

# STRATEGIES TO REDUCE YOUR RESEARCH ADMINISTRATIVE BURDEN

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# PRESENTERS



- + **GARY WHITNEY**
- + Managing Director
- + **Huron's Education and Life Sciences Practice**

## Experience:

Gary has 30+ years experience in software and technology products. He assists clients with automation and deployment strategies in the areas of research compliance, grants and contracts administration and clinical trials management.

Prior to joining Huron, Gary served as the VP of sales and marketing for Click Commerce. He co-founded Click Commerce's ".com" predecessor, Webridge, an enterprise web-based solutions startup.

# PRESENTERS



- + **Steven Abbott**
- + Product Manager
- + **Huron's Education and Life Sciences Practice**

## Experience:

Steven has extensive experience in a variety of roles, the most recent of which include project management; account management; deployment coordination; technical support; pre-sales support; and product management.

He spent the last three years as the Product Manager for Click IACUC, Click Safety, Click IRB, Click COI, and Click Animal Operations. In addition, he is using his prior experience as a Project Manager for customer implementations for discovery and gap analyses.

# PRESENTERS

- + **MATTHEW FARIS**
- + Senior Director
- + **Huron's Education and Life Sciences Practice**

## Experience:

Matthew's experience includes expertise in managerial and regulatory accounting, operational cost analysis, and the evaluation of research compliance and internal control assessments for colleges and universities.

He has also managed the selection, installation, software development, and upgrade of Enterprise Resource Systems (ERP) for both private and public sector clients.

# ASK US YOUR QUESTIONS: LEVEL 3 CHAT PANEL

← Ask a Question



 HURON | WEB MEETING

Enter a question in this dialog area at any time.

Chat with presenter

Send

# JOIN THE CONVERSATION!



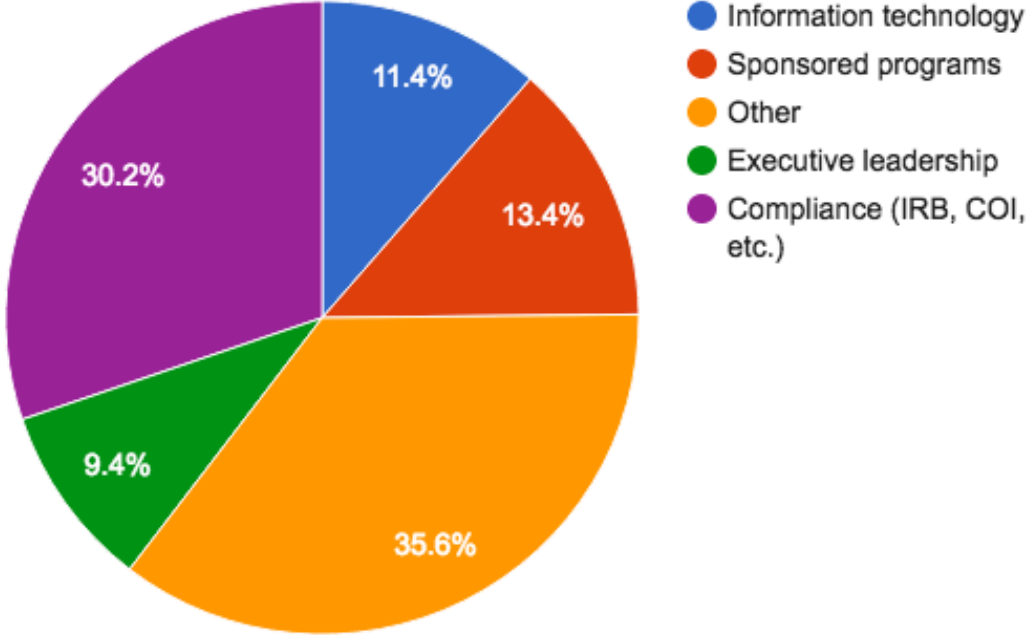
**#HuronResearchSuite**

Keep the conversation going during and after the webinar.



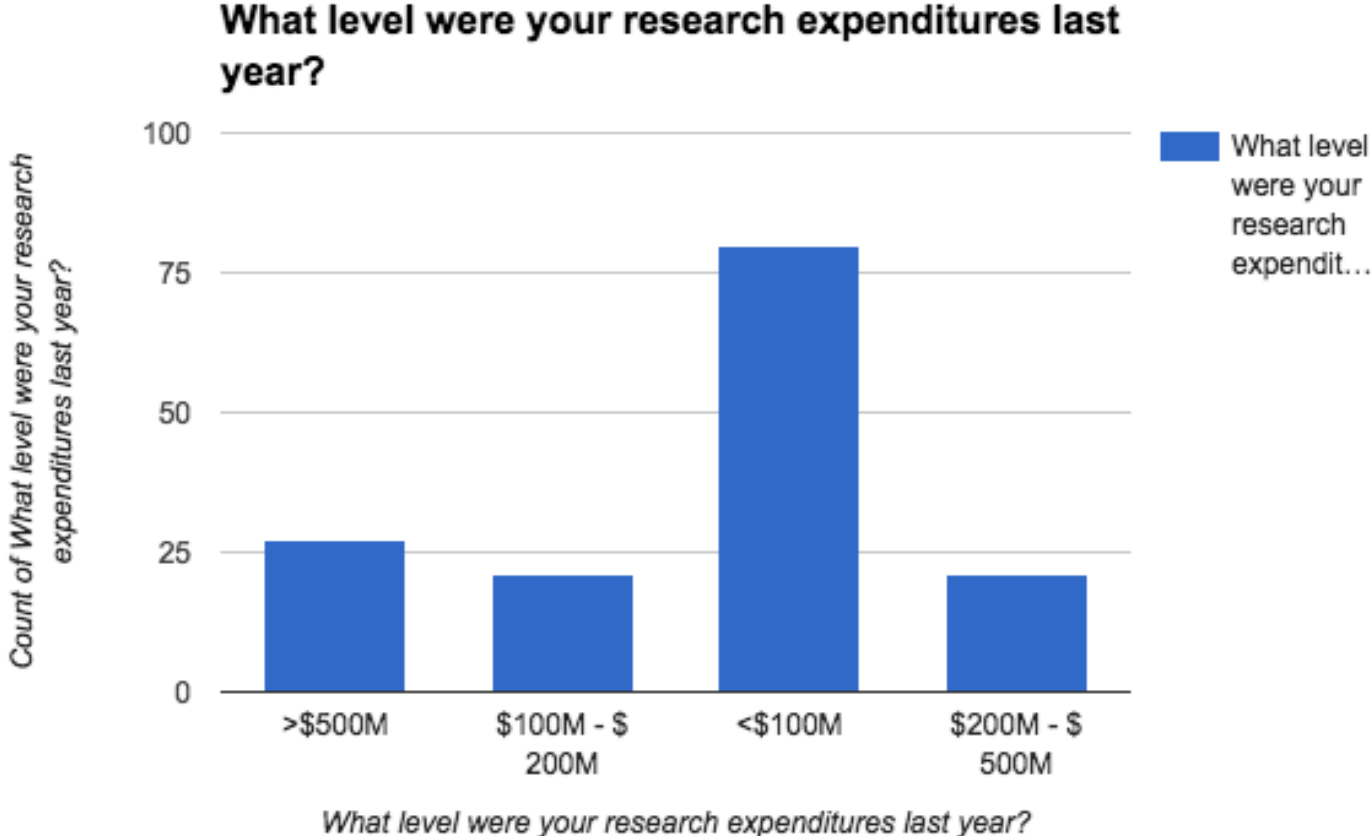
# WHO IS ATTENDING THE WEBINAR TODAY?

What is your primary job function?





