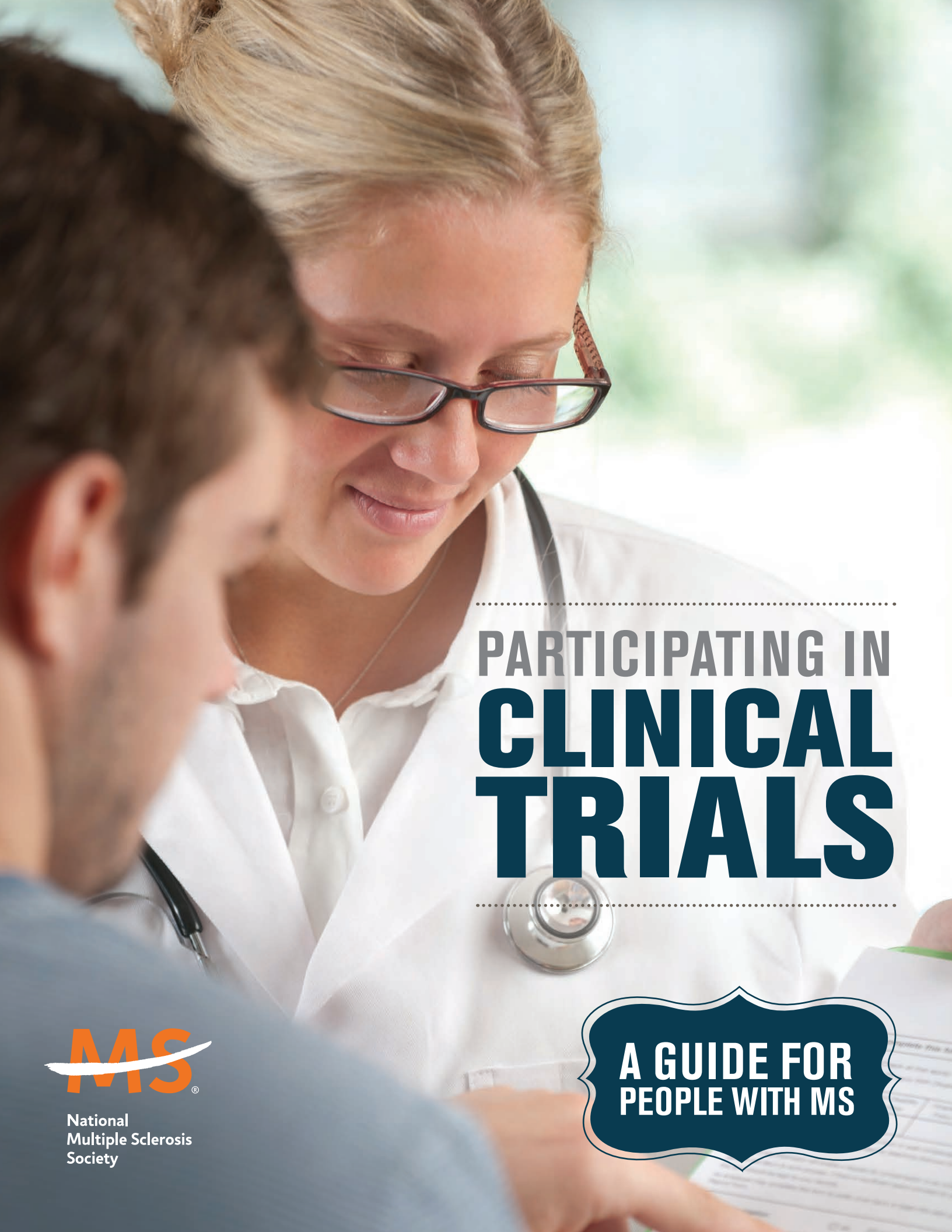

PARTICIPATING IN CLINICAL TRIALS

A GUIDE FOR PEOPLE WITH MS

National Multiple Sclerosis Society

If you have ever taken a medication or received rehabilitative physical therapy, then you have experienced the benefits of clinical research. Clinical trials help to determine if treatments are safe and effective. There is an urgent need for people with multiple sclerosis (MS) who are willing to volunteer in clinical trials testing MS therapies. Studies are enrolling diverse populations and are monitored to ensure that the rights and safety of all participants are protected. Without the help of people with MS, it would be impossible to develop new and better therapies.

