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

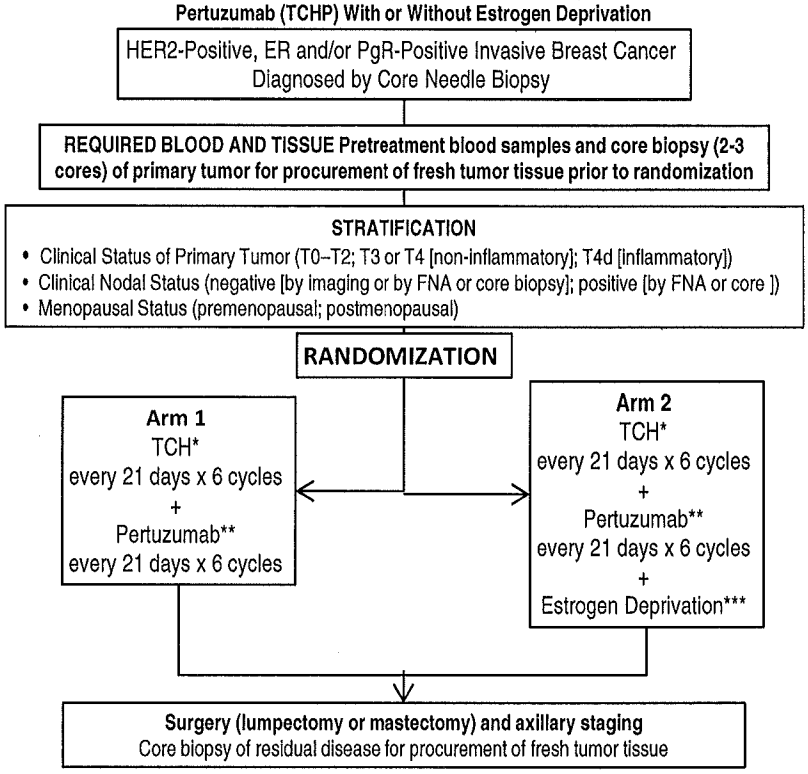
2. RN/CRA Communication
   a. Calendars for data submission (Coordinator On-Line, local systems, web based systems)
   b. New consult list in excel
   c. Checklist for newly activated trials
   d. Treatment Planning Approval
   e. Protocol Deviation Documentation/Quality Improvement Checklist
   f. Helpful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

Contact: Primary RN: Chris Wilson RN 628-1930; #4370.
Kit Munson RN 628-4712 #4559; /Cheryl Wood RN 828-4549 #4649

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:** _____

INFORMED CONSENT PROCEDURE
FOR PARTICIPATION IN CLINICAL TRIALS

Missouri Baptist Cancer Center
Clinical Research Program

Patient_____ **Study number** _____

Investigator_____ **Date informed consent form was presented** _____

1. I presented the informed consent document for this study to the patient after a complete discussion of the risks and benefits associated with participation in this clinical trial.

2. The patient was provided with an opportunity to ask questions. The patient's questions were answered to the patient's satisfaction.

3. The patient was offered an opportunity to take the informed consent document home and to consider carefully the opportunity to enroll in this clinical trial.

4. The patient was given the telephone number of the clinical research associate involved with this study at our institution, in case additional questions or concerns arose.

5. After considering all of the information relevant to this particular study, the patient signed and dated the informed consent document and was enrolled in this clinical trial.

The patient was given a photocopy of the informed consent document for the patient's personal records.

Investigator's signature _____ **Date** _____

Informed Consent Process Checklist (Protocol Name _____)

Patient Name: _____ **MR #:** _____ **ECOG status** _____

(ICF Version Date: _____)

The patient was given the opportunity to review the consent and to have questions answered. Y or N

The patient has been informed about the risks and benefits of the study and that participation is voluntary and one has the right to withdraw without prejudice. Y or N

Randomization was discussed. Y or N or N/A

The patient was educated about: (circle all that apply) medication side effects/ radiation side effects/ study length/ tests or procedures required for the study/ and/or _____.

The patient has been informed about the costs related to taking part in the study and has been informed about any tests/procedures that will be paid for by the study. Y or N

Study specific procedures that are beyond standard of care were obtained after the informed consent was signed. Y or N or N/A

The mental status and emotional capacity of the patient was adequate to give an informed consent. Y or N

The need to avoid pregnancy/causing pregnancy was discussed. Y or N or N/A

A copy of the signed informed consent was given to the patient. Y or N

Research staff contact information was given to the patient. Y or N

Patient agreed to: (circle all that apply) additional blood samples/ tissue samples/ QOL/ and/or _____. Y or N or N/A

HIPAA signed ☐ Release of Information signed ☐ Contact Sheet ☐
Permission for photo to be taken for identification purposes: Y or N
Life Expectancy form signed by MD ☐ or N/A ☐

PROCEDURE FOR BLOCK REQUEST TO THE STUDY GROUP: It has been explained to the patient the advantages and disadvantages of releasing to the study group, especially if it is the **only** paraffin block containing diagnostic material.
The patient understands and agrees to participate in the study. Y or N or N/A

Research RN: _____ **Date:** _____

Consent packet was copied and filed in patient's medical record.

Date: _____ **Signature:** _____

Date of initial discussion with MD:	Patient Name:
Date of initial discussion with research staff:	D.O.B.:
Date of follow-up discussion:	Protocol:

Informed Consent Process

Y / N The subject has expressed an understanding of the nature and implications of his/her disease, can make a reasonable decision and clearly communicate that decision: The informed consent was reviewed.

Y / N The patient was given the opportunity to review the consent and to have questions answered.

Y / N The patient was given a telephone number for the enrolling physician as well as the research staff in the even there were further questions.

Y / N A copy of the signed informed consent was given to the patient.

Y / N Study specific procedures that are beyond standard of care were obtained after the informed consent was signed.

Y / N The patient has been informed that participation is voluntary and one has the right to withdraw without prejudice.

