



**FEDERAL DEMONSTRATION PARTNERSHIP**  
Redefining the Government & University Research Partnership

# Research Compliance Committee: Phase VII Roadmap Planning

FDP Virtual Meeting January 2021

Melissa Korf, Harvard Medical School



# Session Agenda

- Research Compliance Committee Background and Structure
- Highlights from the 2018 Faculty Workload Survey Report
- Discussion and Next Steps



# Research Compliance Committee (RCC) Goals

The Research Compliance Committee reviews existing and new administrative requirements imposed by federal regulations and program officers related to research compliance with an emphasis on harmonization of requirements across federal agencies, reduction of redundancies, and identification of good practices. This includes but is not limited to human subjects protections, animal care and use, conflict of interest, export controls, and data stewardship.



# RCC History

- RCC is one of the youngest of the FDP Programmatic Committees and was formed in response to the research compliance issues identified in one of the early Faculty Workload Surveys.
- Data Stewardship is our youngest subcommittee and was approved in May 2015.



# Current Committee Structure

## Research Compliance Committee

Melissa Korf

Diane Dean

## Animal Care and Use

Ara Tahmassian

Axel Wolff

## Conflict of Interest

Mary Lee

Diane Dean

## Data Stewardship

Vacant

Vacant

## Export Controls

Doug Backman

Vacant

## Human Subjects

Deb Murhpy

Vacant



# 2018 Faculty Workload Survey report

- Full Report available via the FDP website at:  
<http://thefdp.org/default/assets/File/Documents/FDP%20FWS%202018%20Primary%20Report.pdf>
- Respondents were asked whether they experienced a set of compliance responsibilities. If they did, they were asked to indicate
  - the likelihood that responsibility represented a substantial workload
  - whether the responsibility was a low, medium, or high priority for change to reduce administrative burden



# Prevalence of Compliance Requirements

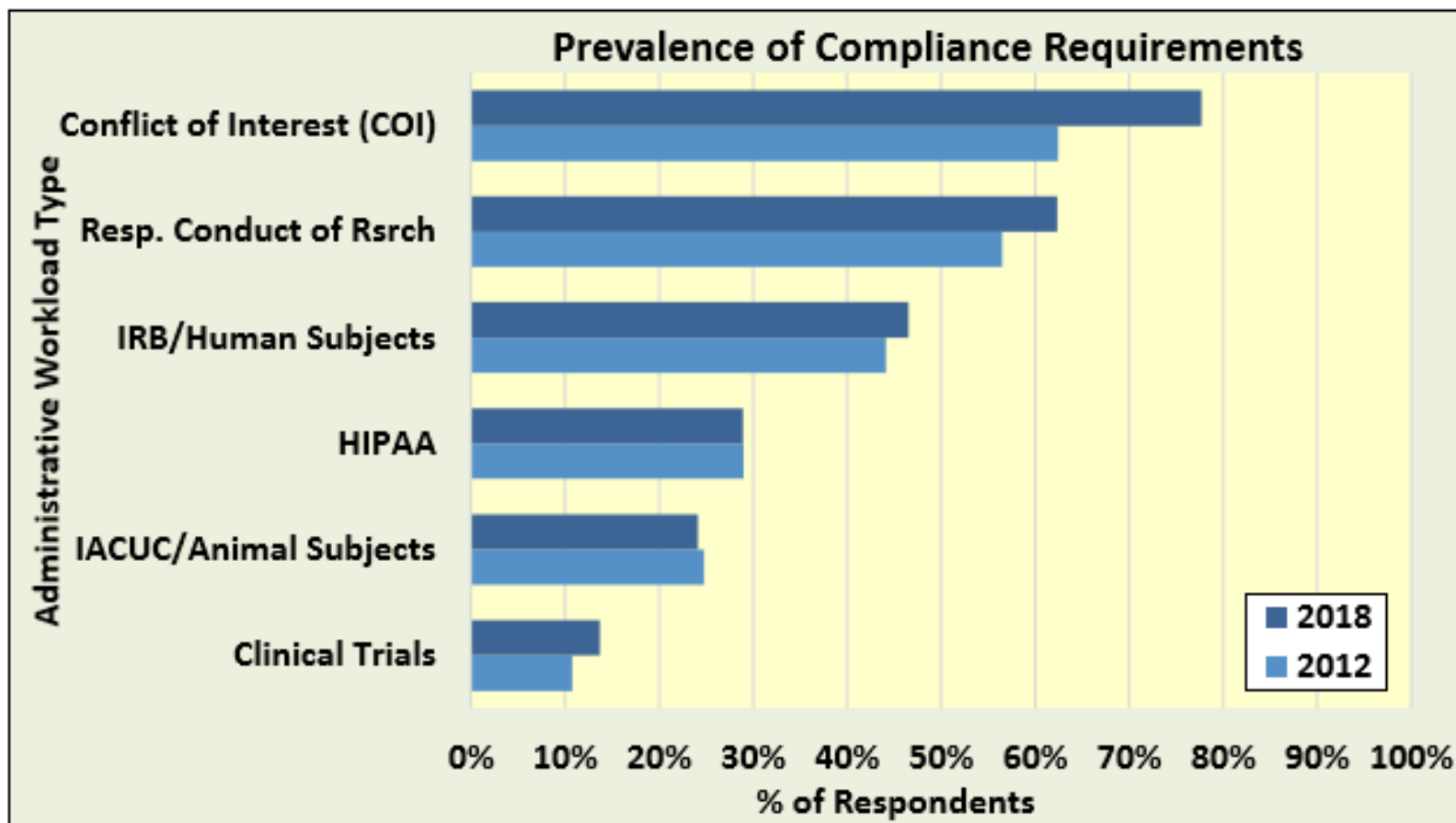


Figure 13. Prevalence of six compliance responsibilities as reported in 2018 and 2012 surveys. Resp.=Responsible, Rsrch=Research.



