ORGANIZATIONAL TIPS

Practical ideas on how to make our jobs easier

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Session Objectives:

a. *Discuss how to identify, access and track appropriate patients for a clinical trial.*
b. *Identify tools to facilitate communication among physicians, patients, nurses and CRAs.*

Agenda:

1. Physician Communication
   a. Provide information for newly approved protocols (e-mail blast, monthly research meetings, tumor conference)
   b. Active protocol listings (excel, word, pocket, web-site)
   c. Packet and consent for new patients (include the pt's initial screening information, background information, schema, eligibility, treatment plan, test schedule and HIPAA/Consent Forms)
   d. "Talking Points", order templates, AE documentation, tumor measurement documentation, patient calendars

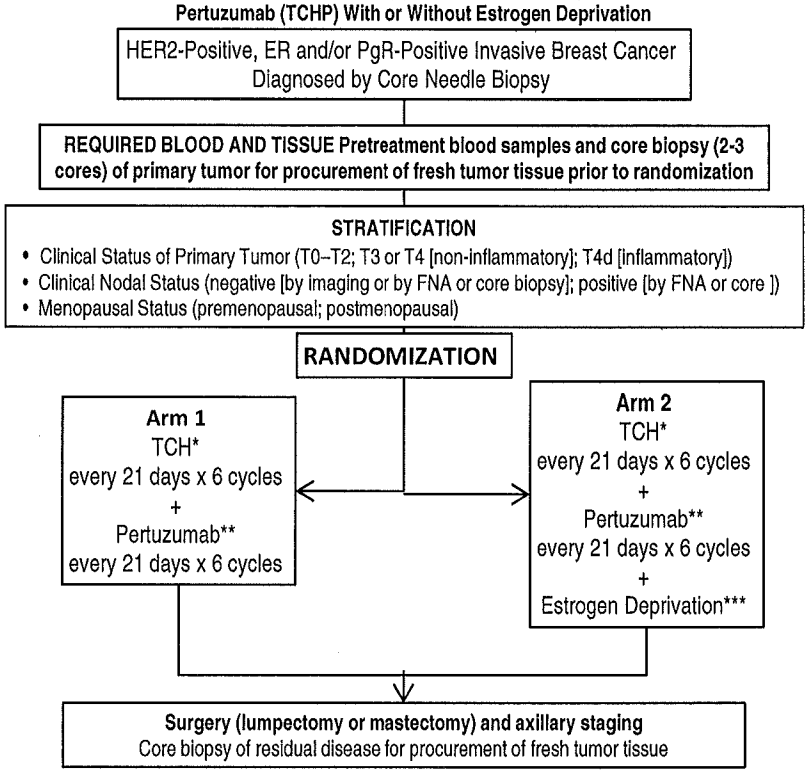
2. RN/CRA Communication
   a. Calendars for data submission (Coordinator On-Line, local systems, web based systems)
   b. New consult list in excel
   c. Checklist for newly activated trials
   d. Treatment Planning Approval
   e. Protocol Deviation Documentation/Quality Improvement Checklist
   f. Helpful hints
   g. Report on meetings

3. Patient Communication
   a. Information packets for patients (patient treatment calendar, diaries, emergency call-in sheet)
   b. Obtain contact names, addresses, email addresses and phone numbers after the patient is registered
   c. RN assessment and note with patient office visit

