

University and Federal Agency Efforts to Reduce Administrative Burden

COGR Meeting
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COGR

About This Session



The purpose of this session is to provide examples of efforts by research institutions and NSF in reducing administrative and regulatory burdens for investigators and administrators and in streamlining the administrative processes.

Panelists

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Introduction



Increasing regulatory burden on the research enterprise and potential approaches for federal agencies and universities to reduce the burden have been raised in a number of recent reports including:

- ▶ Research Universities and the Future of America: Ten Breakthrough Actions Vital to our Nation's Prosperity and Security (NRC, 2012)
- ▶ Faculty Workload Survey Research Report (FDP, 2012)
- ▶ Reducing Investigators' Administrative Workload for Federally Funded Research (NSB, 2014)
- ▶ Sustaining Discovery in Biological and Medical Sciences (FASEB, 2015)
- ▶ Optimizing the Nation's Investment in Academic Research- A New Regulatory Framework for the 21st Century, Part I (NRC, 2015)

Recommendation for Research Institutions



The National Academies report, *Optimizing the Nation's Investment in Academic Research*, made the following specific recommendation to research institutions:

- Conduct a review of institutional policies developed to comply with federal regulations of research to determine whether the institution itself has created excessive or unnecessary self-imposed burden.
- Revise self-imposed burdensome institutional policies that go beyond those necessary and sufficient to comply with federal, state, and local requirements.

