University of California at Davis
OFFICE OF RESEARCH
REGULATORY BURDEN PRESENTATION

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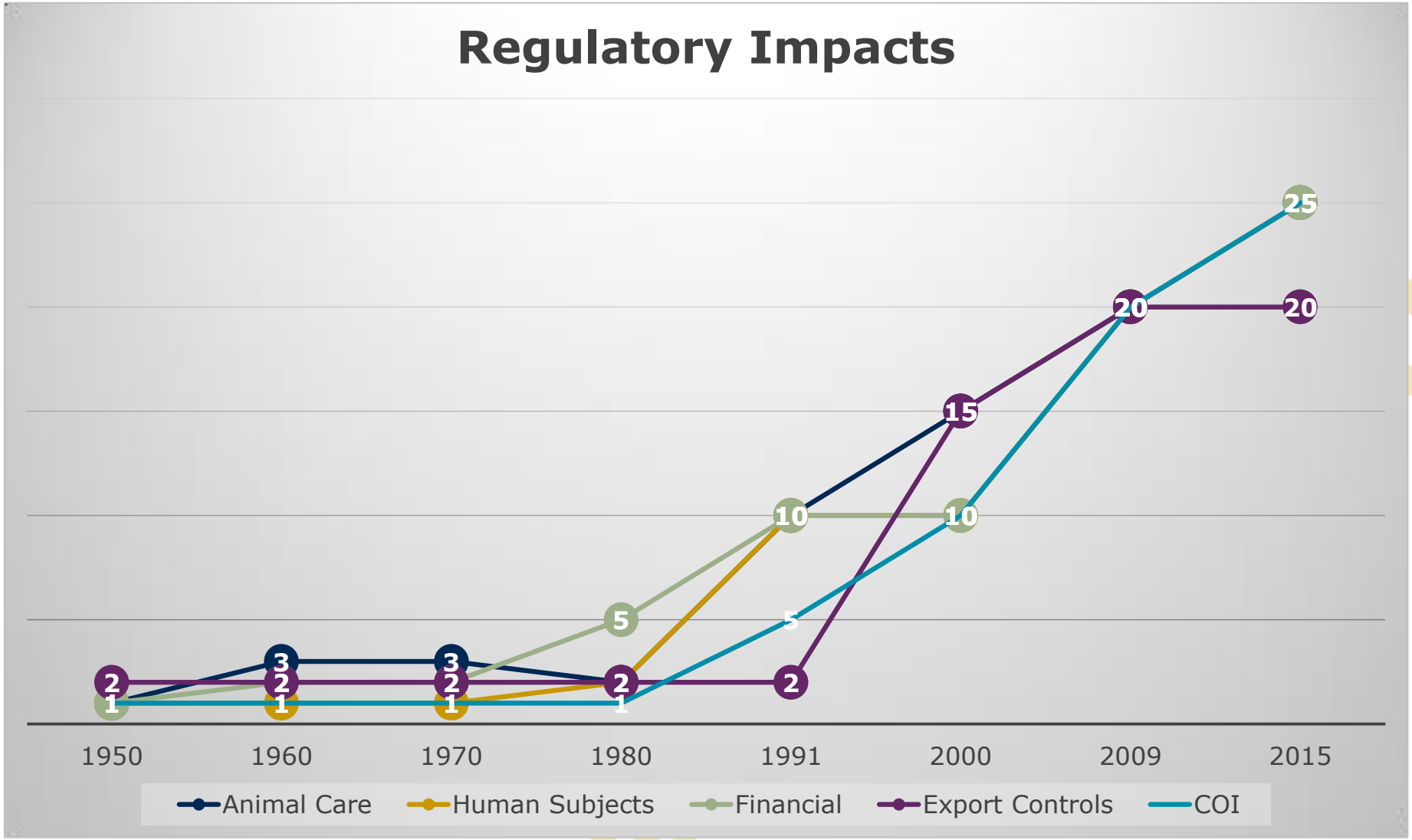
One UCDAVIS