# Substantial Workload of Compliance Requirements

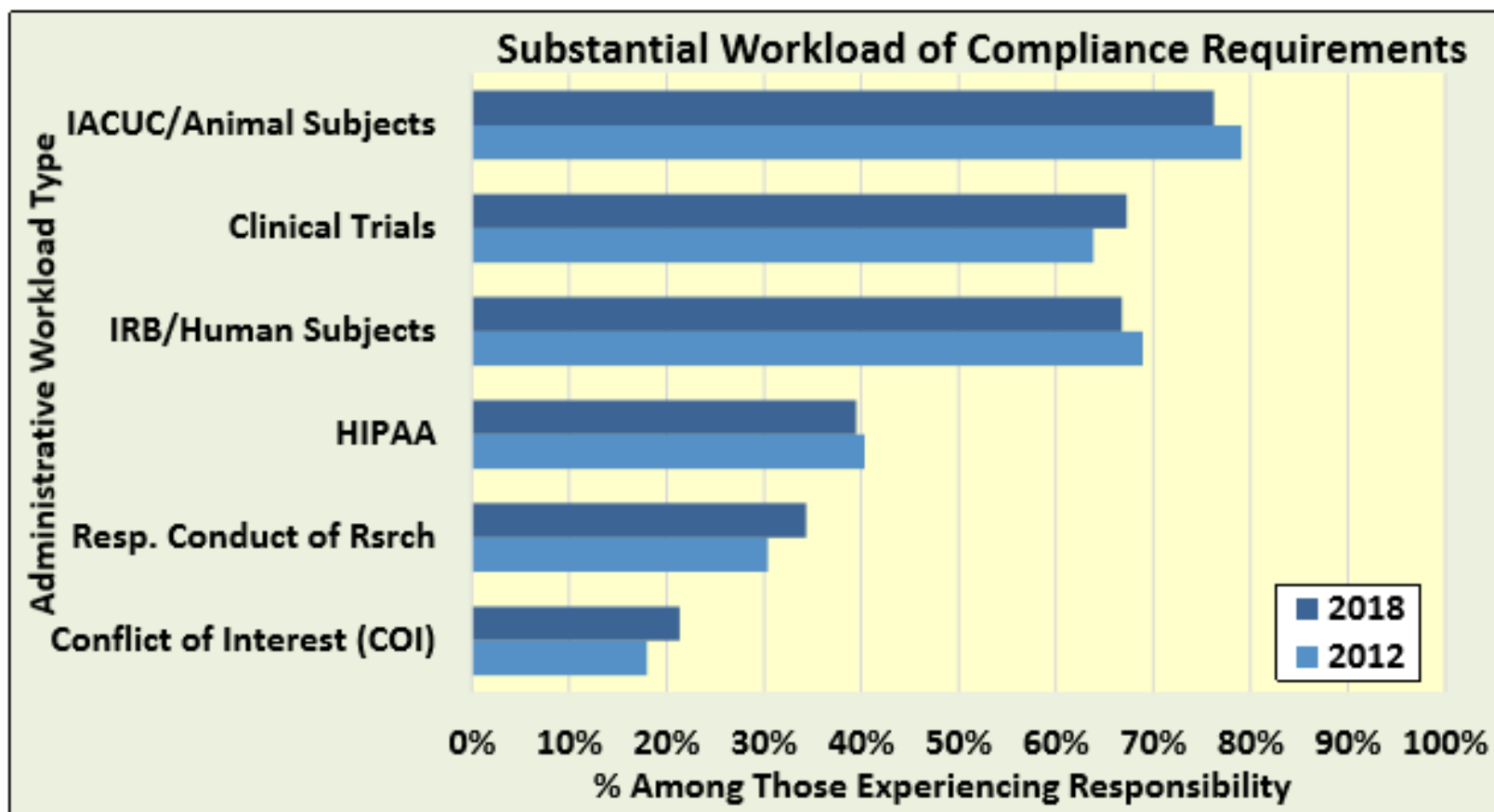


Figure 14. Prevalence of six compliance responsibilities as reported in 2018 and 2012 surveys. Resp.=Responsible, Rsrch=Research.





