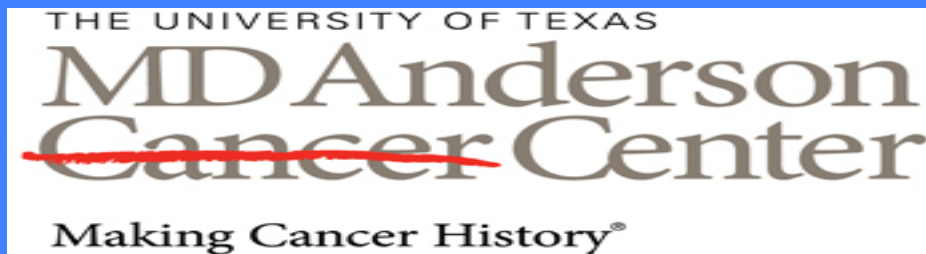


# Alliance A11104/ACRIN 6694: Effect of Preoperative Breast MRI on Surgical Outcomes, Costs and Quality of Life of Women with Breast Cancer

- Isabelle Bedrosian, M.D. FACS
  - Associate Professor
- Department of Surgical Oncology
  - Cancer Center



# Detection of multi-focal/multi-centric disease

- Meta-analysis of 19 studies, 2610 women
- Additional foci of disease detected by MRI only in 16% (6-34%)
- MRI altered surgical therapy in 7.8-33% of women
- Change in surgery as a result of FP MRI 5.5% (95% CI 3.1% -9.55)

# Does preoperative breast MRI have clinical utility?

- Reduce re-operation rates
  - MRI does not improve margin negative rates at first excision
- Reduce local recurrence rate
  - Retrospective data-mixed results
- Reduce contralateral breast cancer rate
  - Significance of MRI detected contralateral breast cancer?

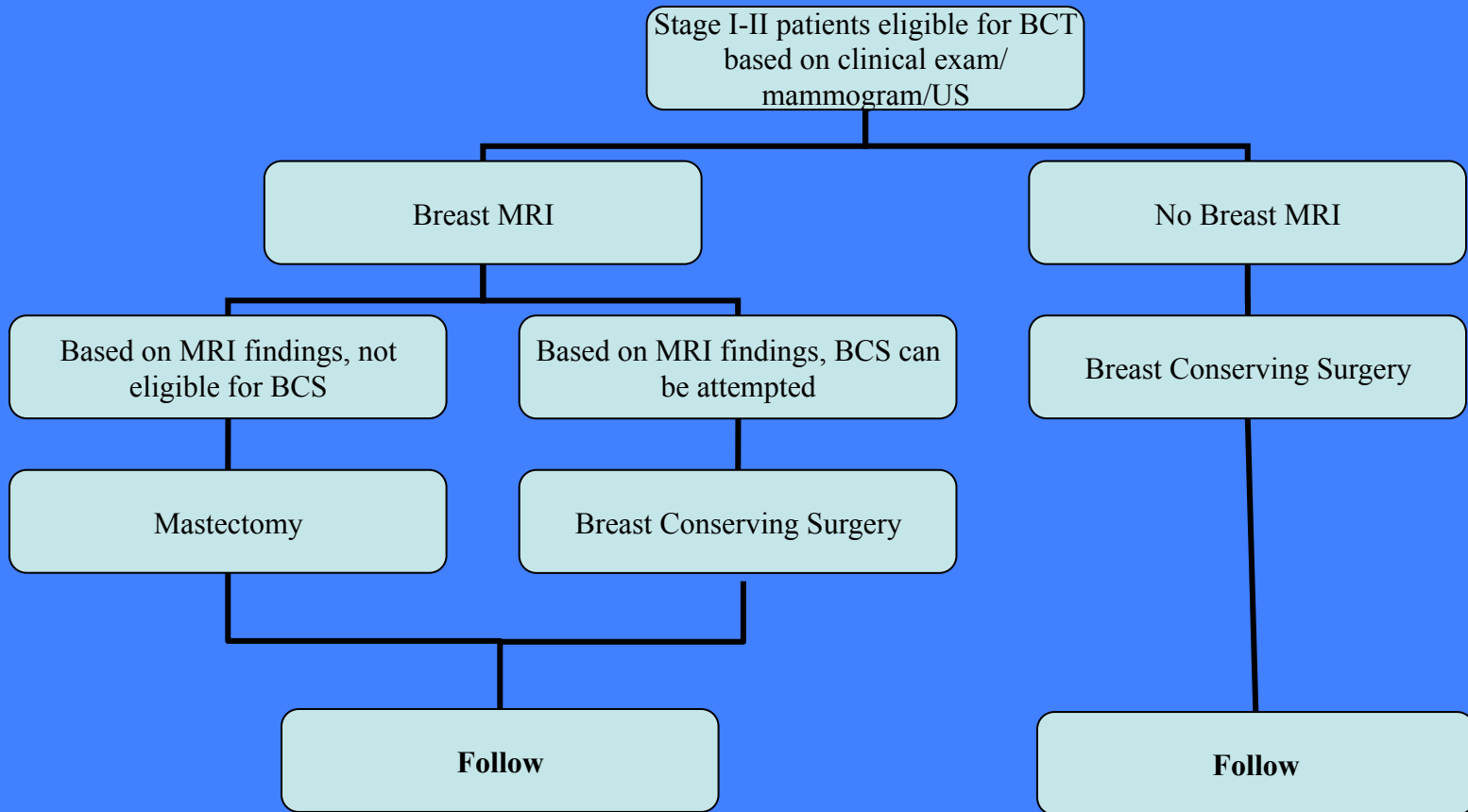
# Tumor subtype and local recurrence rate following BCT

	ER +		ER -	
	ER or PR+, her-2 -	ER or PR +, her-2 +	ER/PR -, her-2 +	ER/PR/ Her-2 -
LR rate at 5 years	0.8%	1.5%	8.4%	7.1%

# Hypothesis

Preoperative breast MRI improves staging and selection of patients with ER/PR/Her-2 negative and Her-2 amplified tumors for BCT, thus lowering rates of local regional recurrence.