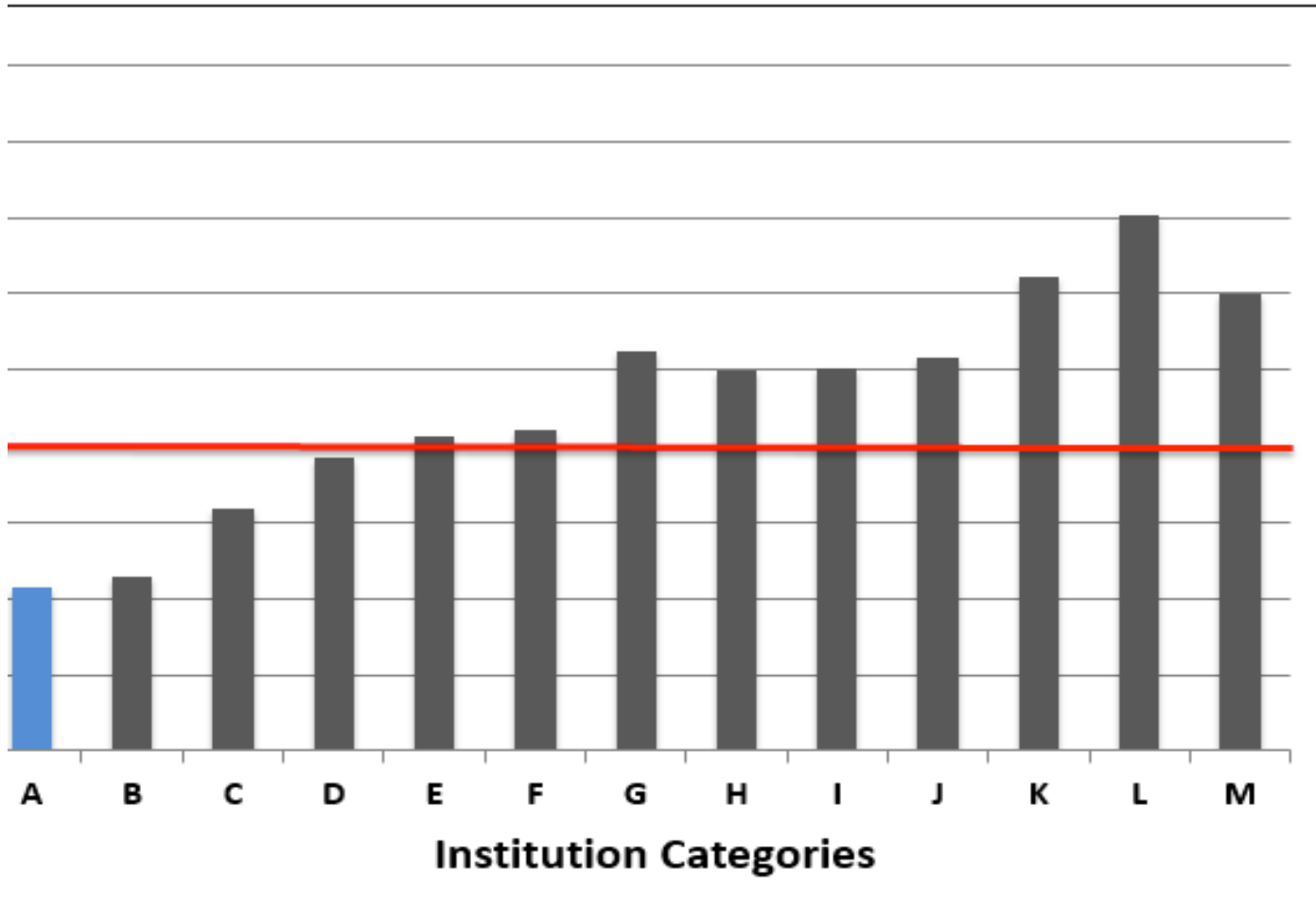
Stanford University

- ▶ **Goal: Balance a culture of compliance and laboratory safety with constant attention to reducing administrative work.**
- ▶ **Leaders work together to cultivate the culture**
 - ▶ Provide tools and systems to facilitate the balance
- ▶ **Research Policy Working Group (RPWG)**
 - ▶ Develop policies, procedures, systems on a collaborative basis
 - ▶ “Road test” policies, systems, etc. in schools/departments (administrators and faculty)
 - ▶ Provides an opportunity to bring troublesome issues to an experienced group who is keen to remedy issues and reduce burden for faculty and administrators
- ▶ **“Open door” to faculty and administrators**

Stanford University

- ▶ Receive feedback from:
 - ▶ Provost's task force on research administration
 - ▶ All information should be in one place >>>> DoResearch
 - ▶ Need integrated systems
 - ▶ Speak with one voice
 - ▶ Surveys on pre and post award activities, eProtocol system and process, training, policies, DoResearch website, etc.,
 - ▶ Identify pain points
 - ▶ Staff issues
 - ▶ Input on processes
 - ▶ Training needs
 - ▶ System simplifications
 - ▶ FDP 2012 Faculty Workload Study: addressing Stanford-specific issues and comments
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2012 FDP Faculty Workload Study



Institution Category
A: VHR Private >\$700M
B: VHR Private \$400-700M
C: VHR Private \$80-400M
D: VHR Public w/ Medical Schools/Ce
E: VHR Public w/ Medical Schools/Ce
F: VHR Public w/o Medical Schools/Ce
G: VHR Public w/ Medical Schools/Ce
H: VHR Public w/o Medical Schools/Ce
I: Independent Research
J: Medical Schools/Ce
K: HR \$80-200M
L: HR <\$80M
M: Large Masters

Stanford University

- ▶ Receive feedback from:
 - ▶ Committee on Research
 - ▶ Input on Faculty Senate policies
 - ▶ Pre and post award topics
 - ▶ Conflict of Interest and Export Controls
 - ▶ Space charge
 - ▶ Users of DoResearch website and Cardinal Curriculum
 - ▶ RPWG members; brainstorming sessions
 - ▶ Faculty

Stanford University

- ▶ **Stanford Express: procurement system/website**
- ▶ **“Lean” projects in School of Medicine**
 - ▶ Clinical Trial Budgeting & Contracting
 - ▶ Grant Award Process
 - ▶ Electronic routing form: intake process and form redesign
- ▶ **Training**
 - ▶ Cardinal Curriculum
 - ▶ “One Click” project
 - ▶ Flipped classroom
 - ▶ How to videos, instructions templates and tools
 - ▶ University-wide, school-wide, department research admin. meetings

Stanford University

- ▶ Collaborate with Dept. of Energy National Lab on conflicting DOE & OMB regulations
- ▶ Culture of Laboratory Safety: more central staff visiting/assisting in faculty labs.
 - ▶ Goal: to evaluate and improve lab safety
- ▶ eProtocol system process and system revisions
- ▶ Support services for Center Grants and large interdisciplinary proposal preparation
- ▶ SeRA system (pre-award) revisions
 - ▶ Dashboard for all actions; expanding functionality
- ▶ DoResearch website enhancements

- ▶ Goal: Simplification, streamlining, and consistency of policies and procedures across the university to minimize burdens while maintaining the highest quality of regulatory compliance and stewardship of research funds.
- ▶ The Sponsored Administration Leadership Committee (SALC) consists of members from the Office of Vice Provost for Research and the leadership of School Sponsored Administration and University Office of Sponsored Research to discuss shared issues, concerns and matters of oversight and grants management.

