Off-campus Trials

Special Considerations

As the sponsor of a multi-center trial, additional considerations may be necessary, including the following:

- Choosing sites for the trial and ensuring that the sites:
  - have the needed patient population
  - conduct a feasibility assessment, perhaps using the electronic medical record
  - develop recruiting plans for the study
  - consider competing studies
  - have experience conducting similar clinical trials
  - coordinators, whether full time or part time, have a back-up if they are gone
  - have appropriate IRB approvals (Check that human protection training credentials/certifications are current for all personnel involved)
- Checking contract/agreements that may involve multiple entities
- Developing a budget for a large study has much more to consider than a single site study. It could take 2-3 years to get it funded and appropriate prices must be put into the budget.
- Confirming the supply of a study drug
- Assuring collaborators are knowledgeable about responsibilities and adherence to Good Manufacturing Practices (GMP)
- Determining if resources are necessary to have placebo made or study drug over-encapsulated
- Determining the experience of the supplier
- Calculating the drug requirements for the life of the study including expiration dates of the drug
- Making sure there is not a current shortage of the drug
- Determining who will conduct stability testing on the drug during the course of the study
- Identifying where the study drug will be kept
- Participating in a benefit/risk assessment to determine whether or not additional insurance is needed to protect UNMC/Investigator/Study Subjects
- Determining a monitoring plan that includes who will do the monitoring and what will be monitored
- Deciding who will handle data collection and analysis and if they have adequate experience
- Establishing data coordination between sites
- Determining who will be in charge of the clinical coordinating center. This is the point person for the sites to call and to push information out to the sites.
- If lab or imaging will be conducted, determining if centralized laboratories will be used
- Identifying experienced personnel to handle lab samples
- Considering the issues of removing identifiers from the samples and shipping labs or images.

The Nurse Manager of the Clinical Research Center, the Nurse Manager of the Eppley Research Institute, and the Research Pharmacist are available to assist with getting this type of project off the ground.

Veterans Affairs Facilities

UNMC has an affiliation with the Veterans Affairs Nebraska Western Iowa Healthcare System (VA-NWIHCS). The Research Service for the local VA is housed at the Omaha VA at 42nd and Woolworth Avenue. Clinical studies, animal studies, and bench research all occur at the VA.

Regulatory Submission Process

The VA IRB and IACUC are considered subcommittees of the Research and Development (R&D) committee at VA. In order for research to begin at the VA, it must have R&D committee approval as well as relevant subcommittee approvals.

All VA forms for IRB submission, IRB Standard Operating Procedures and other resources are available online through the VA research web pages.

Resources for Researchers

The VA has its own IRB and IACUC for human and animal studies done at VA facilities or with VA resources. The VA also provides a limited number of translational bench laboratories on the Omaha NWIHCS campus.

VA Funding Opportunities

There are Merit and Career Development funding programs unique to the VA with specific eligibility requirements. Contact the local VA Research office at 402-995-3542 or 402-995-3544, or through their research web pages.

Study Personnel

All personnel must be credentialed to do research at a VA site. To start the credentialing process, the PI must complete and turn in the New Personnel Information Form (Rev 05-13).

All persons involved with research require a scope of practice based on the individual and all their roles within research (not protocol specific). Once a year, each individual's scope of practice will require a review for any changes. Scope of Practice for Research Personnel (Rev 07-12).

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