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REGULATIONS AND REPORTING REQUIREMENTS FOR BIOLOGICAL AND MEDICAL RESEARCH: FINDINGS FROM FASEB'S SURVEY ON ADMINISTRATIVE BURDEN

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Presentation Outline

- Developing FASEB's Response to the NSB RFI
  - Internal Process
  - Public Survey
- Overview of Survey Findings
  - Respondent Demographics
  - Burdens Identified by Respondents

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National Science Board RFI

- Nine questions covering the following areas:
  - Sources of administrative workload and recommendations for reduction
  - IRB/IACUC requirements
  - Preparation of grant proposals
  - Agency specific requirements
  - OMB reform efforts
  - Professional/institutional information

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Preparing the FASEB Response

- Topic of administrative burden is of long-standing interest to the FASEB community
- Six SPC subcommittees were convened to discuss administrative burdens relevant to each and draft language for inclusion in the FASEB response
- Distribution of a survey that could be easily shared by FASEB societies and beyond to engage a broader audience

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FASEB Survey: Background

- Online survey based on the questions posed in the RFI was generated and distributed by FASEB to obtain broader feedback from the research community
- Survey distributed through:
  - Emails to Society Executives and Public Affairs staff who then distributed link to members
  - Discussions during EB
  - FASEB e-Action alerts
  - Facebook
  - Twitter
  - Story in *Washington Update*
  - Email forwards by other research societies and coalitions (e.g., CNSF), universities, and the Federal Demonstration Project
- **1,324 total responses**

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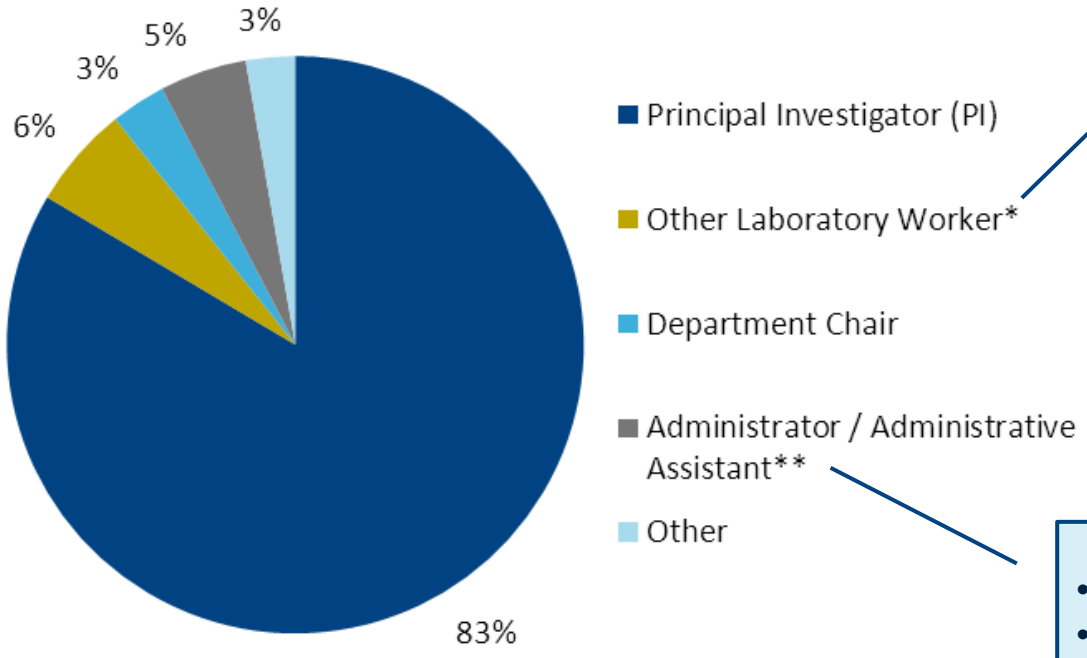
Respondent Demographics

Job Title



- Postdocs
- Staff Scientists
- Grad Students
- Lab Techs

- Institutional Administrator
- Scientific Administrator
- Administrative Assistant

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Institution Type

Category (Respondents could select more than one option)	Number of Responses	Percent of Responses*
Public Research Institution with a Medical School	**769**	**61%**
Private Research Institution	**222**	**18%**
Non-profit Institution	**186**	**15%**
Public Research Institution without a Medical School	**133**	**11%**
Primarily Undergraduate Institution	**30**	**2%**
Minority-Serving Institution	**23**	**2%**
Public Master's Institution	**13**	**1%**
For-profit Institution	**11**	**1%**
Private Master's Institution	**2**	**<1%**
Other	**100**	**8%**
• Federal Laboratory	26	-
• Hospital or Medical Center	9	-
• Variations of Public/Private Research Institutions	50	-
• Uncategorized	15	-

