

<u>Actions to Reduce Administrative Burden</u>	Does your institution plan to implement this action?	If Not, Why Not?	Does your institution already have this in place?
<u>Administrative Support</u>			
Allow limited additional opportunities for direct charging administrative salaries if it meets the requirements of 2 CFR 200 (reaching pre-established institutional minimums, such as 10-20% FTE).			
Provide administrative assistance to faculty to the extent possible.			
<u>Animal Research/IACUC</u>			
Eliminate annual protocol renewals for non-USDA species and non-DOD protocols.			
Discontinue the USDA pain and distress classifications for non-Animal Welfare Act regulated species.			
As the default, implement Designated Member Review rather than Full Committee Review.			
Reduce IACUC requirements for experimental details that are unrelated to the health and safety of animals.			
Adopt NIH OLAW's allowance for "expediting" protocol amendments via a new Veterinary Verification and Consultation (VVC) process, thereby reducing/eliminating full IACUC involvement.			
Expand the scope of administrative approval authority by allowing small changes to protocols to be handled administratively (by IACUC staff or via Veterinary Consultation and Verification process).			
Simplify the IACUC protocol form with standardized language and content requirements and provide template language for importing into protocols. Allow for "procedure libraries" to be selected for protocols. Enhancements to the form could include the following: <ul style="list-style-type: none"> · A standard rodent, pre-approved, pre-operative preparation plan and post-operative recovery plan template. · A built-in commonly used drug formulary that will provide the pre-approved dosage, route and frequency of administration. · Convert formatted text boxes to simple drop down lists for fast data selection/entry and enhanced reporting capabilities. · Drop down list of euthanasia methods/dosages that are pre-approved for a given species 			

<u>Actions to Reduce Administrative Burden</u>	Does your institution plan to implement this action?	If Not, Why Not?	Does your institution already have this in place?
Replace required documentation on how a proposed protocol was not unnecessarily duplicative with a simple attestation.			
Standardize veterinary review procedures and communications to investigators.			
Review SOPs on a less frequent basis (e.g., every two to three years) based on potential risk (e.g., skill of investigative team, outcomes of PAM reporting).			
Allow investigators to provide an approximate number or range of animals needed over the course of a research project rather than an exact number.			
Allow investigators to provide a range of time for post-op observation rather than an exact time (e.g., 4-6 hours instead of every 4 hours) to allow flexibility and avoid findings on deviations from the language where actions were appropriate.			
Replace mandatory triennial regulatory refresher seminar with an array of instructional sessions to streamline protocol writing and review. Solicit feedback on how the institution can assist investigators.			
Adopt standardized models for training and documentation.			
<u>COI</u>			
Use a tiered review process – administrative review; expedited review; and full committee review.			
Include a checkbox on a routing form to indicate whether or not a transaction will trigger an existing or new significant financial interest (SFI).			
<u>Contract-related requirements</u>			
Develop an in-house contract negotiation manual so the staff negotiating contracts have guidelines on what the institution will accept and what may require additional approval/discussion.			
Consider centralizing non-federal contract development, review and negotiation to one or a few individuals in the central grants office for consistency and focused expertise.			
<u>Electronic Systems/Forms</u>			