# WHO IS ATTENDING THE WEBINAR TODAY?



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# STATE OF THE RESEARCH ENTERPRISE

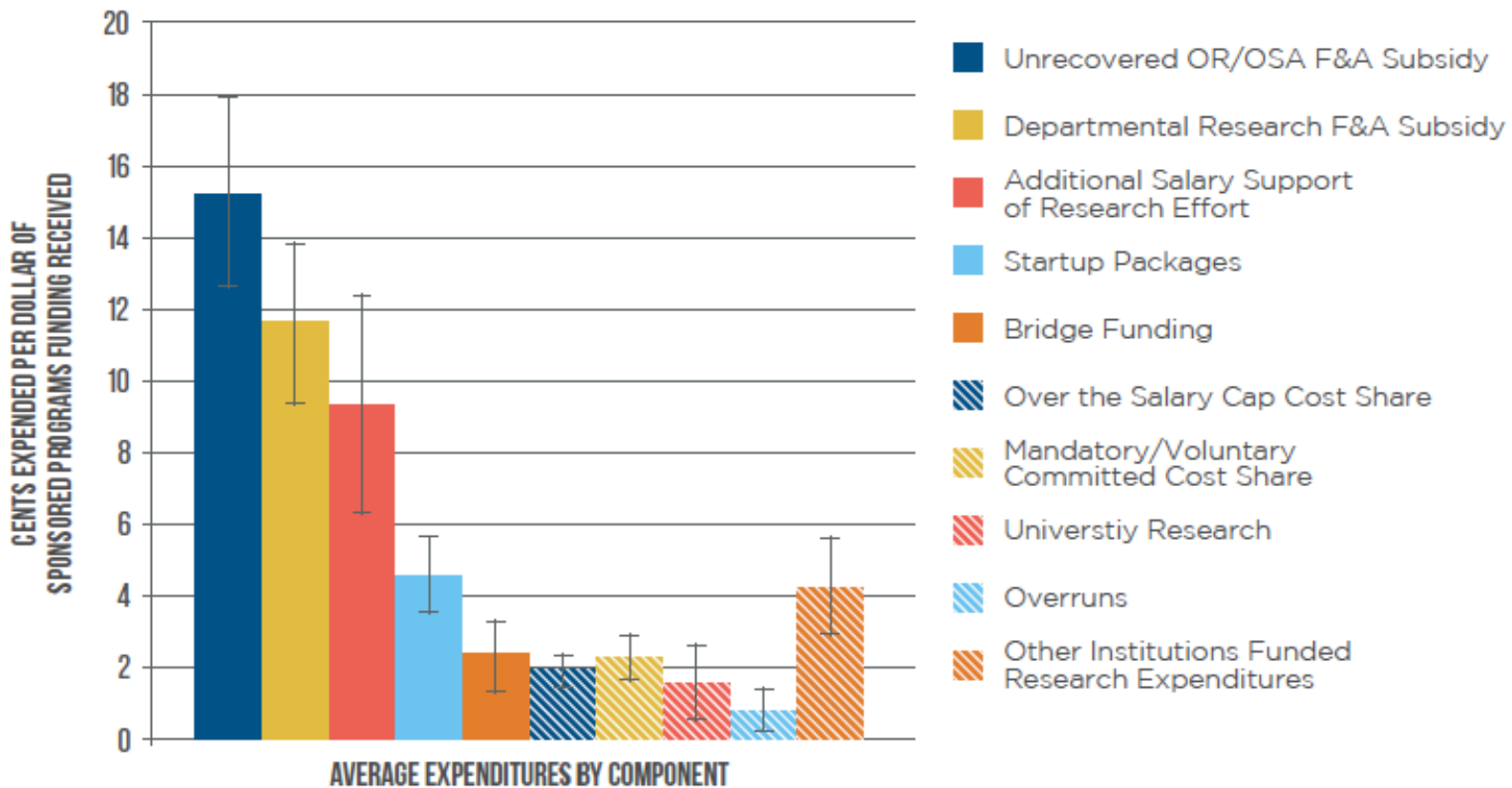
# UNDERSTANDING YOUR INSTITUTION'S INVESTMENT IN RESEARCH

- + Among **46 institutions** surveyed by the Association of American Medical Colleges (AAMC) and Huron – an institution's average research investment was **an additional \$0.53 for each dollar of sponsored research received**
- + Declines in health care reimbursements, state funding, and government research awards are resulting in financial strain, including the funds available to further invest in their research mission.



# WHAT ARE THE MAJOR AREAS INSTITUTIONS ARE INVESTING IN RESEARCH?

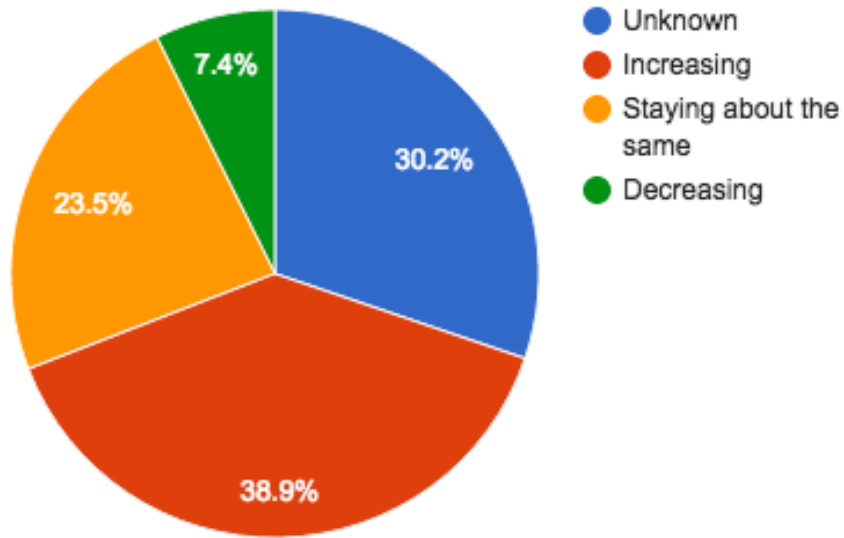
INSTITUTIONAL RESEARCH EXPENDITURES BY INVESTMENT CATEGORY — BREAKDOWN OF THE \$0.53



\*Error bars represent 95% confidence intervals

# WHO IS ATTENDING THE WEBINAR TODAY?

**What is the trend for Research Funding at your institution?**



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# RESEARCH BURDEN

# HOW MUCH TIME DO RESEARCHERS SPEND **NOT DOING RESEARCH?**

+ A 2005 survey\* found that principal investigators (PIs) of federally sponsored research projects spend, on average, **42 percent of their time on associated administrative tasks.**

+ Seven years later, and despite collective Federal reform efforts, a 2012 survey\*\* found the average **remained at 42 percent.**

FEDERAL DEMONSTRATION PARTNERSHIP (FDP)