Clinical trial basics

Many factors are involved in making sure that a study is conducted properly and that the results are valid. The U.S. Food and Drug Administration (FDA) requires therapies to undergo three phases of clinical trials before they can be approved to treat people with MS:

- **Phase I —** The first step is to determine safety and dose. In a small number of healthy volunteers or persons with MS, the investigators determine the safe dose range, identify any safety concerns and understand any side effects of the drug.
- **Phase II —** Another study is undertaken to begin to determine the effectiveness of the therapy in people with MS. A phase II study may last several months or several years, and involves larger numbers of people, further evaluating safety. The study is controlled — that is, the therapy is compared with the standard treatment, or an inactive placebo. Studies in this phase are meant to determine if a larger, more definitive phase III trial is worth the large investment of funds that would be required.
- **Phase III —** If the phase II trial suggests effectiveness and safety, an even larger study is conducted in hundreds or thousands of people to definitively determine the therapy's effectiveness and to gain a better understanding of the therapy's possible side effects. These multi-center studies can span several years and several countries.

Following FDA approval, postmarketing studies (phase IV) might be conducted to assess long-term safety and effectiveness.

What are the benefits of participating in a clinical trial?

Clinical trials that are well-designed and well-executed are an excellent approach for eligible participants to:

- Play an active role in their own healthcare
- Gain access to new research treatments before they are widely available
- Help others by contributing to medical research

What are the risks of participating in a clinical trial?

- There may be unpleasant, serious or even life-threatening side effects to treatment.
- The treatment may not be effective.
- Some trials are placebo controlled, meaning that part of the group of participants will receive a placebo — or sugar pill — that does not contain any active medicine.
- The protocol (clinical trial procedures) may require more time and attention than just receiving a standard treatment from your doctor. For example, you may have to make several trips to the study site, or undergo more treatments and tests.

How are participants protected?

Given these risks, participants in clinical trials are protected in several ways. Most clinical research is federally regulated with built-in safeguards to protect the participant. The trial follows a carefully controlled protocol — a plan that details what researchers will do in the study. There are specific eligibility criteria that determine who can enter a clinical trial. These criteria help ensure that those participating have similar characteristics and that participants do not have other illnesses or current medications that would be unsafe or that would interfere with the study therapy.

An independent Data and Safety Monitoring Board follows the study closely for side effects and any unexpected outcomes. Once the trial is completed, researchers may report the results of the trial at scientific meetings, to medical journals and to various government agencies — but participants' names remain secret and are not mentioned in these reports.

THE TRIAL FOLLOWS A CAREFULLY CONTROLLED PROTOCOL — A PLAN THAT DETAILS WHAT RESEARCHERS WILL DO IN THE STUDY.

Who can participate?

People who wish to enroll in clinical trials are generally required to meet the following requirements or inclusion/exclusion criteria:

- Reside close to the research facility (usually within 150 miles)
- Have the specific diagnosis that is under study
- Meet the study's guidelines relating to age, sex, level of disability and duration of disease
- Be able to understand the possible risks of participating, give consent, and be able and willing to follow study instructions
- Additional requirements unique to each study

These and other entrance criteria attempt to ensure that the trial participants in the treatment and control groups are similar in terms of their MS and other characteristics at the start of the trial. This makes it easier to determine at the end of the trial whether a new treatment shows benefit from a statistical point of view.