# Alliance A11104 Phase III trial



Sample size: 244 patients/arm

# Trial endpoints

- Primary
  - LRR rates at 5 years between the MRI and no MRI arm
- Secondary
  - Rates of re-excision, including conversion to mastectomy
  - Time to local recurrence
  - Overall and disease specific survival
  - Contralateral breast cancer rates
  - MRI technical performance (sensitivity, specificity, PPV)

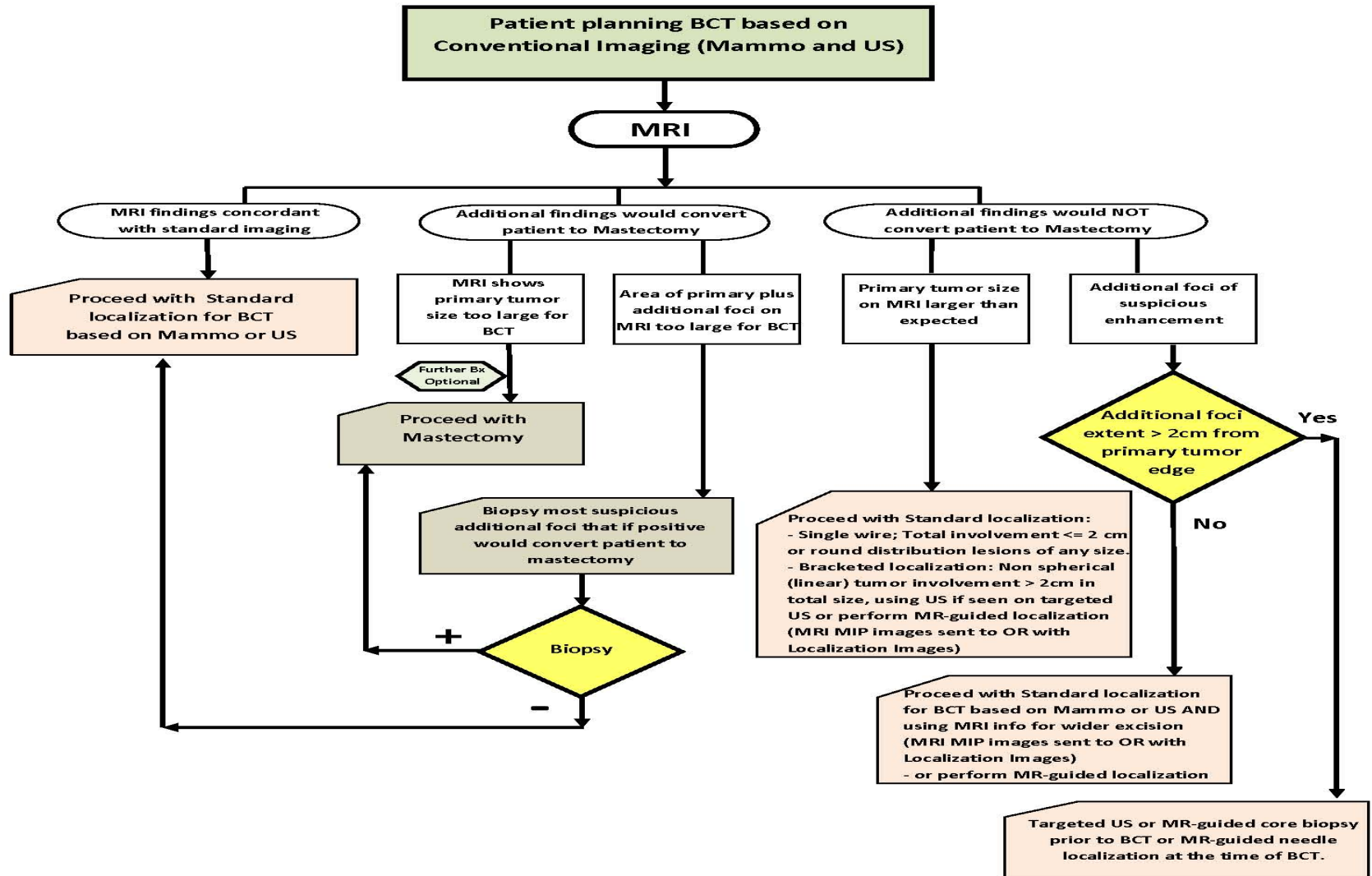
# Eligibility criteria

- Women with
  - her-2 positive breast cancer (ER/PR negative) OR
  - Triple negative breast cancer
- Stage I-II, unilateral cancer
- No previous breast cancer history
- No preoperative chemotherapy
- No plans for partial breast irradiation following lumpectomy
- No BRCA carriers



# MRI Findings Management Flow

**MRI Findings Management Flow Chart:**



# Correlatives

Study	Requirement	Material request
Medical care costs	Required	CRFs with patient status and test data
QOL	Required	questionnaire
Molecular predictors	optional	Tissue

# AMENDMENT 1

- Tomo allowed
- Changes to HER2+ testing (2013 ASCO/CAP)
- Simplify tissue/blood correlative
- Clarify funding for MRI

# Current Status

- Activated 2/22/14
- Prior to activation:
  - 2 steps needed prior to approval to accrue
    - IRB approval, including activation amendment
    - PSA from ACRIN