# High Priority for Change in Compliance Requirements

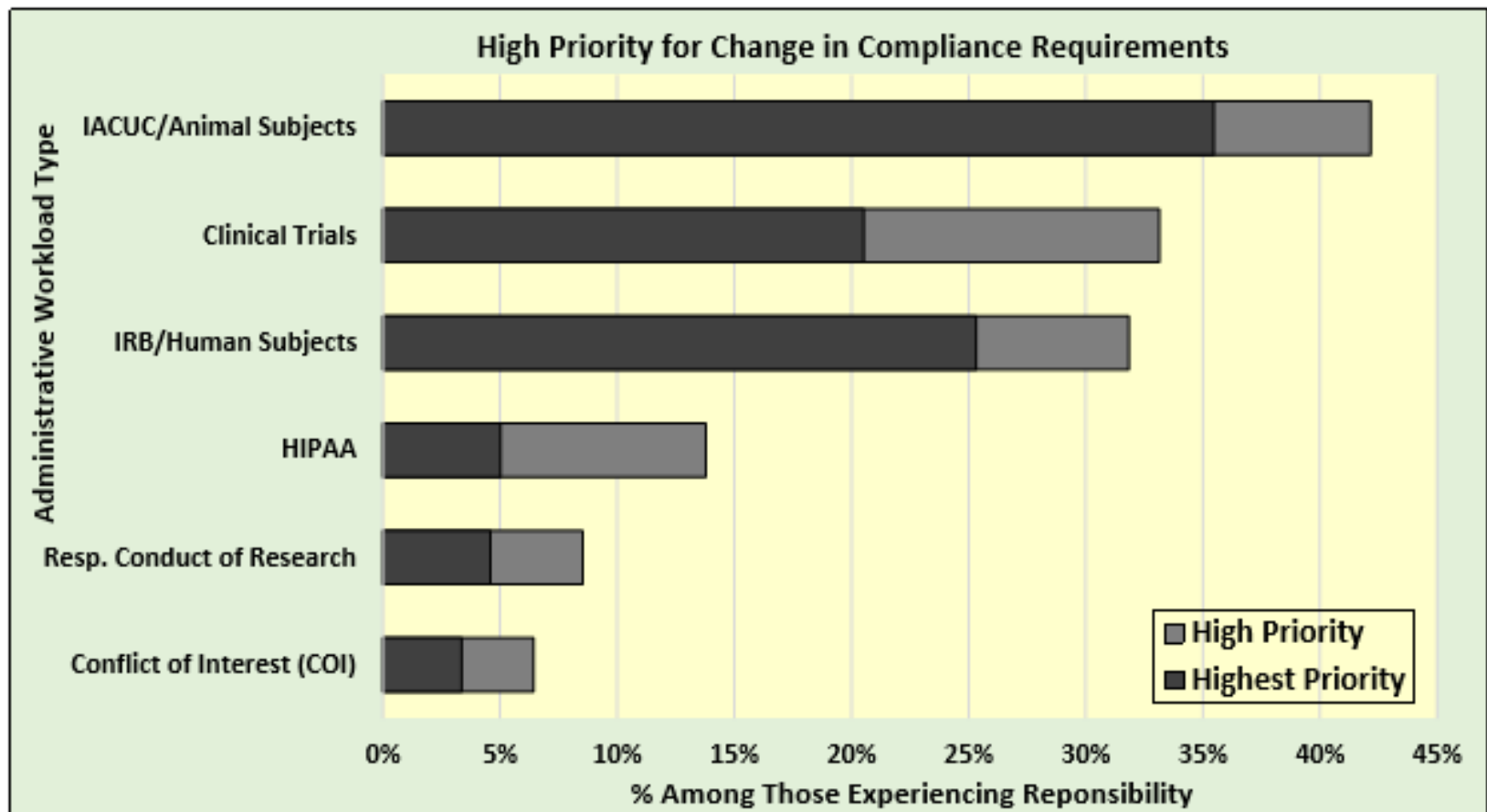


Figure 15. Percent rating each requirement as high and/or highest priority for change in order to reduce unnecessary administrative burden. Resp.=Responsible.



# IACUC Responsibilities

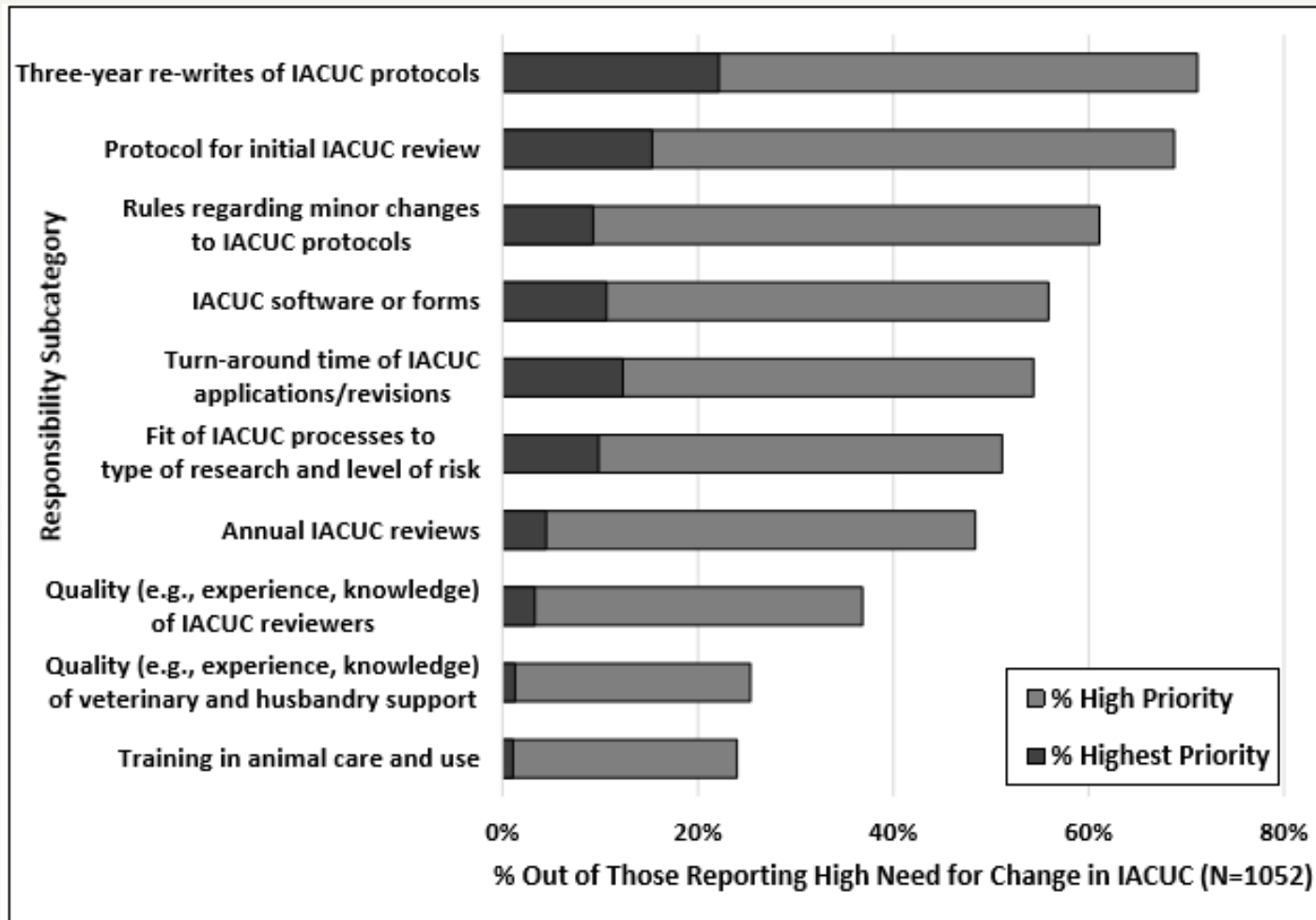


Figure 16. Percent rating each component of IACUC/animal subjects responsibilities as high and/or highest priority for change in order to reduce unnecessary administrative burden.