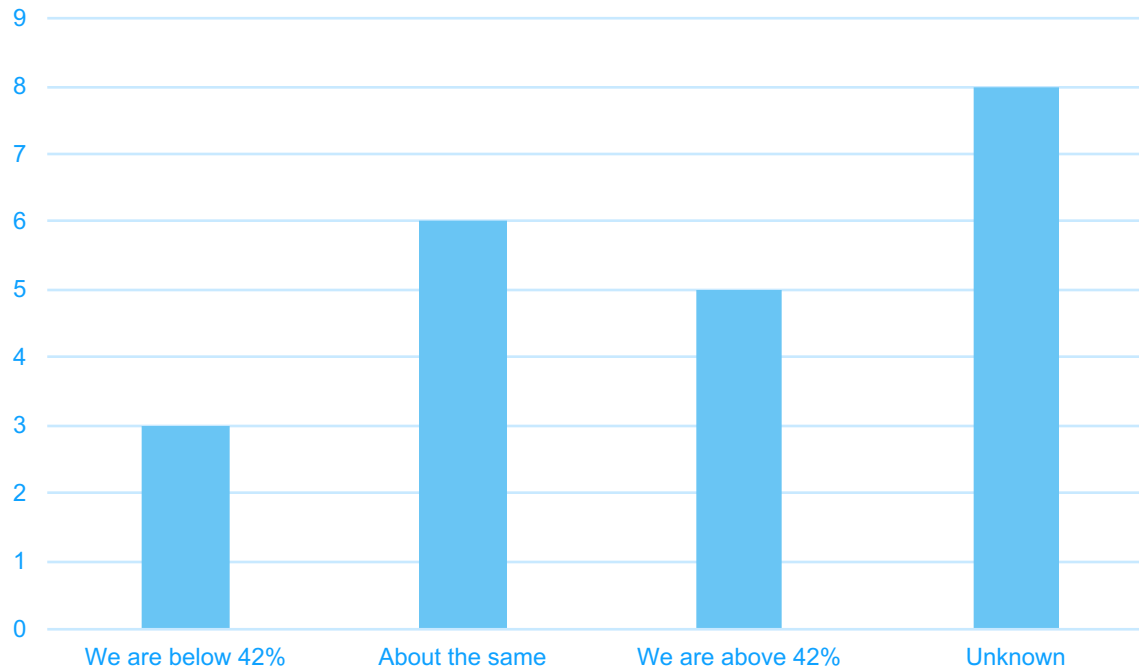


**2012 Faculty Workload Survey  
RESEARCH REPORT**



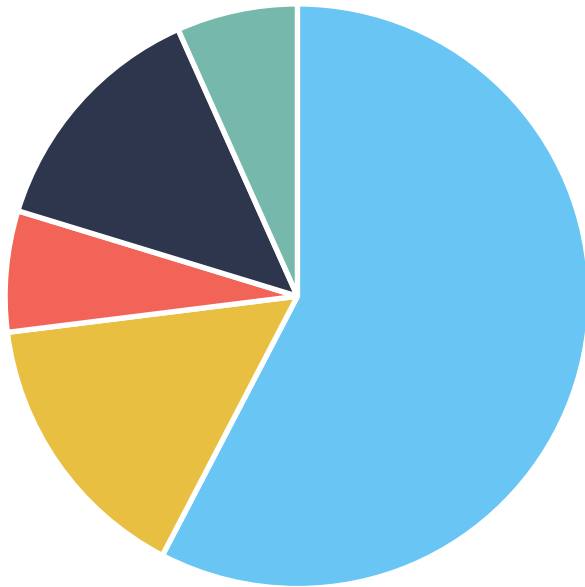
# POLLING QUESTION 1

How does your institution's research burden compare to the FDP results?



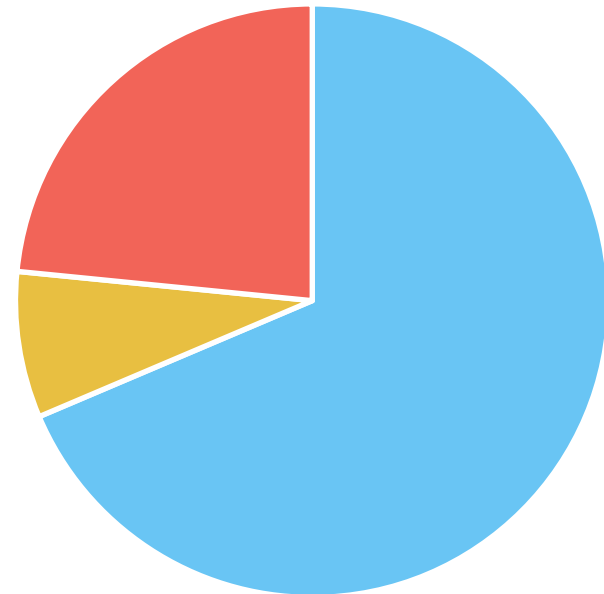
# AREAS IMPACTING RESEARCHER ADMINISTRATIVE BURDEN

2012



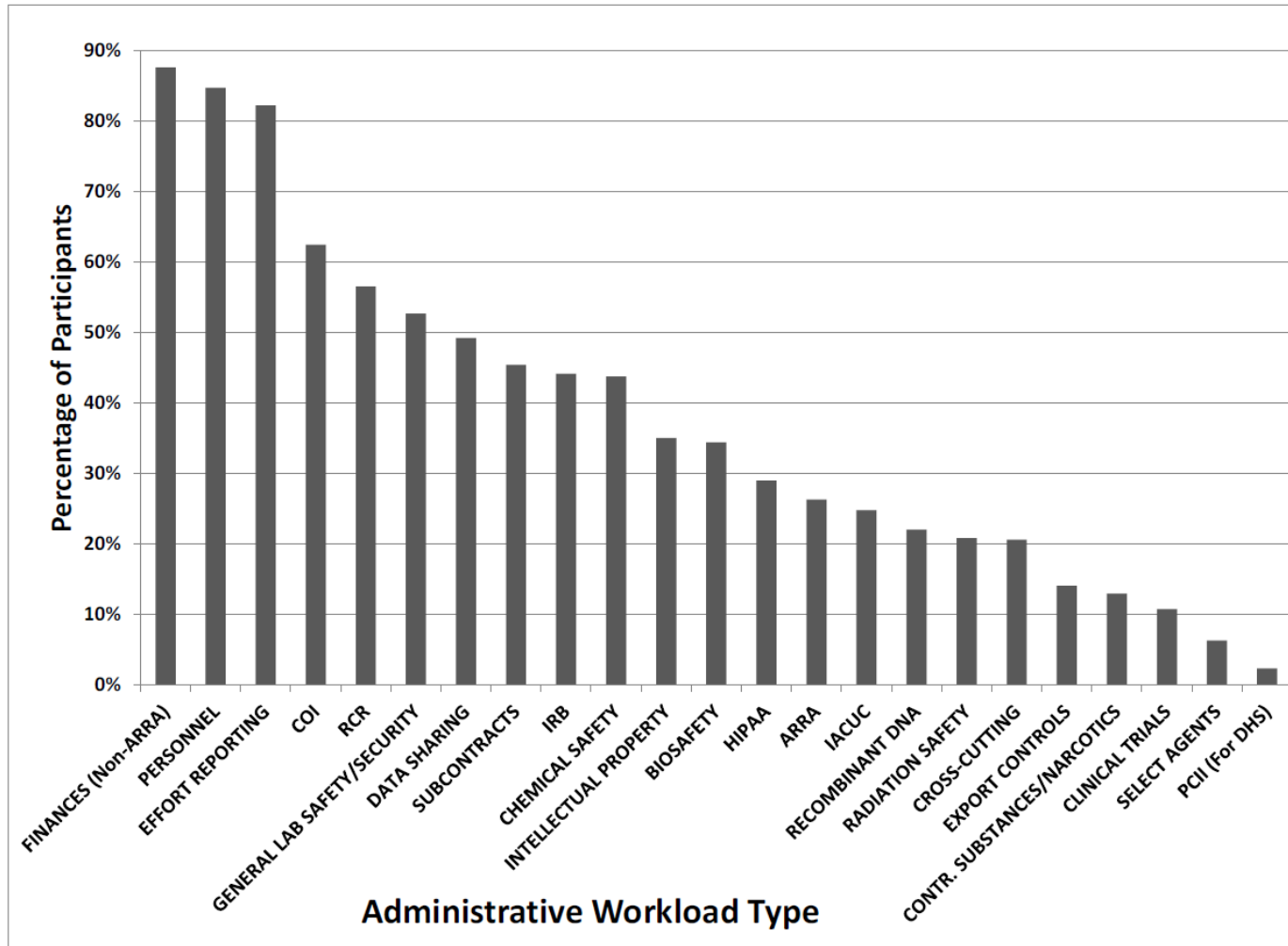
- Active Research
- Proposal Preparation
- Pre-award Administration
- Post-award Administration
- Report prep