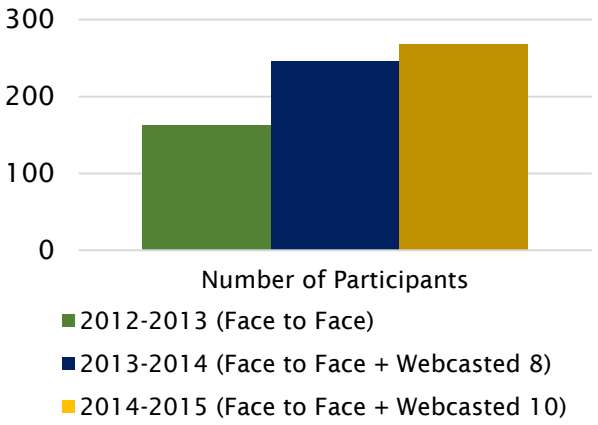
REGULATORY BURDEN OVER TIME



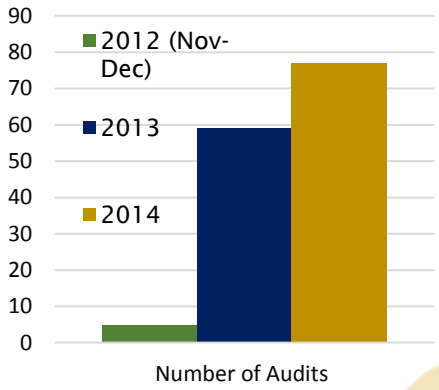
KEY METRICS

Research Compliance & Integrity

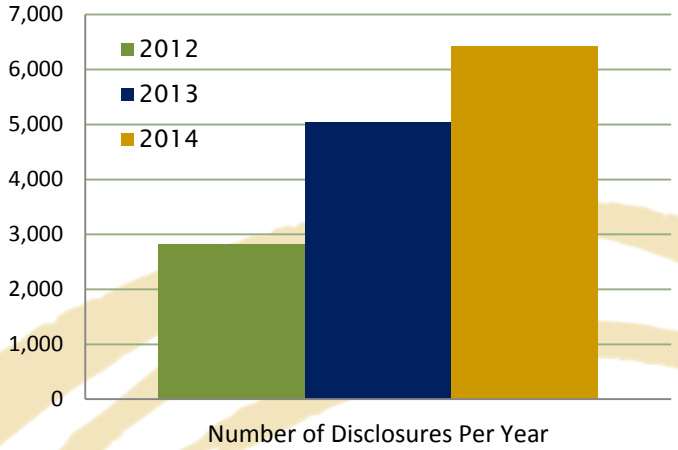
RCR Attendance



Human Subject Study Reviews/Audits

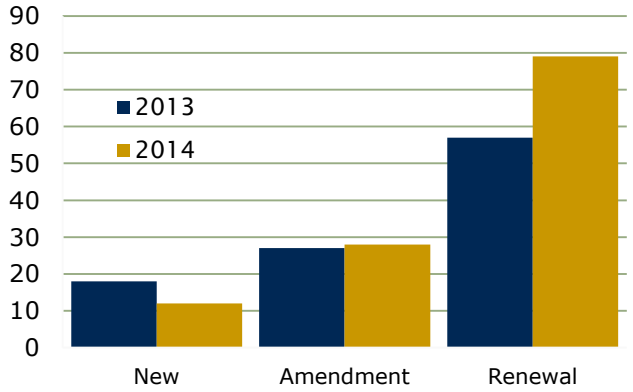


Conflict of Interest Disclosures

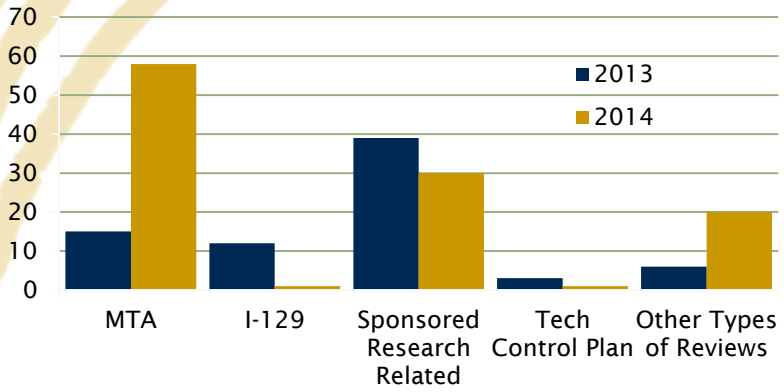


*** no data for 2011 & previous due to lack of resources & no database**

SCRO Reviews



Export Control Reviews



Goals of the Updated Regulations

Reduce fraud, waste and abuse

Streamline Process

Opportunities for Burden Reduction - Systemic

- Give real authority to OMB or another agency to enforce uniformity between federal agencies relative to their budgeting, reporting and regulatory oversight.
- Develop one system for financial draw downs and LOCs instead of each agency (and sometimes divisions of agencies) creating their own unique mechanisms and systems with differing log-in criteria.
- Harmonize regulations and guidance between agencies with overlapping jurisdiction. (Is there a way to "force" individuals to speak with one another?)
- Create clear guidelines for when an agency can create new rules and requirements through "notices" or "FAQs"
- Aggressively encourage OIGs to actually follow the regulations, policies and guidelines that an agency provides to the recipient community.
- Audits are out of control – exorbitant cost for very little cost recovery

