher, so I can ask naïve questions (nonthreatening)
- Just because we're small doesn't mean we're off the radar
- Detailed budgets (but not every paper clip!) and Specific Aims
  - – No animals in budget, but were in aims

WHAT ARE SOME OF YOUR TALES FROM THE TRENCHES?

- Past and how you handled
- Current issues and input from the group