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I began working with pulmonary hypertension patients in 1998, when the only FDA-approved drug was Flolan. I am amazed that in a span of 11 years we now have 8 FDA-approved drugs with several more on the horizon. This has been possible only through research coupled with the dedication of subjects willing to participate in research studies, physicians willing to be principal investigators, and allied health staff willing and able to perform the work, monitor the progress, anticipate the problems, and collect the data.

There is a saying that it takes a village to raise a child. It also takes a multidisciplinary team to generate the best research. A RN study coordinator's job is like working on a puzzle: one must keep track of all the pieces, provide support for others as they complete their portion, and then fit all the pieces together into a successful finished product.

What do RN study coordinators do? They are essential for contributing to all aspects of the project in order to achieve successful completion. Responsibilities include coordinating the process of daily study administration; feasibility evaluation; protocol development; budget and contract negotiation; screening, recruiting, and enrolling participants; consenting, scheduling, testing, data collection, dispensing study drugs, and managing the use of investigational devices; managing and reporting side effects; ensuring accuracy of documentation; maintaining databases; responding to the sponsors' questions; and providing safety and support for the subjects and their families. All of this must occur while following good clinical practice, institutional policies and procedures, and the regulatory requirements necessary for human subject research. To accomplish these objectives, the ideal study coordinator must be pleasant, flexible, compulsive, detail oriented, and extraordinarily well organized.

The investigator, sponsor, regulatory agencies, and subject rely on the RN study coordinator to carry out the study requirements reliably and with a substantial degree of independence. Thus, communication and collaboration with the principal investigator, other team members, sponsor, monitor, and subject are vital pieces of the puzzle. This relationship grows over time through open and effective exchange of information and the development of trust.

The success of any study depends upon all members of the team fulfilling their roles, but in many ways the RN study coordinator is the most vital component of all. The RN study coordinator plays a crucial role in fitting the pieces of the puzzle together for a successful result by providing leadership in the research environment.

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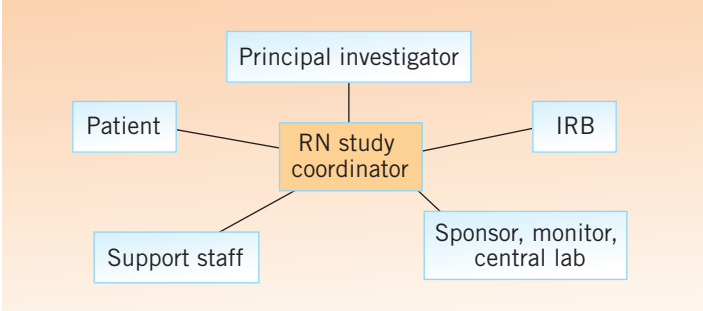
Why would you want to be a RN study coordinator? For some, the ability to spend more time with patients and their families provides satisfaction. Many nurses working in clinical trials comment on the autonomy afforded them, which capitalizes on nursing professionalism. Many also enjoy the collaborative relationships with other members of the research team and find that such collaboration fits well with nursing. The diversity of work and flexibility of involvement in acute and preventive studies are another attraction for study coordinators. There are opportunities for tremendous professional and personal growth and gratification in this profession. — *Louise Durst, RN, PAH Study Coordinator, Mayo Clinic, Rochester, MN* ■



Table—Practical Tips

Manage your files	Keep your electronic and paper files organized and tabbed. If you need help, contact the study sponsor or an experienced study coordinator.
Manage your time	Keep a daily to-do list. Keep a calendar with subject appointments and contact information. Complete the case report form; call the subject if clarification is needed.
IRB	Submit on time; do not let a protocol expire. Work on new submissions and collect the pieces in a timely manner, realizing you won't get everything you need in 1 day.
Contact with the PI	Set up a daily/weekly maintenance meeting. Be organized; have questions written down and items tagged for signature.
Know your subject	What is their preferred phone number? When is the best time to contact them? Where may you leave a message? Respond to subjects' questions/concerns immediately.
Sponsor	Respond to requests. Supply required/requested information at monitoring visits; have it ready. Order supplies before you need them. Treat your monitor as a guest.