STUDY START UP - ONBOARDING GUIDE

New clinical research coordinators must navigate complex issues and procedures for starting clinical trials. This quick guide provides a few tips and critical questions you should ask at the beginning of a new research study.

Timing is critical once a research site is selected by a sponsor. Coordinating timelines and preparing the necessary paperwork is essential to avoiding delays in the study start up. The activities during the first 60 days after site selection include:

- budget development
- contract negotiations
- regulatory document collection and completion
- preparation of materials for Institutional Review Board (IRB) review

Throughout this process, it is essential to maintain clear communications with the various committees, departments, sponsors and the IRB, as well as any external resources, such as the BRANY team.

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The start up of a new study sets the tone for how smoothly it can run. Being organized and thorough can set you up for a successful collaboration among the various parties involved in the study.

It can seem overwhelming to research, collect and organize all these important documents. But once you have a system and procedure in place, you will be more familiar with the process and it will become fluid and much easier.

Here are some important questions you should ask before the study start up process.

TRAINING

Is there any training I need to complete in order to do my job properly and efficiently?

General Training

Like any new position, you'll be more successful if you receive appropriate training. CITI Program (www.citiprogram.org) offers online training and certifications. Your institutions may already be a member of CITI Program.

Typical training for research coordinators includes:

- ☐ Human Subjects Protections (HSP)
- ☐ Good Clinical Practices (GCP)
- ☐ HIPAA (patient privacy) and informed consent procedures.

Institutional Training

Institutions may also have site-specific training requirements, including specific procedures, processes and policies.

- ☐ IRB policies and procedures
- ☐ GCP
- ☐ Financial conflict of interest
- ☐ HIPAA
- ☐ Privacy and security

Study-specific Training

Finally, certain studies may require training specific to that protocol. Studyspecific training can help you better understand the investigational product or other requirements of the study.

- ☐ Familiarize yourself with the schedule of events and the related footnotes within the protocol.
- ☐ Certain scales or quality of life questionnaires may be part of the protocol and you will need to be familiar with these details.
- ☐ Get to know the pharmacist, radiologist and any other key departments that support research.

COMMUNICATIONS

Research is a team effort and there will be multiple people from a variety of departments and organizations with whom you will need to communicate and interact during the study.

Contact Sheet

Develop a contact sheet with the following information:

- ☐ Names
- ☐ Titles
- ☐ Departments
- ☐ E-mail address
- ☐ Phone numbers

Departments

Some of the people you will want to include:

- ☐ Sponsor/CRO representative(s)
- ☐ The medical monitor
- ☐ Study project managers
- ☐ Research team members
- ☐ Pharmacy contacts
- ☐ IRB contacts
- ☐ Clinical trials office
- ☐ Procurement (if devices or equipment is needed)
- ☐ Finance department contacts
- ☐ Central or local lab contacts
- ☐ There may be other departments impacted by the research (for example, radiation safety office, cancer review committee, pathology, etc.). Include representatives from these departments

BUDGETS

What are the elements of the budget we need to consider?

Developing a study budget for the first time can seem daunting, but it is an essential part of the contract negotiation with the sponsor. A detailed budget ensures the study site is compensated for the time, effort and resources it takes to conduct a clinical trial.

CTCA or MCA

The first step in developing a budget may include conducting a Clinical Trial Coverage Analysis (CTCA) or Medicare Coverage Analysis (MCA) to determine what Medicare or other insurers will reimburse vs. what the sponsor must

- ☐ Clinical Trial Coverage Analysis (CTCA)
- ☐ Medicare Coverage Analysis (MCA)

Recruitment and Screening Activities

For study start up, two critical line items to include in the budget are recruitment (including advertising costs) and screening procedures for trial participants. Be sure to include the time and resources it takes for you and others to do the following:

- ☐ Review the inclusion/exclusion criteria
- ☐ Translate informed consent into various languages (if needed)
- ☐ Develop or modify informed consent documents
- ☐ Execute the screening procedures per protocol, including taking medical history and reviewing medications

Other Activities

Other activities that should be accounted for in a budget include:

- ☐ Prepare lab samples
- ☐ Setting up the pharmacy for dispensation
- ☐ Maintaining supplies and materials for the protocol
- ☐ Personal Protective Equipment
- ☐ Preparing and modifying submissions to the IRB

Each step may require multiple people to be involved. You should consider thoroughly the time required and be sure to account for it in the budget.

IRB SUBMISSION PACKET

Research is a team effort and there will be multiple people from a variety of departments and organizations with whom you will need to communicate and interact during the study.

Common Documents Requirement

IRB requirements vary from one institution to the next. However, there are some common documents they require in order to conduct a review of the protocol. These may include:

- ☐ Protocol
- ☐ Consent form
- ☐ Advertisements
- ☐ FDA form 1572
- ☐ Drug/Device Brochure
- ☐ FDA IND/IDE Correspondence, as applicable
- ☐ For device studies – Statement of Investigator Form
- ☐ Conflict of Interest forms
- ☐ Subject materials

Other Regulatory Documents

In addition to what you prepare for the IRB, you will likely need to organize several documents to keep on file and to provide to the sponsor. It's best to do this in a single location. For example, you can organize a large binder with labeled tabs for each section. Regulatory documents may be maintained in paper binders or electronically, depending on your institutional requirements.

- ☐ Sponsor financial disclosure forms (for the investigator and subinvestigators/staff listed on the FDA form 1572)
- ☐ Updated CVs for the principal and subinvestigators, including their current medical licenses
- ☐ Human Research Subject Protection Training Certificate for all key individuals included on the IRB application
- ☐ Lab certificates (CLIA, CAP, etc.), lab director CV's, lab reference ranges for all labs listed on the FDA 1572 form and lab manuals
- ☐ Protocol and Drug Brochure Signature Pages
- ☐ Fully executed Clinical Trial Agreement (CTA)
- ☐ Pre-trial and trail initiation monitoring report

The FDA has a full list of expected regulatory documents in Good Clinical Practice: Integrated Addendum to ICH E6(R1), Section 8 Essential Documents.

Every study is a little different and may require slightly different documents or materials. The sponsor may describe the documents they require for the study, and your institutions may have specific requirements. Be sure you understand the nuances unique to your organization.

If you need help with clinical trial study start up at your institution, please contact our experts at BRANY:

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