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Adapting to a Challenging Environment: Tips to help Researchers Pause/Terminate a Study

Study Pause/Closure Checklist

The following is a simple checklist to begin gathering your portfolio data and develop a plan of action if you are required to pause or terminate a study. The checklist includes the steps to follow to ensure everyone involved is fully informed and familiar with your plan of action to pause or terminate a study.

Review your research portfolio and determine the impact to the participants, especially focusing on subject safety for greater than minimal risk, drug/device studies or clinical trials.

Maintain a detailed list of all studies. You can find most of this information within your IRB electronic system and REDCap, but a separate list with this information should be maintained in a central location as this situation is constantly evolving. At a minimum, a list including the following information should be kept in a manner in which reports can be quickly pulled.

- IRB/IBC/IACUC Protocol Number
- Grant/Funding Number (if applicable) – contact information for grants office
- Title of Research
- Principal Investigator Name
- Research Personnel names and contact information
- Collaborators' names and contact information
- List all sites and contact information
- IRB of Record and contact information (whether internal or external)
- Funding: FDA, HHS, DoD, CDC, etc.
- Type of research: clinical trial, drug/device, vulnerable populations, repository, (identifiable or not)
- Does the study include DEI, foreign aid, any other executive order requirements
- Does the study maintain identifiable private information (maintain communication with Privacy Officer)
- Number of subjects
- Subject status (each subject separately, if appropriate. i.e. drug/device studies)
- Subject names and contact information (for quick communication if needed)

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Document the plan and disseminate to all study team members and collaborators for consistent implementation of changes

The plan should include:

- How to and who will gather the detailed list of all active studies and how and where will it be documented and maintained
- Document the roles and responsibilities of all individuals (e.g. PI, research coordinators, collaborators, sites)
- Determine timeframes for each activity
- Create a structure for efficiently and accurate reporting when necessary. (who will be responsible for gathering data, writing reports, and communicating with the appropriate individuals). Where will this information be maintained for future review.
- Create the communication plan. Who will approve all communications, who will create the communication, disseminate and document. This includes communication to the IRB, institution, funders, institutional officials, etc. and where required subjects.
- If it is necessary to terminate a study, be sure to include in your plan how to ensure the safety of subjects during the process of the termination and thereafter, i.e. does a subject need to be transferred to clinical care, weaned off investigational drug, etc.

Conduct a study team meeting, including any external collaborators or sites to discuss the plan and ensure everyone understands their roles and the importance of details.

Communicate with any offices necessary to share your plans, meet reporting requirements or get answers to any questions (e.g. IRB, Office of Sponsored Program, legal, pharmacy, Privacy Officer, sites, collaborators, etc.)Remember to document all communications, especially those with participants.

Determine what information needs to be shared with participants for each phase of the research. This would include changes in activities, what to do during the pause or termination.

Maintain records of any study changes and update relevant protocols or study materials. Ensure your records are organized, easily accessible, and have the ability to modify in real time.