

# Setting Up a Clinical Research Program in the Community Hospital Setting

Claudia Goggin Fredian, RN, BSN, CCRP  
Alexian Brothers Medical Center

**Abstract:** *This article describes the processes involved in starting up a clinical research program in a community hospital setting. The rationale, assessments and procedures for implementing such a program are discussed. Included are suggestions for forming a team and developing Standard Operating Procedures to reflect the Code of Federal Regulations.*

## Introduction

Historically, clinical research was viewed as an entity that occurred in an academic setting, at large university medical centers. With the advent of CCOP's (Community Clinical Oncology Programs) initiated by cooperative groups in the 1980's and more recently, the CTSU (Clinical Trial Service Unit), clinical trials have emerged in the community hospital setting. More and more community hospitals are becoming research centers, or at least want to become research centers. The reasons are clear. In order to compete in the marketplace, community hospitals must offer services that are innovative and current. The internet is reaching virtually everyone and patients are more informed. They are aware of what the latest treatments and theories are and want that cutting edge medical care available to them. Additionally, patients would prefer not to travel to university hospitals far from home for their medical care.

With that incentive, many community hospitals are initiating clinical trial research programs. This is not a small task and can have many pitfalls. There are more areas to develop in the community setting than in a university setting. The existence of private practice physician groups requires the more

coordination and attention. The need for experienced research investigators and coordinators is essential. Additionally, a strong effort should be made to achieve a cooperative relationship with ancillary departments.

## Institutional Commitment

The initiation of a research program at a community hospital requires both a philosophic and financial dedication of the institution. This is crucial in the success of a program. You will be unable to accomplish your goals without this support. You should meet with the key people in your institution to see that this is their goal and that they understand the burdens that accompany setting up a program and the long-term dedication needed for the research program. In general, research is not initially profitable or even a break even proposition. Over time, it may become a break even or profitable endeavour for some institutions, but it does not need to be. It is meant to be a service to the community by way of scientific advancement. Patients can participate in the latest medical treatments and the future of medicine depends on these outcomes of clinical trials.

While the community hospital has been set up in a more fragmented framework with medical staff being affiliated with more than one hospital, the community hospital

has, in my experience, had more cooperative tendencies between ancillary departments. For many years they have had a servicing attitude to keep physicians on staff, which carries over to all areas. This will be a clear advantage to starting a research program.

## Assess the Resources

The first step in starting a research program is assessing the ability of the hospital and staff to conduct the trials. Your hospital may wish to hire a consultant to do the groundwork. If not, then you will need to make the assessment and recommend a plan of action.

You will need to know your target population for the studies. What are the numbers for your hospital? I am an oncology clinical research coordinator, so for my purposes, the cancer registry can tell me how many patients are diagnosed each year at our hospitals. For other types of research, you can contact the hospital administration to find out how many patients are seen each year in your area of interest. (i.e. cardiovascular, pulmonary, immunology, etc.) This is crucial information. You do not want to go any further if you do not have enough of a patient population to draw from for your clinical trials. Only about 2-8% of patients will ultimately be eligible and consent to participate.

Secondly, you will need to assess the physicians as potential investigators. What is their background in research? Have they successfully conducted clinical trials in the past? Were they industry trials or cooperative group trials? Their experience needs to be recent. Cooperative group affiliation will open more doors for your program as industry trials can be viewed as primarily profitable. You also need to know if they are interested in conducting research. In the private practice setting, they may have left the university setting to pursue a less demanding practice. Research is very demanding and labor intensive.

If you have physicians who are experienced and want to conduct clinical trials, do they belong to the same private practice group or do they come from competing groups within the same specialty? It is very important if you are setting up an in-house program, that all groups be allowed to participate. This may be the most delicate part of setting up your program. In the university setting, all physicians of a specialty are in practice together under a department heading. In the community setting, there are financial competitions in place between private practice groups. The hospital will not want to offend any physician on staff.

The good news is that physicians have strong professional values. I have not yet encountered a physician group that refused to let other groups participate as investigators. While they may compete financially, they have respect for their cohorts. You will need to create a teamwork effect. Your role will be to meet with each appropriate physician group separately and let them know your goal for the patient population. Be impartial and inform them that you will be contacting all physician groups about their interest in participating in clinical trials. A good respectful rapport must be developed from the beginning.

