

NIH News in Health

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Be a Partner in Clinical Research Help Others, Help Yourself

Did you know that you can participate in clinical research? Whether you're healthy or sick, young or old, male or female, you're probably eligible to participate in some type of clinical study. Maybe you or a loved one has an illness, and you'd like to help scientists find a treatment or cure. If you're healthy, you can help researchers learn more about how the body works or how sickness can be prevented.

Clinical research, also known as clinical studies or clinical trials, offers hope for many people, because it helps to find better treatments. Clinical trials are at the heart of all medical advances. And volunteer participants are essential to clinical trials.

Clinical research occurs at places such as hospitals, universities, doctors' offices, and community clinics. Studies may be funded by foundations, medical institutions, pharmaceutical companies, and federal agencies such as NIH.

People with an illness or disease sometimes join a clinical trial to receive an experimental treatment or to have the additional medical care and attention offered by clinical trial staff. But many participants also say they volunteer to benefit others. "This will be my chance to give back and help other people, maybe even my family in the future," said one NIH clinical trial volunteer who was battling cancer.

Our medical care is better today because of what clinical trials uncov-



ered years ago. Dr. Lauren Wood, a physician-researcher at NIH, credits clinical trial volunteers for helping to transform AIDS from being a certain death sentence into a treatable, chronic (long-term) disease.

Many HIV-infected volunteers who received experimental AIDS drugs more than 2 decades ago went on to survive and thrive, and treatments given to pregnant mothers kept the virus from passing to their newborns. These antiretroviral drugs have since become standard therapy.

"I've seen these patients grow up, graduate from high school and college, launch their careers, and start families of their own," Wood says. "They're living their lives because of clinical research."

A patient volunteer—someone with a known health problem—can

help researchers better understand, diagnose, treat, or cure that disease or condition.

But healthy volunteers, who have no known major health problems, also play an important role in clinical research. They help researchers learn things that may indirectly help themselves and people they know. Healthy volunteers are usually paid for their efforts.

Both types of volunteers are needed, because researchers can learn more about a disease by comparing patient volunteers to healthy volunteers.

All clinical studies have guidelines about who can participate.

Patient volunteers may be selected based on the type and stage of a disease, previous treatment history, and other medical conditions. The selection criteria help to ensure that researchers are studying the right people to help find answers to important medical questions.

Clinical researchers often look for people of different ethnicities, races, ages, and sexes. "We want to have adequate representation from a variety of people, so we can make sure that we develop appropriate treatments," Wood says. Some disorders affect certain groups of people more

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than others, so it's especially important to have clinical research volunteers from the at-risk or affected population.

"We've found that certain racial or ethnic populations may **metabolize** or handle drugs in different ways. Sometimes drugs are metabolized differently based on age, sex or even ethnicity," Wood says. Having a variety of volunteers allows research-

ers to determine the proper treatments and doses for different types of people.

If you're thinking about participating in a clinical trial, members of the research team will talk with you about the details of the study; this is called informed consent. They'll give you a document to sign that includes an overview of the study, such as its purpose, length, procedures, and who to contact for more information.

Members of the research team will also explain the risks and potential benefits of the study. "Volunteers should feel free to ask as many questions as they need to make things clear," says Dr. Christine Grady, an expert in patient protection and bioethics at the NIH Clinical Center. "You can also take the informed consent form home and discuss it with your doctor or somebody else who can help you understand it better."

If you decide to sign the informed consent form, you're still free to withdraw from the study at any time, even after it begins. Informed consent is not a contract; its purpose is to make sure that you know enough about the study to decide whether or not to participate.



Web Links

For more about volunteering for clinical research, click the "Links" tab at: <http://newsinhealth.nih.gov/issue/Mar2015/Feature1>

Clinical study participants are protected by a group of experts known as an Institutional Review Board (IRB). "Before the study even starts, clinical research involving humans is almost always reviewed by an IRB," Grady says. "The IRB makes a judgment about whether or not the risks are acceptable and whether the benefits of doing the research justify the risks."