What you need to know

If you are thinking about participating in a clinical trial, here are some key questions to ask before making a decision:

- What is the purpose of the study?
- Why do researchers believe this new treatment being tested might be effective?
- Has the treatment been tested before?
- How many people have been exposed to the treatment?
- What are the side effects and risks of the treatment under study?
- How do the possible risks, side effects and benefits in the study compare with my current treatment?
- What kinds of tests and treatments are involved?
- How often will I have to come to the study site?
- How might this trial affect my daily life?
- How long will the trial last?
- Who will pay for the experimental treatment, or any of the tests?
- Will I be reimbursed for other expenses such as mileage, parking or meals?
- What type of long-term, follow-up care is involved with this study?
- How will I know if the experimental treatment is working? Will results of the trial be provided to me?
- If the treatment works can I continue receiving it?
- Does this study include a placebo (an inactive substance or "sugar pill" used as a comparator to the drug under study) or another treatment already on the market? If so, what is the probability that I will receive a placebo?
- Who else will know that I am participating in this study?

Find out how the study is controlled

Well-designed clinical trials should be "controlled" in such a way that the hopes and expectations of the participants and the researchers do not bias the trial outcomes or the interpretation of those outcomes. In most controlled studies today, one or more groups of participants — the treatment or experimental groups — receive the treatment being tested, and the other group — the control group — receives a previously approved treatment or an inactive placebo. Often both the participants and the researchers are "blinded", meaning neither knows which treatment any individual is taking until the trial is over and the data have been analyzed. Special circumstances, such as illness or unintended pregnancy, may allow the treatment to be revealed before the trial has concluded. In this case, the individual would not be able to continue in the trial.

If you are considering becoming involved in a study in which the experimental therapy is being compared to an inactive placebo, make sure that you understand your treatment options with therapies already on the market, and that you know what the probability is that you will receive the inactive placebo.

Seeking diversity

Clinical research trials of new treatments today often welcome cultural, ethnic and gender diversity. In fact, recent research indicates that MS affects African Americans and Caucasians differently, underscoring the need to include diverse groups in treatment studies.

It wasn't always this way. For many years, only white males were allowed into most clinical trials. A few trials involving African Americans were conducted in ways that would now be considered unethical. This is no longer the case. Trials today are monitored for safe and ethical treatment of all volunteers.

Studies involving diet, supplements and exercise

Some trials do not involve medications, but instead test diets or rehabilitation strategies such as exercise or devices that assist with mobility. Remember that even participating in something that sounds like it could be a normal part of your routine — how you eat or exercise — requires a thoughtful decision.

MAKE SURE THAT YOU UNDERSTAND YOUR TREATMENT OPTIONS WITH THERAPIES ALREADY ON THE MARKET.

Find out exactly what is entailed — the type of exercise, supplement or diet, and the length of the study. Discuss it with your neurologist and/or primary care provider, particularly if you have any other conditions such as heart disease, cancer, high blood pressure, kidney or liver disease, diabetes, use blood thinners, have had recent surgery or an eating disorder. Make sure the studied diet, supplement or exercise isn't contraindicated (not advised) for those issues. Be up front about vitamins or other supplements you are already taking, in case they interfere with or duplicate the supplement under study. Make sure you understand from the investigators the duration of exercise time and what types of discomfort that you might expect from the exercise program, so that these do not cause you undue concern.

Remember that, like any clinical trial, you can feel free to discuss concerns at any time with the coordinators and your care providers.

Understand informed consent

Your agreement to participate in any study must be based upon a process known as "informed consent." This requires the study coordinator or investigator to thoroughly explain the clinical trial, including:

- The risks and benefits of the study therapy
- The study schedule
- Tests or procedure to be done before and during the trial
- Your responsibilities during the trial
- The study staff responsibilities
- Alternative treatments
- Your rights as a study volunteer and who you can call if there are any problems or questions

Once you have been given all of this information and all of your questions have been answered, you will be asked to sign the consent form. Your consent indicates that you understand all of the above, but is not a contract of any type. You are a volunteer and can withdraw consent at any time. Informed consent doesn't stop when you agree to participate; it also includes getting updates throughout the study, and knowing that you can ask questions of the research team at any time before, during or after the study.