Y / N The mental status and emotional capacity of the patient was adequate to give an informed consent.

Y / N Randomization was discussed.

Y / N The need to avoid pregnancy/causing pregnancy was discussed.

Y / N During the informed consent process, the patient was accompanied by family member(s)/friend(s) _____.

Zubrod performance status must be 0 or 1 =_____.
The subject has a life expectancy of greater than 10 years.
I have reviewed the eligibility criteria with this patient and at this point he/she appears eligible.

Research Staff:_____ Date:_____

Informed Re-consent Process Checklist (Protocol Name _____)

Patient Name: _____ **MR #:** _____ **ECOG status** _____

(ICF Version Date: _____)

The changes to the protocol were discussed with the patient. Y or N

The patient wishes to continue on the study. Y or N

The patient was given the opportunity to review the consent and to have questions answered. Y or N

The mental status and emotional capacity of the patient was adequate to give an informed consent. Y or N

A copy of the signed informed consent was given to the patient. Y or N

Research staff contact information was given to the patient. Y or N

Research RN: _____ **Date:** _____

A copy of revised consent and re-consent checklist was filed in patient's medical record.

Date: _____ **Signature:** _____

Date: _____

Dear _____

I am sorry I missed you when I called today. As I explained in my message I am enclosing a letter for you to sign and date supporting your wish to withdraw your consent permanently from any further follow up (clinical or survival) to the protocol _____.

If you would, please sign and date the enclosed letter and return it to me. I am enclosing a self-addressed stamped envelope for your convenience.

Thank you for your participation in this study. I wish you the best of health and if we can be of any assistance please call.

Thank you,

PATIENT INFORMATION:	PROTOCOL INFORMATION:
Patient: Medical Record #: Physician:	Protocol Sponsor: Title: Patient Number:

WITHDRAWAL OF CONSENT FOR STUDY PARTICIPATION

I, withdraw my consent to participate in the above-mentioned study and do not wish to be contacted in the future.

PATIENT SIGNATURE _____ Date _____

PATIENT NAME _____

WITNESS SIGNATURE _____ Date _____

WITNESS NAME _____

PHYSICIAN SIGNATURE _____ Date _____

NSABP B-52 ON-STUDY CHECKLIST

PATIENT'S NAME _____ **MR#** _____

- ❒ Email RN with assigned tx
- ❒ Forward two copies of confirmation and treatment assignment with a "DOC" blue pack to research nurse who will notify primary care nurse. Add the date Ht & Wt was taken prior to randomization
- ❒ RN consent note
- ❒ Verify confirmation schedule with A form
- ❒ Copy of Confirmation Sheet with Ht, Wt and BSA to Pharmacy
- ❒ Give research RN a supply of unsigned Rxs for all study-supplied drugs; she will get appropriate MD signature
- ❒ If pt is being treated at Stony Point, send to SP: □ Confirmation Schedule □ Dose Mod pgs □ Dose rounding pgs □ Treatment Schedule (Blue Packet)
- ❒ If patient is being treated here, provide research nurse with a Massey Cancer Center Folder including her card, emergency call in sheet, and other schedules if applicable.
  □ Confirmation Schedule □ Dose Mod pgs □ Dose rounding pgs □ Treatment Schedule (Blue Packet)
- ❒ Prepare a protocol chart
- ❒ Flag Chart for Audit
- ❒ Create a pt schedule
- ❒ Put day of first treatment in appt book and add pts name to the list on file cabinet
- ❒ Create and file a Follow-Up Card
- ❒ Update Follow-Up list
- ❒ Contact Sheet
- ❒ Request Block of Tumor from Pathology
- ❒ Enter pt in ONCORE; print out a yearly report and a protocol report and file in notebook
- ❒ Reorganize the work-up folder with a new checklist. File back in research nurse's box
- ❒ Outstanding documentation still needed for on-study
  - ❒ _____
  - ❒ _____

Eligibility Check

Screening Date:_____ Protocol: _____
Patient's Name: _____ DOB: _____
Physician: _____ Location: _____

Registering/Randomization CRA:_____

Registration/Randomization Date: _____
Start Date: _____
Patients must initiate treatment within_____working days of registration.
Consent Date:_____ **HIPAA Date:** _____

Labs
Completion Date: _____
Required #of days prior to registration: _____

Radiology
Completion Date: _____
Required # of days prior to registration: _____

Previous Treatment
Last treatment: _____
Required # of days prior to treatment on this protocol: _____

Medication Review: _____

Needed/Issues:_____
_____
_____

2nd eligibility check by: _____ **Date:**_____

Needed/Issues:_____
_____
_____

PATIENT ENROLLMENT WORKSHEET

PATIENT NAME:		**PROTOCOL:**	
MR#:		**DATE OF REFERRAL:**	
PHYSICIAN:		**COORDINATOR:**	

DATE	TASK	QA REVIEW		
		☑	Initials	Date of review
	Confirm correct version of Informed Consent	☐		
	HIPAA and Informed Consent given to patient			
	HIPAA and Informed Consent signed/dated by patient	☐		
	HIPAA and Informed Consent signed/dated by witness	☐		
	Informed Consent signed/dated by investigator	☐		
	Informed Consent process documentation complete	☐		

	Preliminary review of eligibility *(comments):*	Completed within 24 hours of referral
	Baseline tests ordered *(comments):*	
	Physician notification regarding referral *(comments):*	Completed within 48 hours of referral

	Planned registration/randomization date	
	Planned treatment start date	
	Case deemed eligible by Coordinator	
	Coordinator Signature:	

Comments:	

REQUIREMENTS FOR PATIENT REVIEW OF ELIGIBILITY:

Provide completed patient enrollment forms, signed/dated HIPAA and Informed Consent, consent process documentation All source document that confirms eligibility or is a protocol entry requirement (i.e. "X" list items) and all source documents that may not confirm eligibility or a protocol entry requirement, but help to understand or support the case *(i.e., other surgeries, other pathology, PCP progress notes, other lab, etc.)*

