

# Oral 5 Strain Probiotic for GI Toxicity Mitigation During Pelvic Radiation

NCT07231588

---

Status	RECRUITING
Phase	Early Phase 1
Sponsor	University of Cincinnati
Enrollment	20 participants

## Key Eligibility Criteria

---

### Inclusion (5)

- Patients must have histologically confirmed malignancy for which the standard of care treatment is at least 30 Gy of pelvic RT to the pelvic lymph nodes.
- a. Eligible diagnoses include: i. Lower GI cancers (anal, rectal) ii. Gynecologic cancers (cervical, vulvar, vaginal, endometrial) iii. Prostate cancer with lymph node involvement
- Age ≥18 years.
- ECOG performance status ≤2 (or Karnofsky ≥60%, see Appendix A).
- Ability to understand and the willingness to sign a written informed consent document.

### Exclusion (13)

- Patients with inflammatory bowel disease (IBD - such as Crohn's or Ulcerative Colitis).
- Patients who are currently receiving any other investigational agents. Patients who have received other investigational agents previously who are no longer receiving these investigational agents may be eligible at the discretion of the PI.
- Patients with uncontrolled intercurrent illness or any other significant condition(s) that would make participation in this protocol unreasonably hazardous, in the opinion of the Investigator.
- Patients with a prior or concurrent malignancy whose natural history or treatment have the potential to interfere with the safety or efficacy assessment of the investigational regimen in the opinion of the Investigator.
- Patients who have received previous radiation therapy to the pelvis at any time.

... and 8 more (see full listing online)

## Locations (1 total)

---

University of Cincinnati Medical Center, Cincinnati, Ohio, United States