If you decide to stop participating, it's important to let the nurse or coordinator know your reasons for leaving the study, so that they can minimize the potential impact on the study results.

Coordinate your medical care

Before participating in a clinical trial, discuss the study with your doctor. If you decide to participate, put your doctor in touch with the doctor running the study. Give your doctor permission to share medical information. That will help ensure your safety during a clinical trial.

Even if your own doctor is running the study, be sure to tell the doctor or the nurse/study coordinator if you are taking medication for a condition other than your MS. Even a routine treatment for an unrelated condition might interact with the study therapy during a clinical trial. This could accidentally interfere with the study's results, or even be harmful to you.

Know what costs are covered

Understand who is covering the costs of the study. The consent form should outline any costs that will be billed to you or to your insurance. In most cases, the research team covers the cost of the study therapy and any medical care performed to fulfill the study's goals. Contact your health insurer — with the protocol or consent form in hand — to find out whether treatment for any side effects or routine care will be covered so that you understand fully what you might be expected to pay.

Resources on clinical trial participation in MS

CenterWatch

A publishing and information services company that provides information on clinical trials, including a list of MS studies currently recruiting patients.

10 Winthrop Square, Fifth Floor
Boston, MA 02110
617-948-5100; toll-free: 866-219-3440
customerservice@centerwatch.com
centerwatch.com

CISCRP

The Center for Information and Study on Clinical Research Participation educates and empowers patients, medical and research professionals, the media and policymakers about clinical research participation.

56 Commercial Wharf East
Boston, MA 02110
877-MED-HERO (877-633-4370)
info@ciscrp.org
ciscrp.org

Clinical Trials in MS

People with MS, and sometimes family members, can make a difference by volunteering for clinical treatment trials and other research studies. Read more about these opportunities on the National MS Society website:

nationalMSsociety.org/research/participate
1-800-344-4867

ClinicalTrials.gov

A registry of clinical trials that are currently recruiting participants with many disorders in the United States and around the world; searchable by disease.

clinicaltrials.gov

NARCOMS

This registry of people willing to participate in MS research was initiated by the Consortium of MS Centers to facilitate multicenter studies. As of May 2007, the number of participants surpassed 32,000. Information is available in Spanish.

NARCOMS Coordinating Center
The University of Alabama at Birmingham
RPHB 507
1720 2nd Ave. S.
Birmingham, AL 35294-0022
Toll-free: 800-253-7884
MSregistry@narcoms.org
narcoms.org

ResearchMatch.org

A not-for-profit secure website, designed to provide people who are interested in participating in research the opportunity to be matched with studies that may be the right fit for them. A collaborative effort of the national network of medical research institutions affiliated with the Clinical and Translational Science Awards, a part of the National Institutes of Health.

researchmatch.org

The National Multiple Sclerosis Society ("Society") is proud to be a source of information on multiple sclerosis related topics. The information provided is based on professional advice, published experience, and expert opinion, but does not constitute medical or legal advice. For specific medical advice, consult a qualified physician. For specific legal advice, consult a qualified attorney.

The Society does not endorse products, services or manufacturers. Such names appear here solely because they are considered helpful information. The Society assumes no liability for the recipient's use of any product or service mentioned. The Society does not independently verify whether the information provided by each service provider is accurate. The Society undertakes no responsibility to verify whether the service provider is appropriately licensed and certified and has applicable insurance coverage.

Early and ongoing treatment with an FDA-approved therapy can make a difference for people with multiple sclerosis. Learn about your options by talking to your healthcare professional and contacting the National MS Society at **nationalMSsociety.org** or 1-800-344-4867.

The National MS Society's mission is for people affected by MS to live their best lives as we stop MS in its tracks, restore what has been lost and end MS forever. To fulfill this mission, the Society funds cutting-edge research, drives change through advocacy, facilitates professional education, collaborates with MS organizations around the world, and provides services designed to help people with MS and their families move their lives forward.

National
Multiple Sclerosis
Society

nationalMSsociety.org
1-800-344-4867