SCREENING NEW CONSULTS

- *Every new consult seen should be screened for possible protocol eligibility.*
  - Coordinators evaluate the electronic schedule for each physician
  - You can prepare a "new consult list" in excel for tracking for all the new consults evaluated
    - This excel tracking for new consult contains the patient's name, physician, diagnosis, potential protocol, area to comment on info pending, if patient entered, why a patient was not entered, etc.
- *Important to have an Active Protocol Listing*
  - Either on your website or a pocket listing to assist with identification of an appropriate trial for your patient.
  - Your site should have a system of prioritizing trials.
- *If a patient appears to be eligible for a protocol communicate with this information as soon as possible.*
  - For sites with EMR an alert can be entered to the patient file
  - Meet, call, text or Email the physician regarding the potential trial for his/her patient.
  - Remember to check the number of days the patient is post surgery/diagnosis. Many trials have a limited time frame for eligibility. This information is found in the eligibility section of all protocols.
- *If a new consult does not have records available, our research staff takes the appropriate steps to see the records are obtained before the patient's office visit (if possible.)*
  - Complete records on hand will make the patient's first visit go as smoothly as possible as well as assist with determining eligibility.
  - For outside consults to your institution, provide a listing to your administrative staff of common reports needed for specific disease sites. (i.e. new breast cancer patient would need path/op from bx, definitive surgery, SLN bx, ALND if indicated, ER/PR/HER2, Flow, etc.)
- *If we do not have a cooperative group trial available for a patient it may be possible to utilize one of our pharmaceutical trials.*

A Randomized Phase III Trial Evaluating Pathologic Complete Response Rates in Pts with Hormone Receptor-Positive, HER2-Positive, Large Operable & Locally Advanced Breast Cancer Treated with Neoadjuvant Therapy of Docetaxel, Carboplatin, Trastuzumab, & Pertuzumab (TCHP) With or Without Estrogen Deprivation



- **TCH:** Docetaxel 75 mg/m2 IV + carboplatin AUC of 6 IV every 3 wks for 6 cycles + trastuzumab IV (administer a loading dose of 8 mg/kg; then 6 mg/kg every 3 weeks for the remaining doses)

** **Pertuzumab:** Administer a loading dose of 840 mg IV; then 420 mg IV every 3 wks for Cycles 2–6.

*** **Estrogen deprivation therapy** determined by menopausal status: ***Premenopausal: Aromatase inhibitor plus ovarian function suppression utilizing goserelin (LHRH agonist) or equivalent***
Postmenopausal: Aromatase inhibitor

SELECTED ELIGIBILITY Section 4.0

- Patients should have a life expectancy of at least 10 yrs, excluding their dx of breast cancer
- Women of reproductive potential must agree to use an effective non-hormonal method of contraception during study therapy (chemotherapy, trastuzumab, pertuzumab, and estrogen deprivation therapy) ***and for at least 6 months after the last dose of study therapy.***
- • ***Submission of tumor samples is required for all patients (see Section 7.1)***
- The patient must be female. The patient must be ≥ 18 years old
- The patient must have an ECOG performance status of 0 or 1 (see Appendix A)
- Clinical staging for the primary tumor can be cT1c (must be 2.0 cm) or T2–T4 if clinically node negative. If the regional lymph nodes are cN1 and cytologically or histologically positive or if cN2–N3 with or without a biopsy, the primary breast tumor can be cT0–T4
- The diagnosis of invasive adenocarcinoma of the breast ***MUST have been made by core needle biopsy.***
  - ➢ Nodal status – negative
    - Imaging of the axilla is negative;
    - Imaging is suspicious or abnormal but the FNA or core biopsy of the questionable node(s) on imaging is negative;
  - ➢ Nodal status – positive
    - FNA or core biopsy of the node(s) is cytologically or histologically suspicious or positive
    - Imaging is suspicious or abnormal but FNA or core biopsy was not performed
- Patients may be premenopausal or postmenopausal at the time of randomization.