A monitoring team usually also assesses study findings as a clinical trial proceeds. The team stays aware of any potential problems that may arise, and makes sure such issues are addressed.

After a study is completed, clinical researchers carefully examine the information they've collected. The results are often published in scientific journals. If the new approach proves to be safe and effective, it may become standard practice.

There are all kinds of clinical studies. Some evaluate new drugs or new combinations of drugs, new surgical procedures or devices, or new ways to use existing treatments. Others look at certain aspects of care, such as improving the quality of life for people with chronic illnesses.

"Participating in clinical research is essential to helping us get good care from our physicians," Grady says.

We all benefit when people step up and volunteer to participate in clinical research studies. Talk with your health care provider about clinical trials and whether participation is right for you. To learn more about participating in clinical trials, including personal stories of research volunteers, visit NIH's Clinical Research Trials and You website at www.nih.gov/health/clinicaltrials. ■



Wise Choices Find Clinical Studies

If you're thinking about participating in clinical research, you can learn more at www.nih.gov/health/clinicaltrials. The websites below can help you find studies that need volunteers:

- **ClinicalTrials.gov** Search for federally and privately supported clinical trials worldwide. Learn about a trial's purpose, who may participate, locations, and contact information for more details.
- **Clinicalstudies.info.nih.gov** Find clinical studies taking place at NIH's Clinical Center in Bethesda, Maryland.
- **ResearchMatch.org** Create a volunteer profile for yourself or for someone else as their parent or guardian. This NIH-funded resource is a free, secure registry that will keep you informed of clinical research studies that need volunteers matching your profile.



Definitions

Metabolize

To change a food or drug in the body into another form through chemical reactions.

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Better Check Your Bowels

Screening for Colon and Rectal Cancer

Colorectal cancer is the second-leading cause of cancer death nationwide. But it can usually be cured when caught early. Screening tests like colonoscopy can save lives by catching problems before symptoms even appear, when treatments might work best.

So no matter how busy you feel, if you're age 50 or older—or even younger if you're at high risk—you should make time to talk with your doctor about getting screened for colorectal cancer.

“Screening is effective, and it's been shown through clinical studies to reduce deaths,” says Dr. Carrie Klabunde, an NIH expert in cancer screening and prevention.

But although screening is known to save lives, many Americans ages 50 and older don't get screened for colorectal cancer. The most common reason, says Klabunde, is that “people don't realize this screening is something they need to do.” Other

common reasons include costs and inconvenience, such as taking time off from work.

Colorectal cancer is cancer of the colon or rectum, both of which are part of the large intestine. Scientists don't yet know what causes colorectal cancer, but certain factors affect your risk. Smoking, excess weight, or having 3 or more alcoholic drinks per day raises your risk.

“The risk for colorectal cancer rises with age,” Klabunde adds. Your risk also doubles if you have a close relative who had colorectal cancer.

The 3 recommended tests for colorectal cancer are colonoscopy, flexible sigmoidoscopy, or home stool tests. Each test has different benefits and drawbacks. Your health care provider may recommend one or more of these options.

Colonoscopy is the most accurate. The day before the test, you need to drink a special liquid or take prescription pills to cleanse your colon. A doctor inserts a tiny camera attached to a long, thin, flexible tube into the rectum and colon. Any growths the doctor sees, including **polyps**, can be removed during the procedure. Most polyps are harmless (benign), but some (called adenomas) can become cancer.

Flexible sigmoidoscopy also uses a camera attached to a tube, but the exam looks only at part of the large intestine. To prepare, you'll need to have an enema (an injection of water into the rectum to cleanse the colon) the night before or the day of the procedure. Sigmoidoscopy may let you know if there's a reason to have a colonoscopy.

Another option is a home stool test. You can take this test in the pri-



vacuity of your home using inexpensive or free kits from your doctor's office or pharmacy. After collecting a small sample of your stool, you mail or deliver it to a doctor or lab, where it will be tested for tiny amounts of blood, which could signal a problem.