# IRB/Human Subjects Responsibilities

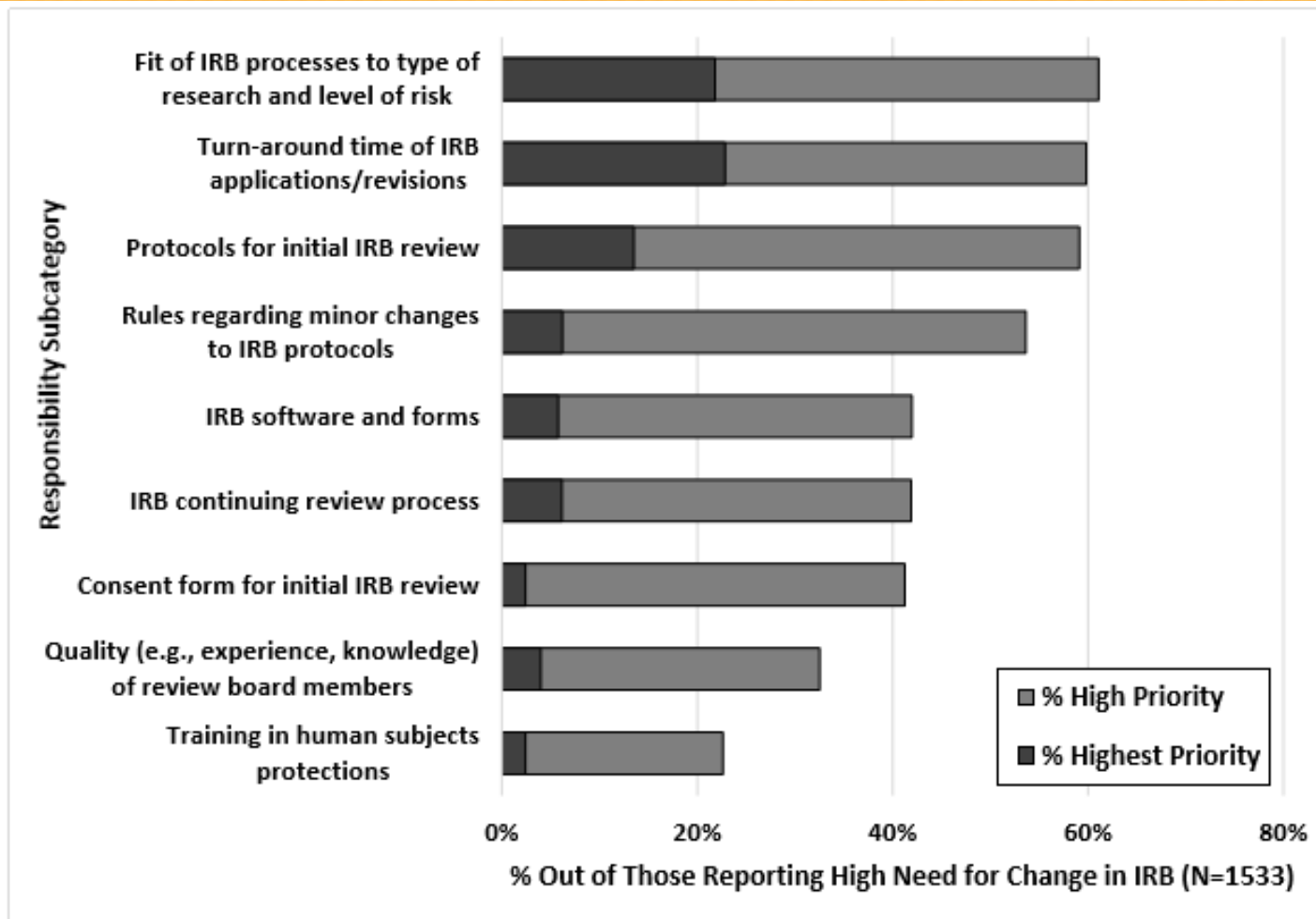


Figure 17. Percent rating each component of IRB/human subjects responsibilities as high and/or highest priority for change in order to reduce unnecessary administrative burden.



