Study Initiation

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Regulatory Binder
The Regulatory Binder contains essential study documents which individually and collectively permit the evaluation of the conduct of the trail and the quality of the data produced. Filing these documents in a timely manner can greatly assist in the successful management of a trial. See the sample Regulatory Binder Table of Contents.

Delegation of Responsibility Log
Conducting a clinical trial is clearly a team effort with every member in the study team playing an important role. However, the overall responsibility for a clinical trial rests with the Principal Investigator. The Principal Investigator then delegates specific responsibilities to various members within the team. These responsibilities should be formally assigned. The Delegation of Responsibility & Staff Signature Log helps track the responsibilities of the various team members.

Study Flowsheet
For some studies creating simple reminders or worksheets will help staff obtain the required data in a timely fashion and greatly helps in reducing the number of missing data points. The Study Flowsheet can serve as a reminder to ensure that all protocol specific procedures are completed in a timely manner.

Schedule of Assessments
The protocol should clearly outline the activities that are to be performed for the research study. This includes a plan for administration of study treatment and a list of assessments and procedures that are to be performed for the duration of the study. The Schedule of Assessments lists all the study related activities and the time points at which they should be performed.

Need assistance or have clinical study management questions? Please contact ResearchGo

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