  For study purposes, postmenopausal is defined as:
  - Age 56 or older with no spontaneous menses for at least 12 months prior to study
  - Age 55 or younger with no spontaneous menses for at least 12 months prior to study entry (e.g., spontaneous or secondary to hysterectomy) ***and with a documented estradiol level in the postmenopausal range according to local institutional/laboratory standard; or***
  - Documented bilateral oophorectomy
- HER2-postive by FISH or IHC (3+);
- ER and/or PgR positive assessed by current ASCO/CAP Guideline Recommendations for hormone receptor testing (http://www.asco.org). Patients with > 1% ER or PgR staining by IHC are considered positive
- Adequate organ function (determine by labs) refer to section 4.0 in protocol
- LVEF ≥ 50 ***% regardless of the cardiac imaging facility's lower limit of normal***

Continue slide 3

SELECTED ELIGIBILITY Section 4.0 Continued

- Adequate organ function Within 6 weeks prior to randomization, see protocol

Selected ineligibility

- FNA alone to diagnose the breast cancer
- Excisional biopsy or lumpectomy performed prior to randomization
- Surgical axillary staging procedure prior to randomization. Pre-neoadjuvant therapy sentinel node biopsy is not permitted
- Definitive clinical or radiologic evidence of metastatic disease (Chest imaging [mandatory for all patients] and other imaging [if required] must have been performed within 90 days prior to randomization)
- **Synchronous bilateral invasive breast cancer**
- Synchronous or previous contralateral invasive breast cancer. (Patients with synchronous and/or previous contralateral DCIS or LCIS are eligible)
- Any previous history of ipsilateral invasive breast cancer or ipsilateral DCIS. (Patients with synchronous or previous ipsilateral LCIS are eligible)
- Treatment including RT, chemotherapy, targeted therapy, or endocrine therapy for the currently diagnosed breast cancer prior to randomization
- Previous endocrine therapy such as raloxifene or tamoxifen (or other SERM) or an aromatase inhibitor for any malignancy.
- Previous therapy with anthracycline, taxanes, carboplatin, trastuzumab, or other HER2 targeted therapies for any malignancy.
- Any sex hormonal therapy (BCP; HRT) –pt's eligible if dc'd prior to study entry.
- Hx non breast malignancies (except in situ & basal cell and squamous cell cancer of skin) within 5 years prior to randomization.
- **Cardiac disease** section 4.1.13
- Uncontrolled hypertension defined as sustained systolic BP > 150 mmHg or diastolic BP > 90 mmHg. (Patients with initial BP elevations are eligible if initiation or adjustment of BP medication lowers pressure to meet entry criteria)
- **Active** hepatitis B or hepatitis C with abnormal liver function tests
- **Active** infection or chronic infection requiring chronic suppressive antibiotics
- Patients known to be HIV positive with a baseline CD4 count of < 250 cells/mm3 or have a history of AIDS indicator conditions
- **Nervous system** disorder (paresthesia, peripheral motor neuropathy, or peripheral sensory neuropathy) ≥ grade 2, per the CTCAE v 4.0
- Malabsorption syndrome, ulcerative colitis, resection of the stomach or small bowel, or other disease significantly affecting gastrointestinal function

NSABP B-52 version 8/16/13 NeoAdjuvant

REQUIRED STUDIES	Prior to study Entry
H&P, Ht/Wt, assessment of BP and BP meds, Performance Status.	w/in 6 wks
Menopausal status (Section 4.2.7) An estradiol level may be required. Section 4.2.7.	
CBC/diff/platelet; Comp Met , total bili	
Creatinine clearance (calculated or measured)	
♀ childbearing potential: Serum βHCG	w/in 2 wks
CHEST imaging * (Chest CT or CXR (PA & Lat)	w/in 90 Days
2-D Echo (with number not range of LVEF%) or MUGA	w/in 90 Days
ECG	w/in 90 Days
Liver imaging (required if Alk Phos is > ULN but ≤ 2.5xULN)	w/in 6 wks
Bone Scan (required if Alk Phos > ULN but ≤ 2.5 x ULN or unexplained bone pain)	w/in 6 wks
Imaging (mamm., ultrasound, and / or MRI) of ipsilateral axilla	w/in 6 wks
Bilateral Breast Imaging: MRI is permitted before entry as a substitute for mamm. (U/S is not). Imaging will be unilateral for pt's who have had mastectomy w/out reconstruction. **Ipsilateral breast w/in 90 days Contralateral breast w/in 180 Days**	
Marking of primary tumor REQUIERED	Before therapy begins
The BAHO questionnaire must be administered after the informed consent is signed but before randomization (see Section 8.0).	