Once you have potential investigators in place, assess the institution's ability to conduct research. Is there an Institutional Review Board (IRB) in place? If so, is it registered and does it have an assurance number with the OHRP (Office of Human Research Protections)? If not, you can contact the OHRP to apply for an assurance number. Their website ([www.ohrp.osophs.dhhs.gov](http://www.ohrp.osophs.dhhs.gov)) has the information you need to set up an IRB from the ground up. The elements required and process to achieve your goal is clearly defined. This process can take about one month if some elements are in place or up to six months if the IRB needs to be formed entirely. Aside from membership, they will need to have policies and procedures in place. This can be time consuming. There are resources for this. Commercially available SOP's can be adapted for your institution. If they need to write them without a source, they will need to follow the OHRP's guidelines and the Code of Federal Regulations (CFR's) that apply.

You will also need to evaluate the support systems in place for conducting clinical trials. You will need to have the pharmacy on board and trained according to FDA guidelines for conducting clinical trials. The Code of Federal Regulations will mandate the procedures for the pharmacy to follow in conducting clinical trials. They will need to have policies and procedures in place reflecting the CFR's and have the mechanisms in place to follow them. The FDA website ([www.fda.gov](http://www.fda.gov)) has information on the appropriate CFR's. The pharmacy's role in clinical trials should not be underestimated. If they do not pass an FDA audit, your institution could lose the ability to conduct research either temporarily or permanently.

Ideally, the pharmacy should have a dedicated pharmacist who is responsible for clinical trials'

implementation. It should also be realized that while this may be a part time responsibility of a pharmacist when you start up, the role will expand as research grows. Financial considerations should be taken into account. This is where it is important to have the support of hospital administration. As you recall, I started out by saying that the support of your institution is crucial to the success of a program.

It should be anticipated that the pharmacy department may want the research department to reimburse them for management of clinical trials. These are factors that are taken into account when preparing budgets for both departments. It is best to meet with the administrator of the pharmacy initially before undertaking clinical trials involving investigational drugs. In this way you will be able to discuss the plan and implementation of your studies, along with any financial issues.

#### **Standard Operating Procedures**

Provided you have evaluated all the above components of your program, you now need to focus on getting your department in full compliance with federal guidelines. You must have a policy and procedure manual that reflects adherence to all the Code of Federal Regulations (CFR's) requirements for conduct of research on human subjects. You should be very familiar with these. Your institution can purchase SOP's (Standard Operating Procedures) from a commercial research organization or possibly from another institution. The commercial organization SOP's are an excellent source, and need only to be adapted to reflect the specific elements of your research center. If you are making an affiliation with a university hospital, they may be willing to let you re-format their policies and procedures for your institution.

If neither of these options is available to you, then you will have

a great deal of work ahead of you. Start by reviewing the CRF's and organizing them into categories that follow your institution's format for policy and procedure manuals. (If you need copies of the CRF's, you can get them on the internet at [www.fda.gov](http://www.fda.gov) or [www.access.gpo.gov/nara/cfr/](http://www.access.gpo.gov/nara/cfr/) ). The usual policy and procedure manual categories include: General Administration, Protocol Management, Human Subject Management, Data Management, and Quality Management. Within each category there will be several policy and procedures.

For General Administration, you may be able to refer to existing Departmental Policies that you or your employees follow. Examples of policies contained in this section are Job Responsibilities for each member of the research team with attached job descriptions. If you utilize contracts for Principal Investigator Physicians or other research team members, you need to have a policy on management of these contracts. Additionally, a policy on orientation, continuing education and training of staff should be included. Depending on your hospital's administrative manual, you may need to include a policy on preparing a budget for your department. Any methods which involve another department (such as pharmacy or laboratory) may already be covered in that department's policy and procedure manual. These do not need to be duplicated, but may be referred to by a brief descriptive policy in the research department SOP's.

The second category of policies is Protocol Management. Areas to be covered include the procedures you utilize in study initiation, IRB submissions and communications, site visits and communications with the sponsor(s), drug monitoring procedures, management of regulatory documents and patient records and close out of studies.

