

Frequently Asked Questions

Questions:

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1. My doctor asked me if I would like to be part of a clinical research study. What is clinical research?

Every day, news headlines report new treatments and medicines for all kinds of diseases or new guidelines for living healthier and longer. Most treatments do not appear overnight. Behind the headlines are much hard work, time, money, and many patients who are willing to volunteer for the clinical studies to find those treatments.

Investigators carefully look at a specific health problem (such as depression or Alzheimer disease) and think of possible ways to improve treatments or solve the problem. Many times the solution involves the use of new medications or some new uses (or combinations) of old medications. If the medication is new, it must first be tested on animals to see if it works and is safe. Even if animal testing is successful, it does not necessarily mean the medication will be safe for people. At this point, both new medications and new uses for old medicines must be tested, according to very strict Federal laws, on human **volunteers**. This is what clinical research is. Without clinical research studies and patients who voluntarily participate in them, new advances in medical care would be very slow, and there would be little proof that new treatments really work or are safe.

2. Who pays for clinical research studies?

Research is expensive and time-consuming. Funding can come from many different sources. Investigators can apply for funds from organizations such as the National Institutes of Health (NIH) or the Alzheimer Association. Most studies involving new drugs are funded by drug companies and are watched very closely by the Food and Drug Administration (FDA).

3. I'm not sure I want to be part of a medical "experiment." Is that what this is?

Investigators must follow strict rules to test new treatments and medicines. Only after receiving as much information as possible about the risks and benefits are patients **invited** to participate in research studies on a strictly voluntary basis. Patients are **encouraged** to ask questions and are able to say no at anytime.

We very closely monitor all study patients and if we suspect any problems, we can immediately **break the code** (find out what the medication is), stop the study, and treat the problem.

4. What is an "IRB?"

Before any research study can be done, it must first be written up in a formal document know as a protocol and sent to the University of Nebraska Medical Center's **Institutional Review Board (IRB)** for approval the plan. The IRB is made up of other

scientists, doctors, clergy, ethicists and others. Their job is to protect patients who agree to participate in clinical studies. The IRB particularly looks for answers to these types of questions:

- "How much risk and benefit will the patients experience if they participate in this study?"
- "Is the study open to all patients no matter what the race, religion, or sex?"
- "How are the patient's privacy and confidentiality protected?"
- "Does the patient receive enough information in order to give *informed consent*?"

It is rare that the IRB accepts a study without some changes being requested. Once the study is accepted, the IRB will continually watch over the study and review the progress.

5. Why should I participate in a clinical research study?

To constantly improve and find better ways of treating patients with problems such as depression or Alzheimer's disease, we must rely on patients to agree to *voluntarily* participate in our studies. Volunteers give many reasons for participating in our research studies:

- To help learn more about depression or Alzheimer's disease for myself and anyone who lives with one of these challenging diseases.
- To get free medication.
- To advance science.
- To be the first to try a new treatment.
- To be more closely monitored by my doctor.
- To be part of a study like the one in the newspaper.

Without our patients and their willingness to help, our studies would not exist and progress toward better treatments would be slow. Currently, thousands of patients all around the world are benefiting from studies done at UNMC.

6. What do studies done in the Psychopharmacology Research Consortium pay for?

If you are involved in a study that involves medication, we will provide the study medication free. Occasionally, your physician may want you to take other medications that are not officially part of the study. These other medications will be your responsibility. Any tests done as part of the study protocol (which might include, physical exams, blood tests, heart tracings {EKG}) are typically provided free of cost.

7. My doctor asked me to be in a study that provides medicine. I was also told that I may be receiving a placebo. What is that?

A *placebo* is a pill that looks just like the real drug, but actually has no active medication. To be able to prove scientifically that a medication really works, many clinical research studies are *double blinded*. That means that neither you nor your doctor will know if you are taking a placebo or the medication under study. We do this so the patients, doctors, and nurses remain unbiased. This ensures that personal opinions and beliefs do not influence the results of the clinical research study.

We have learned from studies using a placebo that a certain proportion of patients improve even though they are taking a placebo. The number of patients who respond to a placebo is compared to the number of patients who improve on the study medication. This provides stronger evidence for the effectiveness or lack of effectiveness of the study medication.

8. Who is allowed to see the study information about me?

All information gathered during the study is kept in your UNMC medical record as the official record. In studies which are sponsored by a pharmaceutical company, information about your participation is also made available to the company. However, any information that identifies you is removed so that your name is not released.

At UNMC, a **study coordinator** (nurse or physician assistant) monitors patients enrolled in all studies. She/he assures that all patients get their medicines, paperwork is up-to-date, and problems are solved.

No one else can view your file, nor will we give out information without your written permission. Each patient involved in a study receives a study number which is used to refer to specific patients. In order to share what we have learned in our studies, we will write papers for medical journals, present our results at national/international conventions of medical professionals, and occasionally participate in press conferences to discuss new and interesting results. In all of these cases the privacy of persons who have participated in the research study is maintained.

9. If you are asked to be part of any clinical research study, here are a few questions you might ask:

- What is the purpose of the study?
- Why is my doctor asking me to participate? Is he or she being paid for my participation?
- How many patients will be enrolled in the study?
- How long will the study last?
- What is involved in the study? What are the medications or treatments? Are any of the medications a placebo? Are the medications FDA-approved, or is this study testing brand new medications?
- What are the risks of being in the study?
- What are the benefits of being in the study?
- If something happens to me because of the study, who will pay for medical treatment?
- How is my privacy protected and who can see the information?
- Can I continue to see my regular doctor?
- If I don't want to be in the study, what are my alternatives? What other choices do I have?
- What is the cost to me?
- Will I be paid anything to participate?
- What happens if I sign the informed consent form, then change my mind? What do I do?
- Can I be dropped from the study without my permission?
- Will you tell me the results of the study?

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Rheumatoid Arthritis Investigational Network RAIN
[Section of Rheumatology](#) Department of Internal Medicine
University of Nebraska Medical Center
983025 Nebraska Medical Center
Omaha, Nebraska 68198-3025