

FDP 2012 FACULTY WORKLOAD SURVEY COMPLIANCE HIGHLIGHTS

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FDP Compliance Committee
Retreat



FDP
Federal
Demonstration
Partnership

Focal Areas of Interest

- IACUC/Animal Care and Use
- IRB/Human Subjects Research Protections
- COI/Conflict of Interest
- Export Controls
- Data Sharing
- Laboratory Safety

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

- Protocol Hassles
- Training & Retraining
- Reports
- Cross-Agency Issues
- Institutional Issues

Number of comments: 627

Keywords searched: IACUC, CUC, Animal

IACUC/Animal Care and Use

Area	Drill-Down Items	N	Mean	% w Substantial Workload
IACUC/Animal Care and Use		2511		
	Preparing IACUC protocols for initial review		3.62	90.1%
	Completing annual IACUC reviews and three-year re-writes of protocols		3.38	81.9%
	Completing protocol revisions requested by reviewers		3.29	78.3%
	Fulfilling federal requirements for training in animal care and use		2.75	56.4%
	Satisfying federal requirements for funded projects (e.g. tracking animal		2.63	51.1%
	Maintaining veterinary medical records		2.25	38.0%

Protocol Hassles

- Length of protocol, overly and unreasonably detailed
- Time commitment (electronic vs. paper protocols)
- Unnecessary, overly picky modifications
- Procedures for changing the protocol too time consuming
- Protocol renewal difficulties → research delays

Training & Re-training

- Training is excessive and cumbersome (esp. new employees—takes much too long)
- Re-training already-trained individuals is unnecessary
- Training not a good fit (e.g., wild animals)

Completing Annual Reports

- Reporting use of animals
 - Pointless and troublesome
 - Hard to document exact strains of animals
 - Problems when animals arrive to lab dead
- Excessive, time consuming, unneeded

Institution-Level Concerns

- Lack of standardization, inconsistency among reviewers
- IACUC overly concerned with legal responsibilities of the institution, instead of the welfare of animals
- Creating safety requirements that are not required at the federal level

INSTITUTIONAL REVIEW BOARD (IRB)

- Low Risk Research
- Delays
- Multiple IRBs
- Reviewers
- Training
- Changing Requirements

Number of comments: 842

Keywords searched: IRB_, human

IRB/Human Subjects Protection

Area	Drill-Down Items	N	Mean	% w Substantial Workload
IRB/Human Subjects Protection		3890		
	Preparing IRB protocols and consent forms for initial review		3.50	87.7%
	Completing protocol revisions requested by reviewers		3.04	69.5%
	Waiting for feedback from review		3.00	64.0%
	Completing annual continuing review of protocols		2.92	66.0%
	Ensuring that study procedures meet protocols		2.87	62.6%
	Fulfilling federal requirements for training in human subjects protections		2.64	51.5%

Conducting Minimal Risk Research

- Examples of minimal risk research
 - Exempt studies
 - Studies using archival data
 - Studies using simple surveys
 - Low/no risk studies
- Unnecessary requirements (e.g., forms, training).
- Process is geared towards clinical trials and related research, and isn't always appropriate for social/behavioral research.

Delays

- Completion of requirements is delayed due to the amount of time it takes to get and make revisions and to get and provide answers to questions.
- Research is delayed due to the amount of time it takes to get approval.

Multiple IRBs

- Differences in requirements (e.g., forms, trainings) between IRBs are trivial in content but time consuming to address.
- Completing multiple IRB submissions is redundant and time consuming.
- Lack of communication between IRBs.

Reviewers

- What is considered acceptable or in need of revisions is inconsistent between reviewers.
- Lack of knowledge about the type of research being reviewed.
- Vague answers to questions
- Vague, picky, unnecessary requests for revisions.

Training

- Confusion regarding what training is required and how to access the training.
- People are required to complete training that is unnecessary for their job description.
- Re-training required too often.