ATTACHED SOURCE DOCUMENTATION *(check all that apply)*:

REQUIRED FORMS		REQUIRED FORMS	
HIPAA Authorization Form (All Pages)	☐	Consent Process Documentation	☐
Informed Consent (All Pages)	☐	Protocol Registration/Enrollment Forms	☐
Other:	☐	Other:	☐
Other:	☐	Other:	☐

REQUIRED PATIENT SOURCE DOCUMENTS:		REQUIRED PATIENT SOURCE DOCUMENTS:	
History & Physical Note(s)	☐	CT Report(s) (Specify):	☐
Performance Status	☐		☐
Height/Weight	☐		☐
Vital Signs (temp/pulse/RR)	☐		☐
Other History (Specify):	☐	Other CT (Specify):	☐
Operative Report(s)	☐		☐
Pathology Report(s)	☐	MRI (Specify):	☐
CBC, Diff, PLTS	☐	Bone Scan	☐
Chemistry (Specify):	☐	Mammogram	☐
	☐	MUGA	☐
PT/PTT	☐	EKG	☐
Other Laboratory (Specify):	☐	CXR	☐
Urinalysis	☐	Other X-Rays (Specify):	☐
24h. Creatinine Clearance	☐	Other:	☐
Pregnancy test	☐	Other:	☐
Other:	☐	Other:	☐
Other:	☐	Other:	☐
Other:	☐	Other:	☐
Other:	☐	Other:	☐

PENDING SOURCE DOCUMENTATION *(fill-in spaces and check all that apply)*:

	☐		☐
	☐		☐
	☐		☐
	☐		☐
	☐		☐
	☐		☐
	☐		☐

QA Comments:	

FINAL REVIEW OF ELIGIBILITY CRITERIA BY QA:

☐ Case NOT APPROVED for registration

☐ Case APPROVED for registration

Reviewer Signature: **Date of review:**

	Registration/Randomization Date
	Assigned Treatment:

Missouri Baptist Medical Center

BJC HealthCare℠

Group 2 Trastuzumab
Trastuzumab provided

TITLE OF STUDY: *NSABP B-43* - A Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2-Positive Ductal Carcinoma In Situ Resected by Lumpectomy

Patient: _____ DOB: __/___/___ Pt ID #: _____ Cycle: _____

Ht: ____ inches Wt: _____lbs. BSA: ____ m^2 ANC = _____ PLTS = _____

1. Premedication:
   Acetaminophen 650 mg po 30 minutes prior to Trastuzumab
   Diphenhydramine 25 mg po 30 minutes prior to Trastuzumab

2. Trastuzumab 8mg/kg loading dose (first dose) =_____mg in 250 ml NS IV over 90 minutes, then

3. Trastuzumab 6mg/kg= _____mg in 250 ml NS IV over 30 minutes (if the patient tolerated the initial 90-minute infusion) three weeks following Dose 1.

NOTE: Trastuzumab treatment is a total of two doses only!

General instructions:

If RT is ≥25 fractions: Administer Trastuzumab within 1 week before RT begins or within the first 5 days of RT (on or before Day 5 of RT).

If accelerated RT fractionation is used (16-17 fractions): Administer Trastuzumab within 1 week before RT begins or within the first 2 days of RT (on or before Day 2 of RT).

MD Signature _____ Date: _____ Time:_____

Reviewed by:
MD: APL
CRA: mcd
RPh: bkg

Updated 02/04/2010

Missouri Baptist Medical Center

BJC HealthCare℠

Study SCUSF 0806 – Phase II placebo-controlled trial of Lisinopril and Coreg CR to reduce cardiotoxicity in patients with breast cancer receiving (neo) adjuvant Chemotherapy with Trastuzumab (Herceptin)

Patient: _____ DOB: __/___/___ Pt ID #: _____

Lisinopril 10 mg or Coreg CR 10 mg or Placebo (Supplied by Study) # 96

Dose: Take one capsule by mouth once daily with food for 1 year (or until the last dose of Trastuzumab if Trastuzumab is given for less than 1 year). The dose should be taken around the same time each day.

First dose of Lisinopril or Coreg or Placebo should be taken on the morning of the day patient is scheduled to begin Trastuzumab.

Dispense Bottle #_____.

Refills: every 12 weeks until completion of therapy.

MD Signature _____ Date: _____ Time_____

To Be Dispensed:_____

Reviewed by:
MD: apl
CRA: <initials>
RPh: bkg

Updated Date

Version: date/amendment

NSABP B-47 A Phase III trial of adjuvant therapy comparing Chemotherapy alone to Chemotherapy plus Trastuzumab in Women with Node-Positive or High-Risk Node Negative HER2-Low Invasive Breast Cancer.

Patient name: Last, First
Registration date: 2/10/2012

Dose Dense AC
Group 2B AC followed by Weekly P+H followed by H

	Cycle 1	Cycle 2 **	Cycle 3	Cycle 4
H&P,		2/28/2012	3/16/2012	3/30/2012
Vital signs, Weight		2/28/2012	3/16/2012	3/30/2012
Documented PS		2/28/2012	3/16/2012	3/30/2012
AE assessment		2/28/2012	3/16/2012	3/30/2012
CBC		2/28/2012	3/16/2012	3/30/2012
CMP		2/28/2012	3/16/2012	3/30/2012
Study labs				
2DECHO or MUGA				
Menstrual HX assess				
(if uterus intact and premenopausal at randomization)				
Neulasta Day 2	2/15/2012	2/29/2012	3/17/2012	3/31/2012
Doxorubicin IV	2/14/2012	2/28/2012	3/16/2012	3/30/2012
Cyclophosphamide IV	2/14/2012	2/28/2012	3/16/2012	3/30/2012