2005



- Active Research
- Pre-award Activities
- Post-award Activities

# FUNCTIONAL AREAS IN THE FDP STUDY IMPACTING RESEARCHER ADMINISTRATIVE BURDEN



# EXCESS REGULATIONS SLOW THE PACE OF RESEARCH

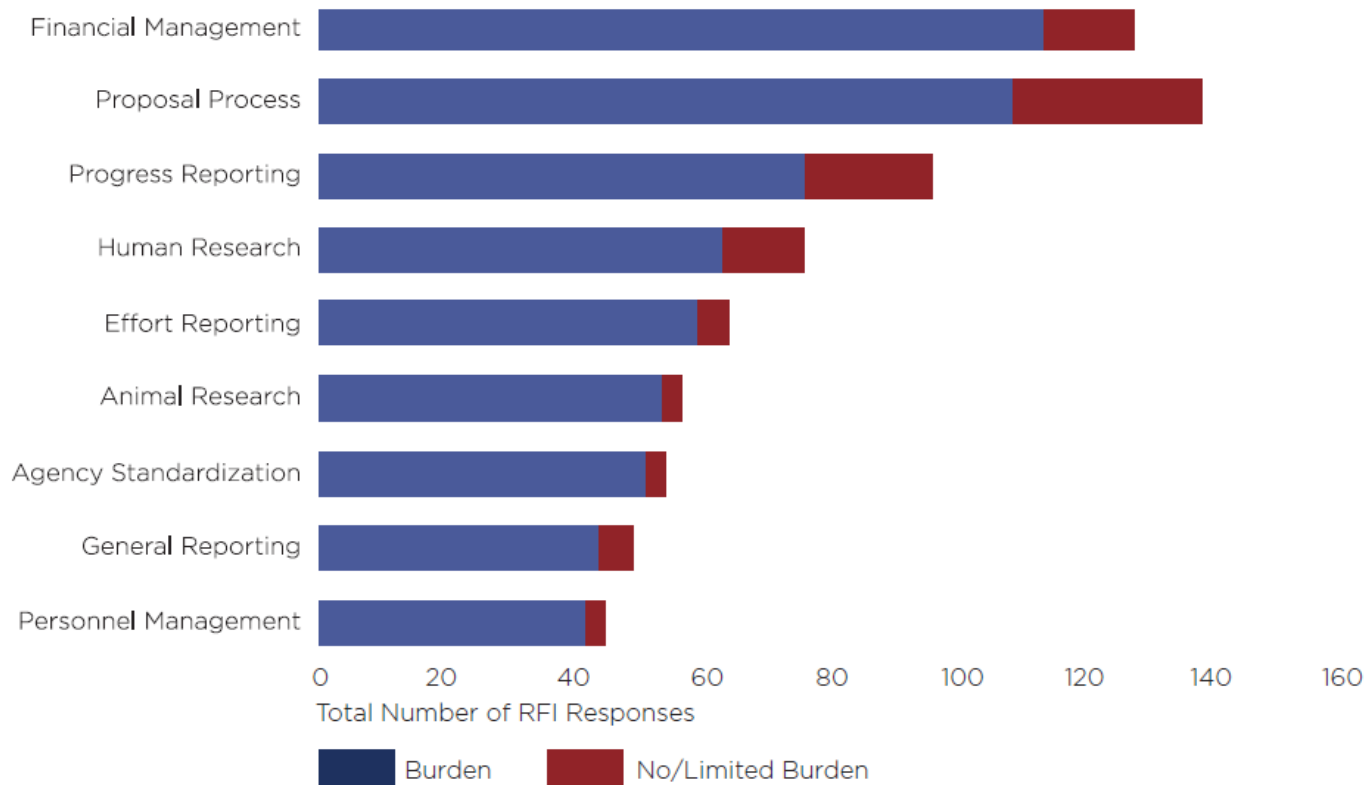
- + Regulatory requirements are essential to ensuring accountability, transparency, and safety when conducting federally funded research.
- + **Excess regulations**, differing agency requirements, and requirements and delays resulting from institutional concerns about liability, however, **slow the pace of research without improving scientific or regulatory outcomes**.
- + Requirements that result in the unnecessary loss of valuable research time must be addressed to fully realize returns on federal investments in research.



# GRANTS MANAGEMENT AND COMPLIANCE

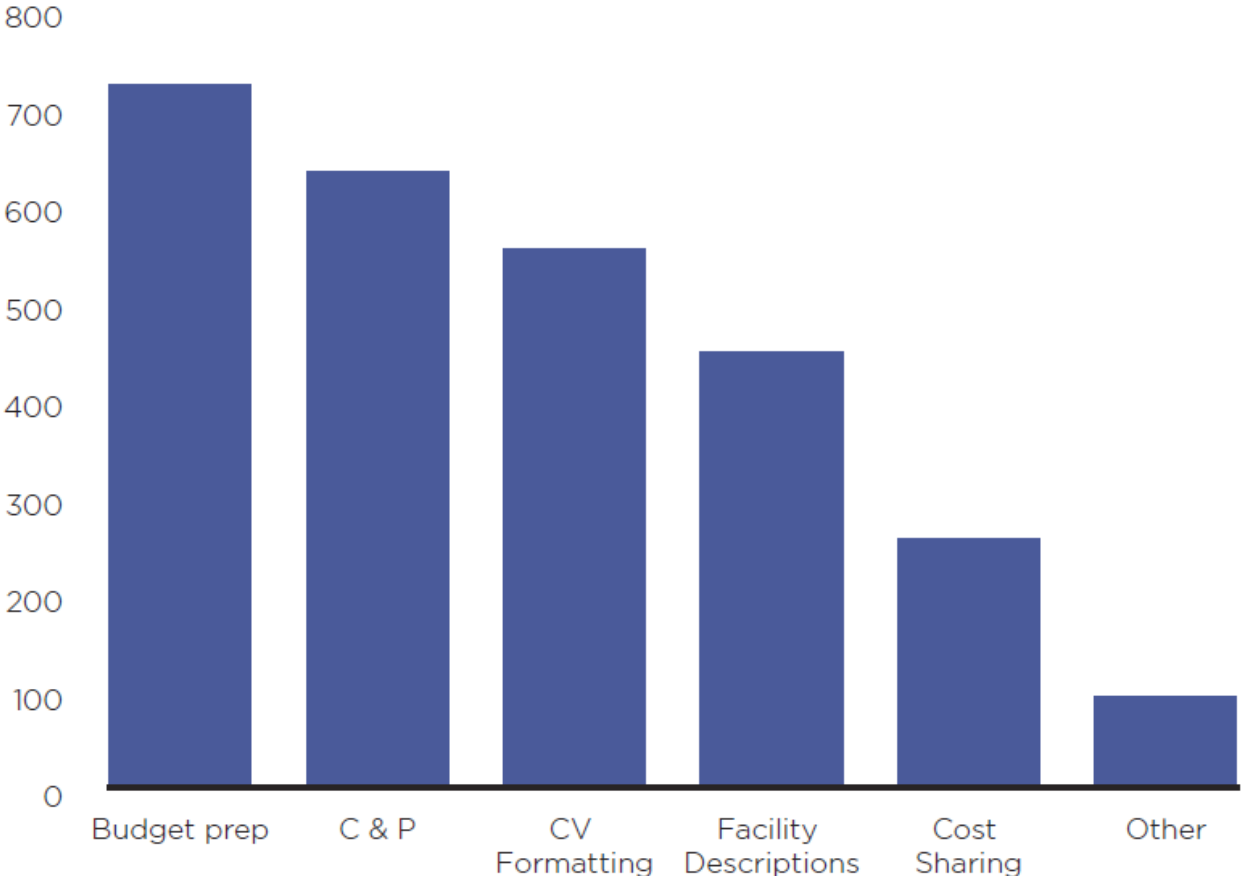
## TOP LIST OF ADMINISTRATIVE BURDEN

Figure 1: Total number of responses that mention each type of burden, limited to those mentioned in 20 percent or more of the responses



# NSB STUDY BURDENS IMPACTING THE PROPOSAL PROCESS

Figure 2: Faculty responses to a follow-up question on proposal-preparation burdens



