

# Adapt to Changing Regulations: Study Management Tips 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.

<b>Manage Study Documentation and Funding</b>	<ul style="list-style-type: none"> <li>• Compile a list of:             <ul style="list-style-type: none"> <li>◦ all funding sources and the corresponding grant numbers</li> <li>◦ approved protocols (e.g. IRB, IACUC, BioSafety, etc.)</li> <li>◦ all other regulatory information or approvals by study (e.g. IND/IDE numbers)                 <ul style="list-style-type: none"> <li>▪ <b>Tip: Use a regulatory binder for <i>each</i> study</b></li> </ul> </li> </ul> </li> <li>• Know which grants/funding are associated with which IRB protocols (even if the study is closed)</li> </ul>
<b>Coordinate Communication</b>	<ul style="list-style-type: none"> <li>• Maintain the contact information for all study team members</li> <li>• Have a plan for pausing study procedures</li> <li>• Know who your primary contact is for any study or funding questions either at your institution or with your funder/sponsor</li> <li>• Read emails sent from your research administration</li> <li>• Plan for regular check-ins with any external collaborators</li> </ul>
<b>Be Aware of “Red Flags”</b>	<p>Potential red flags may include any study that may be perceived as related to:</p> <ul style="list-style-type: none"> <li>• Diversity, Equity and Inclusion (DEI)</li> <li>• Reproductive health or family planning</li> <li>• Climate change</li> <li>• Immigration or refugees</li> <li>• foreign aid</li> </ul>
<b>Know Your Study</b>	<ul style="list-style-type: none"> <li>• Re-familiarize yourself with study procedures and the overall status of your study</li> <li>• Be informed about participant status             <ul style="list-style-type: none"> <li>◦ How many participants are enrolled?</li> <li>◦ At what phase of the research is each participant? (i.e. subjects on investigational drugs)</li> <li>◦ Would any participant require clinical care if the study procedures need to be paused?                 <ul style="list-style-type: none"> <li>▪ If so, do you know how you would transition them to clinical care?</li> </ul> </li> </ul> </li> </ul>
<b>Make Necessary Changes</b>	<p>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:</p> <ul style="list-style-type: none"> <li>• Update the protocol and study materials to reflect modifications to study procedures, for example, changing terminology from “gender to sex”.</li> <li>• Consider removing demographic questions related to any of the “red flags” that are not absolutely necessary for the study</li> <li>• Consider any additional costs that might arise from necessary modifications to study procedures and contact the appropriate institutional department.</li> </ul> <p><b><i>*All changes must be submitted to and approved by the appropriate review board and/or compliance office at your institution.</i></b></p>