

Feasibility

Conducting a feasibility assessment is one of the first steps in conducting a clinical trial and may seem time-consuming at first, but when done right, it will save research staff time and money in the end.

A principal Investigator usually receives a copy of the protocol or at minimum the protocol synopsis. It is important to carefully review the protocol and determine if the appropriate patient population and resources are available for the successful completion of the trial.

Below are things to keep in mind when executing a feasibility assessment:

- Are you reviewing the final protocol or a draft? It is best to ask the sponsor or lead PI for the final protocol.
- Can you meet the enrollment goals? Are the inclusion/exclusion criteria reasonable?
- Is the study schedule reasonable and practical? Will there be a need for 24/7 coverage?
- Do you have adequate staffing?
- Duration of the study.
- Are there unusual imaging or laboratory or specimen requirements?
- Are there any special training requirements?
- Is there an overlap or competing trial already enrolling?
- Every investigator should have a clear financial management plan to adequately support their research operations. The financial management plan should start with conducting a thorough billing coverage analysis (BCA)
- Is the proposed budget adequate to cover the costs of the trial?