This may also be the category to include policies that address the procedures your department utilizes when interacting with other departments or support staff. Be aware of the CRF's that apply to Confidentiality, Investigational Drug Management, and Institutional Review Board CRF's.

The next category, Human Subject Management, refers to those procedures your department utilizes for screening/recruiting, entering patients on protocols, monitoring of patients on protocols, follow up procedures and any special procedures you may routinely do for studies (blood/tissue, radiology or dosimetry submissions). When writing these policies, be generic. The SOP's need to have a basic format that can be applied to any clinical trial. For example, in lieu of "patients will be seen by the physician every 3 months during follow up", instead state "patients will be followed per protocol for the duration of the clinical trial." This will allow for variances between clinical trials. If you have any tools that you give to patients for the self monitoring of side effects or pill taking, include a policy for these along with an attachment of this tool. Also, if you routinely utilize follow up reminder letters or any other type of correspondence to patients, include a policy which states when it is used, for what purpose and include the sample letter as an attachment. Caution: this should be a policy only if your department enforces this policy for all patients on clinical trials. Remember, all policies must be followed and if you only use these communications occasionally for certain studies, then it would be best to leave it out of your policy manual.

The Data Management category includes all the procedures your department follows for collection, maintenance and submission of data. Review the HIPPA

(Health Insurance Portability and Accountability Act) regulations in this area regarding confidentiality. You must include how the patient records are safe-guarded both at your institution and in the methods you use to "send in" the data to the sponsor. This is a very hot topic right now, and if you are not familiar with it, you should get familiar with the guidelines quickly.

The final category is Quality Management. This section should refer to all of your policies. A policy that states how your department monitors that all the previous policies have been followed should be included. For example, self audit procedures, internal audits, sponsor audits, and other external audits. This would also be the category where you should include policies on conflict of interest, misconduct in science and notification to patients of any new information/events regarding the clinical trial in which they are an enrolled subject. Review the Protection of Human Subjects CRF's and you will find the areas to cover here.

Once the Policy and Procedure Manual is complete, have the appropriate Administrators and Research Team members read, sign and date them. Be sure you have included a policy on reviewing your Policy and Procedure Manual periodically.

#### **Apply for Affiliation**

After you have the foundation of experienced investigators, a research coordinator, and an assured IRB, you need to start applying to cooperative groups or industry sponsors for affiliation or as a site to conduct the clinical trials. Your application should reflect a strong experience in conducting clinical trials in the past by investigators, coordinators and the patient population volumes to succeed in accrual to the trials. Put your best foot forward on all applications.

**Ready, Set, Go!**

You are now ready to begin initiating clinical trials in the community hospital setting. Review your process, dot all your i's and cross all your t's and let your community know the resources you have for them. You are on your way to offering the cutting edge medical care to your patients right in their own neighborhood!

## Sample of Policy and Procedure Categories

<b>General Administration</b>	<b>Protocol Management</b>	<b>Human Subject Management</b>	<b>Data Management</b>	<b>Quality Management</b>
Policy Management	Study Initiation	Screening and Recruitment	Data Collection	Internal Audits
Job Descriptions	IRB Submissions and Communications	Entering patients on protocol	Data Submission	External Audits
Orientation and Education	Sponsor Communications	Monitoring patients on protocol	Data Maintenance	Misconduct in Science
Budgets	Regulatory Documents	Follow up of patients on protocol		Notification of Patients
Contracts	Patient Records Management	Communications with Patients		Conflict of Interest
	Drug Accountability	Special Procedures		
	Site Visits			
	Study Close Out			

### Self Study Quiz - Answer Key

(See Pg. 16)

1. a. Essential documents (Section 8.1)
2. b. investigator's brochure (Section 7.1)
3. b. investigator (Section 7.1)
4. a. sponsor (Section 8.3.10)
5. b. investigator/institution (Section 8.3.12)
6. c. both a and b (Section 8.3.24)
7. a. true (Section 8.3.22)
8. b. false (Section 7.1)
9. c. both a and b (Section 7.3.6.c)
10. c. monitor (Section 8.1)