



Digestive Disease Institute

Clinical Research



Discovering New Ways to Diagnose
and Treat Digestive Diseases



What Is A Clinical Trial?

A clinical trial is a scientific study designed to assess whether a new procedure is better than standard therapy, to compare the value of two standard treatments, or to assess the safety and effectiveness of an experimental therapy.

A clinical trial is not an experiment. The medication or treatment must first be found useful and safe in animals. Testing in humans is allowed only on volunteers who understand and accept the risks and benefits of participating in a study (“informed consent”). Volunteers may choose to leave a study at any time.

Clinical trials may be conducted by a single physician, small group of physicians, single institution or many institutions nationally or internationally. Financial support for a clinical trial is normally provided by organizations such as the National Institutes of Health or a pharmaceutical company or device manufacturer. Also, Cleveland Clinic funds many of its own clinical trials.

At Cleveland Clinic, an ethical oversight group – known as the Institutional Review Board – reviews each written research plan and may request adjustments be made before patients can be recruited for a clinical trial.

Why Participate In A Clinical Trial?

Participants can play a more active role in their own healthcare, gain access to new research treatments before they are widely available and help others by contributing to clinical research trials.



Examples of recent clinical trials that have lead to changes in patient care at Cleveland Clinic include a study of the stapled hemorrhoidectomy for prolapsed hemorrhoids, a technique that has been incorporated into our overall approach to treating hemorrhoids. Similarly, a series of other clinical trials led to the development of a Pouch Disorder Classification system, which has since been used worldwide for patient care management.

How To Begin

A large number of clinical trials is ongoing in Cleveland Clinic's Digestive Disease Institute at all times. If you qualify for a clinical trial, your physician will explain why you might want to participate. In all cases, the procedure, technique, device or drug under investigation, and details of what your participation will require, will be carefully explained to you. Enrollment will take place only after you have given consent.

You can be assured that every clinical trial has been approved by the Cleveland Clinic Institutional Review Board and complies with federal regulations regarding patient privacy. Many patients welcome the opportunity to participate in a project designed to benefit patient care. However, if you are uncomfortable participating, simply say "no thanks." It will not affect the care you receive at Cleveland Clinic in any way.

To learn more about the clinical trials offered by Cleveland Clinic's Digestive Disease Institute or to see if you qualify for participation, please call **216.636.5340**. Visit us online at clevelandclinic.org/dditrials.

Selected Registries and Databases

Cleveland Clinic's Digestive Disease Institute is a world leader in the creation and maintenance of healthcare registries and databases. The use of state-of-the-art information gathering methods enables physician-researchers to track patients over time and assess the long-term impact of treatment on health and quality of life.

Colorectal Cancer Database (established 1975)

Included: Patients treated for colorectal cancer

Goal: To provide information in the search for new diagnostic and treatment options

David G. Jagelman Inherited

Colorectal Cancer Registries (established 1979)

Included: Family members of patients diagnosed with familial adenomatous polyposis (FAP), Puetz-Jeghers syndrome (PJS), juvenile polyposis (JP) and hereditary non-polyposis colon cancer (HNPCC)

Goal: To alert family members at high risk for disease and encourage them to be screened

Intestinal Rehabilitation Database (established 2002)

Included: Patients diagnosed with short bowel or intestinal failure

Goal: To track medical, surgical and nutritional history of patients to determine best course of treatment

Irritable Bowel Disease DNA Database (established 2004)

Included: Patients diagnosed with either Crohn's Disease or Ulcerative Colitis

Goal: Identify underlying genetic factors of these diseases to allow better treatment for IBD patients

Laparoscopic Database (established 1991)

Included: Patients undergoing laparoscopic procedures

Goal: To enhance patient care by tracking the success of these procedures

Pelvic Floor Database (established 2007)

Included: Patients seen at the Colorectal Center for Functional Bowel Disorders

Goal: To improve functionality and quality of life

Pelvic Pouch Database (established 1983)

Included: Patients undergoing pelvic pouch surgery (ileal pouch, anal anastomosis)

Goal: To evaluate long-term pouch function and quality of life

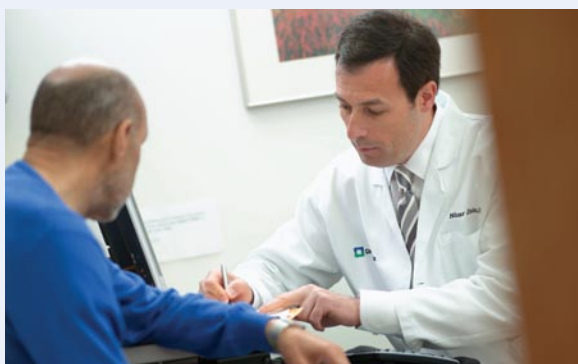
Ripka Family Database for Crohn's Disease Research (established 2001)

Included: Patients being treated for Crohn's disease

Goal: To identify optimal treatment options

Of the top digestive disease centers in the United States, the Cleveland Clinic Digestive Disease Institute (DDI) is the first of its kind to unite all specialists in gastroenterology and hepatology, colorectal surgery, hepato-pancreato-biliary and transplant surgery, and nutrition services within one unique, fully integrated model of care – aimed at optimizing the patient experience.

Our institute is dedicated to finding newer, more effective ways to treat diseases of the digestive system. This is primarily accomplished by evaluating new techniques and protocols in clinical trials (also called clinical research studies). As a patient in our institute, you may be offered the opportunity to participate in a clinical trial. This brochure explains clinical trials, and tells you what you need to know in order to make an informed decision about participating.





Cleveland Clinic

9500 Euclid Avenue, Cleveland, OH 44195

The Digestive Disease Institute is one of 26 institutes at Cleveland Clinic that group multiple specialties together to provide collaborative, patient-centered care. Our colorectal and gastrointestinal specialists serve more than 66,000 patients annually. Innovative procedures and decades of experience enable our physicians to achieve success in preventing and treating the full spectrum of digestive diseases. Cleveland Clinic is a nonprofit, multispecialty academic medical center. Founded in 1921, it is dedicated to providing quality specialized care and includes an outpatient clinic, a hospital with more than 1,000 staffed beds, an education institute and a research institute.

© The Cleveland Clinic Foundation 2008

08-DDI-011