# NATIONAL ACADEMIES REPORT: RECOMMENDATIONS

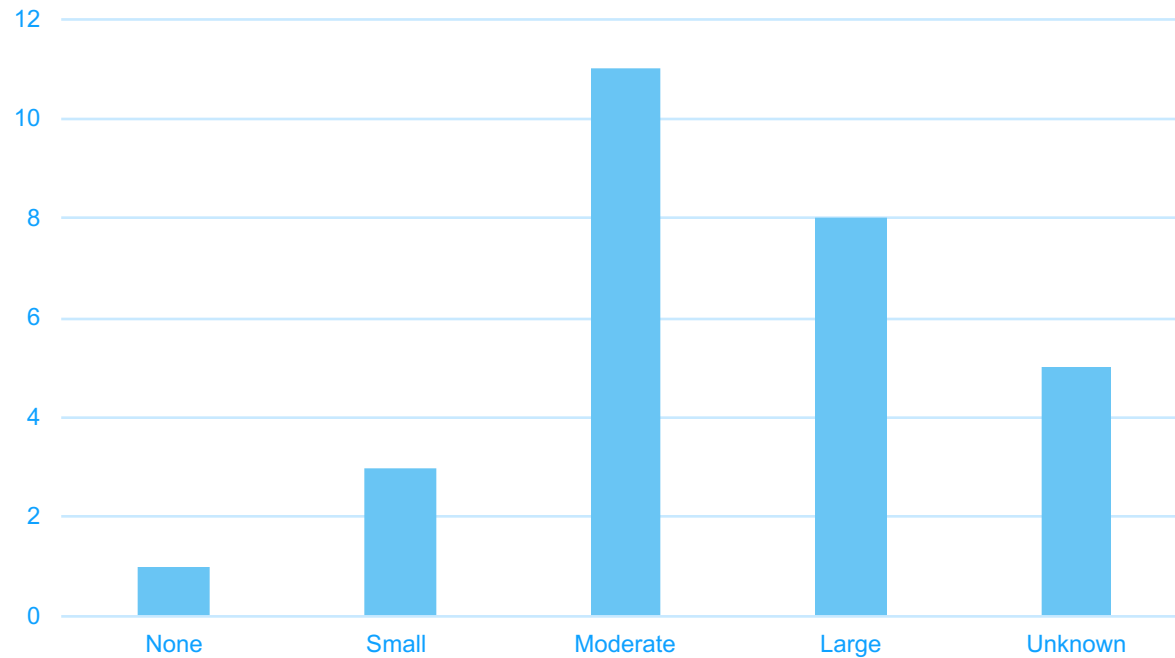
- + Conduct a review of institutional policies developed to comply with federal regulation of research to determine whether **the institution has created additional and unnecessary administrative burden.**
- + **Revise institutional policies that go beyond those necessary** and sufficient to comply with federal, state, and local requirements.





# POLLING QUESTION 2

How big an impact do locally imposed rules have on research burden at your organization?



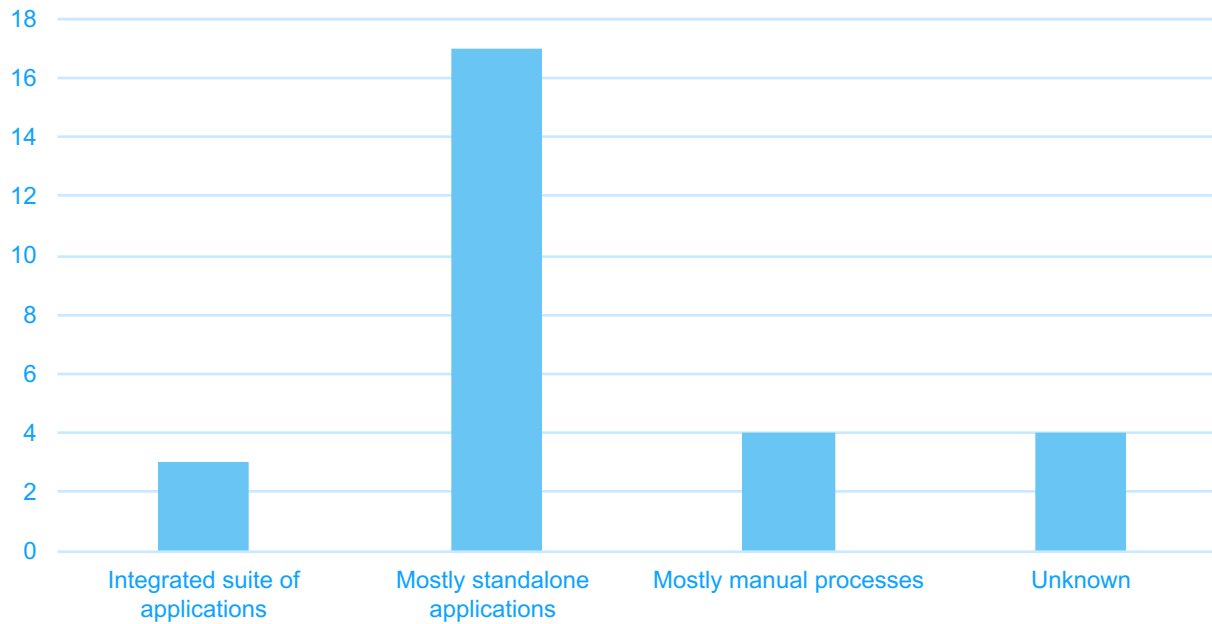
# COGR ADMINISTRATIVE BURDEN CHECKLIST

## SYSTEM RECOMMENDATIONS

- + Develop online systems to reduce or eliminate the amount of requests for action transactions being required and submitted via email, hardcopy or other labor intensive methods.
- + Develop data systems to identify all approvals needed for a study before start-up.
- + Integrate systems wherever possible. Create automated data interchanges/interfaces between core university systems (e.g., grants and IRB, IACUC, IBC, Payroll) to expedite proposal preparation and award oversight tasks.
- + Create a dashboard that will display and link to each transaction/responsibility that requires action.

# POLLING QUESTION 3

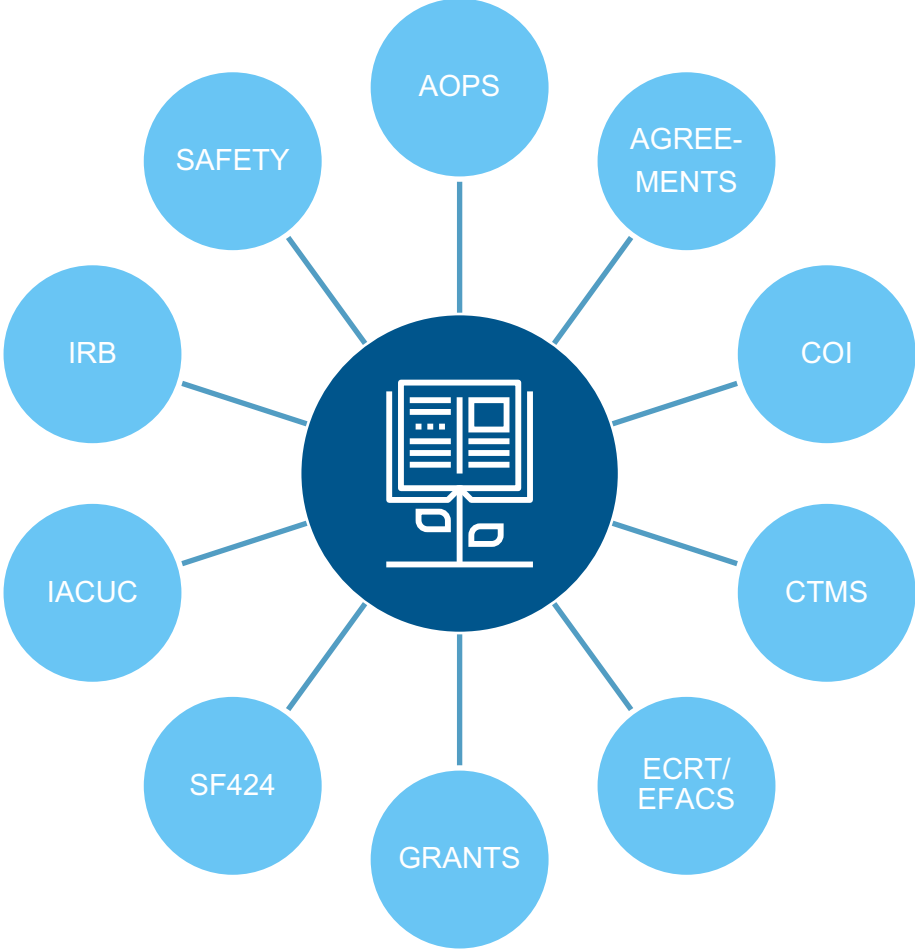
Which best describes the state of your research administrative systems?



