Negotiating the nurse research coordinator role

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Abstract
Ophthalmic nurses may be asked to be part of a research team. This article suggests ways the nurse can prepare for the research coordinator role and negotiate added compensation. Without preparation, the nurse’s workload may not be adjusted to accommodate additional tasks and there may be a lack of remuneration. At worst, the nurse may fail to meet the expectations of the investigator and sponsor.

Nurse research coordinators can learn new marketable skills, increase income, create opportunities for publications and speaking engagements, and widen their professional network. Sources of additional information about the research coordinator role are provided.

S tudy coordinator, research coordinator, research nurse—a role by any other name can be as overwhelming.

An ophthalmic nurse who is part of a busy clinical setting may be ill-prepared, either by education, experience, or available time, for these added responsibilities. Yet it is the competent, efficient ophthalmic nurse who earns the respect and confidence of an ophthalmologist or multi-disciplinary team interested in conducting clinical research. It is the nurse’s proven track record that attracts more responsibilities. This article will suggest ways the ophthalmic nurse can prepare for the role, and negotiate the compensation for the additional responsibilities.

Ophthalmic nurses in academic and non-academic settings may be asked by their employers to be part of a research team. Usually, this responsibility is added to an already brisk professional load. The nurse may be interested, but unaware of the time-consuming nature of the research coordinator role, and perhaps, unaware of the tasks involved. But the role of research coordinator can be challenging and rewarding. Chadwick (1992) has called this role “the job of my professional dreams.”

The pitfalls of neglecting to prepare for the new role may include failure to adjust the nurse’s workload to accommodate the additional tasks, lack of or inadequate remuneration for the new responsibilities, and failure to meet the expectations of the investigator and study sponsor. In addition, Johnson (1986) has suggested that nurses need to be better prepared for the research role so that they can evaluate research proposals and detect their weaknesses.

Benefits of the coordinator role
Nurses can profit in a number of ways from accepting or seeking the role of the research coordinator in their current practice setting. These are summarized in Table I.

Learning new marketable skills and finding new career opportunities are likely outcomes of participating in clinical research. Ophthalmic nurses can use these skills in a variety of settings. Many clinics are actively involved in clinical research, or this can be their sole reason for existing. A brief perusal of any journal devoted to clinical research will show the number of available positions for nurses in research. The experienced research coordinator can choose from a variety of clinical settings, or may opt to move into a research position with drug or device companies that sponsor clinical research.

Hill and Schron (1992) suggest that clinical trials can offer the nurse the unique opportunity to develop and conduct ancillary studies within the sponsor’s planned clinical trial.
An increase in income may be negotiated by the nurse as a result of accepting new responsibilities in clinical research. The nurse can and should discuss this as a benefit of the research coordinator role. The source of income may be the study sponsor, the investigator, or both. Increased opportunities for publications and speaking engagements can become available to the nurse who has functioned as a research coordinator. The nurse should discuss this at the outset with the sponsor and the investigator. Most of the time study sponsors have strict guidelines concerning publications and public speaking—often this is related to patent issues surrounding the company’s new product or new indication for an existing product, or to regulations by the FDA concerning advertising. These guidelines must be adhered to, but at the same time, sponsors are pleased to have their research exposed to interested professionals and the nurse can arrange to speak or write about the research process, the nature of the studies in which they were involved, or a number of other topics related to their therapeutic area. For instance, while the research nurse may not be allowed to speak on the topic of a study for a new glaucoma drug until the study sponsor is ready for this information to become public, he or she may be able to publish or speak on the elements of informed consent or how to recruit study subjects.

An improved professional network is another benefit of involvement in clinical research. Nurses are likely to make contacts in the drug and device industry, and in academia, as well as meeting other investigators, nurse coordinators, and experts in their field of clinical interest.

A manageable workload is an outcome the nurse should seek when negotiating items related to the new coordinator role. Being a study coordinator can be very time consuming. The nurse should discuss in great detail with the investigator and sponsor the nature of the tasks involved in the study and then analyze the amount of time it will involve and ask for alterations in responsibilities to accommodate the new tasks.

