Clinical Trial Feasibility Guide

Feasibility assessments help determine if the Hospital is capable of handling a clinical trial in terms of commitment of resources and it also assists in helping develop a budget. Once an Investigator receives the protocol (or protocol synopsis), the next step is to evaluate the feasibility of actually conducting the study. This involves "dissecting the protocol" from a logistical standpoint and evaluating the following:

- How difficult will the study be to implement?
- How disruptive will the study be to the overall mission of the Hospital?
- Is there access to an adequate subject population?

The Office of Clinical Research should be consulted immediately and included as a partner in conducting a feasibility assessment. The OCR will assist the investigator in scheduling a meeting with all potentially involved parties to be sure adequate resources exist to conduct the trial, that sufficient numbers of patients are likely to be enrolled, and that the timeline for completing the study is realistic. In conducting the feasibility assessment, the following specific details should be addressed:

- Where will patients come from (e.g., existing pool of patients, referral sources, advertising?)
- How much time and resources will be required to recruit subjects? Will the sponsor be willing to provide funding for recruitment of subjects?
- What is the status of ongoing studies, which may compete for similar patients - when will these be ending?
- What is the extent of involvement of the patient/caregiver? Will they require special transportation needs? Is there ample space in the waiting room/exam room to accommodate patients and family members?
- Do you have adequate equipment, facilities and supplies?
- What special equipment is required and does the Hospital have ready access to this equipment?
- If not, will it have to be purchased or will the sponsor provide it?
- What training is involved in learning how to operate the equipment?
- Who will be responsible for maintaining equipment calibration logs?
- Is technical support or service readily available in the event of equipment failure?
- Will a local or central lab be used?
- How and when will specimens need to be shipped? Will dry ice be available (if required)?

- Do you have adequate staff, time and resources?
- How much time will the study require of the investigator? CRC? Ancillary staff?
- What are the current obligations of the study staff? Will new staff be required? Who will be responsible for hiring and training them?
- Is the proposed budget adequate?
- Is the sponsor prepared to provide additional training, equipment or funding to fill in any of the gaps you identify?
- Is the protocol in final or draft form?
- How willing is the sponsor to consider suggestions or modifications should you determine the protocol is not feasible as written?