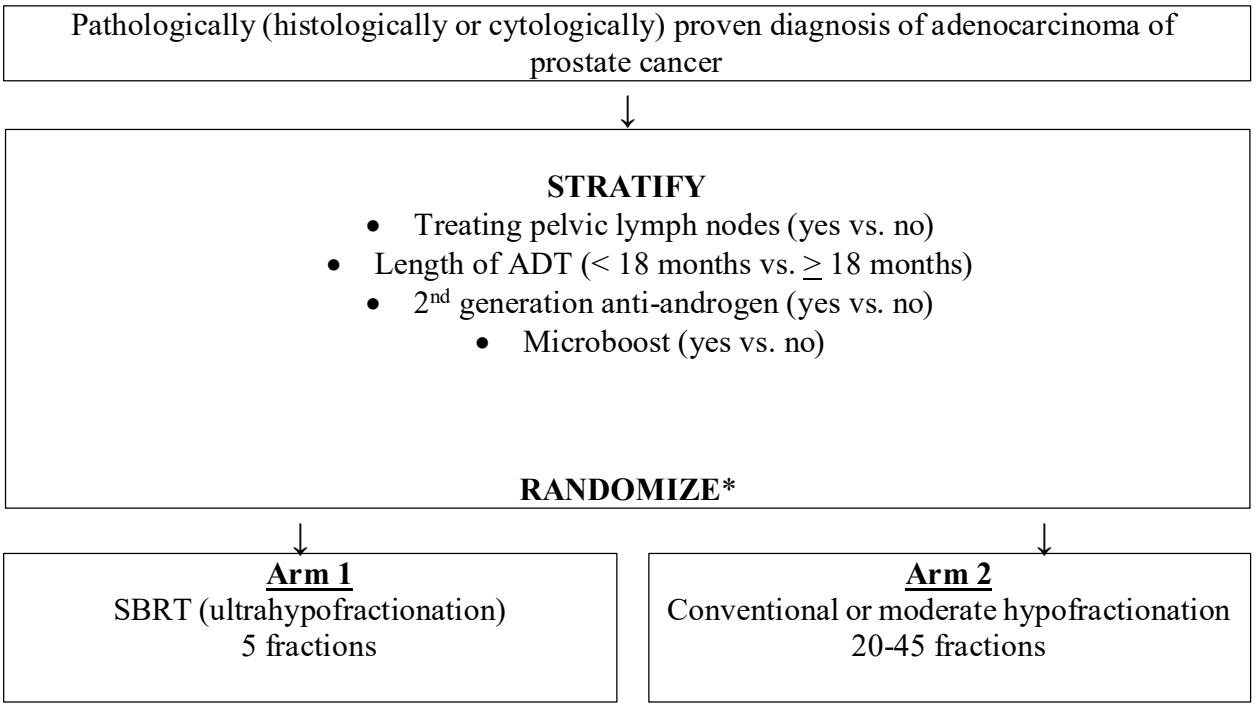
NRG-GU013
SCHEMA



*Randomization is 1:1

3. ELIGIBILITY CRITERIA

3.1 On Study Guidelines

This clinical trial can fulfill its objectives only if patients appropriate for this trial are enrolled. Investigators should consider all relevant factors (medical and non-medical), as well as the risks and benefits of the study therapy, when deciding if a patient is an appropriate candidate for this trial.

HIV and hepatitis status do not impact patient safety and patients with a positive status are eligible for the study.

Physicians should consider the following when evaluating if the patient is appropriate for this protocol

- Patients must have the adequate health that permits completion of the study requirements and required follow up.
- 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 primary outcome are eligible for this trial. *Note: Any patient with a cancer (other than keratinocyte carcinoma or carcinoma in situ or low-grade non-muscle invasive bladder cancer) who has been disease-free for less than 3 years must contact the Principal Investigator.*
- Men who are sexually active should be willing and able to use medically acceptable forms of contraception during treatment and for 90 days after end of Radiation Therapy.

Notes: Per NCI guidelines, exceptions to eligibility criteria are not permitted. For questions concerning eligibility, please contact the Biostatistical/Data Management Center (see protocol cover page). For radiation therapy-related eligibility questions, please contact RTQA (see protocol cover page).

NIH Participant Population Inclusion Policy

NIH policy requires that participants regardless of gender identity 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. Participants of childbearing potential should not be routinely excluded from participation in clinical research. Please see http://grants.nih.gov/grants/funding/phs398/phs398.pdf

3.2 Eligibility Criteria

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

3.2.1 Documentation of Disease

Pathologically (histologically or cytologically) proven diagnosis of adenocarcinoma of prostate cancer.

3.2.2 Definition of Disease

1. High-risk disease defined as having at least one or more of the following:
    - cT3a-T3b by digital exam or imaging (AJCC 8th Ed.) *Note: cT4 by imaging or on digital rectal exam is not allowed.*
    - The patient's PSA value >20 ng/mL prior to starting ADT *Note: Patients taking a 5-alpha reductase inhibitor (ex finasteride or dutasteride) are eligible The baseline PSA value should be doubled for PSAs taken while on 5-alpha reductase inhibitors.*
    - Gleason Score of 8-10
    - Pelvic node positive by conventional imaging with a short axis of at least 1.0 cm

2. Prostate gland volume less than 100 cc prior to initiation of ADT as reported at time of biopsy or by separate measure with ultrasound or other imaging modalities including MRI or CT scan.

3. No definitive clinical or radiologic evidence of metastatic disease outside of the pelvic nodes (M1a, M1b or M1c) on conventional imaging (i.e. bone scan, CT scan, MRI); Negative PSMA PET is an acceptable substitute.

3.2.3 Age ≥ 18

3.2.4 ECOG Performance Status of 0-2

3.2.5 Prior Treatment

- No prior radiotherapy to the region of the study cancer that would result in overlap of radiation therapy fields;
- No prior radical prostatectomy;
- Prior pharmacologic androgen ablation for prostate cancer is allowed only if the onset of androgen ablation (both LHRH agonist and oral anti-androgen) is ≤ 185 days prior to registration; ***Please note: PSA prior to the start of any ADT will be used to define disease in 3.2.2.***

3.2.6 Co-Enrollment with NRG-GU009 (ONLY Applies to Patients enrolled in NRG-GU009)

Patients enrolled in NRG-GU009 must be enrolled in NRG-GU013 prior to radiation therapy treatment planning and start of radiation therapy. For details, see Section 5.4.