CONFLICT OF INTEREST (COI)

- New/ Changing Rules
- Too Complicated
- Repetitive
- Ineffective
- Invasion of Privacy

Number of comments: 82

Keywords used: COI_, conflict of interest

COI/Conflict of Interest

Area	Drill-Down Items	N	Mean	% w Substantial Workload
COI/Conflict of Interest		1431		
	Filing annual and transactional disclosures		2.69	62.2%
	Contributing to the development of management plans		2.40	48.3%
	Complying with terms of management plans		2.36	46.4%

Obstructive COI Rules & Regulations

- New rules are increasingly obstructive and complicated.
 - e.g.: 2012 travel rules
- Agency COI strict restrictions cause delays in research
- Different COI requirements for institution vs. agency
- New COI form required for each grant and IRB

COI Reporting is Overly Complicated

- Rules and regulations are not clear.
- Having to write separate COI report for each collaborator, including subcontracts, for each grant proposal.
- Especially burdensome with multiple projects; redundant paperwork
- When there is no COI to report, the paperwork is still overly complicated.
 - e.g., COI reporting while working with a non-profit organization.

COI Reporting Is Ineffective

- Concept is good, but implementation is largely ineffective- it does not prevent researchers from lying.
- Doubts on whether or not anyone reads COI reports.
- Fails to identify truly important COIs.
 - Too focused on accounting for small sums of money.

Insulting & Invasion of Privacy

- Agencies and institutions should have more trust in researcher's ability to avoid COI.
- Listing of personal investments is an invasion of privacy.
- Reporting money received from outside talks and travel.


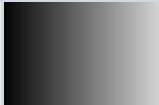
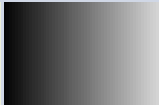
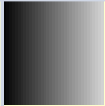


EXPORT CONTROLS

- Interpretation of ITAR (Intl Traffic in Arms Regulations)
- Overly Restrictive Export Law
- Permits

Number of comments: 79

Keywords searched: Export, ITAR

Export Controls

Area	Drill-Down Items	N	Mean	% w Substantial Workload
Export Controls		668		
	Interpreting and adapting to changing federal requirements regarding export controls		 2.97	68.9%
	Ensuring security of controlled information or items		 2.60	54.4%
	Obtaining proper authorizations consistent with federal requirements		 2.58	52.7%
	Completing training regarding federal requirements for export controls		 2.22	37.1%
	Providing federally-required technical and contextual information		 2.14	35.8%
	Obtaining federally-required security clearances		 1.97	31.4%

Export Controls

ITAR Rules and Interpretation: vague, confusing, inconsistent but dire consequences of violations

Overly Restrictive Export Law










- Unnecessary restrictions of sharing materials and ideas with nations that have the same technologies. (e.g., NASA)
- Regulations regarding software sharing are outdated and useless.
- Too many common items are listed on the U.S. export control list.

Permits needed for research-related activities that do not threaten national security; hard to get answers

OTHER AREAS

- HIPAA, Clinical Trials
 - General Laboratory Safety/Security; Chemical Safety
 - Biosafety; Controlled Substances/Narcotics
 - Radiation Safety; Recombinant DNA
 - Select Agents; Protected Critical Infrastructure Information
 - Data Sharing
 - RCR/Responsible Conduct of Research
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General Lab/Chemical Safety

Area	Drill-Down Items	N	Mean	% w Substantial Workload
Genl laboratory safety/security (incl. lab inspections)		2951		
	General laboratory safety requirements		 2.93	73.0%
	Laboratory inspections		 2.78	62.0%
	Fulfilling federal requirements for training in laboratory safety and security		 2.51	48.0%
	Controls on access to facilities, equipment and/or supplies		 2.23	37.1%
	Controls on access to computers and data/information		 2.15	34.8%
	Personnel issues related to laboratory security (e.g. foreign nationals)		 2.00	31.1%
Chemical safety (including chemical inventory manage		2337		
	General chemical safety/security responsibilities		 2.94	73.9%
	Chemical cataloging and inventory management		 2.92	69.5%
	Fulfilling federal requirements for training in chemical safety		 2.64	56.9%

Biosafety; Controlled Substances/Narcotics

Area	Drill-Down Items	N	Mean	% w Substantial Workload
Biosafety (including biohazards and blood-borne pathogens)		1894		
	Fulfilling federal requirements for training in biosafety		2.83	64.6%
	Dealing with federal requirements for handling biohazards		2.79	64.3%
	Dealing with federal requirements for handling blood-borne pathogens		2.28	44.9%
Controlled substances/narcotics		649		
	Dealing with federal requirements for handling controlled substances/narcotics		3.00	71.1%
	Interpreting and adapting to changing federal requirements concerning controlled substance/narcotics		2.73	59.7%
	Fulfilling federal requirements for training in controlled substance/narcotics		2.64	52.9%