Embedded formulas = E12+14 allows for date population

**TX delayed till 3/2/12, due to low neutrophils

	Taxol 1	Week 4	Week 7	Week 10
H&P,	4/17/2012	5/8/2012	5/29/2012	6/19/2012
Vital signs, Weight	4/17/2012	5/8/2012	5/29/2012	
Documented PS	4/17/2012	5/8/2012	5/29/2012	6/19/2012
AE assessment	4/17/2012	5/8/2012	5/29/2012	6/19/2012
CBC	4/17/2012	5/8/2012	5/29/2012	6/19/2012
CMP	4/17/2012	5/8/2012	5/29/2012	6/19/2012
Study labs	4/17/2012			
2D ECHO or MUGA (prior to 1st Taxol)	**4/17/2012**			
Menstrual HX assess	4/17/2012			
(if uterus intact and premenopausal at randomization)				
Paclitaxel IV Weekly	4/17/2012	5/8/2012	5/29/2012	6/19/2012
Trastuzumab weekly for 12 doses	4/17/2012	5/8/2012	5/29/2012	6/19/2012

NSABP B-47 A Phase III trial of adjuvant therapy comparing Chemotherapy alone to Chemotherapy plus Trastuzumab in Women with Node-Positive or High-Risk Node Negative HER2-Low Invasive Breast Cancer.

Patient name:
Registration date:

Dose Dense AC
Group 2B AC followed by Weekly P+H followed by H

	Week 13	Week 16	Week 19	Week 22	Week 25	Week 28	Week 31
H&P,		7/31/2012			10/2/2012		
Vital signs, Weight		7/31/2012			10/2/2012		
Documented PS		7/31/2012			10/2/2012		
AE assessment		7/31/2012			10/2/2012		
CBC							
CMP							
Study labs		7/31/2012					
2D ECHO or MUGA		**7/31/2012**				**10/23/2012**	
Menstrual HX assess		7/31/2012					
(if uterus intact and premenopausal at randomization)							
Trastumumab IV	7/10/2012	7/31/2012	8/21/2012	9/11/2012	10/2/2012	10/23/2012	11/13/2012
Trastuzumab every 3 weeks							

	Week 34	Week 37	Week 40	Week 43	Week 46	Week 49
H&P,	12/4/2012			2/5/2013		
Vital signs, Weight	12/4/2012			2/5/2013		
Documented PS	12/4/2012			2/5/2013		
				********		
AE assessment	12/4/2012			2/5/2013		
Menstrual HX assess						
(if uterus intact and premenopausal at randomization)				********		
Trastumumab IV	12/4/2012	12/25/2012	1/15/2013	2/5/2013	2/26/2013	3/19/2013
				********		
Trastuzumab is given for 51-52 weeks total including time given with weekly Taxol						

******** ***SEE SCHEDULE BELOW FOR ITEMS DUE 12 MONTHS FROM REGISTRATION***

AE ASSESSMENT MUST BE PERFORMED 30 DAYS AFTER LAST DOSE OF HERCEPTIN
CAN BE BASED ON PE OR PHONE ASSESSMENT

NSABP B-47 A Phase III trial of adjuvant therapy comparing Chemotherapy alone to Chemotherapy plus Trastuzumab in Women with Node-Positive or High-Risk Node Negative HER2-Low Invasive Breast Cancer.

Dose Dense AC
Group 2B AC followed by Weekly P+H followed by H

	Month 12	Month 18	Month 24	Month 30	Month 36	Month42	Month 48
H&P,	2/5/2013	8/6/2013	2/4/2014	8/5/2014	2/3/2015	8/4/2015	2/2/2016
VS's, Wt. Ht.	2/5/2013	8/6/2013	2/4/2014	8/5/2014	2/3/2015	8/4/2015	2/2/2016
Documented PS	2/5/2013	8/6/2013	2/4/2014	8/5/2014	2/3/2015	8/4/2015	2/2/2016
Assessments:	2/5/2013	8/6/2013	2/4/2014	8/5/2014	2/3/2015	8/4/2015	2/2/2016
Adverse Event	2/5/2013	8/6/2013	2/4/2014	8/5/2014	2/3/2015	8/4/2015	2/2/2016
Concomitant meds	2/5/2013		2/4/2014		2/3/2015		2/2/2016
Alcohol/Tabacco	QOL		QOL		QOL		QOL
Menstraul HX	2/5/2013	8/6/2013	2/4/2014	8/5/2014	2/3/2015		
2DECHO or MUGA	2/5/2013						
Bilateral Mamm	2/5/2013		2/4/2014		2/3/2015		2/2/2016
Study labs	2/5/2013						
Study labs MH study	2/5/2013	8/6/2013	2/4/2014				

	Month 54	Month 60	Month 66	Year 6	Year 7	Year 8	Year 9
H&P,	8/2/2016	1/31/2017	8/1/2017	1/30/2018	1/30/2019	1/30/2020	1/29/2021
VS's, Wt. Ht.	8/2/2016	1/31/2017	8/1/2017	1/30/2018	1/30/2019	1/30/2020	1/29/2021
Documented PS	8/2/2016	1/31/2017	8/1/2017	1/30/2018	1/30/2019	1/30/2020	1/29/2021
Assessments:	8/2/2016	1/31/2017	8/1/2017	1/30/2018	1/30/2019	1/30/2020	1/29/2021
Adverse Event							
Concomitant meds		1/31/2017					
Alcohol/Tabacco		QOL					
Bilateral Mamm		1/31/2017		1/30/2018	1/30/2019	1/30/2020	1/29/2021

	Year 10
H&P,	1/29/2022
VS's, Wt. Ht.	1/29/2022
Documented PS	1/29/2022
Assessments:	1/29/2022
Adverse Event	1/29/2022
Concomitant meds	
Alcohol/Tabacco	
Bilateral Mamm	1/29/2022

NSABP B-43 A Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2-Positive Ductal Carcinoma In Situ Resected by Lumpectomy