Administrative Burdens

- ▶ SALC established working groups during the implementation of the Uniform Guidance
- ▶ The process streamlined many of the policies and procedures to eliminate requirements that were “above and beyond” regulatory requirements
- ▶ Ensures policies and procedures are developed with interdependencies recognized and addressed
 - ▶ Outcome was elimination of duplications/ redundancies

Other

- ▶ Ad-Hoc Task Force on Clinical Research/Clinical Trials: Review guidelines and develop new procedures
 - ▶ New criteria streamline the process based on risk
- ▶ Human Subjects Protection: during the upgrading of the electronic system many of the IRB processes were unified and streamlined
 - ▶ Efforts are ongoing
- ▶ New “Advisory Committee on Research Administrative Burden Reduction” is being formed for a broader review of all research administrative procedures.

Ad-Hoc Committee on Animal Care and Use Issues

- ▶ A working group of faculty, veterinarians and IACUC administrators
- ▶ Charged with identifying redundant, unnecessary or burdensome requirements
- ▶ To-date, has identified and addressed some 22 burdensome issues
- ▶ Outcome:
 - ▶ Great satisfaction by faculty,
 - ▶ Focus on more important issues
 - ▶ Improved animal welfare
 - ▶ Reduced Committee meeting time

Ad-Hoc Committee on Animal Care and Use Issues Addressed

- ▶ Eliminated annual protocol renewals for non-USDA species and non-DOD protocols: reduced the number of protocols that required annual renewals (or reviews) by 85%.
- ▶ Consolidated redundant policies and PI forms
- ▶ Implemented Designated Member Review (DMR) rather than Full Committee Review (FCR) as default IACUC review procedure
- ▶ Simplified the IACUC protocol form with standardized language and content requirements
- ▶ Standardized veterinary review procedures and communications to PI

Ad-Hoc Committee on Animal Care and Use Issues Addressed

- ▶ Expanded scope of administrative approval authority
- ▶ Replaced required documentation on how proposed protocol was not unnecessarily duplicative with a simple attestation
- ▶ Replaced mandatory (and dull) triennial regulatory refresher seminar with an array of instructional sessions to streamline protocol writing and review
- ▶ Streamlined onboarding process for new animal users to access facilities, reducing lead times from 2-3 weeks to a few days
- ▶ Adopted NIH OLAW's allowance for "expediting" protocol amendments via a new Veterinary Verification and Consultation (VVC) process, thereby reducing/eliminating full IACUC involvement