* PET scans and PET-CT scans are permitted as an alternative to chest x-ray and CT scan of the chest.

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B-52 ELIGIBILITY CHECKLIST

PROTOCOL VERSION DATE: 4/2/2013 (5/8/14)

NAME: MR#:	PHYSICIAN: LAST SURGERY:	ER/PR Status (on primary tumor):
Consent: YES or NO	HIPAA Auth: YES or NO	Request release of block from pathology: (Must have email or verbal notification documented in chart)_____
Her2 status: FISH CEP17 ratio _____ (>2.0) Request / Email to Jorge / cc Millicent (date)_____ IHC result _____(3+)		
Dr. Bear's approval of FISH and ICH YES or NO Date _____		
Blood/Serum collection:_____	Collection of primary tumor samples:_____	
Marking of primary tumor site(section 9.5): marked prior to therapy/before or after randomization:_____		

REQUIRED TESTS	*DATE*	
Within 2 weeks: Expires: _____		
•PREGNANCY TEST (WOMEN OF CHILDBEARING POTENTIAL)		
Within 6 weeks: Expires: _____		
•HISTORY & PHYSICAL w/ PS(0 or 1 appendix A)		PS:
• VITAL SIGNS	Ht:	Wt:
• CON MED SHEET (assessment of BP meds)	BP:	
•Cardiac History		
• Menopausal status (Section 4.2.7)-premenopausal/postmenopausal: 56 or older no menses 12 mo. 55 or younger no menses 12 mo estradiol level OR bilateral oophorectomy		
•Determination of Nodal Status (4.2.6 &4.3.3): axillary lymph nodes evaluated by mammo, ultrasound &/or MRI-suspicious/abnormal FNA or core biopsy (within 6 weeks of randomization). pre-neoadjuvant therapy sentinel node biopsy not permitted.		
•Tumor assessment and measurement (14.0): physical exam in patients with palpable tumor-document presence or absence of cCR.		
• LABS: CBC/Diff/PLT; Total bilibubin/AST or ALT/ Alk Phos;Serum/ creatinine/ creatinine clearance		
• BONE SCAN (or PET or PET-CT) – REQUIRED IF ALK PHOS > ULN OR UNEXPLAINED BONE PAIN		
• LIVER IMAGING (CT,MRI, PET-CT, & PET SCANS) – REQUIRED IF AST > ULN		
•Imaging (mammo, ultrasound, and/or MRI) ipsilateral axilla: (suspicious abnormal nodes-FNA or core biopsy recommended)		
Within 90 Days:		
• 2-D ECHO or MUGA		
• CHEST CT or CXR (PA & LAT)- PET/PET CT is permitted(P.30, Tbl 1, g)		
• ECG		
Within 180 Days:		
• Bilateral Breast Imaging(ipsilateral=90/contralateral=180) – OR MRI permitted baseline and before surgery		
BAHO Questionnaire(section 8.0) (after informed consent prior to randomization)		

CRA SIGNATURE _____ DATE _____

NSABP B-52 (NeoAdjuvant) RN Work Up

NAME:	MR#:	DOB:
HOME PH ( ) - WORK or ALT PH ( ) -	CELL PH ( ) - EMAIL	BEST METHOD OF CONTACT:

Surgeon:	Hem:	RAD:	Performance Status:	LDTR:_____ _____()
Race:	Ethnicity:	Age:	Location: DOC SP	

Diagnosis of invasive adenocarcinoma **MUST** have been made by CORE needle biopsy. DATE:_____

Clinical Staging : _____. Clinical staging for primary tumor can be cT1c (Must be 2.0 CM) **or T2-T4 if clinically node neg.**

Clinical Nodes:_____ biopsy by: FNA___ or core____

If the regional lymph nodes are cN1 and cytologically or histologically positive or if cN2-3 with or without a biopsy, the primary breast tumor can be cT0-T4 Ipsilateral nodes must be evaluated by imaging (mamm, U/S and /or MRI) w/in 6 wks prior to randomization. If suspicious or abnormal, FNA or core bx is recommended, also w/in 6 wks of randomization.