# COI Responsibilities

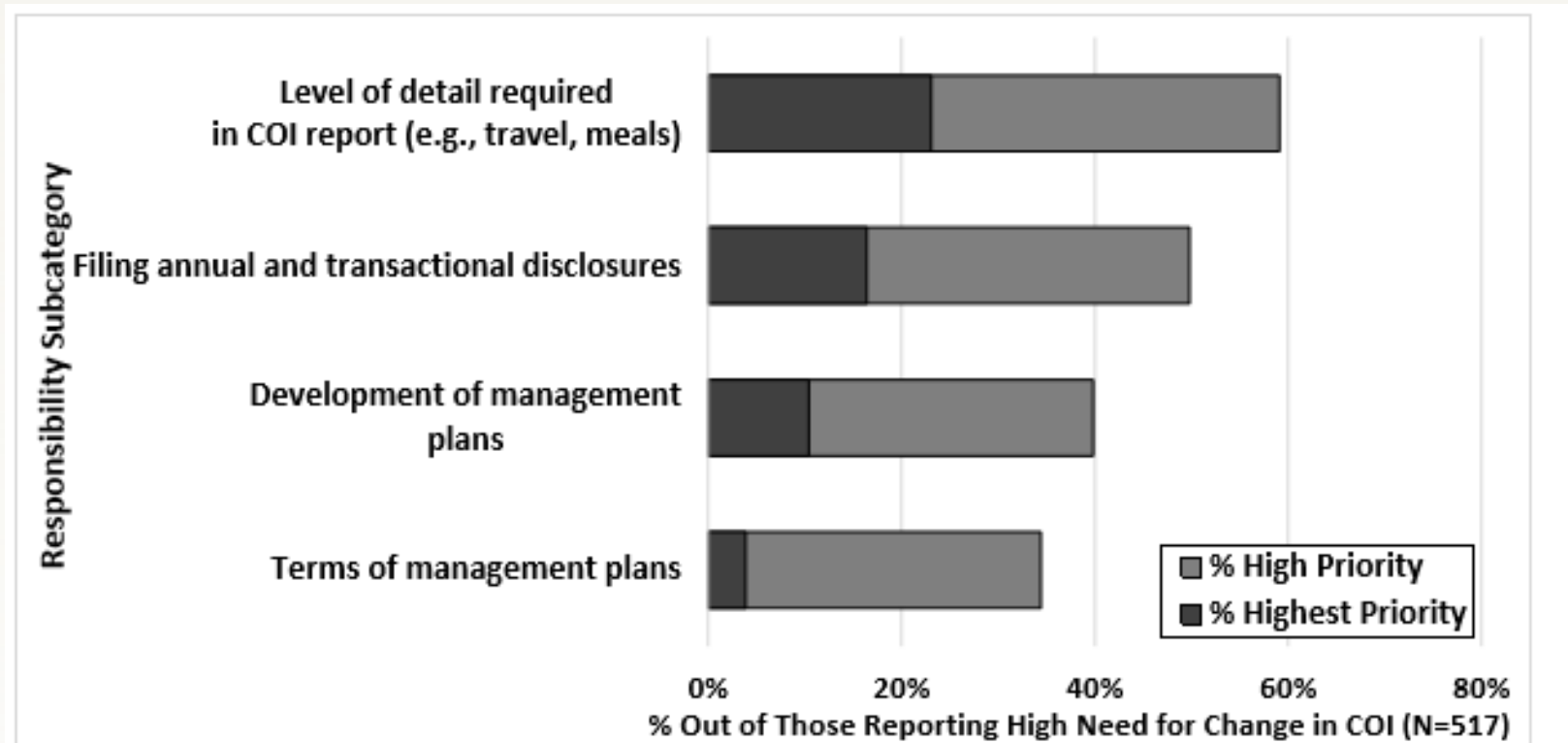


Figure 18. Percent rating each component of conflict of interest responsibilities as high and/or highest priority for change in order to reduce unnecessary administrative burden.



# Data Management appears under Research Administration

Substantial Workload for General Research Admin. Reqs.

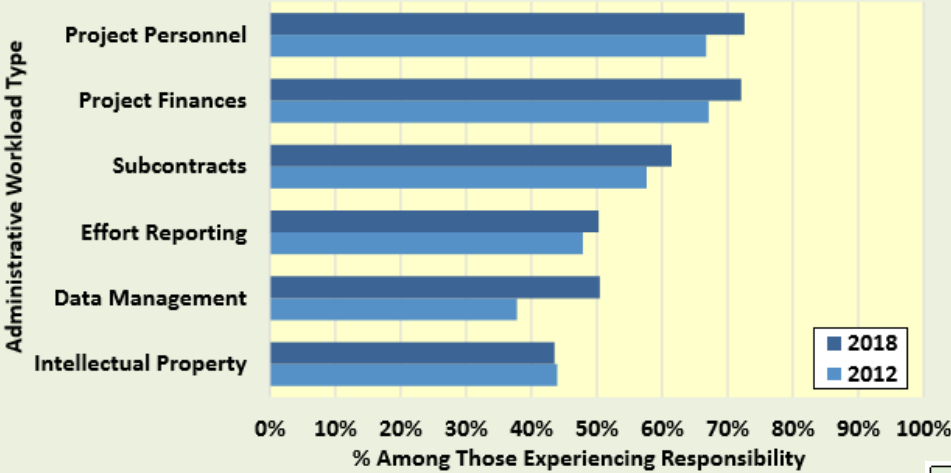


Figure 7. Prevalence of six general research administration responsibilities as reported in 2018 and 2012 surveys. Admin. Reqs.=Administration Requirements.

High Priority for Change in General Research Administration Requirements

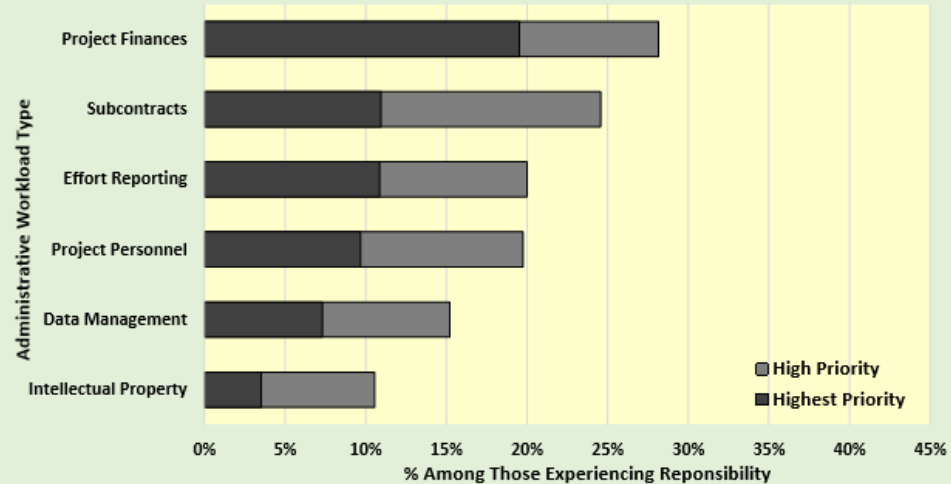


Figure 8. Percent rating each requirement as high and/or highest priority for change in order to reduce unnecessary administrative burden.



