

A guide to

*The Mallinckrodt General Clinical Research Center
at the Massachusetts General Hospital*

Mallinckrodt General Clinical Research Center
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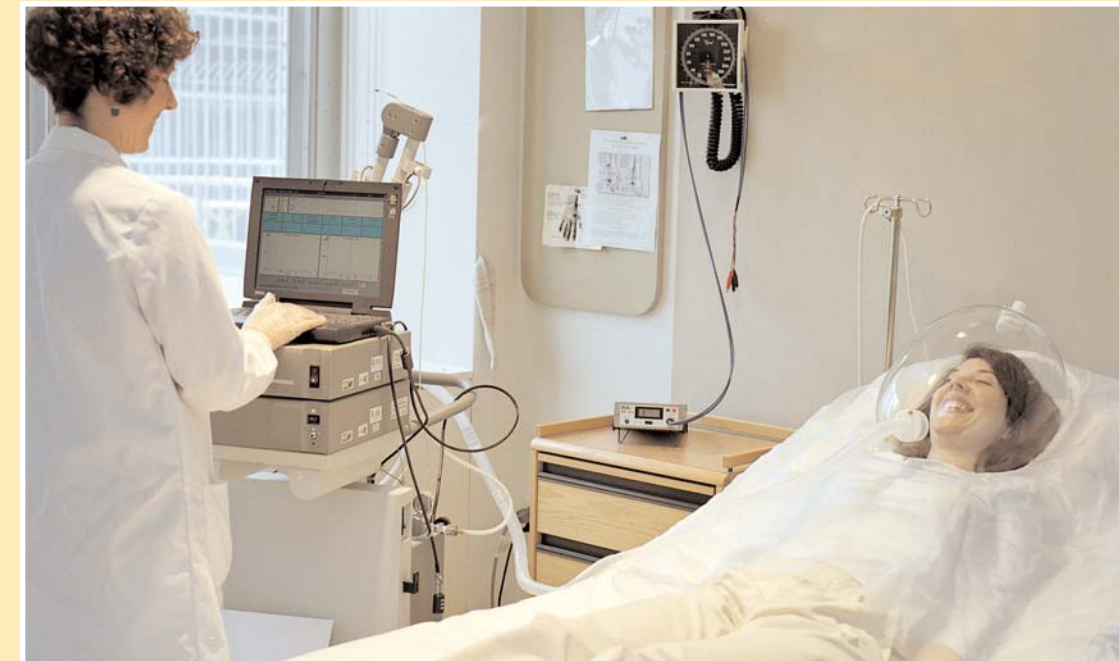


PURPOSE OF THE GCRC

The Mallinckrodt General Clinical Research Center (GCRC) at the Massachusetts General Hospital is one of more than 80 clinical research centers in the United States funded by the National Institutes of Health (NIH). The goal of research conducted on the GCRC is to improve medical care through clinical research.

The Mallinckrodt GCRC provides clinical research facilities, regulatory and biostatistical support and professional and support staff for investigators who conduct human research.

Studies conducted on the GCRC translate scientific discoveries into new diagnostic procedures and therapeutic interventions to improve health care.



The studies carried out at the GCRC include research on normal and abnormal physiology as well as examinations of the cause, prevention, control and cure of diseases. These studies involve people of all ages, races, and ethnic backgrounds.

STAFF

The investigator and study team are supported by GCRC professional and support staff: registered dietitians, registered nurses, clinical lab assistants and clerical staff.

The GCRC nurses conduct the study procedures, administer medications, collect laboratory specimens, provide health education, answer questions about research, and provide for the physical comfort and care of research volunteers while at the GCRC.

The GCRC bionutrition staff assist clinical investigators by providing nutritional consultation services. Nutritionists are responsible for research meals and nutrition assessment and will provide nutritional counseling for the study.

The Research Subject Advocate (RSA) helps ensure that safeguards are in place to protect research volunteers. These advocates work to keep volunteers fully informed and to make sure that studies are conducted safely.

Study coordinators help oversee all elements of the research study, including enrolling volunteers, scheduling visits, answering

questions, and communicating with all those involved to see that the study is carried out accurately and safely.



The Mallinckrodt General Clinical Research Center (GCRC) at the Massachusetts General Hospital

STUDY SITES

The Mallinckrodt GCRC is located on White 13 at the main campus of Massachusetts General Hospital, 55 Fruit St., Boston. There are two satellite locations, one in the Charlestown Navy Yard (CNY) and the other at the Massachusetts Institute of Technology (MIT). Your study team will notify you where your study will be completed.

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FREQUENTLY ASKED QUESTIONS

Q. What are clinical research studies?

A. They are scientific studies that answer questions about normal human functions, diseases and medical care and treatment. The overall aim is to improve our understanding of health and disease and develop more successful means to prevent, diagnose and treat disease.