Patient Name: Last, First Name
Date On Study: 06/27/2014
Group 2- Radiation and Herceptin

	Dose 1 Herceptin	Dose 2 Herceptin	During RT Per Usual Practice	30 Days Post RT
H&P, PE		7/23/2014	**********	**********
RT Oncologist Eval (Post-op)				
Height & Weight				
Menopausal Status				
Menstrual History				
AE Assessment		7/23/2014	**********	**********
Bilateral Mammogram				
Preg Test If Applicable Herceptin IV	7/2/2014	7/23/2014		

Follow up years 1-5 From Randomization:
History and PE every 6 months
Menstrual History at 18 months only
Mammograms every 12 months

Follow up years 6-10 From Randomization:
History and PE and Mammograms yearly

B-52 AE form

Name: **MR#** **Group:** **DATE**

Toxicity Evaluation: *GRADING CTC AE v 4.0.* (CTC AE ATTRIBUTION CODES: 1= unrelated, 2= unlikely, 3= possible, 4= probable, 5= definite

Events	GRADE 1	GRADE 2 Refer to protocol (table 11 & 12)	GRADE 3	GRADE 4	ATTRIBUTION T C H	ATTRIBUTION Pertuzumab	ATTRIBUTION Estrogen Deprivation	Date of onset Date of resolution
Fatigue	Fatigue relieved by rest	Fatigue not relieved by rest; limiting instrumental ADL	Fatigue not relieved by rest; limiting self care ADL		T 1 2 3 4 5 C 1 2 3 4 5 H 1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	
Nausea	Loss of appetite without alteration in eating habits	Oral intake decreased without significant wt loss, dehydration or malnutrition	Inadequate oral caloric or fluid intake; tube feedings, TPN or hospitalization		T 1 2 3 4 5 C 1 2 3 4 5 H 1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	
Vomiting (Despite anti-emetics)	1-2 episodes separated by 5 mins in 24 hours	3 - 5 episodes separated by 5 mins in 24 hours	>6 episodes separated by 5 mins in 24 hrs; tube feedings, TPN or hosp. indicated	Life- threatening consequences; urgent intervention indicated.	T 1 2 3 4 5 C 1 2 3 4 5 H 1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	
Diarrhea **Baseline:** _____ /day	Inc. < 4 stools/day over baseline; mild increase in ostomy output compared to baseline	Inc. of 4-6 stools day over baseline; mod. Increase in ostomy output compare to baseline	Inc. of >= 7 stools /day over baseline; incontinence; hospitalization indicated; severe increase in ostomy output; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	T 1 2 3 4 5 C 1 2 3 4 5 H 1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	
Pt educated on use of antidarrheal meds : loperamide, and non pharm. intervention. (e.g. increasing fluid, eating small frequent meal								
Mucositis: oral clinical exam	Asymptomatic; clinical or diagnostic observation only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; TPN indicated; elective operative or endoscopic intervention indicated; disabling.	Life- threatening consequences; urgent operative intervention indicated	T 1 2 3 4 5 C 1 2 3 4 5 H 1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	
Neuropathy: Paresthesia	Mild symptoms	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL		T 1 2 3 4 5 C 1 2 3 4 5 H 1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	
Neuropathy: Peripheral motor	Asymptomatic	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL; assistive device indicated	Life-threatening consequences; urgent intervention indicated	T 1 2 3 4 5 C 1 2 3 4 5 H 1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	
Neuropathy: Peripheral sensory	Asymptomatic; loss of deep tendon reflexes or paresthesia	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	T 1 2 3 4 5 C 1 2 3 4 5 H 1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	
Definition: A disorder characterized by inflammation or degeneration of the peripheral sensory nerves								
Musculoskeletal & CT: Arthralgia	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	Musculoskeletal & CT: Arthralgia	T 1 2 3 4 5 C 1 2 3 4 5 H 1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	
Definition: A disorder characterized by a sensation of marked discomfort in a joint.								
Musculoskeletal & CT: Myalgia	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	Musculoskeletal & CT: Myalgia	T 1 2 3 4 5 C 1 2 3 4 5 H 1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	
Definition: A disorder characterized by marked discomfort sensation originating from a muscle or group of muscles.								
Dyspnea: Difficulty breathing	Shortness of breath with moderate exertion	Shortness of breath with minimal exertion; limiting instrumental ADL	Shortness of breath at rest; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	T 1 2 3 4 5 C 1 2 3 4 5 H 1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	
Dyspnea grade 1, 2, 3: hold trastuzumab & Pertuzumab r/o heart failure & non-infectious lung disease to determine etiology; see table 11 page 54 of protocol.								
Hypoxia		Decreased O_2 saturation with exercise (e.g., pulse oximeter <88%); intermittent supplemental oxygen	Decreased O_2 saturation at rest (e.g., pulse oximeter <88% or PaO2 <=55 mm Hg)	Life-threatening airway compromise; urgent intervention indicated (e.g., trach. or intubation)	T 1 2 3 4 5 C 1 2 3 4 5 H 1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	
Definition: A disorder characterized by a decrease in the level of oxygen in the body.								
Cough	Mild symptoms; nonprescription intervention indicated	Moderate symptoms, medical intervention indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL		T 1 2 3 4 5 C 1 2 3 4 5 H 1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	
Pneumonitis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL; oxygen indicated	intervention indicated; limiting Life-threatening resp. comp.; urgent intervention indicated (e.g., tracheotomy or intubation	T 1 2 3 4 5 C 1 2 3 4 5 H 1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	
Cardiac Disorders	Trastuzumab and pertuzumab will not be continued (Arms 1 and 2) following any **grade 2** cardiac AE listed in Table 12. Pg 55 (Trastuzumab and pertuzumab should be administered following any of the other grade 2 AEs listed in the Cardiac Disorders section of the CTCAE v4.0, but not listed on Table 12 or in Section 11.5.)							
Other AE's:	Describe and grade with CTC 4.0:				T 1 2 3 4 5 C 1 2 3 4 5 H 1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	