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Funding Sources

Category (Respondents could select more than one option)	Number of Responses	Percent of Responses*
National Institutes of Health (NIH)	1,020	86%
National Science Foundation (NSF)	315	27%
U.S. Department of Defense (DOD)	249	21%
U.S. Department of Veterans Affairs (VA)	98	8%
U.S. Department of Agriculture (USDA)	75	6%
U.S. Department of Energy (DOE)	61	5%
Other	159	13%
• National Aeronautics and Space Administration (NASA)	54	-
• Other Federal Agency or Department	37	-
• Non-Federal	35	-
• Other agencies within the Department of Health and Human Services (DHHS)	26	-
• U.S. Environmental Protection Agency (EPA)	13	-
• Moved to a main category above	8	-
• Unable to Classify	2	-

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Society Membership

- 756 respondents (59 percent) indicated membership in at least one FASEB society
- All 26 societies represented in the responses

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Burdens Identified

Burdens Identified by Survey Respondents

- Survey asked respondents to identify their top three areas of burden (out of 15 total, plus option for “other”)
- Respondents had the option to provide examples of burdens
- Respondents also asked to provide ideas or solutions for reducing burdens

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Ranking of Burdens

Area of Burden	Highest Burden	Second Highest	Third Highest	Total Selected
Grant Proposal Preparation and Submission	675	186	88	949
Laboratory Animal Use and Care / IACUC	211	259	129	599
Training Requirements	42	124	181	347
Human Subject Research Protection / IRB	102	142	98	342
Personnel Management	55	120	131	306
Grant Effort Reporting	50	92	125	267
Laboratory Safety Oversight and Requirements	44	87	128	259
Grant Financial Reporting	33	82	95	210
Conflict of Interest Reporting	17	40	78	135
Administrative Support Funding	30	42	55	127
Management of Sub-contracts	15	39	41	95
Biosecurity/safety and Select Agents Program	11	34	42	87
Agency Specific and Multi-Agency Funded Projects	17	17	32	66
FDA Requirements for Studying Drugs and Devices	11	16	25	52
Data Sharing	5	13	26	44
TOTAL	1318	1293	1274	3885
OTHER*				70*

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Grant Preparation, Submission, Management, and Funding

Key Burdens

- Time required to prepare an application (even longer without admin support)
- Requirements for application and reporting vary among agencies
- Challenges associated with effort reporting
- Delays in time to award
- Challenges with financial tracking and reporting

Suggested Solutions

- Create and utilize common application and progress report forms between agencies
- Allow select sections to be submitted “just-in-time” (e.g., detailed budgets, data sharing plans, etc.)
- Uniform electronic biosketch that can be linked to e-resources (e.g., Pubmed)
- Provide web-based resources to help applicants navigate grant preparation, submission, and management processes
- Limit effort reporting to distinguishing between research, clinical services, and administrative time

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Laboratory Animal Care and Use

Key Burdens

- Duration of IACUC approval (3 years) does not match with duration of typical grant (4-5 years)
- Research delayed by extensive protocol review
- Varied interpretation of the Guide to the Care and Use of Laboratory Animals by PIs, IACUC staff, and other institution officials
- Overlapping oversight by multiple agencies and organizations
- Multiple, uncoordinated inspections disrupt research

Suggested Solutions

- Encourage IACUCs to use Designated Member Review instead of Full Committee Review for protocol amendments that do not significantly affect animal welfare
- Develop standard operating procedures for common procedures that can be cited within an IACUC application
- Create exempt and expedited review categories similar to human subjects regulations
- Provide more resources to encourage more uniform application of requirements

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Training Requirements

Key Burdens

- Lack of uniform training requirements across federal agencies leads to duplicative requirements at the institutional level
- Varied availability and quality of training materials
- Frequency of training renewals/refreshers varies
- Inadequate tracking of completed certifications

Suggested Solutions

- Provide online comprehensive training resource to provide uniform core curriculum in basic lab safety, human subjects protections, and animal care and use
- Centralize tracking for completion of basic training modules so that completion of training is “portable”
- Decrease frequency for renewal of basic laboratory safety training
- Offer shorter “refresher” modules for new regulations rather that repeating full training

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Clinical Research and Human Subjects Protections

Key Burdens

- Length of time to obtain IRB approval is compounded by multiple rounds of protocol revision and review
- Multi-site IRB review for multi-site studies using same protocol
- Application of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule to research is confusing and frustrating
- Increasing complexity of paperwork associated with IRBs deters investigators from human subjects research

Suggested Solutions

- Centralize tracking for completion of basic training modules so that completion of training is “portable”
- Decrease frequency for renewal of basic laboratory safety training
- Offer shorter “refresher” modules for new regulations rather that repeating full training

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Broad Burdens/Common Themes

- Lack of coordination among federal agencies
- Uneven implementation of rules/regulations
- Institutional risk aversion
- Redundant reporting requirements
- Frequent changes to reporting requirements
- Lack of administrative support

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Thank you!