SAVINI CONSULTING

Adapting to a Challenging Environment: Research Readiness Roadmap for Researchers

Use this checklist as a guide to help adopt best practices for study management and ensure compliance and participant safety with the ever-evolving regulatory landscape.

Manage Study Documentation and Funding	• Compile a list of:
	  ◦ all funding sources and the corresponding grant numbers
	  ◦ approved protocols (e.g. IRB, IACUC, BioSafety, etc.)
	  ◦ all other regulatory information or approvals by study (e.g. IND/IDE numbers)
	  ▪ ***Tip: Use a regulatory binder for <u>each</u> study***
	• Know which grants/funding are associated with which IRB protocols (even if the study is closed)

Coordinate Communcation	• Maintain the contact information for all study team members for quick communication • Have a plan for pausing study procedures • Know who your primary contact is for any study or funding questions either at your institution or with your funder/sponsor • Read emails sent from your research administration • Plan for regular check-ins with any external collaborators
Be Aware of "Red Flags"	Potential red flags may include any study that may be perceived as related to: • Diversity, Equity and Inclusion (DEI) • Reproductive health or family planning • Climate change • Immigration or refugees • foreign aid

Know Your Study	• Re-familiarize yourself with study procedures and the overall status of your study
	• Be informed about participant status
	  ◦ How many participants are enrolled?
	  ◦ At what phase of the research is each participant? (i.e. subjects on investigational drugs)
	  ◦ Would any participant require clinical care if the study procedures need to be paused?
	  ▪ If so, do you know how you would transition them to clinical care?

Make Necessary Changes	Given the uncertainty of new regulations, it may not be beneficial to attempt to proactively adjust your study procedures. Once a regulatory change is implemented and required by your institution or funder/sponsor, first determine if the change in the regulations necessitates a change to your study. If a change to your study is needed: • Update the protocol and study materials to reflect modifications to study procedures, for example, changing terminology from "gender to sex". • Consider removing demographic questions related to any of the "red flags" that are not absolutely necessary for the study • Consider any additional costs that might arise from necessary modifications to study procedures and contact the appropriate institutional department. ***All changes must be submitted to and approved by the appropriate review board and/or compliance office at your institution.***