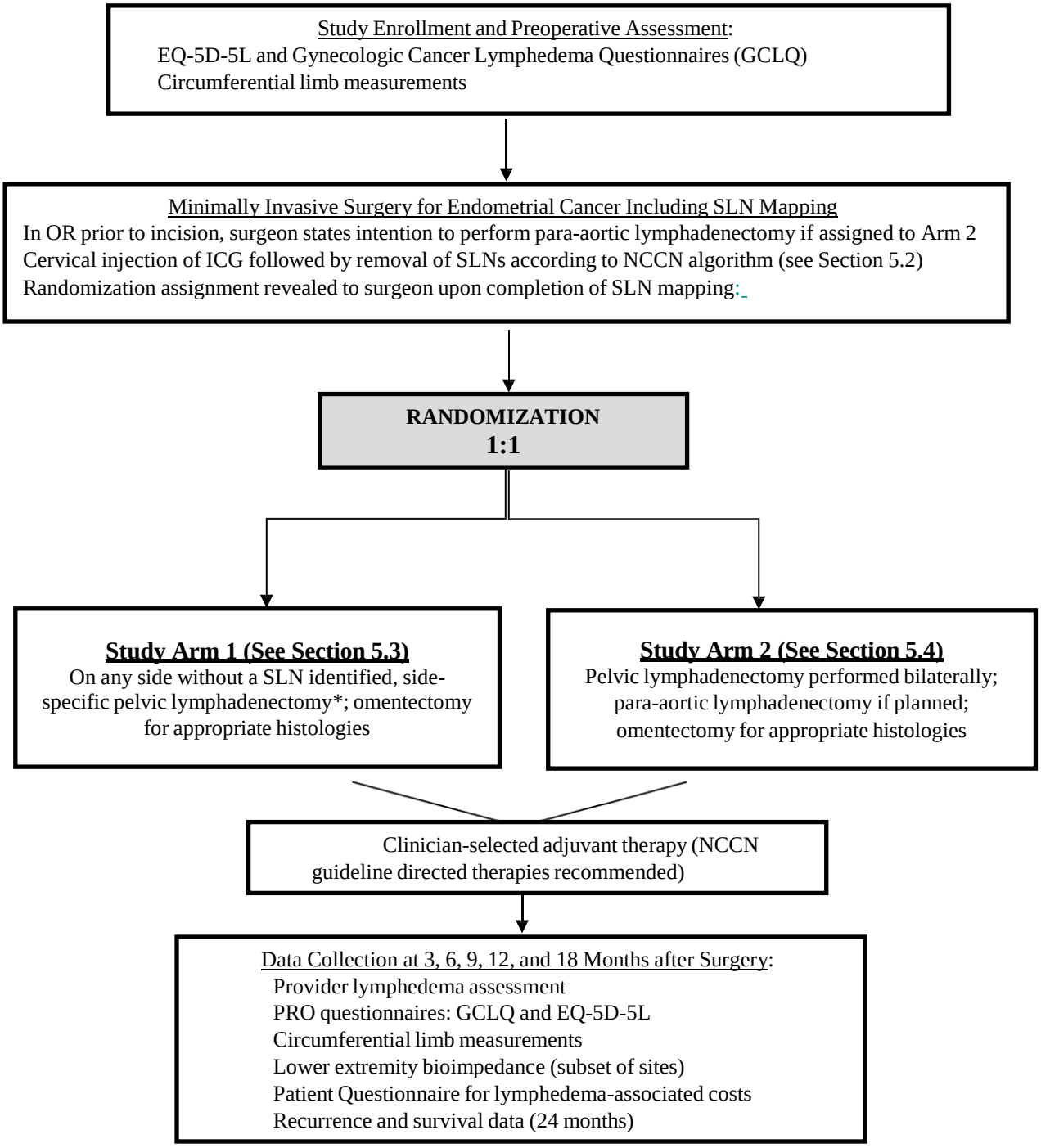
NRG-CC010 SCHEMA



*If surgeon states intention to perform para-aortic lymphadenectomy if assigned to Arm 2, patients in Arm 1 with failed SLN mapping should also undergo side-specific para-aortic lymphadenectomy on any side without a SLN identified.

Legend: GCLQ: Gynecologic Cancer Lymphedema Questionnaire, ICG: indocyanine green, NCCN: National Comprehensive Cancer Network, PRO: patient reported outcome, SLN: sentinel lymph node

3. ELIGIBILITY AND INELIGIBILITY CRITERIA

3.1 Eligibility Criteria

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

3.1.1 Histologically proven diagnosis of endometrial cancer based on endometrial sampling with a plan to undergo laparoscopic or robotic hysterectomy and lymphatic assessment as part of primary management. Biopsy must be performed within 90 days prior to registration.

3.1.2 Clinical stage I endometrial cancer (see Appendix I) based on the following diagnostic workup:

- History/physical examination within 30 days prior to registration is reassuring for the absence of metastatic disease.

3.1.3 Age ≥ 18 years

3.1.4 ECOG Performance Status of 0, 1 or 2 (see Appendix II)

3.1.5 Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial.

3.1.6 The patient or a legally authorized representative must provide study-specific informed consent prior to study entry and, for patients treated in the U.S., authorization permitting release of personal health information.

3.1.7 Patients must speak English or Spanish.

3.2 Ineligibility Criteria

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

3.2.1 Patients whom the surgeon believes is not a candidate for pelvic lymphadenectomy due to medical comorbidities or other technical challenges (i.e. morbid obesity or prior surgery).

3.2.2 History of chemotherapy or immunotherapy for the treatment of endometrial cancer. Progestin-containing therapies such as megestrol, medroxyprogesterone, or levonorgestrel-containing IUD are acceptable.

3.2.3 History of radiation to the pelvis, groin or lower extremities, or surgery to the pelvic lymph nodes or inguinal lymph nodes.

3.2.4 Patients who are going to undergo another elective surgery during the same operative event as their hysterectomy (i.e., sacrocolpopexy, cholecystectomy).

3.2.5 Patients with severe, active co-morbidity defined as follows:

- History of patient or provider identified lower extremity lymphedema
- History of patient or provider identified chronic lower extremity swelling
- History of lower extremity or pelvic deep venous thromboembolism within 90 days of registration
- History of lower extremity cellulitis within 90 days of registration
- For the bioimpedance sub study only: patients with implantable metal devices (i.e. defibrillator, metal joint replacements, etc.) will not be eligible to participate in the bioimpedance sub study but will be eligible to participate in the overall study.

3.2.6 Inclusion of Women and Minorities

NIH policy requires that women and members of minority groups and their subpopulations be included in all NIH-supported biomedical and behavioral research projects involving NIH-defined clinical research unless a clear and compelling rationale and justification establishes to the satisfaction of the funding Institute & Center (IC) Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances must be designated by the Director, NIH, upon the recommendation of an IC Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. Please see http://grants.nih.gov/grants/funding/phs398/phs398.pdf