Have you been recently diagnosed with cancer? Are you a female between ages 15 and 55?

If so, you may be able to participate in this study to aid in reproductive health.

EROS: Engendering Reproductive Health Within Oncologic Survivorship
What is a clinical study?

A clinical study or research study is a way to investigate whether a new intervention is effective. Clinical studies follow tightly regulated and careful procedures to protect patients and improve the treatment of disease. In this study, patients are asked to fill out questionnaires or surveys to improve communication with their doctors and to optimize treatment plans to fit their future reproductive health goals. Some participants will also have the option to take blood tests to track their reproductive hormones.

What does it mean to be “randomized”?

In this study, participating sites will be randomly assigned (by chance) to a study arm. Randomization means that physicians at this center were assigned by chance to either 1) follow the usual care plan of your health care facility or 2) follow the usual care plan of your health care facility plus a study-specific training plan for physicians. This is done because it is unclear which of these 2 plans would be better for patients like yourself.
Why is the E1Q11 study being done?

Cancer treatments, such as surgery, chemotherapy, or radiation therapy, can severely affect a female’s reproductive health. This study concerns all stages of a female’s reproductive health, which early on pertains to the ability to become pregnant and carry a child to term. This is followed by the effects of early menopause or ending of menstruation, pain or discomfort from sexual intercourse, or lack of intimacy from anxiety or distress due to early menopause. The purpose of this study is to evaluate the ability of an educational program for health care providers to improve patients’ understanding of their reproductive risks and receipt of appropriate treatment to achieve their reproductive health goals; it is also to evaluate females’ attitudes, functioning, and practice related to sexuality during the 2 years after cancer diagnosis.

Your oncology medical team members are also study participants in this research.

The first 200 enrolled patients who choose to take part in the optional laboratory study will have their blood drawn at different time points throughout the study. This is to track any changes to their reproductive hormone levels that may occur during and after treatment. Additional consent is required for this portion of the study.

How many females will take part in the E1Q11 study?

About 668 females will take part in this study.

How long is the study?

If you choose to participate, you will be in the study for 24 months (2 years). You may stop participating at any time. However, we encourage you to talk to your doctor before you decide to stop participating.
What is involved, and what will happen in this study?

You will be asked to complete questionnaires at 5 time points. At each time point, 2 questionnaires will be administered by a study team member. Completing these forms should take 10 to 15 minutes.

If you undergo chemotherapy or radiation therapy, you’ll complete 2 additional questionnaires (besides those listed above). Patients undergoing chemotherapy will complete the questionnaires during routine patient care visits within 1 week before each chemotherapy regimen. Patients undergoing radiation therapy will complete the questionnaires within 1 week before starting radiation therapy, and then every 4 weeks until the end of radiation therapy. Completing these forms on a given visit should take about 10 minutes.

Who can participate in the E1Q11 study?*

You can participate in the E1Q11 study if

- You are a female with a diagnosis of any form of cancer, including ductal carcinoma in situ (DCIS)
- You are premenopausal and between ages 15 and 55
- You have not started chemotherapy, radiation therapy, or endocrine therapy before registering in the study
- You had not had a hysterectomy, bilateral oophorectomy, or sterilization of any method
- Pregnancy is permitted, given your ability to participate

*These are the main requirements only. Your doctor will perform a more detailed review of your eligibility if you are interested in participating.
What can I expect to experience during the study?

This study asks you to answer questions pertaining to your reproductive health status and interests. It is not expected to produce any side effects or risks to you. However, completing the questionnaires may remind you of unpleasant aspects of your condition and treatment, which may be an upsetting effect. As some of the questions may be of a sensitive nature, you are free either to complete the surveys independently or not answer the question(s). Those participating in the optional laboratory study may expect blood draws beyond the usual care, although this will be prevented when possible.

If I participate, what rights will I have?

Participation in a clinical study is voluntary, and there is a process to keep you fully informed of all the facts as the study progresses. You will sign an informed consent document that provides details about the study and what will occur.

How can I enroll?

If you would like to participate in this study, let your doctor know. The doctor can tell you if you are eligible and will supply the resources for enrolling.
Who is conducting the study?

The E1Q11 study is being conducted by the ECOG-ACRIN Cancer Research Group. ECOG-ACRIN is a multidisciplinary, membership-based scientific organization that designs and conducts biomarker-driven cancer research involving adults who have or are at risk of developing cancer. The Group is dedicated to its stated purpose, which is to achieve research advances in all aspects of cancer care and thereby reduce the burden of cancer and improve the quality of life and survival in patients with cancer.
How can I learn more about the study?

For more information about the E1Q11 study, please visit Clinicaltrials.gov; search NCT01806129

For more information about ECOG-ACRIN, visit ecog-acrin.org