Lab Safety/Biosafety/Chem Safety

- Concerns about Inefficiencies and Time
- Discrepancies between Goal and Process,
- Problems of Rigidity and Excessive Implementation
- Adversarial Relationships with Env H&S
- Inventory Issues, Complications, Duplication of Effort
- Lack of Standardized Institution-level Procedures

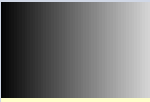





Data Sharing

Data Sharing (N = 2381)		
Responsibility Subcategory	Mean Time Taken from Research (1=None, 5=Very Much)	% with Substantial Workload
Interpreting and adapting to changing federal requirements for data sharing	2.49	49%
Posting data and other resources (e.g. software and curricula) as required by federal funding agencies	2.48	50%
Clearing and posting publications to federal repositories as required by federal funding agencies	2.30	43%
De-identifying and refining data to meet federal requirements for data sharing	2.24	40%
Completing training regarding data sharing requirements on federal projects	1.93	26%









Data Sharing

- Problem of Unfunded Mandate
- Need for Improved Data-sharing Infrastructure
- Inefficiencies in Implementation of Requirements










Radiation Safety; Recombinant DNA

Radiation safety (including radioisotopes)		1136		
	Fulfilling federal requirements for training in radiation safety			2.61 52.8%
	Dealing with federal requirements for handling radioisotopes			2.60 56.0%
	Ensuring security of machines and radioisotopes, including personnel procedures			2.37 41.5%
	Dealing with federal requirements for X-ray machines and other radiation-producing equipment			1.76 25.3%
Recombinant DNA		1036		
	Dealing with federal requirements for handling recombinant DNA			2.92 67.4%
	Fulfilling federal requirements for training in recombinant DNA safety and security			2.78 60.7%


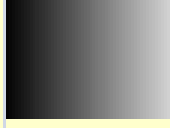
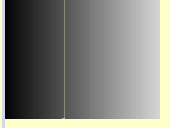
HIPAA and Clinical Trials

Area	Drill-Down Items	N	Mean	% w Substantial Workload
HIPAA		1492		
	Ensuring HIPAA-required data security and integrity		 2.99	69.4%
	Preparing HIPAA-required documentation		 2.82	63.1%
	Fulfilling federal requirements for HIPAA training		 2.71	57.4%
	Interpreting federal requirements regarding HIPAA		 2.64	55.7%
	Dealing with computer difficulties resulting from HIPAA-related firewalls and software		 2.55	49.2%
Clinical Trials		875		
	Posting and updating trial progress to meet federal requirements		 2.51	48.8%
	Completing training regarding federal requirements for clinical trials		 2.36	39.7%
	Posting and updating trial results to meet federal requirements		 2.36	43.1%

Select Agents; Protected Critical Infrastructure

Area	Drill-Down Items	N	Mean	% w Substantial Workload
Select agents		350		
	Dealing with federal requirements for handling select agents		 2.86	58.7%
	Interpreting and adapting to changing federal requirements regarding select agents		 2.78	55.8%
	Fulfilling federal requirements for training in handling select agents		 2.74	54.1%
Protected Critical Infrastructure Information (DHS)		92		
	Interpreting and adapting to changing federal requirements regarding protected critical infrastructure		 2.79	67.4%
	Ensuring security of controlled information or items		 2.75	60.9%
	Obtaining proper authorizations consistent with federal requirements		 2.71	59.8%
	Providing federally-required technical and contextual information		 2.55	54.3%
	Completing training regarding federal requirements for protected critical infrastructure		 2.48	48.9%
	Obtaining federally-required security clearances		 2.42	46.7%

RCR/Responsible Conduct of Research

Area	Drill-Down Items	N	Mean	% w Substantial Workload
RCR		2198		
	Interpreting and adapting to changing federal requirements regarding RCR		 2.61	54.7%
	Tracking and documenting completion of RCR requirements		 2.61	53.3%
	Developing or providing training activities to meet RCR requirements		 2.53	52.0%

For more...

Individual detailed sections on each of these topics is available in the **2012 FDP Faculty Workload Survey Research Report** at