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# HURON CLICK RESEARCH SUITE 8.0

# OUR GROWING SUITE OF SOLUTIONS



# HURON RESEARCH SUITE 8.0: OUR PRODUCT MISSION

1

**Continuity:** each release provides an upgrade path from the prior version, allowing all clients to benefit from continuous solution advancements.

2

**Consistency:** user experience and interaction that is uniform across the entire suite.

3

**Integrated Experience:** delivers a complete suite via single sign-on that directly supports the needs of the researcher, administrator and other stakeholders.

4

**Flexibility:** enables clients to benefit from ongoing updates by allowing the flexibility to adjust their implementation along common usage patterns.

# DRIVING PROCESS EFFICIENCY ACROSS THE ORGANIZATION

## Researchers



- What is the status of my proposal?
- How long will this review take?
- What is the next step for my team in this process?

Efficiency and Funding

## Compliance Staff



- What step is taking the most time in our compliance reviews?
- Are we balancing the workload effectively across analysts and committees?
- What studies are stuck in the system?

Cycle Time and Load Balance

## Sponsored Programs



- How many of our proposals are coming in the last day?
- How long does it take us to negotiate a contract?
- What is our funding win rate?
- Are our customers satisfied?

Process Bottlenecks and Trends

## VP RESEARCH



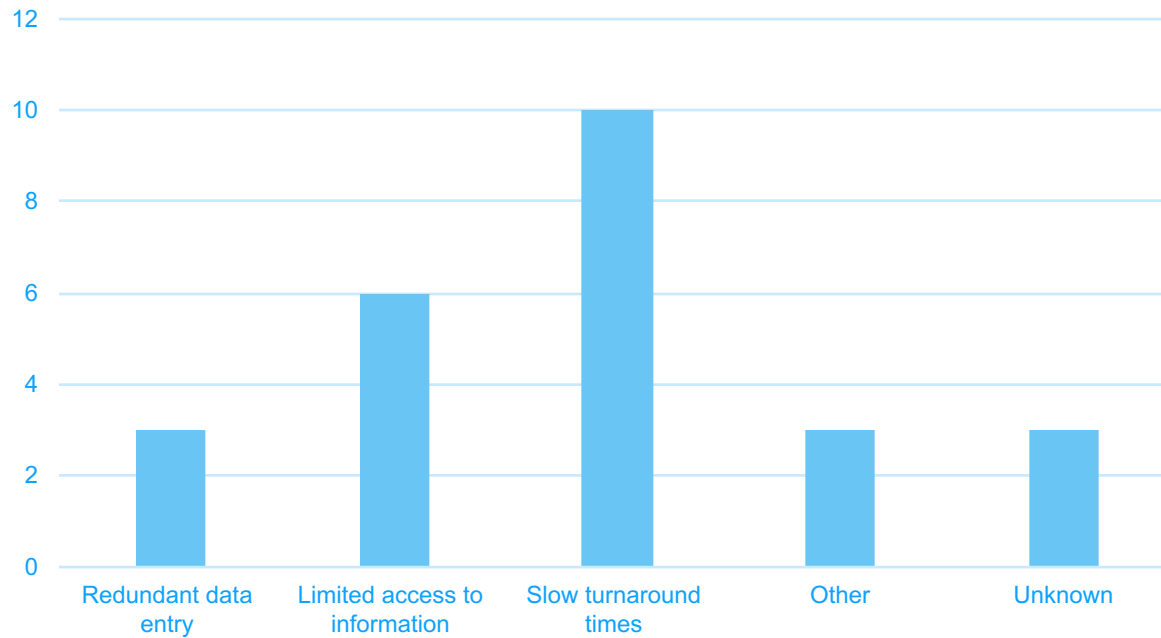
- What is our funding breakdown by sponsor?
- Which PIs are generating the most research?
- What is our organizational compliance risk?

Research Volumes and Alerts



# POLLING QUESTION 4

What would your researchers say is their biggest issue with your current research administration systems?



# GAIN TRANSPARENCY ACROSS THE RESEARCH ENTERPRISE

360-degree view of your research

The screenshot displays the Huron Research Suite interface. At the top, the logo and 'HURON RESEARCH SUITE' are on the left, and 'Hello, Tom Bivens (pi2)' is on the right. A navigation bar contains 'My Inbox', 'Agreements', 'COI', 'CTMS', and 'Facilities'. Below this, a sidebar on the left lists categories like 'Agreements', 'COI', 'CTMS', 'Facility Management', 'Grants', 'IACUC', and 'IRB'. The main area is titled 'My Inbox' and features a filter section with 'Name' (A%) and 'Date Modified' (> 11/1/2016) filters. Below the filters is a table with columns: ID, Name, Date Created, Date Modified, State, and Coordinator. Two items are listed: 'Annual Disclosure Certification for Tom Bivens (pi2) 2016' and 'Amendment for Genome-wide analysis identifies 12 loci influencing human reproductive behavior (Sig Change)'. At the bottom, there are buttons for 'Create New Study' and 'Report New Information'.

**My Inbox**

Filter <sup>?</sup> Name   + Add Filter ✕ Clear All

and Date Modified  ✕

ID	Name	Date Created	Date Modified	State	Coordinator
DC00000116	Annual Disclosure Certification for Tom Bivens (pi2) 2016	11/2/2016 6:23 PM	11/2/2016 6:23 PM	Draft	
AMEND201600018	Amendment for Genome-wide analysis identifies 12 loci influencing human reproductive behavior (Sig Change)	10/12/2016 1:01 PM	11/2/2016 11:31 AM	Clarification Requested (Specialist Review)	Sarah Allen (safa)

2 items      < page 1 of 1 >      25 / page

# IMPROVE GRANT PROPOSAL EFFICIENCY

Ease and efficiency of preparing a Grant funding proposal including automatic calculation of cost shares for a NIH budget

Salary Cap:	\$ 185100.00
Inflation Rate:	3 %
Inflate Period 1:	<input type="checkbox"/>

Add <input type="button" value="1"/> row: <input type="button" value="Add"/>	Period	1
1 Person:	Start:	1/1/2017
Appt:	End:	12/31/2017
Role:	Effort:	50 %
Key:	SalReq:	50 %
F&A Type	Base:	\$200,000.00
Apply Inflation Rate	Req:	\$92,550.00
Base Salary (if inflation applied)	FB Rate:	50 %
	FB:	\$46,275.00
	Total:	\$138,825.00

# STREAMLINED DATA ENTRY

Building blocks enable streamlined data entry and sharing among researchers; also streamlines review through institutionally approved procedures

The screenshot displays the Huron Research Suite interface. At the top, the user is logged in as Rebecca Simms (pi). The main navigation bar includes sections for My Inbox, Agreements, COI, CTMS, and IACUC. Below this, there are sub-sections for Submissions, Concerns, Reports, and Help Center. The central area shows the profile for 'Simms Lab' (TEAM00000001), identifying Rebecca Simms as the Principal Investigator with contact information. A 'Next Steps' sidebar offers actions like 'Edit Research Team', 'Create Protocol', 'Create Procedure', and 'Create Substance'. The main content area features a filter for 'Species: Rat' and 'Procedure Type: %Surgery'. A table lists two procedures: 'Endoscopic Abdominal' and 'Non-Survival Surgery', both for 'Rat' species, with 'Survival Surgery' and 'Non-Survival Surgery' as procedure types, and 'Standard' as the scope. The table includes columns for Name, Execute Activity, Date Modified, Species, Procedure Type, and Scope. Pagination indicates 2 items on page 1 of 1, with 25 items per page.