Gaining control over research activities at the site is one of the greatest benefits in negotiating the coordinator role before the study begins. This can involve setting up appropriate systems in the office to recruit study subjects, purchasing equipment for the study if necessary, arranging staff schedules with the office manager to ensure sufficient coverage on study visit days, and identifying back-up personnel in case of absences. Back-up personnel are critical to the success of the coordinator. It can be quite frustrating to plan a study carefully at your office only to find that on a day you are out no one else knew how to carry out your plans.

<table>
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<tr>
<th>Professional Benefits of the Negotiated Research Coordinator Role</th>
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<tr>
<td>Learn new marketable skills</td>
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<td>Find new career opportunities</td>
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<td>Increase income</td>
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<tr>
<td>Create opportunities for publications and speaking engagements</td>
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<tr>
<td>Expand professional network</td>
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<td>Design a manageable workload</td>
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<td>Control research activities at the site</td>
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Table 1

Negotiating benefits
It is possible, and in fact likely, that the investigator will not have considered or offered all the potential benefits when approaching the ophthalmic nurse about the research coordinator role. This doesn’t mean that the investigator will be resistant to the nurse’s request, but that the nurse should prepare for the negotiation by pointing out how he or she can create a position that will enhance benefits for the investigator as well.

If a clinical research project is planned at your office, read and prepare for a subsequent negotiation. If the new role comes as a surprise, ask if you can take a few days to prepare before you work out the details. Ask to have this time before the investigator makes a commitment to the study sponsor. This time can be very important in reducing your frustration and increasing your professional and personal satisfaction with the job.

Read nursing literature on clinical research in your area of interest. Have a literature search done at your local medical library to find what other nurse coordinators are saying.

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Sources of Additional Information for Nurse Research Coordinators

JOURNALS:
- *Journal of Clinical Research and Drug Development*
  Official Publication of Associates of Clinical Pharmacology
  Elsevier Science Publishing Co.
  655 Avenue of the Americas
  New York, NY 10010

- *Applied Clinical Trials*
  859 Willamette Street
  P.O. Box 10460
  Eugene, OR 97440-2460

PROFESSIONAL ORGANIZATION:
- Associates of Clinical Pharmacology
  1012-14 Street, NW, Suite 907
  Washington D.C. 20005

TRAINING COURSES:
- Barnett/PAREXEL'S Clinical Research Study Site Manuals (6 manuals)
  500 West Dutton's Mill Road
  Aston, PA 19014-3004
  1-800-856-2556

- Barnett/PAREXEL'S Clinical Research Training Programs

- University of Wisconsin’s Study Coordinators’ Training Course
  Milwaukee Extension, School of Nursing
  Continuing Education and Outreach Program
  Cunningham Hall
  P.O. Box 413
  Milwaukee, Wisconsin 53201

- Thompson Publishing Group’s Guide to Good Clinical Practice
  1725 K Street NW, Suite 200
  Washington, D.C. 20006

- ACP Certification Exam for Clinical Research Coordinator
  Associates of Clinical Pharmacology
  1012-14 Street, NW, Suite 907
  Washington, D.C., 20005
  (202) 737-8100
  FAX (202) 737-8101

Table II

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<th>Table II</th>
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<td>about research in your specialty. Read general literature on the topic of clinical research. Journals, organizations, and training courses devoted to clinical research are listed in Table II.</td>
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Determine the investigator’s “currency.” It is likely that if you already work with the principal investigator, you are familiar with what is important to him or her. If not, ask what the investigator wants from the study. Consider that the investigator is likely to be well paid for the study, and may: (1) hope to gain in professional stature from involvement in clinical research, (2) be interested in the challenge of the project, (3) have a humanitarian interest in treating or curing a condition, (3) hope to publish or speak on a clinical issue or disease state, and (4) expect to be able to attract new patients as a physician on the specialty’s “cutting edge.”

Tell the investigator what is important to you—your “currency.” Table III is a summary of the items you will want to include in your “currency.” Note that many of the benefits you expect are similar to the benefits the investigator may expect. Focus on how you can mutually benefit by the role you envision for yourself.

Ask the investigator about an increase in salary or a study-related bonus. You may bring up this item after you have identified for the investigator how you can help the practice by being well prepared for your role and by obtaining support for the research tasks you will be carrying out.