Performance status: _____ Comments: _____

MD/ NP _____ **Date:** _____ **Research RN:** _____ **Date:** _____

Created 5/2014

THE CENTER FOR CANCER CARE AND RESEARCH
ADVERSE EVENT FLOW SHEET

List all medical conditions present at baseline(BL) and check the baseline box. It is only necessary to update the baseline medical conditions if there is a change in the grade, relationship to study drug or disease process, treatment changes, or resolution of the condition / event. Concomitant medications captured here must be reflected on the **Concomitant Medication Form.**

BL	ADVERSE EVENT (USE NCI/CT TERMINOLOGY) NCI CTC VERSION _____	GR	RELATIONSHIP TO STUDY DRUG 1=Definite 2=Probable 3=Unlikely 4=Not related	SAE? (Y/N)	ACTION TAKEN WITH STUDY DRUG 1=None 2=Tx Interrupted / delayed 3=Dose reduced 4=discontinued	START DATE	STOP DATE	CONCOMITANT MEDICATION REQUIRED (LIST)	RN INITIAL

INITIALS	SIGNATURE	INITIALS	SIGNATURE

Physician Signature: _____ Date: _____

Patient Name: _____

THE CENTER FOR CANCER CARE AND RESEARCH

RECIST TUMOR ASSESSMENT WORKSHEET: TARGET LESIONS

	Date of exam: _____ ☐ Baseline ☐ Cycle # _____		Date of exam: _____ Cycle # _____		Date of exam: _____ Cycle # _____	
Type of exam						
Lesion Description (Anatomic Location)	Measurement		Measurement		Measurement	
1.	Bidimensional Measurement (cm)	Longest Diameter & Image #	Bidimensional Measurement (cm)	Longest Diameter & Image #	Bidimensional Measurement (cm)	Longest Diameter & Image #
2.	___X___	_____cm Image #_____	___X___	_____cm Image #_____	___X___	_____cm Image #_____
3.	___X___	_____cm Image #_____	___X___	_____cm Image #_____	___X___	_____cm Image #_____
4.	___X___	_____cm Image #_____	___X___	_____cm Image #_____	___X___	_____cm Image #_____
5.	___X___	_____cm Image #_____	___X___	_____cm Image #_____	___X___	_____cm Image #_____
6.	___X___	_____cm Image #_____	___X___	_____cm Image #_____	___X___	_____cm Image #_____
7.	___X___	_____cm Image #_____	___X___	_____cm Image #_____	___X___	_____cm Image #_____
8.	___X___	_____cm Image #_____	___X___	_____cm Image #_____	___X___	_____cm Image #_____
9.	___X___	_____cm Image #_____	___X___	_____cm Image #_____	___X___	_____cm Image #_____
10.	___X___	_____cm Image #_____	___X___	_____cm Image #_____	___X___	_____cm Image #_____
SUM OF LONGEST DIAMETERS ➢						
New Lesions						
A.			___X___	_____cm Image #_____	___X___	_____cm Image #_____
B.			___X___	_____cm Image #_____	___X___	_____cm Image #_____
Physician Signature and Date -OR-	_____ Signature _____ Date		_____ Signature _____ Date		_____ Signature _____ Date	
RN Signature and Date AND Date of Radiology Report	_____ Signature _____ Date _____ Date of Report		_____ Signature _____ Date _____ Date of Report		_____ Signature _____ Date _____ Date of Report	

NOTE: These measurements/assessments supersede any other source pertaining to lesion measurements/assessments for the above dates

THE CENTER FOR CANCER CARE AND RESEARCH

RECIST TUMOR ASSESSMENT WORKSHEET: NON-TARGET LESIONS

	Date of exam: _____ ☐ Baseline ☐ Cycle # _____	Date of exam: _____ Cycle # _____	Date of exam: _____ Cycle # _____
Type of exam			
Lesion Description (Anatomic Location)	Status (Present / Absent)	Status: (Increased / Decreased / Stable / Absent)	Status: (Increased / Decreased / Stable / Absent)
1.			
2.			
3.			
4.			
5.			
6.			
7.			
New Lesions			
A.			
B.			
Physician Signature and Date -OR-	Signature Date	Signature Date	Signature Date
RN Signature and Date AND Date of Radiology Report	Signature Date Date of Report	Signature Date Date of Report	Signature Date Date of Report

NOTE: These measurements/assessments supersede any other source pertaining to lesion measurements/assessments for the above dates

ASSESSMENT OF OVERALL RESPONSE:
COMBINE ALL DATA FROM TARGET AND NON-TARGET FLOW SHEETS

Target Lesions	Non-Target Lesions	New Lesions	Overall Response
CR	CR	None	CR
CR	Non-CR/Non-PD	None	PR
PR	Non-PD	None	PR
SD	Non-PD	None	SD
PD	Any	Yes or NO	PD
Any	PD	Yes or No	PD
Any	Any	Yes	PD

TITLE OF STUDY:

New Protocol Check list **Date Completed**

Before Approved
• Paperwork for IRB (include in description last amendment)
• Put protocol in MOSAIQ
• Download / activate protocol in CREDITS
• Study Calendar
• Talking Points / Eligibility Packet (info. For MD's)
• Copy to Pharmacist
• Order lab kits/ QOL
• Create orders

After IRB Approval
• Set up binder
• Documentation to RSS or COOP GROUP
• Copy for satellite sites
• E-mail Chris: Post on Heartland website (drugs involved)
• Check for recent amendments

INSTITUTION CHECKLIST FOR NSABP B-52 PROTOCOL

Name:

Study #:

Hospital #:

Date of Surgery:

_____ **Consent Form**

_____ **Form ENTRY**

_____ **Path Report**

_____ **Form BLK (tissue)**

_____ **Form BNK (serum)**

_____ **Form RT**

TREATMENT & ADR FORMS **FOLLOW-UP FORMS**

Form TRTAE	Date Sent	Form TRTAE	Date Sent	Date Seen	Date Sent	Date Seen	Date Sent	Date Seen	Date Sent

Research Treatment Plan

To: Patient Financial Counselor
From: Research Department

The Research Department is currently reviewing the follow patient's records in consideration for participation in a clinical trial. Please contact their insurance provider to verify coverage for the treatment plan and participation in this Phase ____ clinical trial.

