Inflammatory Bowel Disease in Children and Adolescents

Volunteering for Clinical Research

What does it mean to be a volunteer in a clinical research study?

Patient participation is the key to conducting medical research. More specifically, "clinical research" is the term used to characterize patient based research designed to answer questions about human disease - the causes, origin, prevention, diagnosis, outcome, and treatment. There are many types of clinical studies with varying degrees of human subject involvement. Clinical trials, for example, are designed to test the safety and efficacy of a new drug or therapy and require direct participant involvement, access to personal data such as health and lifestyle information, and human materials samples for testing the effect of treatment. In contrast, records based studies require access to personal health information, but often times do not involve any direct participant contact. These studies are usually aimed at characterizing trends in the natural course of disease and treatment in individuals and populations. A third type of clinical study requires human material donation, such as blood or tissue used in laboratory analysis. Human materials studies are carried out solely in the lab, and the only participation required by the subject is the donation of human tissue or material (such as blood, biopsy specimen, excreta like urine and stool).

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Whatever the type of clinical research, human participation is ultimately important if we are to advance patient care and the basic science involved in the prevention, diagnosis and treatment of human disease. Aside from this basic necessity, there are many good reasons for parents to involve their children in clinical research. People volunteering for clinical trials can gain access to promising drugs long before they are commercially marketed. Patient care during the course of a study is usually exceptional due to the level of involvement of the investigating physician and the extra scrutiny of co-investigational staff. Some or all of the care provided during a study may be free. Also, the rights of participants are protected in two important ways. First, a physician must obtain approval to conduct the study from an Institutional Review Board which is composed of physicians and lay people charged with examining the study's protocol to ensure the absence of unnecessary risk, and that patient's rights are protected. Second, all participants are required to sign an "informed consent" form. This form details the nature of the study, the risks involved, and what may happen to a patient in the study. Valuable clinical information is usually exchanged during the consent process and offers parents a thought provoking discussion period with their physician and the opportunity to ask additional questions. A solid working relationship between physician and participant resulting in better communication and understanding is just one of the possible benefits resulting from clinical research participation.
Most importantly, the information gained from a study may be beneficial to the participant or to others sometime in the future. While it is relatively rare that participants receive direct medical benefit from clinical research participation, the indirect benefits and the knowledge that a person has taken initiative to promote heath and science are very rewarding.