So You Want to *Start a Research Program!* The experience of a community cancer center in Jupiter, Fla.

by Brenda Gordon, R.N., M.S., OCN[®]

Your physician office or cancer program has gotten its feet on the ground and now you want to start a research program. Excellent. The only way to find the best treatments for patients is through research.

We started the research program at Jupiter Medical Center in 2001. Our first step was to hire a research nurse/coordinator and that should be the first step you take, too. Your research coordinator is the backbone of your new program, and finding the right person for the job goes a long way to ensure the success of your research program. Find someone with an oncology background and previous research experience. Your coordinator should also be extraordinarily detail-oriented, able to deal with people, and able to establish good working relationships with the departments of the hospital (radiology, pathology, and the clinical lab) that will provide services for your trial patients. The Society of Clinical Research Associates and The Association of Clinical Research Trial Professionals have a certification process. Talk to them about finding the right candidate for your facility.

Our next step was connecting with a community clinical oncology program (CCOP). CCOPs are regional clearinghouses for the federally sponsored cooperative group trials, and we now participate actively in the CCOP headquartered at Mt. Sinai Hospital in Miami. You can obtain information about CCOPs at *www.can*- cer.gov or www.ctsu.org, which are funded by the National Cancer Institute (NCI). You can also learn about NCI trials that might be appropriate for your patient population by visiting www.clinicaltrials.gov, a service of the National Institutes of Health developed by the National Library of Medicine.

If you are involved with a CCOP and prove you can enroll patients and keep up with the paperwork, the clinical research organizations (CROs) that broker pharmaceutical company trials will come looking for you. Contact them first if you can, because pharmaceutical trials are lucrative and will help your new research program get on its feet. We work with CROs such as Pharmatech, Theradex, PRA International, and ParExel, all of which can be contacted through the Internet.

Pharmaceutical trials are less complicated to administer than CCOPs and reimburse participating entities at a much higher level. A good mix of pharmaceutical and cooperative group trials will keep your research program solvent.

What essentials will you need to start? First, of course, is your coordinator, followed by a dedicated phone line for a computer with Internet access and a CD-ROM port, a printer, answering service capability, and room for files. If your hospital or office does not have the money for these start-up essentials, look for philanthropic or grant money. As your program grows, you will need more physical space for new staff members,



patient management, and the files to house your reports to study sponsors and your own Institutional Review Board (IRB). Each protocol is a detailed recipe for subject care with logarithms for both follow-up visits and reports to the sponsors and the IRB.

Your expenses will include \$24-\$26/hour for your coordinator; space rental; funds to cover faxing, long-distance phone calls, paper, postage, and other supplies; and money for your coordinator to attend cooperative group meetings, which are required and are usually held out of state. Our research budget at Jupiter is around \$65,000 a year and we have 65 open clinical studies.

Start slowly with one or two trials that will accrue well to get your physicians and staff used to the research process. Educate your staff about the new department and how it will interact with them once patients are enrolled, and educate your physicians on what is expected from principal and sub-investigators.

Our last recommendation is to keep your sense of humor in good working order and have a supply of aspirin in your top desk drawer. Good luck!

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