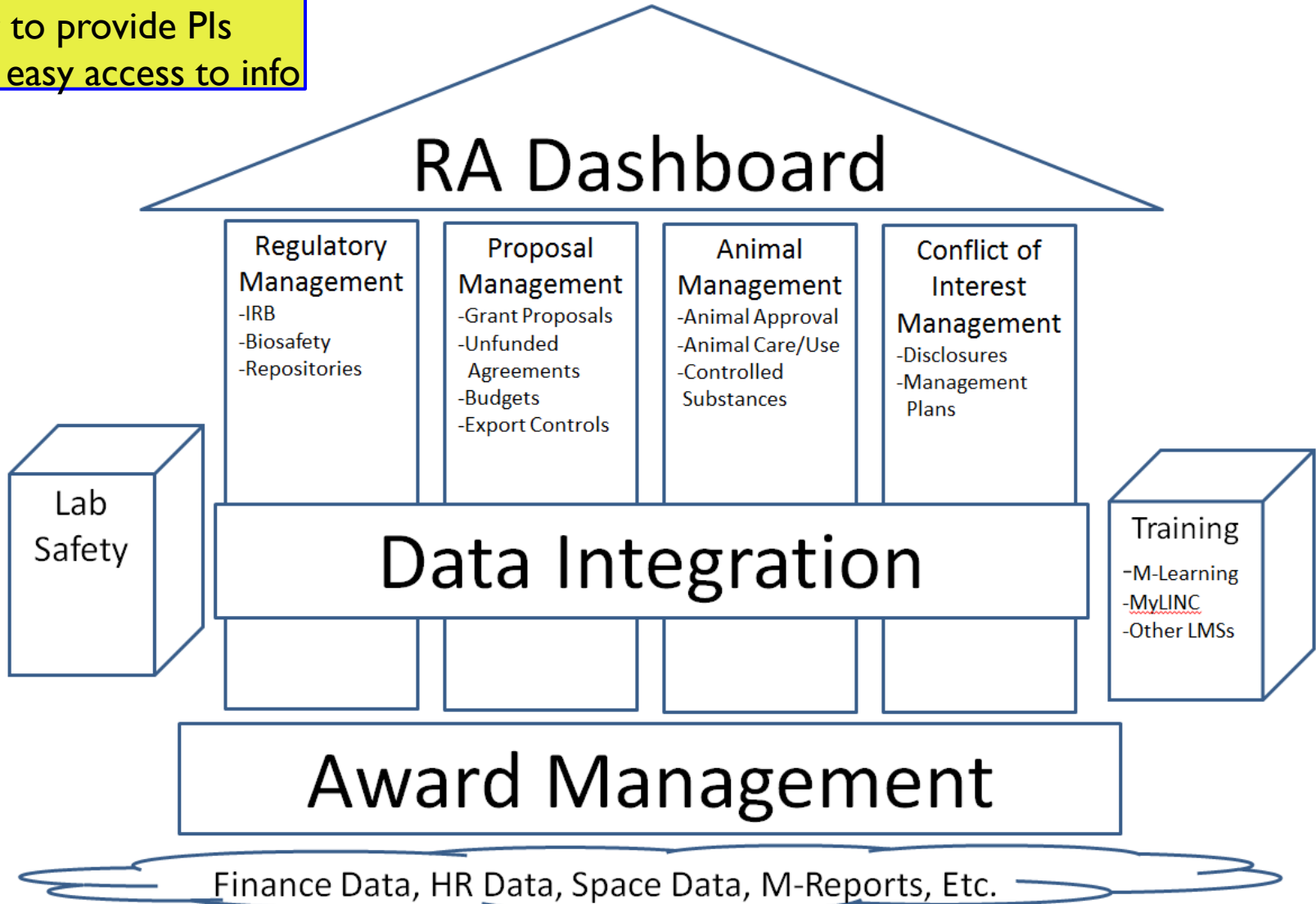
The University of Michigan is committed to continual improvement of its administrative processes and to utilizing the maximum amount of flexibility allowed under the current regulations.

Since 2005 we have been pioneers in piloting streamlined review processes, particularly for human research, animal care and use, and conflict of interest.

Currently, we are engaged in a major initiative to better integrate our information management systems.

- ▶ **Research Compliance Advisory Committee**
Recommends policy and procedural change related to regulatory requirements
- ▶ **Research Administrative Advisory Council (RAAC)**
Recommends policy and procedural change to pre-and postaward processes
(Subcommittees: training; communications; data & metrics; process improvement; faculty advisory)
- ▶ **University Audits**
Strategic reviews, reports to the President
- ▶ **Fast Forward – Clinical Trials**
- ▶ **eResearch Governance Committee**
Guides strategic planning for IT Systems to support research

The RA Dashboard is a “data visualization” layer to provide PIs with easy access to info



Using the major themes of “frustrations” with IRB review from the FDP Faculty Workload Survey:

1. Unnecessary workload for minimal risk research
2. Review delays that disrupt research progress
3. Redundancies and complications with multiple IRBs
4. Issues related to reviewers (e.g. inconsistencies, wordsmithing)
5. Problems related to training requirements
6. Difficulties with changing requirements

1. Reduce unnecessary workload for minimal risk research

Take full advantage of the flexibility in the regulations, including:

- ▶ Limiting the scope of Federal Wide Assurance (“unchecking the box”)
- ▶ Only regulating research that meets the definition of human research (we try not to over-regulate)
- ▶ Granting exemptions by IRB staff reviewers
- ▶ Utilizing and streamlining expedited review
- ▶ Utilizing waivers or alteration of informed consent and waivers of documentation of informed consent

Use Resources Available!

