Researcher Study Coordination Plan Checklist

- Review your research portfolio and determine the impact to the participants, especially focusing on subject safety for drug/device studies or clinical trials
- Conduct a study team meeting including any external collaborators or sites to discuss the plan for pausing the study or changes to study procedures
- Document the plan and disseminate to all study team members and collaborators for consistent implementation of changes
- Communicate with any necessary offices to share your plans, meet reporting requirements, or get answers any questions (e.g. the IRB, Office of Sponsored Programs, etc.)
- Determine what information needs to be shared with participants for each phase of the research
- Maintain records of any study changes and update relevant protocols or study materials.

Note: When we refer to "portfolio", we are suggesting the real-time status of each study and each subject within those studies (if appropriate). For example, for subjects on investigational drugs, we know that each subject is not at the same stage in the study; i.e. first does, second dose, etc.. If you are required to pause or terminate your research, you must immediately obtain safety information such as whether any subjects may need to transition to clinical care, do you have enough investigation drug to safely move subjects off the study, do you have enough supplies in general, are you able to quickly inform your institution about the status of your funding and what may be needed to safely transition your studies?