**Active** TEAM00000001  
**Simms Lab**  
Principal investigator: Rebecca Simms (pi)  
Phone: 503.123.4567  
E-mail: testuser@clickcommerce.com

**Next Steps**

- Edit Research Team
- Create Protocol
- Create Procedure
- Create Substance

Submissions Procedures Substances History Research Team Contacts Archived Procedures Archived Substances Training


Filter ? Species: Rat and Procedure Type: %Surgery

Name	Execute Activity	Date Modified	Species	Procedure Type	Scope
Endoscopic Abdominal	Actions	6/16/2016 9:35 AM	Rat	Survival Surgery	Standard
Non-Survival Surgery	Actions	6/16/2016 9:35 AM	Rat	Non-Survival Surgery	Standard

2 items | page 1 of 1 | 25 / page

# LEVERAGE EXISTING INFORMATION

Ease and efficiency of COI disclosures by eliminating redundant data input


HURON RESEARCH SUITE

You Are Here: [Research Initiated Certificati...](#)

[← Back](#)
[Save](#)
[Exit](#)
[Hide/Show Errors](#)
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[Jump To](#)

## Research Initiated Update for Rebecca Simms (pi) : Disclosure Details

You need to disclose any financial relationship with an external company or organization where you or an immediate family member received remuneration or if you hold equity in said company. [?](#)

On this page, you will be required to provide information on each company / external organization with which you have a financial relationship.  
 If the relationship has not previously been disclosed, click on the "Add Disclosure" button.  
 If the relationship has been previously disclosed, click on the "Modify" link next to the disclosure to update.  
 If the relationship is no longer active (e.g. a consulting agreement that is no longer active), click on the "Remove" link to the right of the disclosure.

[Add Disclosure](#)

### 1. Disclosures under review: [?](#)

View/Edit	Organization	Is Public Company	Relationships	Disclosure Types	Total Value	Is Significant?	Last Updated	Remove
<a href="#">Edit</a>	Biovail Pharmaceuticals, Inc.	yes	Self	<ul style="list-style-type: none"> <li>▪ Sponsored Travel</li> <li>▪ Consulting, advisory, or speaking compensation</li> </ul>	\$3,600.00	yes	11/7/2016 11:56 AM	<a href="#">✕</a>

### 2. Previously reviewed disclosures: (click 'Modify' to enable editing) [?](#)

Modify	View	Organization	Is Public Company	Relationships	Disclosure Types	Total Value	Is Significant?	Last Updated	Remove
<a href="#">✎</a>	<a href="#">View</a>	Abbott Laboratories	yes	<ul style="list-style-type: none"> <li>▪ Self</li> <li>▪ Spouse</li> </ul>	<ul style="list-style-type: none"> <li>▪ Editorial compensation</li> <li>▪ Equity (shares / options) in external company</li> </ul>	\$4,500.00	no	8/8/2016 12:09 PM	<a href="#">✕</a>
<a href="#">✎</a>	<a href="#">View</a>	Pfizer, Inc.	yes	Self	Consulting, advisory, or speaking compensation	\$2,000.00	no	8/8/2016 12:09 PM	<a href="#">✕</a>
<a href="#">✎</a>	<a href="#">View</a>	Rebecca's Statin Company	no	Self	<ul style="list-style-type: none"> <li>▪ Board of directors compensation</li> <li>▪ Equity (shares / options) in external company</li> </ul>	\$0.00	yes	8/8/2016 12:13 PM	<a href="#">✕</a>

[← Back](#)
[Save](#)
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[Hide/Show Errors](#)
[Print](#)
[Jump To](#)

# CUT IRB TURNAROUND TIMES IN HALF!

Huron's IRB HRPP Toolkit has helped organizations cut unnecessary administrative time and cut turnaround times by >50%

The screenshot shows the 'Library' section of the Huron Research Suite. The top navigation bar includes 'My Inbox', 'Agreements', 'COI', 'CTMS', and 'IRB'. The 'IRB' tab is active, and the 'Library' sub-tab is selected. The interface displays a table of IRB documents with columns for 'Name' and 'Document'. There are 11 items listed, and the page is currently on 1 of 2 pages. An 'Export' button is visible in the top right corner of the table area.

Name	Document
HRP-410 - Checklist - Waiver or Alteration of Consent Process	HRP-410 - CHECKLIST - Waiver or Alteration of the Consent Process.doc(0.04)
HRP-411 - Checklist - Waiver of Written Documentation of Consent	HRP-411 - CHECKLIST - Waiver of Written Documentation of the Consent Process.doc(0.04)
HRP-412 - Checklist - Pregnant Women	HRP-412 - CHECKLIST - Research Involving Pregnant Women.doc(0.04)
HRP-413 - Checklist - Non-Viable Neonates	HRP-413 - CHECKLIST - Research Involving Non-Viable Neonates.doc(0.03)
HRP-414 - Checklist - Neonates of Uncertain Viability	HRP-414 - CHECKLIST - Research Involving Neonates of Uncertain Viability.doc(0.03)
HRP-415 - Checklist - Prisoners	HRP-415 - CHECKLIST - Research Involving Prisoners.doc(0.03)
HRP-416 - Checklist - Children	HRP-416 - CHECKLIST - Research Involving Children.doc(0.04)
HRP-417 - Checklist - Cognitively Impaired Adults	HRP-417 - CHECKLIST - Research Involving Cognitively Impaired Adults.doc(0.04)
HRP-418 - Checklist - Non-Significant Risk Device	HRP-418 - CHECKLIST - Non-Significant Risk Device.doc(0.03)
HRP-419 - Checklist - Waiver of Consent Process for Emergency Research	HRP-419 - CHECKLIST - Waiver of the Consent Process for Emergency Research.doc(0.03)

11 items      < page 1 of 2 >      10 / page

# PENNSYLVANIA STATE UNIVERSITY: A HURON CLICK CASE STUDY



- HRPP Toolkit Gap Analysis
- Toolkit Adaptation
- HRPP Business Process Change Implementation