See <http://www.usc.edu/admin/oprs/flex> for information about streamlining practices at other institutions for non-fed sponsored research

- ▶ Granting two- or three-year approval periods (U-M, MSU, Minnesota, USC, UCSF)
- ▶ Using expedited review for all minimal risk projects (categories not listed as eligible for expedited review) (Minnesota)
- ▶ Expanded exemption categories (U-M, Penn State, USC)

See: The Seven Habits of Highly Effective IRBs

https://oprs.usc.edu/files/2013/07/Seven-Habits-of-Highly-Effective-IRBs_JeffCooper.pdf

2. Decrease review delays that disrupt research progress

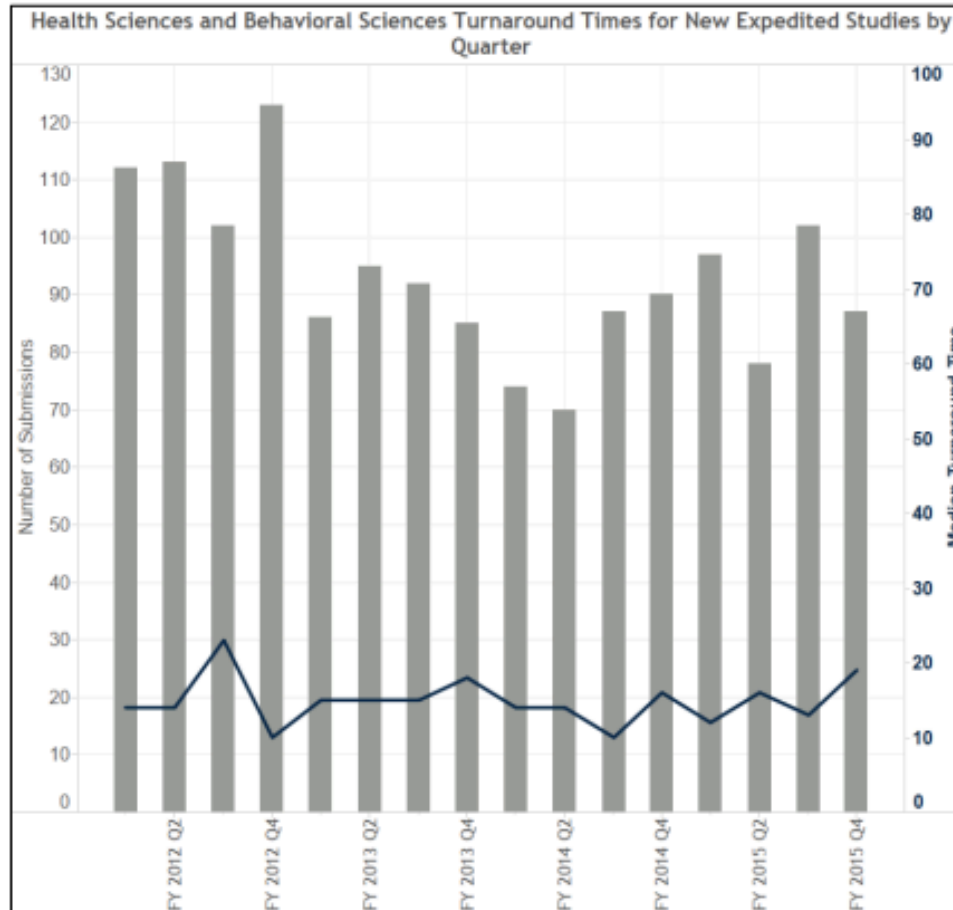
Improve turnaround times while maintaining quality review

- ▶ Track metrics
- ▶ Identify bottlenecks and streamline processes

See: http://research-compliance.umich.edu/sites/default/files/1_irbmetrics.pdf

U-M IRB Metrics

Expedited



Turnaround Time Average per Fiscal Year:

FY2012 = 15.25 days
FY 2013 = 15.50 days
FY 2014 = 13.50 days
FY2015 = 15.00 days

3. Reduce redundancies and complications with multiple IRBs

Utilize single IRB of record when appropriate

- ▶ Develop template agreements
- ▶ Streamline application for ceding or accepting review
- ▶ Standardize processes for review and signature

Questions?