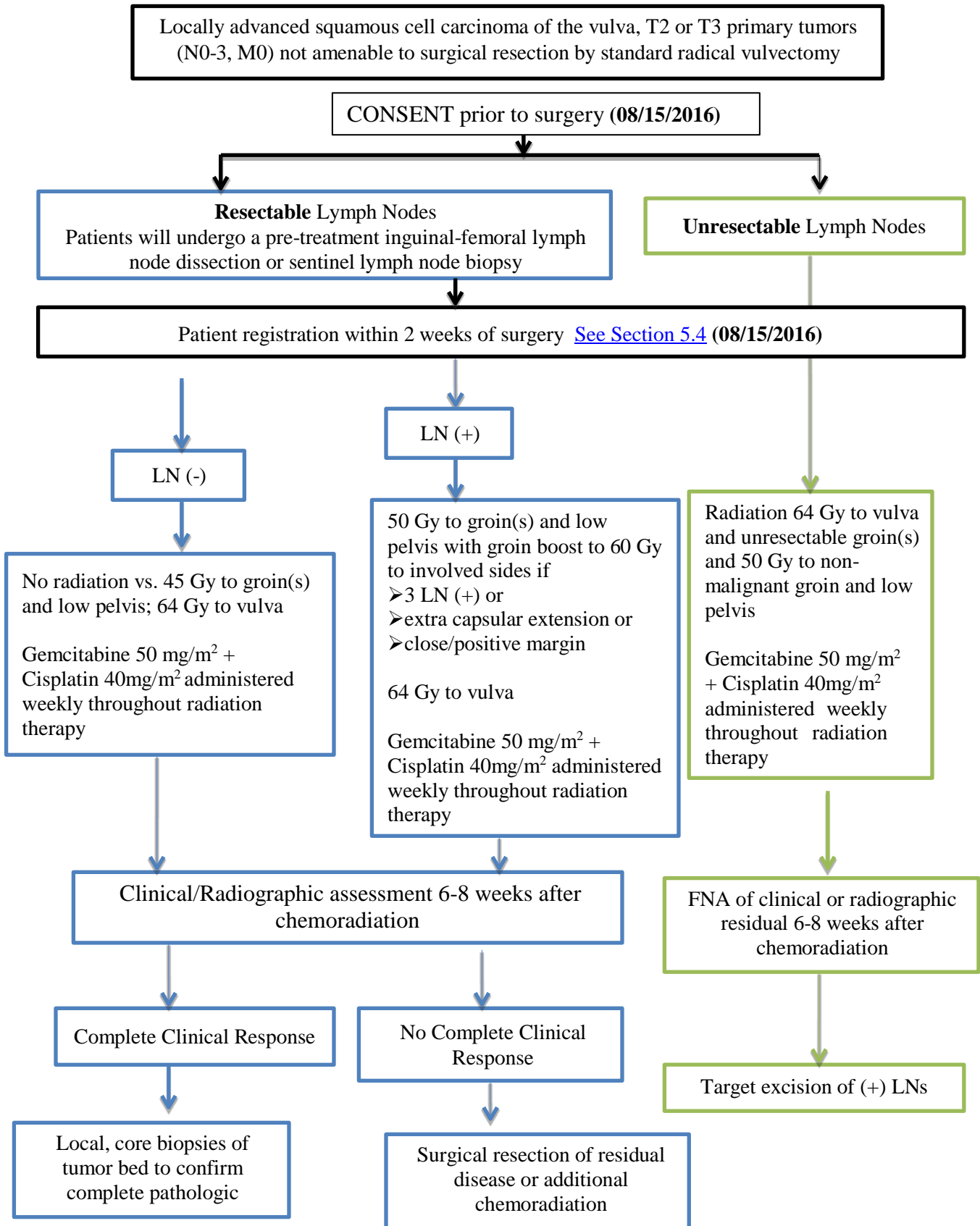


SCHEMA



3.0 PATIENT ELIGIBILITY AND EXCLUSIONS

3.1 Eligible Patients

- 3.11 Patients with locally-advanced, previously untreated squamous cell carcinoma of the vulva.
- 3.12 Patients with T2 or T3 primary tumors (N0-3, M0) not amenable to surgical resection by standard radical vulvectomy.
- 3.13 Patients must have adequate:
 - 3.131 Bone marrow function: Absolute neutrophil count (ANC) greater than or equal to 1,500/mcl Platelets greater than or equal to 100,000/mcl. **(08/26/2013)**
 - 3.132 Renal function: Creatinine ≤ 1.5 x institutional upper limit normal (ULN) or calculated creatinine clearance ≥ 60 ml/min.
 - 3.133 Hepatic function: Bilirubin ≤ 1.5 x ULN. AST and ALT ≤ 3.0 x ULN and alkaline phosphatase ≤ 3.0 x ULN.
- 3.14 Patients judged capable of tolerating a radical course of chemoradiation therapy.
- 3.15 Patients must not be eligible for a higher priority GOG protocol, if one exists. In general, this would refer to any active GOG Phase III protocol or Rare Tumor protocol for the same patient population.
- 3.16 Patients who have met the pre-entry requirements specified in [Section 7.0](#).
- 3.17 Patients must have signed an approved informed consent and authorization permitting release of personal health information.
- 3.18 Patients must be 18 years or older.
- 3.19 Patients with a GOG Performance Status of 0, 1 or 2

3.2 Ineligible Patients

- 3.21 Patients with recurrent carcinoma of the vulva regardless of previous treatment.
- 3.22 Patients who have received prior pelvic radiation or cytotoxic chemotherapy.

- 3.23 Patients with vulvar melanomas or sarcomas.
- 3.24 Patients with circumstances that will not permit completion of the study or the required follow-up.
- 3.25 Patients with evidence of active septicemia, severe infection, gastrointestinal bleeding or severe gastrointestinal symptoms requiring medical or surgical therapy.
- 3.26 Patients with a history of other invasive malignancies, with the exception of non-melanoma skin cancer, are excluded if there is any evidence of other malignancy being present within the last five years. Patients are also excluded if their previous cancer treatment contraindicates this protocol therapy.