Opportunities for Burden Reduction – Sponsored Research

- Adopt FDP piloted successes across all agencies (example: NIH's modular grant submission process)
- Eliminate the DS-2 Disclosure requirement for universities
- Adopt one means of research reporting across all agencies (Data Act, Openness in Research (publication access, etc.)
- Get rid of the NSF 2 month rule.
- Encourage agencies to adopt "waiver of prior approvals" for certain actions in the Uniform Guidance (direct charging of admin costs as an example).
- Training grant reporting requirements and "tables" – need serous streamlining effort (especially with the 8% cap)
- OIGs need to provide guidance regarding what alternates to effort reporting might work for them.
- Do not implement the micro-purchase threshold in the Uniform Guidance.
- Allow streamlined/reduced sub-recipient monitoring when collaborators already have reviews under the Single Audit Act. (UG has made oversight far more prescriptive than before).
- Proposal deadlines – please, use local time (as opposed to eastern time) and please, no more midnight timelines.
- Decrease limited submissions calls – we do the work so the feds don't have to.
- Do I need to mention clinical trials.gov? System implementation is key.

Opportunities for Burden Reduction
Human Research Protection

- Move forward with “Single IRB” initiative but ensure OHRP, NCATS and FDA guidance is harmonized in the process. Systems and infrastructure are important in setting this up.
- Create a more flexible “exempt” category of review in the social and behavioral sciences.
- Address biorepository issues relative to informed consent.
- Divisions of agencies should not be allowed to modify common rule regulatory definitions of human subjects, etc. through use of “notices” and “guidance” (example is GWAS data repository notices)
- Do not enforce rules on ALL research (unchecking the box has significant value from a burden perspective)
- Do not implement HIPAA standards for all human research protocols (whether or not data includes PHI)
- New funding programs should follow the common rule (example: PCORI treasury department funding under affordable care act is not governed by OHRP common rule standards)

Opportunities for Burden Reduction
Conflict of Interest

- Repeal low thresholds in the PHS COI rules as well as many of the reporting requirements and replace with a regulation more in line with NSF's approach. (reporting to agency only if you identify a COI that is otherwise not "manageable").
- Allow COI reviews to be "just in time"
- Create a "common rule" for COI instead of allowing agencies to proliferate their own unique rules and reporting requirements – especially in a post Uniform Guidance world.
- Part of it is "us" . Currently, UC Davis has FIVE unique COI and COC reporting systems that our faculty must interact with. Consolidation of these things is desired goal.
- Sunshine Act has actually added value in our review processes.

Opportunities for Burden Reduction
Animal Care and Use

- USDA “strict liability” approach adopted post-age-of-enforcement hampers research. Standards need to be developed relative to a true “negligence” standard.
- Harmonize USDA and OLAW requirements.

Opportunities for Burden Reduction Technology Transfer and Industry Collaborations

- COI rules and tax code rules (safe harbor) slow or hamper industry collaboration and economic development.
- iEdison needs serious investment and upgrading for reporting federally funded intellectual property with cross checks with the PTO and should be used for reporting of inventions for all federal agencies.

Opportunities for Burden Reduction
National Security related regulations

- Expedite the harmonization process of export control lists between agencies (Commerce, State, Treasury, etc.)
- Harmonize the Export control listings with “select agent” and “controlled substance” and Dual Use Research of Concern rules. (difficult with a state regulatory overlay).
- Provide more consistent guidance and clarifications related to conducing international research outside the U.S. (fundamental research exemption).
- The more responsive an agency is in this complex environment, the better off we will all be.
- Ensure the enforcement agencies (FBI, etc.) recognize importance of fundamental research vs. espionage act enforcement.
- Encourage and educate contract personnel to follow their own guidelines relative to “restricted but unclassified” terms and conditions for fundamental research.

FUTURE REGULATORY BURDEN CONCERNS

- UG
  - Internal controls and OIG response
  - Subrecipient monitoring
  - Micropurchases
- NIST and FISMA
- NPRM for Human Subjects
- OIG enforcement
- Subaccount draw down mechanisms
- Data Act ramp up
- Pub Med for all
- Institutional reporting. Research.gov, FFATA, clinical trials.gov, HERD, Starmetrics, agency specific . . .
- Audits
- Global Funding and harmonizing other countries regulations with US regulations