<u>Actions to Reduce Administrative Burden</u>	Does your institution plan to implement this action?	If Not, Why Not?	Does your institution already have this in place?
Develop online systems to reduce or eliminate the amount of requests for action transactions being required and submitted via email, hardcopy or other labor intensive methods.			
Develop data systems to identify all approvals needed for a study before start-up			
Provide clear guidance on IT security for data, bio-specimens, etc.			
Integrate systems wherever possible.			
Create automated data interchanges/interfaces between core university systems (e.g., grants and IRB, IACUC, IBC, Payroll) to expedite proposal preparation and award oversight tasks.			
Create a dashboard that will display and link to each transaction/responsibility that requires action.			
<u>Export Control</u>			
Using an electronic routing system for sponsored proposals, route proposals for national security-related sponsors to the Export Controls Officer, i.e. DOD, DHS, NASA etc.			
Provide a decision tree to determine whether export regulations and export license requirements are applicable to specific projects.			
Provide a tool for Restricted Party Screening.			
<u>Financial Management</u>			
Use the same budget categories in institutional reports as funding agencies.			
Provide "real time" financial reports.			
Simplify documentation for expense justifications.			
Allow per diem reimbursement for travel.			
Provide budget calculators for creating budgets.			
Develop standardized tools for reconciling awards for reporting, invoicing and closeouts to ensure that everyone is using the same tool with correct data.			
Develop milestone structure in your system to track reconciliations, invoicing, reporting, etc.			
Develop additional exception reports for monitoring.			
Utilize Terms and Conditions functionality in financial systems to assist with flagging awards for compliance terms.			

<u>Actions to Reduce Administrative Burden</u>	Does your institution plan to implement this action?	If Not, Why Not?	Does your institution already have this in place?
Alter financial systems to allow local administrators to enter budgets directly.			
Move all effort reporting to semi-annual.			
Consider payroll certification and other measures as an alternative to effort reporting.			
Use master agreements and/or Accelerated Clinical Trial Agreement (ACTA) Clinical Trial Contract templates for industry-funded agreements.			
Keep a master database of sponsors/programs with lower F&A rates you are prepared to accept (e.g., foundations)			
<u>General</u>			
Consider limited use of metrics to understand realistic turnarounds and to determine best use of institutional resources to streamline high-impact activities.			
Look for opportunities and strategize to address burdens across categories (within this document).			
Don't write the rules for the exception.			
<u>Human Subjects Research</u>			
Only propose consent changes that are tied to regulation or subject's comprehension or safety and provide a rationale.			
Focus all reviews to subject rights and welfare.			
Identify mechanisms for reducing turnaround times.			
Tier review to risk and focus on higher risk.			
Appoint staff to serve as voting members of the IRB and allow them to conduct expedited review, as appropriate.			
Allow small changes to protocols to be handled administratively, including administrative requests to add, delete or change a funding source. Consider an administrative request system for study team additions and removals (where not the PI) to avoid the need for formal amendments. Provide interface to sponsored projects systems to allow PIs to identify sponsored funding from a drop-down list of active awards or recently submitted competitive proposals.			
Adopt standardization of best practices for inclusion in the protocol.			

<u>Actions to Reduce Administrative Burden</u>	Does your institution plan to implement this action?	If Not, Why Not?	Does your institution already have this in place?
Reduce human subjects training requirements to what is necessary for safety and tailor training to the research being conducted. Consider adopting a training decision tree that rapidly directs investigators and their staff to the correct training for their work.			
Employ flexibility where allowed and avoid over-regulation for non-federally supported protocols. Limit the scope of the Federal Wide Assurance (“uncheck the box”).			
Grant two- or three-year approval periods for non-federally supported and non-FDA regulated studies.			
Use expedited review for all minimal risk non-federally supported projects (categories not listed as eligible for expedited review).			
Utilize waivers or alteration of informed consent and waivers of documentation of informed consent where appropriate.			
Only regulate research that meets the definition of human research. Consider using the 2008 guidance from OHRP on the engagement of institutions in human subjects research to determine cases when your institution is not engaged and no review is required.			
If a Clinical and Translational Scient Award (CTSA) institution, have umbrella reliance arrangements with the other institutions in your CTSA {for examples see: https://catalyst.harvard.edu/programs/regulatory/reliance.html }			
Proactively offer to enter into single-study reliance agreements in order to avoid duplication of review where this would reduce administrative burden and cost.			
Offer a web tool outside your normal submission system for determining if something requires IRB review at all, along with guidance about the difference between “research” as defined by 45 CFR 46 and quality improvement, public health practice, and other non-research activity.			
Create checklist-style forms to capture the required and best-practice findings at your IRB meetings, which are partially pre-filled prior to the meeting by the IRB analyst who screened the study.			
International Research			

