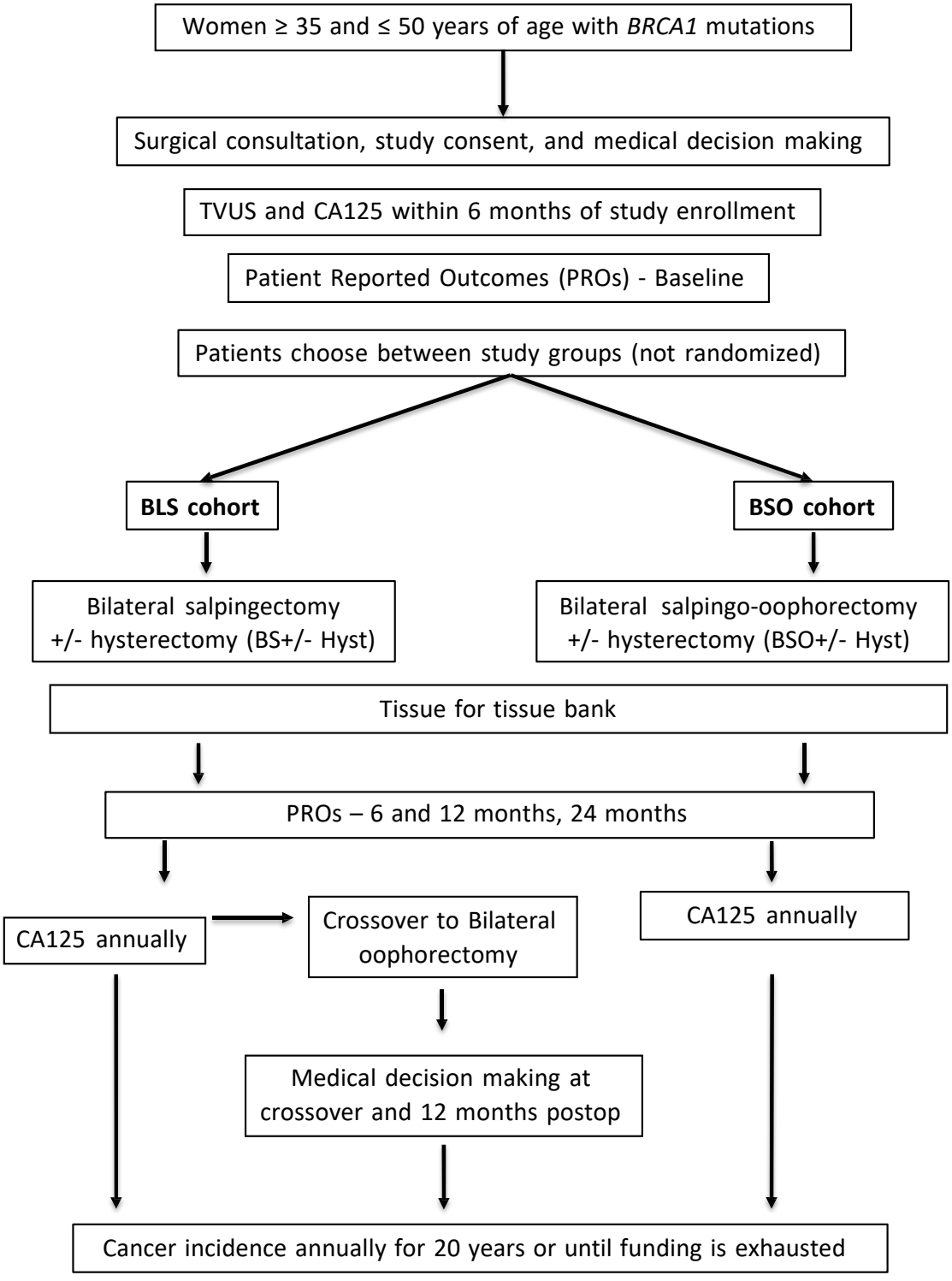
NRG-CC008 SCHEMA

A NON-RANDOMIZED PROSPECTIVE CLINICAL TRIAL COMPARING THE NON-INFERIORITY OF SALPINGECTOMY TO SALPINGO-OOPHORECTOMY TO REDUCE THE RISK OF OVARIAN CANCER AMONG BRCA1 CARRIERS [SOROCk]



BLS – bilateral salpingectomy, BSO – bilateral salpingo-oophorectomy

3. ELIGIBILITY AND INELIGIBILITY CRITERIA

Note: Per NCI guidelines, exceptions to inclusion and exclusion criteria are not permitted. For questions concerning eligibility, please contact the Biostatistical/Data Management Center (see protocol cover page).

Submission of tumor tissue is required for all patients. Investigators should check with their site Pathology Department regarding release of tissue biospecimens before approaching patients about participation in the trial. (See Section 10 for details.)

3.1 Eligibility Criteria

A patient cannot be considered eligible for this study unless ALL of the following conditions are met.

3.1.1 Women 35-50 years of age, inclusive.

3.1.2 Patients who have declined or elected to defer RRSO after proper counselling to clearly explain the standard of care for BRCA1 mutation carriers (for the BLS with delayed oophorectomy arms) or patients who are undergoing RRSO (for the RRSO arm).

3.1.4 At least one intact ovary and fallopian tube.

3.1.5 Positive CLIA-approved test results for pathogenic or likely pathogenic germline *BRCA1* mutation in the patient herself. Documentation of the result is required.

3.1.7 Premenopausal; defined as <12 months of amenorrhea. However, for those patients with ≥ 12 months of amenorrhea who may be pre-menopausal or patients with a prior hysterectomy with at least one retained ovary/tube, levels of FSH, LH, and in the pre-menopausal range per local institutional standards will be acceptable.

3.1.8 Concurrently planned or prior hysterectomy is permitted as long as at least one fallopian tube and one ovary had been retained.

3.1.9 Transvaginal ultrasound (TVUS) and CA-125 within 180 days of registration.

3.1.10 The patient or a legally authorized representative must provide study-specific informed consent prior to study entry.

3.1.11 Patient must have negative urine pregnancy test within 14 days prior to registration based on local institutional policies.

3.2 Ineligibility Criteria

Patients with any of the following conditions are NOT eligible for this study.

3.2.1 Women with a history of any prior cancer who have received chemotherapy within the past 12 months, hormonal therapy in the past 90 days, or radiotherapy to abdomen or pelvis at any prior time.

3.2.2 Prior history of ovarian cancer, including low malignant potential neoplasms (LMP), primary peritoneal carcinoma, or fallopian tube carcinoma.

3.2.3 Patients medically unfit for the planned surgical procedure.

3.2.4 Patients with abnormal screening tests (TVUS, CA-125) suspicious for occult or gross pelvic malignancy or neoplasm within the past 180 days.

a) An abnormal TVUS is defined as morphologic or structural variations suspicious for ovarian malignancy or complex cystic lesions (simple cysts <5cm in maximal diameter are not exclusionary).

b) An abnormal CA-125 is defined as a level >50U/ml in this study population of premenopausal women if they are not current users or oral contraceptives; an abnormal CA-125 is defined as a level >40U/ml for premenopausal women who are current users of oral contraceptives (Skates 2011).

3.2.5 Women who are currently pregnant or plan to become pregnant in the future.