

How to Guide PIs on Study Management

PIs are your partner in study management. Guide your PIs using the following 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.