# Data Management Responsibilities

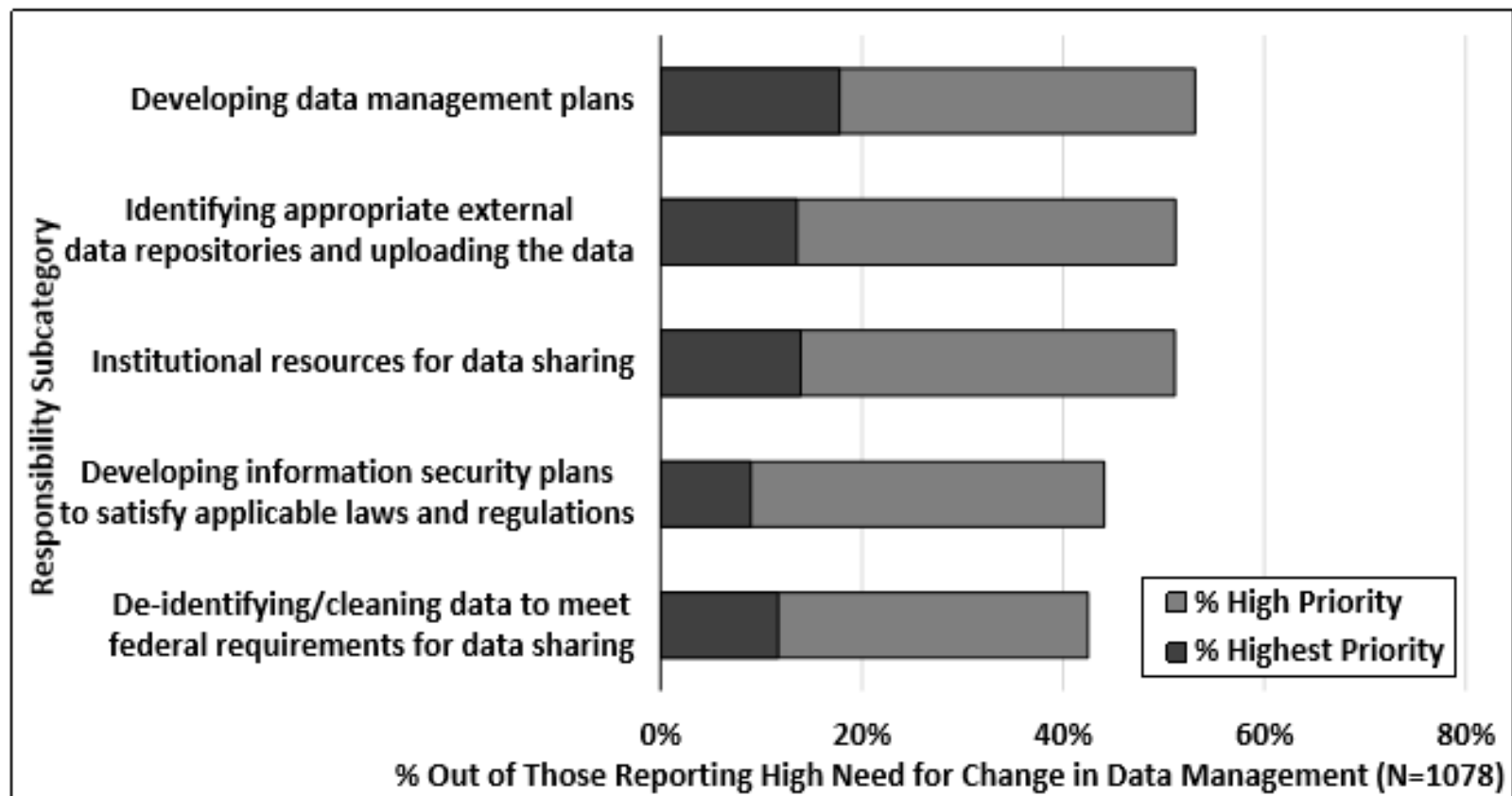


Figure 11. Percent rating each component of data management responsibilities as high and/or highest priority for change in order to reduce unnecessary administrative burden.



