RESEARCH STUDY PARTICIPATION

by Bonnie Black, RN, ANP

There are a handful of academic medical centers in the United States that conduct research on the autonomic nervous system, including Vanderbilt in TN, Mayo Clinic in MN, the Harvard system in MA, New York University in NY, University of Texas in Dallas, TX, and the National Institutes of Health (NIH) in MD. Patients are recruited to participate in research. For a list of ongoing studies, visit *www. clinicaltrials.gov.*

Once you have been recruited for study participation, you and the research coordinator will select a mutually agreeable date for your screening visit. The screening could be separate from actual study participation, or it could be the initial part of the whole research experience.

The informed consent document is generally available in advance and is written in language that you should be able to understand. The reading level is purposefully chosen to be one that most readers can comprehend. You may need to review it a couple of times for details, but it should be very thorough about all aspects of the study. The format of the consent generally follows a template provided by the institution's Institutional Review Board, and it is reviewed and approved by a group of professionals in the conduct of human research. The consent form should be current and should include an approval date and an expiration date.

Every detail of the study should be outlined for you in the consent agreement. However, the coordinator is usually happy to outline in general terms how participation works and answer any questions. He or she would let you know a time frame for arrival to the unit and a general outline of your study days. Some studies are conducted during an inpatient stay, and others are outpatient studies and one comes and goes to the facility.

Ask the coordinator about appropriate clothing if she or he does not mention what to wear. The autonomic nervous system studies usually require the application of blood pressure cuffs, cardiac or other electrodes that are applied to the skin, and other recording devices. Casual, loose-fitting clothing is always appropriate. Bring a pair of slip-on shoes for walking down the hall in the hospital to protect your feet and allow for easy removal for the study. The investigator may specify shorts if they expose the upper leg during testing, as the appropriate garment allows easier access.

The study staff makes every attempt to recruit in advance patients or healthy controls that are appropriate for the study. They do this by reviewing outside records and, in some cases, make use of questionnaires. However, sometimes after the patient is selected it becomes clear the patient is not an ideal candidate for the study; then, a withdrawal takes place that could be the decision of the investigator or the subject. This is the best decision for all concerned, and is the best utilization of time and resources.

Whether you are staying at home or at a hotel, bring comfort items that help you get a good night's rest, such as a favorite blanket or pillow. Medical equipment, such as a C-pap machine, urinary

catheters, and such, should be mentioned to the coordinator if you have any question about bringing your own.

Most autonomic studies do involve some discomfort due to study procedures. You should weigh your desire to participate with your actual clinical situation. Something as simple as lying quietly for several hours may be excruciating for a patient with chronic back pain. Blood samples that are a crucial part of a study may be almost impossible on a subject with a history of very poor intravenous access. A study that requires standing for periods of 10 minutes is not realistic for a patient who has been confined to bed for the past month. Patients can be both eager to help and desperate for help, and this may lead them to imagine they can comply with the rigors of a study when, realistically, they cannot. Discuss the described study procedures with the co-investigators and decide together if study participation is appropriate for you.

If you are fortunate to live in close proximity to a study center, travel there may not be time-consuming or difficult. Otherwise, it takes some planning. There may or not may not be funds to defray the cost of travel. If possible, plan to arrive early enough to be rested so you can start the screening process with a clear mind. Departure from the study center should be planned to allow for the appropriate rest needed to drive, fly, or otherwise travel home.

It is helpful to understand that the primary focus of a research study is to help the researchers learn more about a given condition. Their role is not to give you all the answers you have about your specific case. However, the researcher and the study results may help you and your doctor gain more knowledge about your condition, and this may help you devise an effective therapy program.

Bonnie K. Black, RN, ANP, BC graduated with a BSN from the University Of Nebraska Medical Center College of Nursing and earned her certification as an Adult Nurse Practitioner from an early program at the University of Vermont/VNA. She initially worked in cardiology and neurology for the Depart-ment of Veterans Affairs. She started the western VA Pacemaker Surveillance Program that provided trans-telephonic follow-up for veterans with implanted cardiac pacemakers. In 1994, she joined the faculty and staff of the Vanderbilt Autonomic Dysfunction Center, Vanderbilt University Medical Center as a research nurse. She recruits patients for studies in autonomic cardiovascular control from all over the United States and abroad.