

Frequently Asked Questions

Do I Get Paid (Compensated)?

Most studies include a monetary stipend for participating. However, you are not considered an employee of Charles River. You will receive a set stipend for each study you complete to compensate you for your time and travel. The amount varies based on the requirements of the study (for example, the time commitment and the number of blood samples required). A recruiter will tell you the stipend for the study you are considering, and this will also be listed in the Informed Consent Form you will receive at screening. In addition, participants receive meals, lodging, transportation if needed and the direct benefit of medical care and laboratory testing during the time of study participation.

What types of studies are done and what is Phase I Research?

Charles River Clinical Services performs Phase I clinical research. Most Phase I studies are "pharmacokinetic studies." This means that the sponsor is trying to determine how a drug is absorbed, distributed, metabolized, and eliminated from the body. Pharmacokinetics may vary for a specified dose and route of administration (intravenous-IV, or orally, for example). We usually study the absorption by obtaining blood samples. We study the metabolism and elimination through samples of blood, urine, or other body products. "Placebos," or inactive medications for comparison, are also sometimes used in Phase I studies.

How do I arrange my schedule to participate?

Initiating a trial often takes weeks and at times months; therefore, exact dates are often not specified until two to four weeks before the study begins. Each study is unique, and can vary from a few days to months. Most studies do require you to stay overnight and in our facility for the time specified in your trial. Some trials, called outpatient studies, require only visits to the facility with no overnight stays. A recruiter can answer specific questions regarding the schedule of a study you are interested in.

Are there risks to participating in pharmaceutical trials?

All efforts are made to minimize risk in participating in trials. This is why each study has very specific requirements for participation. One way risks are minimized is through a standardized review process. All clinical trials in the United States must be approved by an independent review group (called at "Investigational Review Board," or IRB). The IRB is responsible for evaluating the ethics of the trial and to ensure that subjects' rights and welfare are protected. The IRB is comprised of respected individuals and doctors who are independent and have no direct interest or participation in the study. They may review the data while a clinical trial is in progress to assess safety considerations. Each study will have a list of risks in the Informed Consent Form, which you will review prior to giving your consent to participate in any trial.

Will the study drug have any side effects?

Although all drugs have the potential to cause side effects, we would not anticipate any long-term side effects following participation in a study. The common short-term side effects are headaches, backache, indigestion and drowsiness although some of these may be related to the clinical environment. Any known side effects of the investigational product involved in the study are outlined for you in the consent form. The physician will perform your physical examination and will review your medical history to determine if you have any increased risk of side effects. If the risk is unacceptable, you will not be allowed to enter the study.

What is "Informed Consent?"

Informed Consent Form or ICF means that all potential participants are informed of the details of the study, and willingly consent to be a part of the study. Participants will receive and read

through this form as screening. The Informed Consent process is very important to the staff of Charles River. We want those who enroll to understand the goals, risks, time commitments, details of the study, and safety monitoring.

Participation is strictly voluntary! At Charles River, we consider this an ongoing process. The study is explained at the time you are scheduled for a screening visit. You then read the IRB-approved informed consent document in its entirety, and must discuss the contents of the form with an Investigator or other qualified member of the clinical team. Adequate time is provided to answer all of your questions.

Only after you have done this and the consent is signed, we proceed with drawing blood and other study-related procedures. You will be given a copy of the consent to keep. When you are admitted to the facility, the guidelines involving the study are reviewed again to confirm that you are still willing to participate.

Why do your trials require staying at Charles River?

Not all trials require overnight stays, but most do. Overnight stays include all day and all night; you will not be able to leave the facility during your scheduled visits. The study sponsor has to submit the most reliable data possible to the FDA. Since there are many variables involved with drug absorption and metabolism, it is important that all participants have a standardized diet, activity, and daily routine. These measures are necessary so the data will reliably answer the questions being addressed by the study.

On the majority of studies, depending on weather conditions and staffing levels, volunteers are taken on supervised daily walks. Participation in any clinical trial is entirely voluntary and you are free to withdraw your consent at any time, however you are encouraged to talk to the study doctor prior to withdrawal.

Will I be told everything about the study?

Yes, before participating in any study you will be required to screen for a study. Screening appointments are specific to the study you are going to participate in. At this appointment you will be given a document about the study called an Informed Consent Form. You will be given time to read this information and the screening staff will also go over this with you to ensure that you understand the information and to confirm that you are completely happy with the contents. After that, the staff will take a summary of your medical history, you will give urine and blood samples and your blood pressure and heart rate will be measured. For the final part of the medical you will be given a physical examination by one of our clinicians. Each study is different so there may be additional tests to those mentioned above, this will be explained when you make your appointment.

Is my stipend taxable?

Yes, we will give you a W-4 form at screening and send you a 1099 at the end of the year depending on how much you have received in stipends over the year.

Will this affect my SSI (Supplemental Security Income)?

No, this will not affect your SSI since you are not considered an employee; you will not receive a W2.

How do I get started?

Step 1: Register

You can register online or call and speak to a recruiter who will take down basic information as well as a thorough health and lifestyle questionnaire. Recruiters can be reached at 253-779-8815 or toll free at 877-697-8839. Registration only takes a few minutes and it allows you to be added

into our database to be called for future studies; you only need to register once. Once registration is complete, a recruiter will determine if we currently have any studies that you may be eligible for and schedule a screening appointment for you.

Step 2: Come in For Your Screening Appointment

Your screening appointment will last about 2-3 hours. You will read the informed consent, go over your health history, have your blood drawn, and receive a physical examination. It will take roughly 2-3 days for your results. Your medical history, physical examinations, and laboratory results will determine if you are eligible for the study.

Step 3: Stay in touch!

We may or may not be actively enrolling participants for trials you qualify for at the time of your availability. With your permission, we will keep you in our database and when an appropriate trial comes up we will contact you. Feel free to check with us once a month for updates, especially if you change your address or phone number.

You may contact a recruiter anytime you have questions about participating in a study.

How does your referral bonus program work?

Referral Bonus Policy

1. You may receive \$100 for any person you refer who completes his/her first study if they screen within 30 day of registration. Your referral must provide us with your full name and phone number at the time of registration. Please ask a recruiting supervisor for details.
2. Some studies may be exempt from the referral bonus (i.e. blood draw or screening studies). Please ask a recruiting supervisor for details.
3. Referral bonuses will be mailed to you 2-3 weeks after the official completion date of the study, which includes any final outpatient visits or phone calls. You will not have the option to pick up your check.
4. We will make one attempt to contact you in regard to your referral bonus. You have 30 days from the date of first attempted contact to claim your bonus. Verbal communication is required before a check request is made to ensure that we have the correct contact info. If we do not have a recent W-9 on file for you, one must be received before your check is requested. Please speak to recruiting supervisor Renee Parker (x302) with any questions regarding pending referral bonuses.