# Prevalence of Safety/Security Requirements

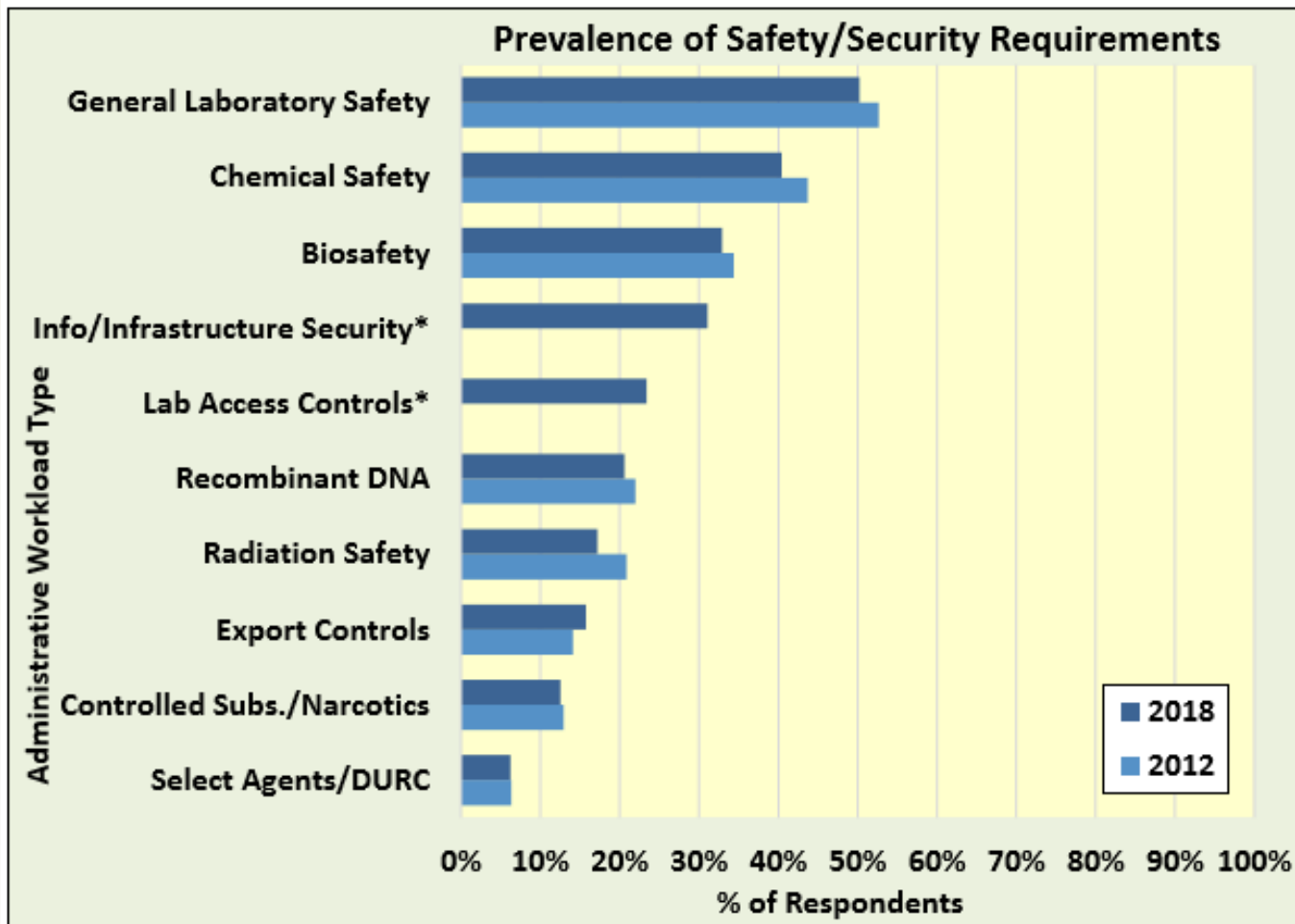


Figure 19. Prevalence of ten safety and security responsibilities as reported in 2018 and 2012 surveys. Info=Information, Subs.=Substances. \*Items were not included in 2012 survey.



# Substantial Workload of Safety/Security Requirements

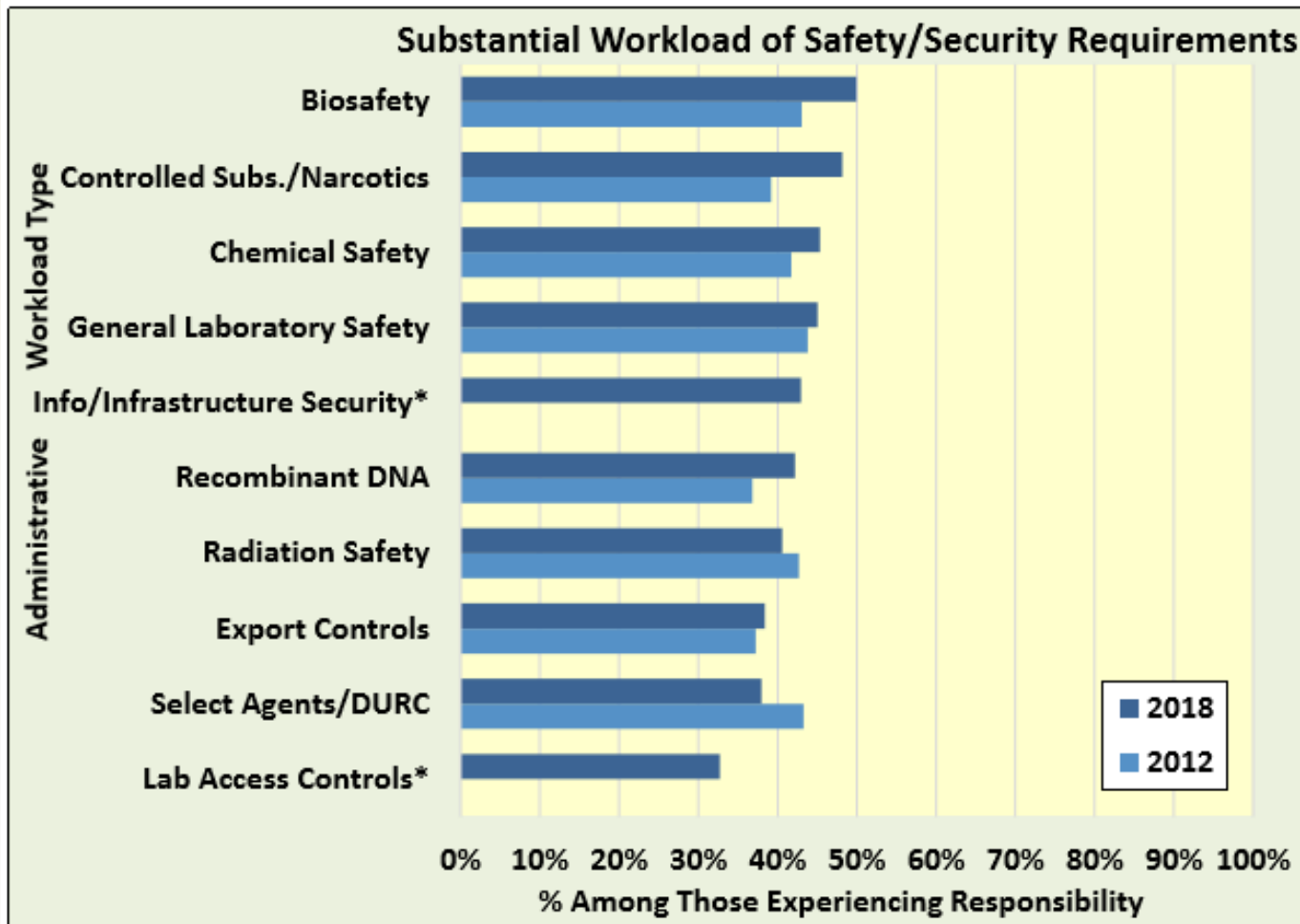


Figure 20. Prevalence of six safety and security responsibilities as reported in 2018 and 2012 surveys. Info=Information, Subs.=Substances. \*Items were not included in 2012 survey.





