Lahey Hospital & Medical Center

Office of Research Administration Clinical Trials

FREQUENTLY ASKED QUESTIONS (FAQ)

► DO I HAVE TO BE A LAHEY PATIENT TO PARTICIPATE IN A CLINICAL TRIAL AT LAHEY?

No. Anyone fitting the eligibility criteria can be accepted in a Lahey clinical research trial.

► WHEN WILL I KNOW WHETHER I AM ACCEPTED IN A STUDY?

You usually know the day of your screening visit, or first research visit. The timeframe varies by clinical study. Most drug studies require additional tests and evaluation of your medical history before you are accepted. This may take a little time.

► HOW WILL I KNOW WHEN I HAVE BEEN ACCEPTED?

The study principal investigator (PI) or the study coordinator will let you know once you are accepted. You must meet all study eligibility in order to enroll into a study. Sometimes, when you meet with the principal investigator, you are accepted immediately into the study. Other times a study coordinator will call to let you know if you have been accepted, answer any further questions and arrange your next study visit.

► WHAT IS THE TIME PERIOD FROM NOTIFICATION TO THE START DATE?

Typically, trials start immediately or within a week, but can vary. You appointment schedule will be reviewed with you when you are accepted into the study.

► WILL I HAVE SOMEONE AT LAHEY WHOM I CAN CONTACT IF I HAVE QUESTIONS OR PROBLEMS?

Yes. The study coordinator will arrange an appointment schedule for you and help to answer any questions you may have about the study. You will also receive a list of contacts once you become a volunteer in the study.

► WHAT IF I DECIDE NOT TO PARTICIPATE IN THE STUDY?

You need to contact the study coordinator before the study begins so another patient volunteer can take your place.

► WILL OTHER LAHEY LOCATIONS BESIDES BURLINGTON BE DOING THE SAME STUDY?

Sometimes Lahey Medical Center, Peabody and Lahey Outpatient Center, Lexington are involved in the same study, but most research is conducted at one location.

► WHAT ARE PHASES I, II AND III OF A STUDY?

In Phase I, the first test outside of the laboratory, a small number of patients receive the new treatment and researchers study its safety. In Phase II, researchers determine the effects of the treatment on disease. In Phase III, the new treatment is compared to standard treatment to see which is more effective.

► WILL I GET PAID TO BE IN THE STUDY?

Typically, patients are not paid for study participation. Payment depends, however, on the particular study. Sometimes you may receive a parking voucher to cover parking costs.

► DOES MY INSURANCE COMPANY PAY FOR ME TO PARTICIPATE IN A STUDY?

If you are participating in "research only," then insurance does not pay to have you participate. If you need "standard of care" along with the study, then your insurance pays that part. HMO patients may need a referral to participate in a study and should contact their provider to verify coverage.

► ARE ALL RISKS IN TAKING EXPERIMENTAL MEDICATIONS OR TREATMENTS EXPLAINED TO ME BEFORE THE STUDY BEGINS?

Yes. The doctor or principal investigator (PI) will inform you of any risks before you start the trial.

► DO I HAVE TO HAVE ALL MY REQUIRED TESTS DONE AT LAHEY ?

All testing is done in compliance with the study protocol. Most of the time, this requires testing to be performed at Lahey. This makes it easier and more efficient to track results and maintain test accuracy in the study.

►WHAT HAPPENS IF I GET SICK OR HAVE A REACTION TO A STUDY MEDICATION?

Immediately contact the PI or doctor who heads your study. If you cannot reach the doctor and are having a severe reaction, go to the nearest emergency room.

► WHAT IF I HAVE TO MISS OR CANCEL A SCHEDULED APPOINTMENT?

Appointments are based on the study protocol and must be conducted within a certain timeframe. Contact your study coordinator if you know that you have to miss an appointment. She or he will try to work around your schedule. Most appointments are "time-sensitive" and need to be rescheduled quickly.

► WHAT IF I HAVE TO QUIT A STUDY BEFORE IT ENDS?

You always have the right to quit a study at any time. If you want to quit a study before it ends, you need to notify the study coordinator as soon as possible. You may be asked to return to the clinic for a final visit.

► WILL I BE TOLD IF PLACEBOS ARE USED IN MY STUDY?

Yes. Before the trial begins, you will be informed if placebos or inactive substances will be given. However, along with your study doctor you won't be told who will or will not receive them.

► WILL MY OWN DOCTOR BE REGULARLY INFORMED ABOUT MY STATUS IN THE STUDY?

Generally no. Participation in a research study is not always part of routine clinical care. Your doctor may request information about your status in the study, however this is not routinely offered.

► DO I SEE MY REGULAR DOCTOR WHILE IN THE STUDY?

Yes. Participation in a research study is not a substitute for routine clinical care. It is important that you continue ongoing care with your primary physician.

Lahey Hospital & Medical Center

► CAN I CONTINUE TAKING THE MEDICATION AFTER THE STUDY ENDS?

Generally, no. Once a study ends, patients do not continue taking the medication unless a treatment extension is offered by the sponsor of the study. Drugs in research studies are usually not approved by the Food and Drug Administration (FDA) and are not available by prescription. Drugs already approved by the Food and Drug Administration (FDA) may be continued after the study is completed. Non-FDA approved medications must be stopped.

CONTACT

To learn more about Research Trials at Lahey, please contact:

Research Administration

781-744-8027

http://www.lahey.org/Education_and_Research