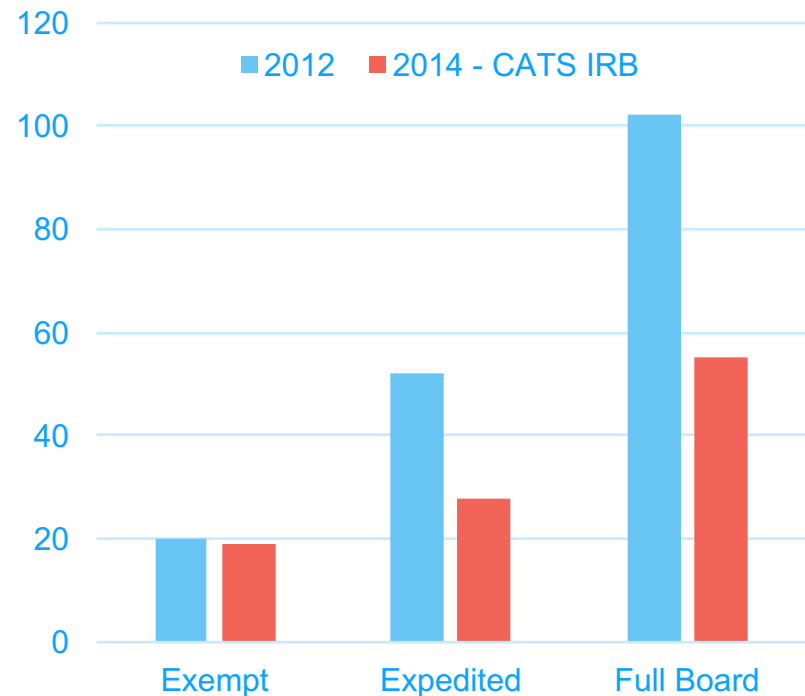


- Huron IRB Solution Implementation
- Training and education



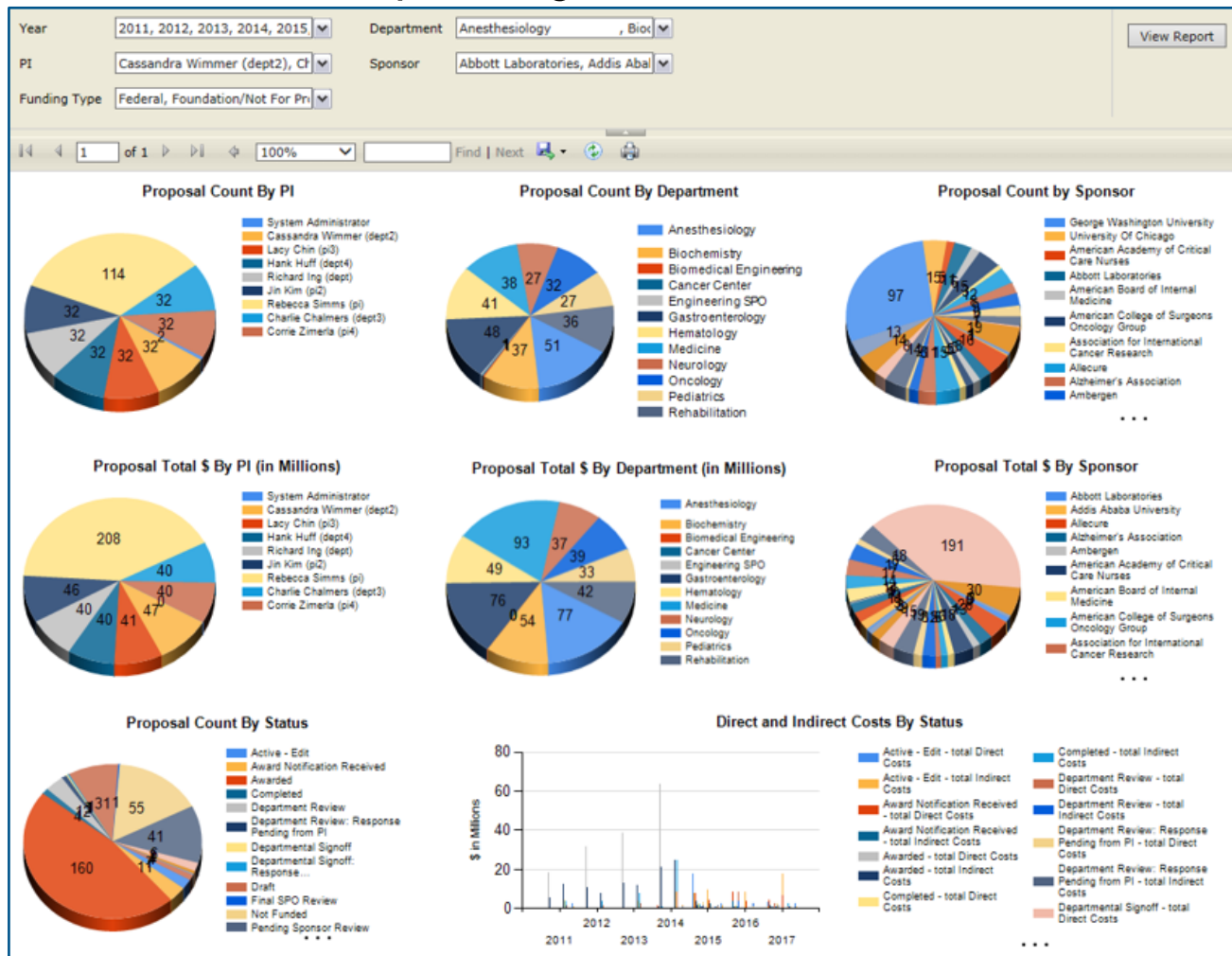
- Post-implementation Support

Average Number of Days  
from Submission to Approval



# INSTANT ACCESS TO KEY METRICS

Turnaround and other advanced reports that enable you to review how efficiently the business is operating





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# SPECIAL CONSIDERATIONS

# ON THE HORIZON: SPECIAL CHALLENGES FOR 2017

- + Single IRB Review Requirement
- + Notice of Proposed Rule Making (NPRM)

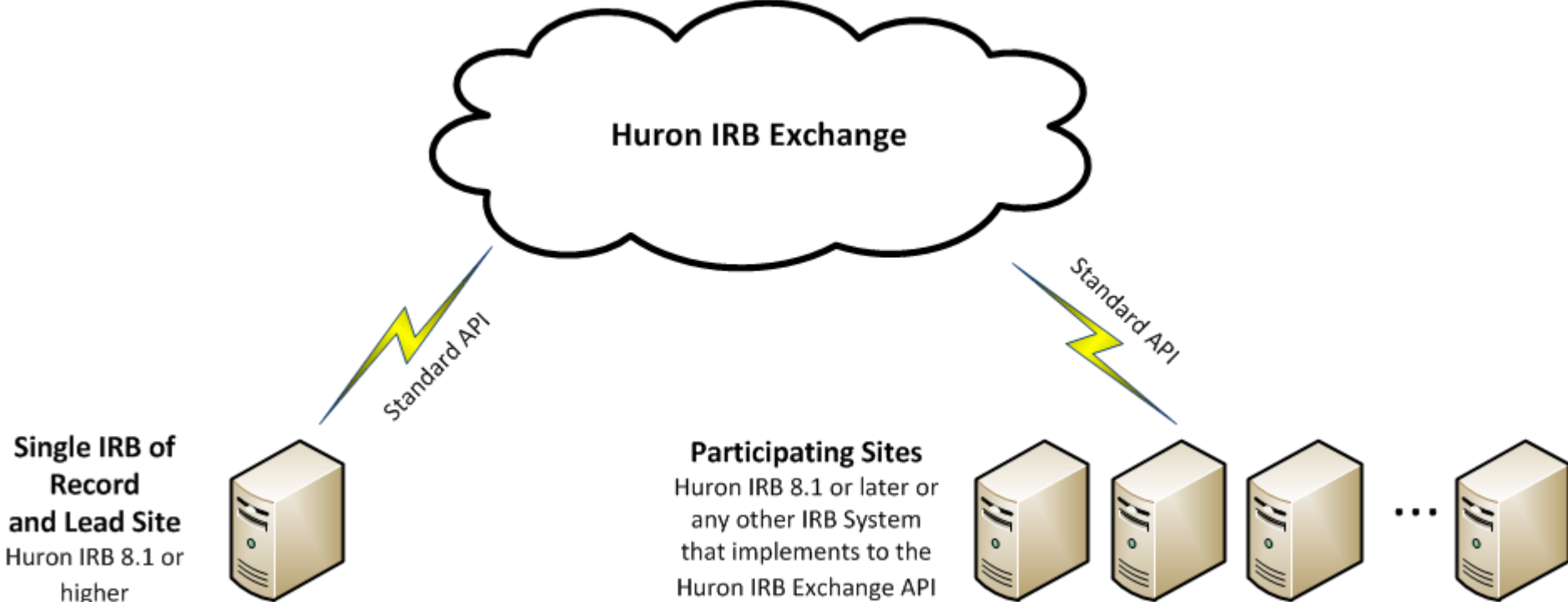
# NIH POLICY UPDATE: SINGLE IRB REVIEW

The NIH Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research establishes the expectation that all sites participating in multi-site studies involving non-exempt human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects.

This policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after May 25, 2017.



# MULTI-SITE STUDIES REQUIRE CROSS-INSTITUTION COORDINATION



# JOIN OUR UPCOMING WEBINAR: PREPARE NOW FOR THE NIH'S SINGLE IRB REVIEW

Prepare Now for The NIH's Single IRB Review

**Thursday, Nov. 10**

**12 – 1 p.m. (CT)**

*Features an in-depth analysis of the Single IRB policy, the automation implications of the shift at research institutions, and a detailed discussion of how Huron's industry leading Click IRB solution is being extended to fully support single IRB reviews.*

# Q&A

# STAY CONNECTED:

- + Visit [huronconsultinggroup.com/researchsoftware](http://huronconsultinggroup.com/researchsoftware) for up-to-date resources and information
- + Subscribe to our weekly Clinical Research Management Briefing newsletter:  
[www.huronconsultinggroup.com/CRMB-Subscribe](http://www.huronconsultinggroup.com/CRMB-Subscribe)



**THANK YOU**