Saint Sebastian
PHASE III TRIAL CONCEPT SUBMISSION

National Cancer Institute
Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

NOTES: Concepts must be submitted in electronic format, using Word 97 or WordPerfect for Windows 95/98 suite or scheme may be converted to page format to secure accurate decipher. To complete the form electronically, use the mouse pointer or the Tab key to navigate. Please do not add the text note, these forms are to be filled out for NCI and fill out the form, these forms are to be filled out for NCI and fill out the form, these forms are to be filled out for NCI.

I. ADMINISTRATIVE

Title of Concept: A Randomized Phase III Study of Conventional Whole Breast Radiation Therapy (WBRT) Versus Partial Breast Irradiation (PBI) for Women with Stage I, II or II Breast Cancer

Sponsoring Organization's Local Protocol Number:

Study Chair Name (performance): Frank Victor, MD
Study Chair Signature (not required):
Study Chair Address: NSABP Operations Center, 100 Allegheny Center, 5th Floor, Pittsburgh, PA 15212-5238
Study Chair Phone: 412-366-0200
Study Chair Fax: 412-366-4661
Study Chair e-mail: frank.victor@nsabp.org
Name(s) of co-chair or discipline chairs: Adrienne Aronson, MD, Robert Kramer, MD

II. Statistical/Drug Management Officer(s):

(Must be NIH funded. If not currently responsible for large scale NCI clinical trials, submit a separate document describing data management resources to be used for the trial, and Data Safety & Monitoring Board)

Name of Responsible Individual: John Bryant, PhD

Signature of Responsible Individual (required):

Responsible Individual Address: NSABP Operations Center, One Sterling Place, 500 North Craig Street, Suite 500, Pittsburgh, PA 15219
Responsible Individual Phone: 412-366-4294
Responsible Individual Fax: 412-366-1877
Responsible Individual e-mail: bryant@northwestern.edu
NSSN Grant Number: U01CA12007 NSABP Operations Center U01CA69651 U01CA69694

III. Anticipated participant(s) - Limitations: Groups expected to accrue patients (include letters committing support). For Consortium or Long protocols, this section is not required.

NSABP Membership
Cancer Trials Support Unit (CTSU)
Thomas B. Julian, M.D.
NSABP Protocol Officer

David Parda, M.D.
NSABP Radiation Protocol Officer

Doug Arthur, M.D.
NSABP Co-Chair

Julia White, M.D
RTOG Chair

Rachel Rabinovitch, M.D.
RTOG Co-Chair

Stephanie Land, Ph.D.
NSABP Statistician

David Parda, M.D.
NSABP Radiation Protocol Officer

Robert Kuske, M.D
NSABP Co-Chair.

Frank Vicini, M.D.
NSABP Chair

Thomas B. Julian, M.D.
NSABP Protocol Officer
Betty Martin
Lorraine Quartles
Kathryn Winter
Wendy Bergantz
Debra Grant
Renya Hochstdeler
Betty Martin
Lorraine Quartles
Kathryn Winter
Wendy Bergantz
Debra Grant
Renya Hochstdeler
RTOG OPERATIONS
Charlene
NSABP B-39/RTOG 0413
Phase III Trial of Whole Breast Irradiation (WBI) vs. Partial Breast Irradiation (PBI)

Operable Breast Cancer
Invasive or DCIS (≤3 cm), 0-3 Positive Nodes
Treated with Lumpectomy

External Beam Whole Breast XRT

Partial Breast Irradiation
Athena-
Greek Goddess
Of Wisdom
Accrual Management

- NSABP is the “lead” group (CTSU).

- Any NSABP site (single or multiple groups) can randomize only through NSABP.

- Non-NSABP sites must randomize through CTSU.
Accrual Management

• This Trial involves surgery and radiation therapy.

• The Trial requires long term follow-up

• Site capabilities will vary.

• Dual sites - one group may be more established and better able to conduct the Trial.
Accrual Management

• At sites with active NSABP and RTOG membership, the local NSABP and RTOG PIs have the option (after joint agreement) of electing all accrual from that site to be credited to the RTOG.

• If electing RTOG, entry and randomization would occur through the CTSU. Otherwise, entry and randomization would go through NSABP.

• Renewal of this arrangement could occur on an annual basis, but the recommendation would be to maintain this for the duration of trial accrual.
Accrual Management

• A declaration form will be developed for signature of both the NSABP and the RTOG local PIs and submitted to the NSABP Headquarters.

• CTSU will be notified of the decision rules.

• NSABP sites that elect to award accrual through RTOG will receive full accrual credits toward the 10 patients/year requirement.

• RTOG sites that elect to award accrual through NSABP will receive full accrual credits toward the yearly requirement.
Accrual Management

• Accrual credits will not be retroactive after the joint agreement.

• NSABP will develop an accrual reporting process to RTOG.

• Federal funding for this Trial is approximately $2,000 per randomization from either the NSABP or RTOG. Funding allocation at a site is a local matter. The NSABP and RTOG memberships are strongly encouraged to discuss with each other the allocation issues at their respective sites.
Data Management

• NSABP is the owner of all data and will be responsible for primary/secondary endpoint analyses and QOL analysis.

• RTOG will collect cosmesis data and provide analysis.

• NSABP will manage randomization and with RPC/ITC manage PBI treatment planning data for credentialing and QA/QC.

• RTOG will collect and review WBI planning data.
THE PINNACLE PBI TRIAL
Michael - The Archangel