Patient Name: _____

Physician/site: _____

Study Number: _____

Treatment Plan:

Proposed treatment start date: _____

Drug/Dose (calculated)/route/frequency/total number cycles:

1. _____
2. _____
3. _____
4. _____

Drug(s) provided _____

Services provided (i.e. administration fees, etc.):

1. _____ 2. _____
3. _____ 4. _____
5. _____ 6. _____

_____ _____
Coordinator Signature Date

☐ Insurance approved this treatment plan and participation in the clinical trial referenced above.
☐ Insurance denied this treatment plan and participation in the clinical trial referenced above.

_____ _____
Patient Financial Counselor Signature Date

RESEARCH

NON-STANDARD OF CARE PROCEDURE AND BILLING INSTRUCTIONS

This patient is enrolled on a clinical trial. The tests / procedures listed below should ***NOT*** be billed to the patient or their insurance company. Please bill this / these tests / procedures to the contract account number listed below.

Patient: _____

Date of Birth: _____

LAB TESTS

Lab Test ordered: _____

Facility to perform test: _____

Bill to contract account number: _____

PROCEDURES

Procedure ordered: _____

Facility to perform procedure: _____

Bill to contract account number: _____

Attach this page to order for above tests and send with the patient. The patient should present this form at the time of registration for the above tests.

Please send invoice for above test/procedure to:

Your Institution and Address Contact Information

For questions about this form or the tests ordered please call _____ at _____.

PROTOCOL DEVIATION DOCUMENTATION FORM

Study Sponsor or Principal Investigator	Subject Number And Initials	Primary Coordinator of Study	Date of Occurrence	Notification Date

Protocol title and number	
Principal Investigator	
Deviation Category	☐ Informed Consent Issue ☐ Eligibility Criteria ☐ Study therapy: Incorrect drug / investigational agent ☐ Study therapy: Incorrect dosing / dose modification ☐ Schedule of event error ☐ Tumor measurement / disease response issue ☐ Regulatory Issue ☐ Pharmacy mixing error ☐ Other
Specific details regarding the incident, cycle number and dates:	
Plan of Action to prevent event from occurring in the Future:	

_____ _____

Clinical Research Coordinator Completing the form Date

_____ _____

Principal Investigator Signature Date

The original deviation form should be filed in the Regulatory Binder for the study and a copy filed in the patient's CRF or medical record if the CRF's are completed electronically. A copy of this form must be sent to the IRB with a cover letter. A copy of the IRB cover letter and IRB response must be filed in the Regulatory Binder.

Original 11/6/2003

CONTINUOUS QUALITY IMPROVEMENT RECORD
COORDINATOR REVIEW

The Supervisor will randomly choose research patients and conduct this review. The results will be filed in the Research Coordinator's anecdotal file and be used to complete the coordinator's annual performance review.

Coordinator: _____

Study: _____ Date of review: _____

	Coordinator Review	Yes	No	N/A	Comments
CONSENT PROCESS REVIEW					
1	Current consent form signed				
2	Consent signed by individual performing consent process				
3	Consent signed and dated by investigator with same date as patient				
4	If investigator signed on different date explanation is documented				
5	Documentation of consent process in source				
ELIGIBILITY REVIEW					
1	Patient eligibility verified				
2	Confirmation of diagnosis by pathology report				
3	Staging performed and documented per protocol				
4	Tumor assessment documented prior to registration				
5	Performance status documented				
6	Laboratory parameters within protocol limits				
7	Eligibility verified-documented				
8	Protocol exception documented if appropriate				
TREATMENT REVIEW					
1	Pink sheets consistently completed				
2	Patient visit consistently recorded on calendar				
3	BSA calculated and documented accurately				
4	Protocol specific instructions recorded on treatment sheet for treatment room RN's				
5	Treatment doses calculated and documented accurately				
6	Protocol specific treatment administered				
7	Treatment modifications recorded accurately				
8	Treatment discontinuation documented in source				
TOXICITY GRADING REVIEW					
1	All adverse events completely recorded on AE flow sheet				
2	Note in narrative record that AE's reviewed with patient at each visit				
3	AE's graded according to protocol specific grading tool				
4	Doses modified according to toxicities per protocol				
5	Serious adverse events recorded on AE flow sheet				
6	SAE's reported within 24 hours to sponsor and CCOP/Main Member Institution with documentation provided				
7	SAE follow-up reports completed appropriately				
8	Hospital chart copy on file as necessary				
9	Information from hospital chart recorded in CRF				

10	Concomitant meds from SAE recorded in CRF				
11	AE's from hospital chart recorded in CRF				
12	AE's followed for 30 days after treatment discontinuation or until resolution or the condition is considered chronic				
13	AE flow sheet signed by investigator when complete				
14	If patient enters another study, current AE flow sheet closed after study specific follow-up period and new flow sheet started				
LAB SCHEDULING AND RESULT REVIEW					
1	Lab tests ordered according to protocol				
2	Lab abnormal values addressed as needed				
3	Central lab specimens processed accurately and sent				
4	Lab kits ordered as needed				
DATA VERIFICATION REVIEW					
1	CRF's completed within 2 weeks of patient visit				
2	CRF's are neat and legible				
3	Corrections made with single line through original entry, correction written and labeled with initials and date				
4	Data queries are completed in a timely manner				

DRUG ACCOUNTABILITY REVIEW					
1	Study specific drug accountability log complete				
2	All heading information on log complete				
3	Study drug logged in on day of receipt				
4	Receipt verification returned to sender on day of receipt with signed copy in accountability book				
5	Drug dispensing logged on day drug dispensed				
6	Accountability records are accurate				
7	Study drug stored according to protocol specifications				
8	Storage temperature logs are completed daily on days office is open				
SOURCE DOCUMENT MANAGEMENT REVIEW					
1	Source documents are available for review				
2	Documents are legible				
3	Charts are maintained in reverse chronological order				
4	Hospital charts are copied and on file as needed				
5	Completed patient charts are filed in research department or in storage				

Reviewer signature: _____ Date:_____

Audit Preparation Checklist

Patient Name: _____ **Protocol:** _____

List all deviations noted during the preparation process on back of this form. We'll have a centralized folder for these notes.

