Overall E1Q11 Study Objective

To examine an intervention of a reproductive health assessment and algorithm to improve the adoption of appropriate reproductive health management

Study Objectives

Primary Objective

- Evaluate the success of the implementation of reproductive health programming (Didactics, EROS Reproductive Health Assessment and EROS Trial Algorithm) among reproductive-aged females (15-55 y) with cancer

Accrual goal = 668 patients. Unit of randomization will be the institution rather than the individual patient (ie, a cluster randomized approach). Sites randomized to arm A—nonintervention will function with usual standard practice related to reproductive health. Sites randomized to arm B—intervention will receive training and intervention materials, with 3 components: 1) didactics, 2) a reproductive health assessment and navigating algorithm, and 3) network development.

Each site randomized to arm B will receive training to provide information regarding oncofertility, oncocontraception, and sexuality-related issues. RHA should be completed by the appointed clinician at each office visit. Only one provider is required to complete the Provider Reproductive Health Values Survey (specific to patients) at baseline, 3, 6, 12, and 24 months from study entry. An additional Provider Reproductive Health Values Survey (general) will also be completed by a provider at baseline and 30 months from site initiation. RHA = reproductive health assessment.
Study Objectives (cont)

Secondary Objectives
• Assess the degree of discrepancy between patients and clinicians in their estimates of significance of the reproductive health goals for the patient
• Evaluate baseline and follow-up reproductive health assessments for trends in reproductive health choices relating to oncofertility, oncocontraception, and pregnancy over the 2-year study period
• Identify clinical and demographic factors that predict the adequacy of reproductive health care management

Correlative Objective
• Perform a longitudinal study following endocrine markers of fertility in a cohort of the first 200 registered EROS trial patients who agree to participate

Quality of Life Objective
• Perform a longitudinal study of sexual function using the PROMIS sexual function survey in all subjects participating in the EROS trial

Main Eligibility Criteria*
• Female and presenting with initial diagnosis of any type of cancer, including ductal carcinoma in situ (DCIS)
• Premenopausal within the reproductive age of 15-55 years
• Premenopausal criteria include the following: not currently on hormonal contraception with menses in the past 6 months; no menses in the past 6 months without hormonal manipulation, and confirmed follicle-stimulating hormone (FSH) < 23 mIU/mL; age < 47 years and on hormonal contraception, with confirmed FSH < 23 mIU/mL
• No chemotherapy, radiation therapy, or endocrine therapy initiated prior to registration to study
• No prior hysterectomy, bilateral oophorectomy, or sterilization of any method
• Pregnant females are eligible
• Cognitive ability to participate in the trial

*When evaluating patients for this study, please refer to the full protocol for the complete list of eligibility criteria.