INELIGIBILITY • Patient must not have: (refer to protocol for details)
• metastatic disease
• grade III/IV cardiac disease (NYHA criteria), unstable angina, MI within last 6 months, or serious uncontrolled arrhythmia
• GI impairment or disease that may alter drug absorption
• hepatitis, uncontrolled diabetes, uncontrolled pulmonary disease, or organ allograft or other history of immune compromise
• chronic systemic corticosteroid use (topical or inhaled are allowed)
• live attenuated vaccine ≤ 7 days prior to registration
• strong CYP3A4 inhibitors or inducers ≤ 14 days prior to registration
• prior mTOR inhibitors (rapamycin, everolimus, temsirolimus, or deforolimus)
• other investigational drug ≤ 28 days prior to registration (concurrent bisphosphonate is allowed; concurrent trastuzumab is not)
• prior malignancy, except:
  » adequately treated basal or squamous cell skin cancer
  » in situ cervical cancer
  » other cancer from which patient has been disease-free for 5 years
• be pregnant or nursing; women and men of reproductive potential must agree to use effective, non-hormonal contraceptive method

e³ Breast Cancer Study
evaluating everolimus with endocrine therapy (s1207)

Adjuvant/neoadjuvant chemotherapy, surgery, radiation therapy

Registration, Stratification, Randomization

5 yrs endocrine tx w 1 yr everolimus
5 yrs endocrine tx w 1 yr placebo

THIS PROTOCOL CARD IS A SCREENING TOOL ONLY AND SHOULD NOT BE USED IN PLACE OF THE PROTOCOL
“Phase III, Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer”

Patients at CCOPs must also be offered the opportunity to take part in correlative behavioral and health outcomes (BAHO) study S1207-E01, led by NSABP.

**ELIGIBILITY** • Patient must have:

- histologically confirmed diagnosis of invasive breast carcinoma (multifocal, multicentric, synchronous bilateral, or inflammatory br ca is allowed)
- positive estrogen and/or progesterone receptor (by ASCO/CAP guidelines)
- negative HER2 status (by IHC or gene amplification)
- completed neoadjuvant or adjuvant taxane or anthracycline based chemotherapy
- fit in one of four high-risk groups:
  - A. completed adjuvant chemotherapy, node-negative, tumor greatest diameter ≥ 2 cm, and Oncotype DX® Recurrence Score (RS) > 25
  - B. completed adjuvant chemo, 1 – 3 positive nodes, and RS > 25
  - C. completed adjuvant chemo and ≥ 4 positive nodes
  - D. completed neoadjuvant chemo and ≥ 4 positive nodes
- had either breast-conserving surgery with whole-breast radiation, or total mastectomy; must have negative margins
- had axillary staging by sentinel node biopsy or axillary lymph node dissection (ALND)
- if ≥ 4 positive nodes, must have breast/chest wall & nodal basin radiation & ALND
- if 1 – 3 positive nodes, sentinel node biopsy alone is allowed if patient had whole breast or chest wall radiation and primary tumor < 2 cm
- all radiation therapy completed ≥ 21 days prior to registration and radiation toxicites > grade 1 resolved
- all chemotherapy completed ≤ 21 weeks prior to registration
- adequate bone marrow, hepatic, and renal function; fasting cholesterol ≤ 300 mg/dL; triglycerides ≤ 2.5 x IULN; Zubrod PS of 0 – 2

See back of card for **INELIGIBILITY** factors.