# High Priority for Change in Safety/Security Requirements

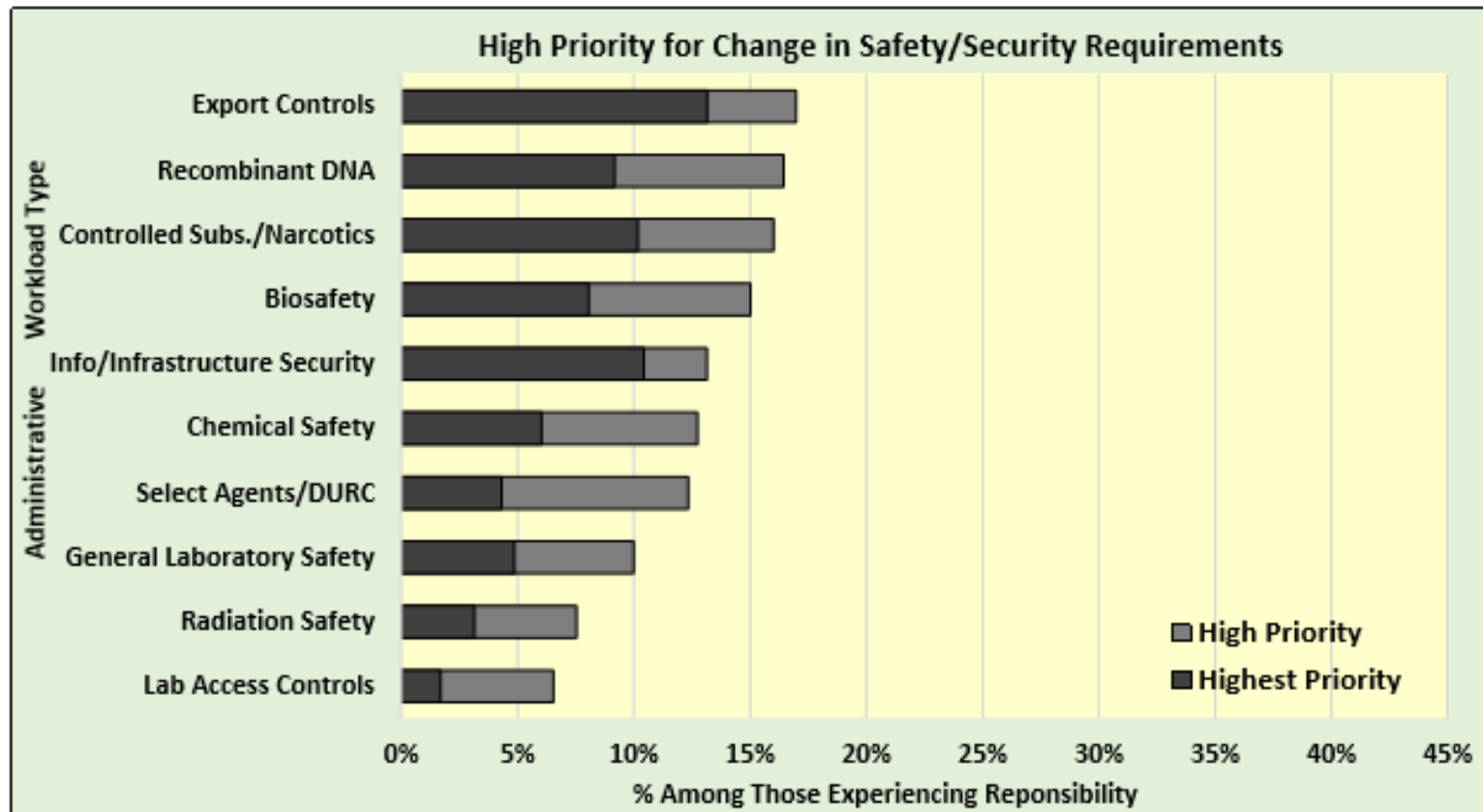


Figure 21. Percent rating each requirement as high and/or highest priority for change in order to reduce unnecessary administrative burden. Resp.=Responsible, Rsrch=Research.



# Responsibility Components Identified as High Priority by at Least 50% of Those Asked

<b>IRB/Human Subjects</b>	<i>Fit of IRB processes to type of research and level of risk</i> <i>Turn-around time of IRB applications/revisions</i> Protocols for initial IRB review Rules regarding minor changes to IRB protocols
<b>IACUC/Animal Subjects</b>	<i>Three-year re-writes of IACUC protocols</i> <i>Protocol for initial IACUC review</i> <i>Rules regarding minor changes to IACUC protocols</i> IACUC software or forms Turn-around time of IACUC applications/revisions Fit of IACUC processes to type of research and level of risk

<b>Data Management</b>	Developing data management plans Identifying appropriate external data repositories and uploading the data Institutional resources for data sharing
<b>Conflict of Interest</b>	Level of detail required in COI report (e.g., travel, meals) Filing annual and transactional disclosures
<b>Intellectual Property</b>	Materials Transfer Agreements



# Discussion

- Does RCC have the right subcommittees in place to address the highest priority areas identified in the survey?
  - Is this supported by administrative and faculty member experiences?
- If we had to identify a top 10 list of priorities for this phase, what should they be?
- Other thoughts?



# Next Steps





# How to get involved!

- Email [Melissa Korf@hms.harvard.edu](mailto:Melissa_Korf@hms.harvard.edu) if you're interested in one of the vacant co-chair positions.
- If you're interested in becoming more involved in a specific subcommittee, reach out to the co-chairs to ask how you can help!
- Sign up for the Research Compliance listserv (<http://thefdp.org/default/mailling-lists/>)