TOPAZ | Technologies

The Business Case for a Software Solution Worksheet

Actions to Reduce or Eliminate Administrative Burden in Research Compliance

Human Subject Research

Administrative Burden	Action to reduce or eliminate burden	Software Solution	Researcher Training	ORC staff training	Board member training	SOP
Returning consent forms for correction	Only propose consent changes that are tied to regulation or subject's comprehension or safety and provide a rationale.			X		
Returning consent forms for correction	ORC staff makes corrections to the consent forms on behalf of the PI and send to PI for approval.	X				
Mission creep of IRB	Focus all reviews to subject rights and welfare.	X		X	X	
IRB review takes too long	Identify mechanisms for reducing turnaround times.	X		X	X	
Unnecessary workload for low risk research	Tier review to risk and focus on higher risk.	X		X	X	X
Inconsistent reviews; nitpicking protocols	Appoint staff to serve as voting members of the IRB and allow them to conduct expedited review, as appropriate.					
IRB review takes too long	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.	X		X		X
IRB application is too long	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.	X				
IRB application is too long	Adopt standardization of best practices for inclusion in the protocol.	X				
Required training takes too long	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.					X
Unnecessary workload for low risk research	Employ flexibility where allowed and avoid over-regulation for non-federally supported protocols. Limit the scope of the Federal Wide Assurance ("uncheck the box").	X		X	X	X
Unnecessary workload for low risk research	Grant two- or three-year approval periods for non-federally supported and non-FDA regulated studies.	X		X	X	X
Unnecessary workload for low risk research	Use expedited review for all minimal risk non-federally supported projects (categories not listed as eligible for expedited review).	X		X	X	X
Unnecessary workload for low risk research	Utilize waivers or alteration of informed consent and waivers of documentation of informed consent where appropriate.	X		X	X	X
Unnecessary workload for low risk research	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.	X	X	X		X

Administrative Burden	Action to reduce or eliminate burden	Software Solution	Researcher Training	ORC staff training	Board member training	SOP
Review by multiple IRBs	Proactively offer to enter into single-study reliance agreements in order to avoid duplication of review where this would reduce administrative burden and cost.		X	X		X
Unnecessary workload for low risk research	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.	X	X	X		X
IRB Minutes take too long to draft	Create checklist-style forms to capture the required and best practice findings at your IRB meetings, which are partially prefilled prior to the meeting by the IRB analyst who screened the study.	X		X		
Clinical trials registration	Create a process where clinical trials registration is handled by ORC staff instead of investigators			X		X
Review by multiple IRBs	Create standard guidance and waiver forms for single IRB review; adopt NIH policy and create "catch areas" in proposal development to address single IRB review early on.	X	X	X		X

Actions to Reduce or Eliminate Administrative Burden in Research Compliance
Animal Research

Administrative Burden	Action to reduce or eliminate burden	Software Solution	Researcher Training	Staff training	Board member training	SOP
Annual review of animal protocols	Eliminate annual protocol renewals for non-USDA species and non-DOD protocols.	X			X	X
Pain and distress classifications for non-USDA animals	Discontinue the USDA pain and distress classifications for non- Animal Welfare Act regulated species.	X			X	X
Too many protocols go to full board review	As the default, implement Designated Member Review rather than Full Committee Review.	X			X	X
Sending amendments for full board review	Adopt NIH OLAW's allowance for "expediting" protocol amendments via a new Veterinary Verification and Consultation (VVC) process, thereby reducing/eliminating full IACUC involvement.	X		X	X	X
Sending amendments for full board review	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).			X	X	X
Protocol re-write at triennial review	Instead of requiring a complete re-write of the protocol every 3 years, treat as an opportunity for postapproval monitoring, assessment of progress to date, and plans for the future direction of the project.	X			X	X
Animal Use application too long	Reduce IACUC requirements for experimental details that are unrelated to the health and safety of animals.	X			X	
Animal Use application too long	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: • 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	X				
Animal Use application too long	Replace required documentation on how a proposed protocol was not unnecessarily duplicative with a simple attestation.	X				
Animal Use application too long	Allow investigators to provide an approximate number or range of animals needed over the course of a research project rather than an exact number.	X				