DATE: Primary Tumor: ER____ PR: ____ **Her-2 must be positive:** FISH (CEP17 ratio) _____ *or* IHC (3+) _____.

VCUHS standard for positive FISH is a ratio of ≥ 2.2. SYNCHRONOUS BILATERAL BREAST CANCER NOT ELIGIBLE

MEDICATIONS: See Concomitant Med list	**ALLERGIES:**

Menopausal status: **POST-MENOPAUSAL:** ☐ Age 56 or older with no spontaneous menses for at least 12 months prior to study entry; **OR**	☐ Age 55 or younger with no spontaneous menses for at least 12 months prior to study entry (e.g., spontaneous or secondary to hysterectomy) and with a documented **Estradiol level** the postmenopausal range according to local institutional/laboratory standards. **ESTRADIOL LEVEL** _____**DATE:** _____; **OR**	☐ A prior documented bilateral oophorectomy. **DATE:** _____	☐ **PRE-MENOPAUSAL:** Women failing to meet the Previous criteria. **Date of last Menses:** _____

IUD removal date: **Birth Control Method:**

HT _____ WT_____ BP_____ Date _____ w/in 6 wks

Labs and Tests	Required Value	Timing		Date of test	RESULTS:	ULN
Serum HCG all premenopausal women	negative	w/in 2 wks				
ANC	≥ 1200/mm³	w/in 6 wks				1.9 - 7.9
Platelets	≥ 100,000/mm³	w/in 6 wks				172 - 440
Hgb	≥ 10.0 g/dL	w/in 6 wks				12.0 – 15.0
Total bili exceptions Sect 4.2.11 #13)	≤ 1. x ULN	w/in 6 wks				0.0 – 1.3
Alk Phos	≤ 2.5 x ULN	w/in 6 wks	**NOTE:** Alk Phos & AST cannot both be > the ULN; liver imaging if AST or Alk phos > ULN; Bone scan if alk phos ≥ 2.5 x ULN or bone pain.			0 - 120
AST	≤ 1.5 x ULN	w/in 6 wks				0 - 50
ALT	≤ 1.5 x ULN	w/in 6 wks				0 - 50
Total Protein		w/in 6 wks				6.4 - 8.5
Serum Creatinine → OR		w/in 6 wks				0.50 -1.00
Creatinine clearance (calculated) → OR	60mL/min	w/in 6 wks				
ECHO or MUGA	LVEF% ≥50%	w/in 90 days				
ECG (EKG)		w/in 90 days				
Chest Imaging (Chest CT or Chest x-ray)						
Bilateral Breast Imaging: MRI is permitted before entry as a substitute for mamm. (U/S is not). Imaging will be unilateral for pt's who have had mastectomy w/out reconstruction. **Ipsilateral breast w/in 90 days Contralateral breast w/in 180 Days**						

☐ **Reviewed w/pt: REQUIRED TUMOR BLOCK MUST BE RELEASED TO THE STUDY GROUP;** ☐ **BLOOD SAMPLES - Optional**

☐ **Reviewed w/pt: Contact research nurse if considering participation in another investigational study/clinical trial.**

☐ **Reviewed w/pt: Required tobacco, alcohol and comorbid conditions questionnaire to be completed after signed consent.**

