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Op-Ed

Volunteering for Clinical Research Studies and Public Health

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THE ULTIMATE GOAL OF MEDICAL RESEARCH IS TO PROVIDE therapies and, hopefully, cures for the many diseases plaguing humankind. But a great many patients and healthy volunteers are vital to bringing new drugs and therapies to market. To ensure the public's health, it is essential that everyone seriously consider volunteering for clinical research studies.

Six types of clinical studies typically require human volunteers: (1) *natural history studies*, which provide information about how diseases or illnesses progress; (2) *prevention trials*, which study better ways to prevent diseases from occurring or recurring; (3) *screening trials*, which study the best ways to detect certain diseases or conditions; (4) *diagnostic trials*, which study tests and procedures to better diagnose certain diseases; (5) *quality-of-life* studies, which explore ways to improve the quality of life for patients with chronic illnesses; and (6) *treatment trials*, which test new treatments, including drugs, surgery, and radiation therapy.

Clinical treatment trials, and especially randomized clinical trials, are probably the most common studies for which investigators seek volunteers. Not surprisingly, many patients with the specific illnesses being studied volunteer for such trials, and more than 40,000 such trials are currently under way. Before anyone volunteers for a clinical trial, he or she should seek a detailed explanation of the study's goals, inclusion and exclusion criteria for volunteers, and the potential risks and benefits. It is important to note that before any trial can begin, many experts must review and approve it, and after the trial has begun, experts provide oversight using specific guidelines. Moreover, no one can be involved in a clinical trial without first providing informed consent. The information presented to the volunteer before a consent form is signed is a detailed explanation of the trial, including its potential risks and benefits.

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Clinical trials have 4 phases, 3 of which involve volunteers. Those trials that do not involve volunteers are *phase 4 trials*, in which researchers track the safety of a drug or treatment after the Federal Drug Administration (FDA) has approved it.

Phase 1 trials involve a relatively few (20 to 80) volunteers; they study the safe dose range for drugs and their side effects. These studies begin by giving small doses of the study drug to healthy volunteers and gradually increase the dose to the point of safety.

Phase 2 trials involve a few dozen to 300 patient volunteers who have some type of the disease being studied to whom the drug or treatment from the phase 1 trial is being given. The goal of these trials is to determine both the type of disease for which a drug dosage is effective and the safety of the drug. Only about 70% of phase 1 trials ever advance to phase 2 trials.

Phase 3 trials can use hundreds to thousands of volunteers. In these studies, the test drug or treatment is compared with a placebo and/or a currently used drug or treatment. These trials confirm the effectiveness of the treatment and monitor the side effects. In randomized clinical trials, the treatment drug, placebo, or currently used drug is assigned arbitrarily to each volunteer. These trials can be either single- or double-blind. In a single-blind trial, only the volunteers do not know which treatment or drug they receive, and in a double-blind trial, only the pharmacist knows who received which drug or treatment. That is, the volunteers and the investigators are "blinded" because neither the volunteer nor the investigator knows who received the study drug or treatment or who received the placebo or current drug. Phase 3 trials are necessary for FDA approval of the drug or treatment.

To ensure the volunteers' safety, an ethics committee, such as an institutional review board, must approve the planning for the phase 3 trial, and the trial is supervised by a data-monitoring committee. The volunteers are given health insurance; their privacy is protected; and all volunteers are fully informed about the risks and benefits. The volunteers for these trials may receive a new drug or treatment not otherwise available to the public. In some studies, volunteers receive a monetary reward. Other volunteers join a trial simply to help improve treatments for future patients. Volunteers should also consider that they may have to make trips to a hospital or clinic, complete paperwork, provide blood or other specimens, or even experience some unpleasant side effects. However, investigators do everything possible to ensure the

volunteers' safety, comfort, and freedom from annoyances that might interfere with their normal functioning.

Some pharmaceutical companies conduct or sponsor drug trials and seek volunteers online, and they often provide financial remuneration for the volunteers. However, the best place to obtain information about all currently ongoing trials is from the National Institutes of Health (NIH).[1] All human clinical trials must be registered on the clinicaltrials.gov website as soon as the first volunteer is enrolled, thereby guaranteeing that the NIH is aware of all clinical trials.

The public's health depends on discovering new treatments for diseases or illnesses. New drugs can be brought to market only after FDA approval, which requires clinical trials. If you care about the future of medicine and health care, you should consider volunteering for these studies. Our collective health may depend on it.

Reference

1. NIH clinical research trials and you. National Institutes of Health website. https://www.nih.gov/health-information/nih-clinical-research-trials-you/personal-stories. Updated December 3, 2016. Accessed December 15, 2016.

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