Q. What is my role in the conduct of the clinical research study?

A. Your role as a human volunteer is essential to the conduct of clinical research and to the advancement of medical care. In order to make sure that your participation is beneficial to medicine, it is important to keep all of your scheduled appointments. Please completely answer questions regarding how you feel and whether you have taken your medication as directed. The completion of study tasks provides essential information on the best way to prevent, diagnose and treat disease.

Q. What can I expect when I arrive on the GCRC?

A. When you arrive at the hospital, please ask at the Information Desk for directions to White 13 or follow signs to the unit. Upon arrival on the unit, please register at the Reception Desk. The receptionist will direct you to the waiting area and notify the clinical investigator and study team of your arrival.

You will be asked to provide your name and MGH blue registration card and complete a nursing assessment form that includes your allergies, medications and past medical history. You will read, discuss, and sign a form describing the study in detail. The informed consent

process is conducted with the clinical investigator or study staff. Your visit will begin after you have given consent and have had the opportunity to answer questions. Your safety is the priority in a clinical research study. During your visit, you may also see a nurse, nutritionist or physician.

Q. What should I bring for my visit?

A. If your visit is more than a few hours or is an overnight stay, you should bring the following:

- A complete supply of all medications: prescriptions with pharmacy-labeled containers and appropriately labeled non-prescription medications that you are currently taking. The hospital pharmacy will provide any medication that is part of the study.
- Hospitalization and Health Insurance Cards (even though you are here for a research study)
- Clothing: The Hospital provides standard pajamas and gowns. Please bring any clothing that will make you comfortable. Many of our volunteers choose to wear their own clothes for at least part of every day.
- A copy of any Advance Directive (Living Will or Health Care Proxy) that you may have.
- Personal effects for your use during your stay. A television and VCR are provided in each patient room at no charge.
- If you are here for a daytime visit, please bring your MGH blue registration card. If you do not have an MGH blue card, please call telephone registration at (617) 726-9090 or toll-free at (877) 726-9090, Monday through Friday, 8am to 8pm.
- You may bring your laptop computer and do work while you are here.
- Note that for many study visits, you will be asked to remove all jewelry. Please leave any valuables at home.

Q. Do I have to fast before my visit?

A. Each research study has individual requirements. You may be required to fast prior to your visit. This means nothing to eat (only water), usually for 12 hours prior to your visit. Please follow all the instructions provided by the study team and clinical investigator.

Q. Will meals be served during my visit?

A. Some studies will require you to eat specially prepared meals. If your study requires that you follow a special meal plan, you will receive careful instruction from the bionutrition staff. If no special meal plan is required, standard meals are served to overnight (inpatient) volunteers. Daytime outpatient volunteers may receive meal tickets, depending on the study, for use in our hospital cafeteria. Food is not provided for family members or other guests.

Q. May I have visitors?

A. Visitors are allowed at any time that will not interfere with the study process. Consult with your nurse, nutritionist or study coordinator if you plan to receive visitors.

Q. May I smoke during my visit?

A. Smoking is permitted in hospital-designated areas when it does not interfere with the study process. Please ask study staff if smoking will conflict with the study.

Q. What if I have to cancel my appointment?

A. If you are unable to keep a scheduled appointment, please contact your study coordinator immediately.

Q. Will anyone know that I am participating in a study?

A. Many safeguards are in place to protect your identity and confidentiality. You will be informed before the study of who will have access to your information.

Q. Will my insurance company receive a bill?

A. All research charges are covered by the study. If you or your insurance company receive a bill, please call your study coordinator and forward the bill to GCRC Administration, White 1301, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114.

Q. How can I participate in future studies?

A. Open studies are posted on the MGH research website at <http://crnet.mgh.harvard.edu/home/home.asp>

BEFORE YOU LEAVE

Clarify your post-visit instructions. Your clinical investigator, study team, GCRC nurse or GCRC nutritionist may have specific instructions for you to follow that may include a special meal or study medication. Notify the Reception Desk that you have completed your visit.

PARKING

At the MGH, you may park in either of the two garages located in front of the hospital's main entrance off Cambridge St. Many studies will pay for your parking. Check with the study team.

Valet parking with a fee is available at the Wang ACC Lobby entrance. For additional information, please contact the Parking Office at (617) 726-8886. For directions, please visit the MGH website at: <http://www.mgh.harvard.edu/directions.html>.

At the GCRC in the Charlestown Navy Yard, parking is available at the garage adjacent to Building 149. For studies at MIT, the study team will notify you for options to travel.

QUESTIONS?

If you have additional questions, please contact your study coordinator or clinical investigator.