Another screening test, called virtual colonoscopy or CT colonography, can scan the colon from the outside. But its effectiveness is still under study. For more details about different screening options for colorectal cancer, visit gutcheck.cancer.gov.

Don't wait for symptoms to appear. Talk with a health care provider about when you should begin screening for colorectal cancer and, if so, which test(s) to get. And check with your health insurance company to see if screening costs are covered (they usually are). ■



Wise Choices

What To Ask About Colorectal Screening

Everyone ages 50 to 75 (and younger people at increased risk) needs to have a plan for colorectal cancer screening. Ask your doctor:

- When should I start getting screened for colorectal cancer?
- Which screening test do you recommend for me?
- How can I prepare for the test?
- What should I expect during the test?
- Are there any risks involved?
- Who will perform the exam?
- Will I need someone to come with me?
- Who will give me the results, and when?



Definitions

Polyps

Growths on the inside lining of the colon or rectum



Web Links

For more about colorectal cancer screening, click the “Links” tab at: <http://newsinhealth.nih.gov/issue/Mar2015/Feature2>



Health Capsules

For links to more information, see these stories online:
<http://newsinhealth.nih.gov/issue/Mar2015/Capsule1>

Are You at Risk for Alcohol-Medication Interactions?

Many people may be both drinking alcohol and taking prescription drugs that interact with alcohol, according to a new NIH-funded study. The finding highlights the need to talk with a health care professional about the risks of drinking alcohol while taking prescription medications.

About 71% of U.S. adults drink alcohol. Alcohol can interact with many commonly prescribed medications, including drugs to treat pain, diabetes, and high blood pressure. Alcohol can make some medications less effective or even useless. Combining alcohol with medications may cause other side effects, such as nausea, fainting, and loss of coordination. More severe effects include

internal bleeding, heart problems, and difficulty breathing. Older adults are especially at risk for alcohol-medication interactions.

To learn more about alcohol and prescription medicine use, a team led by NIH's Dr. Rosalind Breslow analyzed data from more than 26,000 U.S. adults. The researchers found that about 42% of adults who drink also use medications that interact with alcohol. Nearly 78% of adult drinkers over age 65 use such drugs. Among the most frequent drinkers (5-7 drinks per week), 38% use medications that interact with alcohol.

The scientists note that the available data couldn't confirm whether drinking and medication use over-

lapped. These are potential, rather than actual, rates. Still, they highlight the possible scale of this problem.

"Our findings show that a substantial percentage of people who drink regularly, particularly older adults, could be at risk of harmful alcohol and medication interactions," Breslow says. "We suggest that people talk to a doctor or pharmacist about whether they should avoid alcohol while taking prescribed medications." ■

Measles: Preventable with Vaccines

Measles is a highly contagious disease caused by a virus. It starts with a fever, followed by a cough, runny nose, and red eyes. A rash of tiny, red spots then breaks out and spreads. Measles can be especially dangerous to children under 5 years old. It can lead to pneumonia, swelling of the brain, and even death. The good news is that measles can be prevented by getting a vaccine.

Measles spreads through the air when an infected person coughs or sneezes. It's so contagious that if one person has it, 90% of those around him or her will also become infected unless they're protected by a vaccine or "natural immunity" from a previous measles infection.

Thanks to vaccines, measles was completely eliminated from the U.S. 15 years ago. But since then dozens of cases have appeared, with a spike in 2014, when more than 600 measles cases arose. In 2015, over 140 measles cases have already been reported nationwide. Most of these infected people hadn't been vaccinated.

The best way to protect against measles is to get the measles-mumps-rubella vaccine (the MMR shot). Doctors recommend that all children get the MMR shot beginning at age 12-15 months, with a second dose at 4-6 years of age. Most health insurance plans cover the cost of vaccines. Learn more about measles at www.nih.gov/health/measles.htm. ■



Featured Website

National Center for Complementary and Integrative Health

<https://nccih.nih.gov>

The NIH center that studies complementary health approaches has a new name and Web address. Get a wealth of easy-to-understand information about complementary and integrative practices. Learn what the science says about herbal remedies, acupuncture, yoga, and more.

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