Administrative Burden	Action to reduce or eliminate burden	Software Solution	Researcher Training	Staff training	Board member training	SOP
Animal Use application too long	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.	X				
Communication lacking	Standardize veterinary review procedures and communications to investigators.			X		
SOP review	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).			X	X	X
Required training	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.		X		X	X
Required training	Adopt standardized models for training and documentation.	X	X		X	X
AAALAC Accreditation	Careful analysis of required compliance to ensure that administrative burden is not shifted to researchers when can be handled by ORC staff or software solution.	X	X	X	X	X
USDA Registration	Careful analysis of required compliance to ensure that administrative burden is not shifted to researchers when can be handled by ORC staff or software solution.	X	X	X	X	X
Controlled Substances / Individual DEA Registration	DEA-registered AV can direct dispense controlled substances to researchers.					X
Semi-Annual Inspections	Schedule vivarium separate from labs; schedule the labs in short blocks to allow for better time management; engage other "safety groups" to conduct lab visits in conjunction			X	X	
Post-Approval Monitoring	conduct in conjunction with semi-annual inspections; engage other "safety groups" to conduct lab visits in conjunction			X		X

Actions to Reduce or Eliminate Administrative Burden in Research Compliance
Research with Biohazards

Administrative Burden	Action to reduce or eliminate burden	Software Solution	Researcher Training	ORC staff training	Board member training	SOP
Several inspections by different groups	Consolidate laboratory inspections for various disciplines.			X		X
Unnecessary workload due to multiple department requirements	Coordinate data between Health and Safety, IACUC, and IBC activities to eliminate duplicative requests, policies, or procedures.	X		X		X
Unnecessary safety requirements	Implement the APLU-AAU recommendations on culture of safety.	X		X		X
Unnecessary safety requirements	Develop risk-based policies and procedures for laboratory specific hazards.		X	X	X	X
One size fits all training requirements	Implement function/role-based training requirements (e.g., investigator specific, waste disposal person, etc.).	X	X		X	X
Duplicative training requirements among several departments	Provide all didactic training online and focus on hands-on training for in-person sessions.	X		X	X	X
NIH Guidelines imposed on non-recDNA research	Differentiate review processes for research subject to NIH Guidelines and research that is not	X		X	X	X
Delay in research review	Increase board meeting availability; create flexibility for research not subject to NIH Guidelines	X		X	X	X
Biohazard registration form is too long	Simplify the registration form with standardized language and content requirements and provide template language. Allow for "procedure libraries" to be selected for protocols. Enhancements to the form could include the following: • Convert formatted text boxes to simple drop down lists for fast data selection/entry and enhanced reporting capabilities. • Drop down lists of pre-approved procedures, chemicals, etc.					
Too much reporting is required to several departments	Create efficiencies among departments and determine which reporting is required to be done by researcher and what can be done by department staff	X		X		X
Research with Biohazards commonly known as safe is treated the same as research with dangerous biohazards	Classify biohazards appropriately and require less information for low risk biohazards and flexible approval processes	X		X	X	X
University takes worst-case scenario approach to research which leads to inefficiencies	Classify biohazards appropriately and take a risk-based approach to compliance requirements	X		X	X	X

Actions to Reduce or Eliminate Administrative Burden in Research Compliance

Electronic Systems / Forms

Administrative Burden	Action to reduce or eliminate burden	Software Solution	Researcher Training	ORC staff training	Board member training	SOP
Too many forms to choose / forms too long	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.	X		X		X
Too many forms to choose / forms too long	Create smart forms with branching logic to eliminate unnecessary questions and sections not relevent to the proposed research	X		X		
Approval delays	Develop data systems to identify all approvals needed for a study before start-up	X		X		X
IT issues not recognized until after research is approved leading to delays and increased costs	Provide clear guidance on IT security for data, bio-specimens, etc.	X	X	X		
Multiple systems for different steps in the process (grants, Board review, EHS, Finance, etc.)	Integrate systems wherever possible.	X				
Multiple systems for different steps in the process (grants, Board review, EHS, etc.)	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.	X				
Unnecessarily complex start to finish process	Create a dashboard that will display and link to each transaction/responsibility that requires action.	X				