Clinical Research Nurse: _____ **Date:** _____

MD signature:_____ **Date:**_____

B-52 Ineligibility Criteria (Patients with one or more of the following conditions are NOT eligible)	Circle
Was FNA alone used to diagnose the breast cancer?	Yes No
Was excisional biopsy or lumpectomy performed prior to randomization?	Yes No
Did the pt have a surgical axillary staging procedure prior to randomization? Pre-neoadjuvant therapy sentinel node biopsy in not permitted.	Yes No
Is there definitive clinical or radiologic evidence of metastatic disease for this pt?	Yes No
Did the pt have synchronous bilateral invasive breast cancer?	Yes No
Did the pt have synchronous or previous contralateral invasive breast cancer?	Yes No
Does the pt have a hx of ipsilateral invasive breast cancer or ipsilateral DCIS?	Yes No
Did the pt have tx including RT, chemotherapy, targeted therapy, or endocrine therapy for the currently dx breast cancer prior to randomization?	Yes No
Did the pt have previous endocrine therapy such as raloxifene or Tamoxifen (or other SERM) or an aromatase inhibitor for any malignancy?	Yes No
Did the pt have previous therapy with anthracycline, taxanes, carboplatin, trastuzumab, or other HER2 targeted therapies for any malignancy?	Yes No
Will the pt continue to receive sex hormonal therapy, e.g., birth control pills, ovarian hormone replacement therapy?	Yes No
Does the pt have a history of non-breast malignancies within the past 5 years? If yes, were the other malignancies limited to one or more of the following: in-situ cancers tx only by local excision, and basal and squamous cell carcinomas of the skin?	Yes No
Does the pt have angina pectoris that requires the use of anti-angina medication?	Yes No
Doses the pt have ventricular arrhythmias except for benign premature ventricular contractions?	Yes No
Does the pt have supraventricular or nodal arrhythmias requiring a pacemaker or not controlled with medications?	Yes No
Does the pt have conduction abnormality requiring a pacemaker?	Yes No
Does the pt have valvular disease with a documented compromise in cardiac function?	Yes No
Does the pt have symptomatic pericarditis?	Yes No
Does the pt have a hx of myocardial infarction documented by elevated cardiac enzymes or persistent regional wall abnormalities on assessment of LV function?	Yes No
Does the pt have a hx of documented CHF?	Yes No
Does the pt have a hx of documented cardiomyopathy?	Yes No
Does the pt have active hepatitis B or hepatitis C with abnormal liver function test?	Yes No
Does the pt have intrinsic lung disease resulting in dyspnea?	Yes No
Does the pt have poorly controlled diabetes mellitus?	Yes No
Does the pt have active infection or chronic infection requiring chronic suppressive antibiotics?	Yes No
Is the pt known to be HIV positive with a baseline CD4 count of <250 cells/mm3 or have a hx of AIDS indicator conditions? Pt taking anti-retroviral therapy that may have a potential overlapping toxicity with the study therapy are not eligible.	Yes No
Does the pt have a nervous system disorder (paresthesia, peripheral motor neuropathy or peripheral sensory neuropathy) ≥ grade 2 per CTCAE v4.0?	Yes No
Does the pt have malabsorption syndrome, ulcerative colitis, resection of the stomach or small bowel, or other disease significantly affecting gastrointestinal function?	Yes No
Does the pt have other non-malignant systemic disease that would preclude the pt from receiving study treatment or would prevent required follow-up?	Yes No
Does the pt have any conditions that would prohibit administration of corticosteroids?	Yes No
Does the pt have chronic daily tx with corticosteroids with a dose of ≥ 10 mg/day methylprednisolone equivalent (excluding inhaled steroids)?	Yes No
Does the pt have know hypersensitivity reaction to any of the study drugs or excipients of these drugs (e.g., polysorbate 80), including sensitivity to benzyl alcohol?	Yes No
Women of childbearing age: pregnancy test performed results:	Yes No
Is the pt pregnant or lactating at the time of study entry?	Yes No
Does the pt have psychiatric or addictive disorders or other conditions that in the opinion of the investigator would preclude the pt from meeting the study requirements?	Yes No
Has the pt used any investigational product within the past 30 days?	Yes No
Does the pt have an ECOG performance status of 2+?	Yes No

Clinical Research Nurse: _____ **Date:** _____

MD signature: _____ **Date:** _____