For example, after reading on clinical research you are able to identify how important it is to recruit study subjects on time. Tell the investigator that as research coordinator, you would like to create and maintain a database to locate study subjects easily. Ask for office support and equipment to do so. Clarify for the investigator how, after the initial investment of time and money in the system, it will save staff time and will meet the sponsor’s expectations for subject enrollment. Point out how this may enable the investigator to conduct more studies at the site.

Suggest to the investigator that you be the primary contact with the sponsor and that you meet early with the sponsor to work out study details. Remind the investigator that you are interested in publishing and speaking on topics related to the research and that you could work together to present on these topics at professional meetings.

Ask the investigator to notify the office personnel that you will be the primary study coordinator and that you will be afforded the assistance necessary to complete the research related tasks. The investigator should also clarify for the office personnel what priority the study has with respect to their other tasks.

Identify a back-up in your office and ask the investigator to agree to free up sufficient time
for you and your colleague to plan and coordinate the study. Work with the investigator to identify for the entire office how research will benefit them and the practice. This may be difficult, as the administrative tasks for the office staff will multiply as the study begins and the immediate return to them may be hard to identify. The investigator may wish to offer bonuses for completing enrollment on time, and returning all completed forms to the sponsor on time. Occasionally, sponsors may offer the investigator financial inducements for the office staff. Ask the investigator if financial inducements have been offered and if they are available to the staff.

Training for yourself and others involved in the study is another item to be negotiated with the investigator. Training can be accomplished through reading, watching videos, and attending professional meetings.

Professional meetings with your peers can be a good source for training. Associates of Clinical Pharmacology (ACP) is an international professional organization devoted to clinical research and the development of healthcare products. Their annual meeting offers the nurse the opportunity to meet with others doing the same kind of work, perhaps even in the same specialty area. In addition, ACP offers certification for study coordinators. Explore with the investigator support for your efforts in becoming certified, with time off, and payment for resource books, journals, and for the examination itself. Determine if the investigator will pay for membership in professional associations devoted to clinical research. Inquire about increasing your remuneration as research coordinator if you become certified.

Once you have determined the scope of your new position, work with the investigator in delineating the expectations of the study sponsor. Meet with or call the study sponsor early. Suggest input into the protocol. Help the investigator and sponsor identify problems you foresee prior to starting the study. Sponsors evaluate the investigator and other personnel at the site to determine if they want to use the site again. Ask the study sponsor about their post-study evaluation. Review the items that will be evaluated with all study personnel. Take this opportunity to arrange with the sponsor the details of publication and speaking rights. Express your interest in involving yourself in dissemination of the study results. Your greatest contribution to this early meeting with the study sponsor is to present to the sponsor a realistic picture of what your study site can and cannot do. The sponsor will appreciate this information since studies are quite expensive and timing is essential. The sponsor may have already spent several million dollars and as many as 10 years on this project before approaching the investigator. The study is one of the last tasks in preparing a portfolio of information for product approval or new indications.

**Opportunities**

Taking on the task of a research coordinator can present the ophthalmic nurse with new and challenging opportunities to expand professional horizons. The nurse can avoid the frustrations and pitfalls of a poorly defined role, or one in which there is inadequate support, by negotiating his or her preferred role in advance of making study commitments. A future article will provide highlights about the research process itself, from the perspective of the nurse coordinator. It will include tips on how to fulfill your commitment to the investigator, meet the sponsor's expectations, and produce study results that are valid and useful to the sponsor.

**Items to Negotiate**

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<td>On-site support, including clerical support, back-up staff, and computer assistance</td>
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<td>Publication and speaking plans</td>
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<td>Initial and on-going training in clinical research</td>
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<td>On-site reference library</td>
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<td>Support for attendance at professional meetings on topics in clinical research</td>
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<td>Support for certification as a clinical research coordinator</td>
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**Table III**

Patricia Brown is the owner of Advanced Clinical Services in Mission Viejo, CA. She was previously employed by Allergan, Inc. for 10 years, the last 3 years as Manager of Clinical Development. Patricia joined ASORN in 1984.

Jill Fishbaugh is the Cornea Center Clinic Coordinator for the Department of Ophthalmology. She is also certified as an eye bank technician. Jill is a member of INSIGHT's Editorial Board and joined ASORN in 1986.

**References**