<u>Actions to Reduce Administrative Burden</u>	Does your institution plan to implement this action?	If Not, Why Not?	Does your institution already have this in place?
Develop and maintain a global research operations support group of key leaders in various central admin offices to develop standard processes and troubleshoot issues.			
Consider partnering with other IHEs to provide a central information repository on best practices and guidelines for international research activities.			
<u>Laboratory Safety/Radiation/Biosafety</u>			
Consolidate laboratory inspections for various disciplines.			
Coordinate data between Health and Safety, IACUC, and IBC activities to eliminate duplicative requests, policies, or procedures.			
Implement the APLU-AAU recommendations on culture of safety.			
Develop risk-based policies and procedures for laboratory specific hazards.			
Implement function/role-based training requirements (e.g., investigator specific, waste disposal person, etc.).			
Provide all didactic training online and focus on hands-on training for in-person sessions.			
<u>Personnel Management</u>			
Develop/require a training program for all administrators to ensure understanding and consistent/appropriate handling of tasks and reduction of errors.			
Create templates for common communications.			
<u>Proposal or report preparation</u>			
Consider making proposal review processes more risk-based or conditional, adding parallel rather than sequential workflows, and changing some approvals to informational copies.			
Implement online proposal development/routing tool.			
Expand limited signature authority to experienced staff in non-management positions (once they have demonstrated proficiency).			

<u>Actions to Reduce Administrative Burden</u>	Does your institution plan to implement this action?	If Not, Why Not?	Does your institution already have this in place?
Develop and maintain proposal review guidelines and criteria to ensure central office review is focused on key areas and not redundant, over zealous or non-value added.			
Consider granting limited signature authority for low-risk activities (i.e., NCE's and just-in-time requests).			
Consider the institutional risk of delegating submission of Research Performance Progress Reports (except final) to investigators.			
Develop and enforce internal proposal deadlines to ensure sufficient time for meaningful and value-added review.			
<u>Purchasing</u>			
Provide a website that facilitates search and purchase of items that have been strategically sourced.			
Develop and provide an simple and effective conflict of interest policy that addresses procurement.			
Provide a simple and effective sole source justification form and process.			
<u>Subcontracts</u>			
Develop a system for departments/researchers to request subcontracts (includes vendor vs sub determination and full request details).			
Have the office of sponsored projects set up subcontract purchase orders. This allows the purchase order number to be available quickly to enter into the subcontract.			
Maintain a central tracking system for subrecipient entities information to minimize redundant requests for information and time required to obtain information.			
Utilize the Federal Demonstration Partnership's (FDP) standardized subaward agreement templates and terms and conditions clause library to streamline issuance.			
Reduce risk assessment activities on institutions that are subject to Single Audit. For FDP member institutions, consider joining the FDP Expanded Clearinghouse.			
Consider issuing unilateral modifications to a subset of low risk subrecipients and/or for certain low-risk transactions, such as anticipated incremental funding or no-cost extensions.			
<u>Technology Transfer</u>			

<u>Actions to Reduce Administrative Burden</u>	Does your institution plan to implement this action?	If Not, Why Not?	Does your institution already have this in place?
Consider adopting a written triage process for all new inventions. This takes more time upfront, but reduces burdens down the road in managing a large technology portfolio and provides faculty with better and more consistent feedback.			
<u>Training</u>			
Optimize training time and content (e.g., to what is essential for safety purposes and to meet federal/agency requirements and tailored to discipline and career stage) to appropriately balance administrative burden between investigators and training providers.			
Offer shorter refresher modules.			
Utilize online training mechanisms whenever feasible.			
Consider using standardized models (e.g., CITI with short customizations for institution-specific guidance) for training and documentation.			
Provide documentation of training to reduce administrative burden, in particular for faculty and students transferring to another institution.			
Monitor websites, policies, procedures, training, and communications to confirm consistency across all forms of communications.			