

Consider participating in a Clinical Trial with

ATLANTIC INSTITUTE OF CLINICAL RESEARCH

Play a more active role in your health care, and perhaps receive financial help with your medicines and gain access to new treatments before they are generally available to the public.



What Is A Clinical Trial?

A clinical trial is a research program conducted with patients to evaluate a new medical treatment, drug or device. The purpose of clinical trials is to find new and improved treatment for medical conditions.

Once a patient agrees to participate in a clinical trial they will be given a consent form to read. The consent form will explain the purpose, duration, required procedures, risks, potential benefits and the financial reward the patient receives.

To contact Atlantic Institute of Clinical Research:

Phone	386-238-3220
Fax	386-238-3228
Email	psmith@fhcp.com
Location	350 N. Clyde Morris Blvd. Daytona Beach, FL 32114
Hearing Impaired Hours of operation	TRS Relay 711 Monday through Thursday, 7 am to 5 pm Friday, 7 am to 4:30 pm

FREQUENTLY ASKED QUESTIONS

SUBJECT QUESTION	ANSWER
Is there any cost to be in a clinical trial or to have any required testing done?	NO
Is there any cost to my insurance company?	NO
Will I be paid?	Yes; you will be paid for your time and effort
How long is the study? When do I get medicine? How many doctor visits? Can I get a copy of my test results?	All of these answers depend on the specific study
What type of lab tests are done on the studies?	Most studies require the basic lab tests: CBC, chemistry, and urinalysis. Other tests are study specific
Who will find out I'm in a clinical trial?	Your participation in a clinical trial is entirely confidential. You will be identified only by your initials and individual study # when you enter a study.
What if I want to discontinue the study?	You can leave a study at any time. The research dept. does ask that you return study supplies (diary, unused medication in its container).
What will I do at the end of the study?	Sometimes studies go into extensions. This means that you would be eligible to receive <i>open label</i> medication for a given period of time. <i>Open label</i> means you will know what medication you are receiving. Sometimes a study doctor will write you a prescription for a similar medication.
Do I continue to see my PCP during study?	Yes; a clinical trial is a limited term treatment for your medical problem. We are only treating your study-related condition. Your PCP will need to treat your other medical needs.

ATLANTIC INSTITUTE OF CLINICAL RESEARCH

IS CURRENTLY ENROLLING THE FOLLOWING CLINICAL TRIALS:

HORMONE REPLACEMENT THERAPY

HYPERTENSION

OSTEOARTHRITIS OF THE KNEE

OSTEOARTHRITIS or RHEUMATOID ARTHRITIS

OPIOID INDUCED CONSTIPATION

TYPE 2 DIABETES

COMING SOON:

ENDOMETRIOSIS

OVERACTIVE BLADDER

TYPE 2 DIABETES W/CARDIAC RISK

FHCP membership NOT required to participate in these studies. No insurance is necessary. No cost to participate. You may be paid for time and travel.

FOR MORE INFORMATION ABOUT THESE STUDIES, PLEASE CALL: 386-238-3220.

ATLANTIC INSTITUTE OF CLINICAL RESEARCH GENERAL INFORMATION

Atlantic Institute of Clinical Research (AICR) is located onsite at the Daytona Beach branch of Florida Health Care Plans (FHCP), a staff-model HMO. It is affiliated with FHCP but is a separate, for-profit corporation which can serve the community at large.

Address

Atlantic Institute of Clinical Research
350 N. Clyde Morris Blvd.
Daytona Beach, FL 32114

Contact Numbers

Office: 386-238-3220
Fax: 386-238-3228

Business Hours

Monday-Thursday 7:00AM to 5:00PM
Friday 7:00AM to 4:30PM

Staff

David L. Williams, MD	Medical Director
Patricia Smith, CCRC	Clinical Research Director & Study Coordinator
Beverly Wells, CCRC	Finance Manager & Study Coordinator
Sandy Alonso, RN, CRC	Recruiter/Coordinator
Christina Gibson, LPN, CCRP	Study Coordinator
Toshiko Wilson, CPT	Phlebotomist
Donna Smith	Regulatory Specialist & Administrative Assistant

At AICR, it's *Today's Research...Tomorrow's Cure*

Before a medication is released by a pharmaceutical company, it must be approved by the Food and Drug Administration (FDA). The process takes years of testing in clinical research programs. The research center (AICR) is an excellent setting for patients to be part of a clinical trial, where they benefit by receiving cutting edge medical treatment and the opportunity to learn more about their medical needs and current medical condition. In order for patients to qualify for a study they must meet a medical profile, usually consisting of the symptoms of specific diseases for which they require medication.

Before enrolling in a clinical trial, the study subject (patient) reads an Informed Consent explaining the study and can ask questions of the study coordinator before deciding to participate. No study procedures can take place without a signed Informed Consent from the study subject. Study subjects receive a variety of study-related tests under the supervision of a Florida Health Care physician and a Certified Clinical Research Coordinator. Study costs are covered by the sponsor, meaning they are FREE OF CHARGE to participants (and usually involve patient compensation for time and travel). No medical insurance is required to enroll in a clinical trial.

AICR coordinators conduct clinical research trials in compliance with Good Clinical Practices (GCP) & Federal Drug Administration (FDA) regulations and adherence to study sponsor procedures. Primary importance is subject safety.

The trials are conducted according to the procedures in the ICH (International Committee on Harmonization) Good Clinical Practices and the Declaration of Helsinki. Section 3 of the GCP pertains to institutional review boards. IRBs are required for all clinical trials. Their role is to provide oversight of study conduct in order to ensure subject (patient) safety.

The purpose of clinical trials is to test medications on consenting human subjects according to protocols written by sponsors (pharmaceutical companies) and overseen by institutional review boards before being submitted to the Federal Drug Administration for approval to be sold to the public. In post-marketing studies a previously FDA approved, marketed drug is tested for possible use for a new indication or for continued monitoring for safety concerns. .

Research trials are divided into categories called phases. AICR conducts Phase II through IV clinical trials. AICR does not conduct Phase I trials which are done on healthy patients using experimental drugs that have not previously been given to human subjects. Phase I trials often involve overnight stays. AICR also does not conduct studies involving subjects with cancer or HIV.