

RESEARCH INFORMATION SHEET

Basic Information

Title of Project: The ENDO (Endocrinology, Nutrition and Diabetes Opportunities) Registry

IRB Number: H- 36961

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Background: You are being asked to voluntarily participate in a research study. We are building a recruitment registry called the ENDO Registry. ENDO stands for Endocrinology, Nutrition, and Diabetes Opportunities. If you enroll in the ENDO registry, researchers at BUMC may contact you by phone, text or email (based on your preference) to tell you about studies that you might be able to participate in.

Participation in research studies is always completely voluntary. You have no obligation to participate in the ENDO registry. You are not required to participate in any research studies you learn about because you are enrolled in ENDO.

Your doctor may also be an investigator involved in creating this registry. Being an investigator means your doctor is interested in both you and the study. You may want to get a second opinion about being in the registry. You can do so now or at any time during the involvement in the registry. Another doctor who is not an investigator can give you a second opinion about being in the registry. You do not have to agree to enroll in this registry even though it is offered by your doctor.

Purpose: Our goal is to have a way for people to learn about research studies at Boston Medical Center (BMC) and the Boston University School of Medicine (BUSM) that they may be eligible for.

What Will Happen in This Research Study

If you agree to participate, we will ask you to complete a short questionnaire. It will take 10-15 minutes. The questionnaire will ask for the following information:

- Basic information about the most convenient way to contact you
- Demographics
- Medical history

You may skip any question you would prefer not to answer. You may complete the questionnaire in-person, over the phone, or through a secure website called REDCap. If you are a BMC patient, we may check your medical record to confirm information you provide to us. The information on the registry questionnaire is the only information that ENDO researchers may collect from your medical record. Once you are enrolled in the ENDO registry, you may be contacted by research teams at BUMC who think you may be a good fit for their study. They will use the contact information you provided in the ENDO questionnaire. They will contact you by your preferred method: by phone, email, or text.

Your information will remain in the ENDO registry database indefinitely. You can request to be removed from the ENDO registry at any time for any reason. Your decision about taking part in the ENDO registry or to withdraw will not impact the care you receive at BMC or anywhere else that you get care.

Risks and Discomforts

There is very little risk involved with enrolling in the ENDO registry. The primary risk of this study is called breach of confidentiality. This is when someone outside of the research team accesses your personal health information from the study. To protect your confidentiality, only study staff who are trained in Health Insurance Portability and Accountability Act (HIPAA) compliance, which is training on keeping your health information private and secure, will have access to the study data. Any personal information you share during the study is stored in a secure, password-protected database that only trained ENDO researchers can access. Study staff will not voluntarily give out confidential information.

Potential Benefits: There are no direct benefits to you if you enroll in the ENDO registry. However, you may benefit from participating in one of the research studies that contacts you because you are enrolled in the registry.

Costs: There are no costs to you for being in this research study. However, you may choose to receive text messages from the ENDO registry study team. Your wireless carrier may charge you for the text messages that the study sends to you. You can tell us to stop sending you texts at any time.

Payment: You will not be paid for being in this registry.

Confidentiality

We will do our best to keep your information safe. However, we cannot guarantee confidentiality.

Federal and state agencies, if they are required by law or are involved in research oversight, may access information about you from this study including your health information. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.

We will protect your information by keeping all data in a password-protected database that only the ENDO study team has access to. If you choose to fill out the paper survey, we will separate your identifiable information (such as your name, address, and phone number) from your health information. Your health information will be assigned to an ID number to protect your identity. Paper documents will be maintained in a locked file cabinet in a locked research office. Your information will be kept in the indefinitely, unless you provide written notification that you would like to be removed from the registry.

We might use our research data in future studies. These future studies might be done by us or by other investigators. Before we use your data, we will remove any information that shows your identity.

Use and Disclosure of Your Health Information

Boston Medical Center wants to use and/or share your health information as part of this research registry. The law requires Boston Medical Center to get your authorization (permission) to do so.

Health information that might be used or given out during this research includes:

- Information from your hospital or office health records at Boston Medical Center. This applies to information that is reasonably related to the aims, conduct, and oversight of this registry.
- New health information from forms filled out as part of this registry.

The reasons that your health information might be used or given out to others are:

- To do the research described here
- To make sure we do the research according to certain standards set by ethics, law, and quality groups or otherwise as required by law

The people and groups that may use or give out your health information are:

- Researchers involved in this research study from Boston Medical Center
- Researchers from other institutions or organizations that are involved in this research study
- Other people at BMC who may need to access your health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations
- People or groups that the researchers use to help conduct the study or to provide oversight for the study
- The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research
- Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study

Some people or groups who get your health information might not be obligated to follow the same privacy laws that we follow. We ask anyone who gets your health information from us to protect the privacy of your information. However, after your information has been shared with others, we cannot promise that it will be kept private.

The time period for using or giving out your health information:

- Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

- You have the right not to consent to this form, which allows us to use and give out your health information for research. If you do not verbally agree with this consent form, you cannot be in the registry. This is because we need to use the health information to create the registry. Your decision not to consent to this form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits.
- You have the right to withdraw your permission to use or share your health information in this registry. If you want to withdraw your permission, you must write a letter to the Principal Investigator. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to create the registry. If you withdraw your permission, you cannot continue to be in the registry.
- You have the right to see and get a copy of your health information from the Principal Investigator that is used or shared for research

Subject's Rights

By consenting to be in this registry you do not waive any of your legal rights. Consenting means that you have been given information about this registry and that you agree to participate in it. You will be given a copy of this form to keep.

If you do not agree to be in this registry or if at any time you withdraw from this registry you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact Dr. Caroline Apovian at 617-638-8556.

You may also call 617-638-7207 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus Institutional Review Board (IRB). The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

Agreement to Participate in the ENDO Registry

By agreeing to be in this research, you are indicating that you have read this form (or that it has been read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to enroll in the ENDO registry.

If you have any questions, please contact the principal investigator, Dr. Caroline Apovian, at 617-638-8556 or caroline.apovian@bmc.org. Alternatively, you may contact Mary-Catherine Stockman (Study Coordinator) at mary-catherine.stockman@bmc.org or 617-638-5921.