

COMMENT AND PERSPECTIVE FROM THE OFFICE OF THE DEAN, UNIVERSITY OF CINCINNATI COLLEGE OF MEDICINE

March 17, 2014

Clinical trials are an important aspect of our research mission. As an academic medical center we must remain at the forefront of providing the latest treatment options while creating new knowledge through clinical research. It is the responsibility of every clinician to discuss the option of clinical trial participation with patients. I have asked Christopher Lindsell, PhD, associate dean for clinical research, to expand on the importance of clinical trials.



Thomas F. Boat, MD
Vice President
for Health Affairs,
Christian R. Holmes
Professor and Dean,
College of Medicine

Recognizing the Value of Clinical Trials



Chris Lindsell, PhD
Associate Dean for
Clinical Research,
College of Medicine

The driving force behind all research in the College of Medicine is to improve the health of our community and provide better options tomorrow than exist today. Our health system is uniquely positioned to offer patients the most advanced treatment options through our clinical trials; unfortunately few of our patients are given the opportunity to participate. Nationally, a third of cancer patients want to be in a clinical trial and another 38 percent are willing if asked, but only 15 percent are told by their doctor that they could be in a clinical trial.

It is true that some patients don't want to take part in research. Some are concerned about costs, some fear they will only get placebo. Others may distrust the researcher, or be concerned about complying with the protocol. Yet, the vast majority of patients in clinical trials say their experiences are positive and that they receive good or excellent care. In fact, three-quarters of cancer trial participants recommend being in a study to other patients. The primary problem with accrual into trials is not patients' attitudes, but physicians.

Overcoming the Challenges

Making clinical trials available to our patients is a top priority for the college, UC Physicians and UC Health. We recognize it takes time to discuss research with patients, or that a trial might require

scheduling more visits or more testing. The pressures to provide efficient care can understandably make talking to patients about clinical trials a low priority. These may be the reasons why we offer so few of our patients the opportunity to participate in research. In the Dean's Office, we are working to overcome the challenges of lack of time, limited staff resources and burden of study coordination by:

- exploring ways to increase the number of relevant trials that are open, and to make you aware of these opportunities
- investing in an infrastructure that will make participation in clinical trials easy and rewarding for our providers and our patients
- working on a comprehensive plan to make support available to you so that together we can make prevention, diagnostic, screening and treatment trials available to every eligible patient who wants to participate

This is a priority because nearly all clinical trials have benefit. For some patients, the benefit is having new treatment options available when all else has failed, or the possibility of helping other patients with the same problem. For others, it is getting access to cutting edge technologies and getting more attention from experts in the field. Being in a study can help patients deal with the day-to-day struggles of living

Making clinical trials available to our patients is a top priority for the college, UC Physicians and UC Health.

CONTINUED ON BACK

The Issue

March 17, 2014

CONTINUED FROM FRONT

with a chronic disease, or help them cover the cost of their care. Whatever the benefit a patient feels, the most influential factor in their decision to enroll in a study is the discussion they have with their doctor about research.

Patient Options

Our physicians should be talking to every patient about enrolling in research. As we do so, we should be respectful of our patients' background and their attitudes and beliefs. For example, the information about risks and side effects in the informed consent document can conflict with the patient's sense of hope. Patients can fear getting a placebo and not the experimental treatment. They might believe that the experimental treatment is likely to be ineffective, or that it has more adverse effects than standard care. We all know that there are unknown risks of new therapies. It is incumbent on us to clearly articulate this in a way that does not promote fear and distrust. If the potential benefits of the study do not outweigh the possible risks, the IRB and FDA will not allow the trial to progress in the first place.

Perhaps one of the greatest challenges to overcome is when a physician's beliefs conflict with the research. Even if you think clinical trials are inferior to the care you are providing, or if you believe your patients will react negatively to discussions about research, patients should have the option to be in a clinical trial. Every patient has the right to be autonomous in their decision making and we must respect that autonomy.

Providing a patient the opportunity to participate in a clinical trial is not the same as asking them to be experimented on. It is well known that simply being enrolled in a clinical trial can improve a patient's outcome, regardless of what therapy he or she gets. Whether it is the placebo effect, or a factor of the increased clinical scrutiny research participants enjoy, it remains the case that they will generally do better in the trial than otherwise. If you believe that your patients deserve the best possible care, why would you not search for a clinical trial opportunity for every one of them?

Chris Lindsell, PhD
Associate Dean for Clinical Research
chris.lindsell@uc.edu

Whatever the benefit a patient feels, the most influential factor in their decision to enroll in a study is the discussion they have with their doctor about research.

CLINICAL RESEARCH AT THE UNIVERSITY OF CINCINNATI AND UC HEALTH

The UC College of Medicine partners with its affiliated health system, UC Health, to conduct clinical research. UC's Institutional Review Board regulates and provides oversight of clinical research studies, and the UC Health Clinical Trials Office provides a range of services to investigators, including contracting, budgeting and study recruitment marketing.

UC Health Clinical Trials Office

2830 Victory Parkway, Suite 325
513-475-8031
uhealth.com/research
clinicaltrials@uhealth.com

UC Institutional Review Board

51 Goodman Drive,
University Hall, Suite 300
513-558-5259
irb@ucmail.uc.edu

Want to promote your studies online?

The Clinical Trials Office is currently developing an online clinical trials search for advertising studies directly to the public. Working with the UC Institutional Review Board, the office has developed a way for investigators to quickly enter into ePAS the information necessary for advertising studies to interested participants. For step-by-step instructions, contact Wendy Newman at wendy.newman@uhealth.com.

University of Cincinnati College of Medicine

Office of the Dean

3230 Eden Avenue | PO Box 670555

Cincinnati, OH 45267-0555

513-558-7333 | thomas.boat@uc.edu | med.uc.edu