Consent

_____ Confirm that there is an original signed consent form for each patient in the Research Chart and a copy of the consent in the patient chart. Flag with blue colored tag.
_____ All areas completed (yes/no boxes, investigators signature, etc.).
_____ If there was a reconsent issue, double check to be sure that it is present. Flag this item. It will probably be the only item flagged in the Research Chart.

Randomization

_____ Identify the stratification factors from confirmation of registration form and confirm that they were correctly marked. Confirm that the patient received the correct treatment!!! No need to tag.

Eligibility – Flag with 2" green tags

_____ Working from the Eligibility and Tests to be Performed sections of the protocol, confirm and tag each criterion (path, labs, scans, initial PE, etc.) in the clinic chart. Mark tags with appropriate name (path, CBC, CMP, CT, etc).
_____ Confirm in the research chart that all prestudy data has been submitted including data forms, path, op, CTs, etc.

Treatment – initial treatment flag with reg tags, subsequent treatment Blue tags

_____ Tag chemotherapy orders and administration notes only generally as they will run consecutively. Be sure that administration dates, nursing note dates, flow sheet dates concur. Be sure any dose mods or delays are explained in notes.
_____ Tag RT consult and end of treatment notes.

Toxicity – flag

_____ Tag only grade 3 or higher unexpected toxicities. Remainder should be evident in notes.

Response (if applicable, flag with yellow tags)

_____ Tag method of measurement for each designated time interval. Mark CR, PR, SD, etc. Determine where we can find films for auditors for each assessment. Make list of these patients and we will gather all films, etc. at one time for all.

Follow-up

_____ Double check to see that follow-up intervals are correct. If our docs didn't see patient, be sure that we have note from other source and flag it since it probably won't be in MD notes. Double check that all data forms are submitted.

CRA HELPFUL HINTS

WHY DIDN'T I THINK OF THAT!

1. Print up a sheet of labels to include patient initials, protocol number and patient ID. These can be used to put on any supporting documentation that needs to be submitted or these can be used to place on your sample submissions.

2. If specimen kits are not provided, make one ahead of time and put them in labeled baggies. This saves time for you and a covering co-worker. (Be sure to check expiration kits on tubes and provided kits!)

3. Keep a frozen specimen log. This should include the patient name or initials, the patient protocol #, visit name (prestudy, month 3, etc.), collection date/time, study and shipment date. (Why?? You will be ready to ship when dry ice becomes available and you won't forget about a specimen!)

4. If a patient is taking oral study medication, make up a hand out sheet with the medication directions in LARGE print. Include a contact name and phone number. Print this information out on colored paper to give to the patient.

5. When a patient signs consent try to get at least three contact names with phone numbers (Cell/home/work) as well as an address (even email!) for use in long term follow-up.

6. Think about sending the patient a thank-you letter for participating in a clinical trial. This really makes the patient feel as though they have made a difference in cancer treatment for future generations.

7. Excel listings can be your organizational friend!

8. Protocol Recruitment Strategies: visit tumor conference; physician team planning meetings; present clinical trial information to support groups/church groups, etc. to promote trials; evaluate each new patient who

is seen in your clinic for possible trial participation; market tools for patients- bags, pins; update physicians on new trials and remind them about the older trials; physician sticker reward program.

9. HELPFUL WEBSITES:

CTCAEv4.0 MedDRA Codes=
http://safetyprofiler-ctep.nci.nih.gov/CTC/CTC.aspx

Calculated Creatinine Clearance Calculator=
http://www.clinicalculator.com/english/nephrology/cockroft/cca.htm

Date wheel to calculate cycles=
http://www.datewheel.net

Obituary search of over 900 national and international newspapers=
http://www.legacy.com/pressrepublican/Obituaries.asp?Page=ObitFinder

Free printable calendars=
http://www.printfree.com/CalendarsPrintableYearly.htm

National Library of Medicine=
http://www.nlm.nih.gov/medlineplus/

NCI Website=
http://www.cancer.gov/

NRG Oncology Website
http://www.nrgoncology.org/

10. Communication!

SUGGESTIONS FOR AVOIDING "LOST-TO-FOLLOW-UP" FOR PATIENTS IN NSABP TRIALS

Maintain confidentiality, observe the relevant aspects of the Privacy Rule and comply with any local guidelines of your Privacy Officer when trying to locate patients through outside parties.

- Maintain a relationship with the patient and patient's family:

  All individuals following the patient should establish a working relationship with the patient. Send birthday cards and recognize personal events to maintain close contact and an excellent rapport.

  Request three additional contacts such as friends and family who would be aware of any contact changes.

- Maintain an updated contact list.

  Check with patient every six months to determine if there have been any contact changes.

  Maintain a current list of all doctors who the patient sees with the addresses and phone numbers and obtain releases from them.

- Work with patient's treating physician and request that he or she contact the patient directly by phone.
- Contact the patient by mail requesting a response:

  Send a brief fill-in-the-blank type form with the labeled space for the patient's signature and date. Send a stamped or prepaid, addressed return envelope.

- If nonresponsive to regular mail, utilize certified, return receipt request mail.
- Utilize the telephone directories on the Internet. These will list telephone numbers and addresses with a defined area.
- Contact the tumor registry in every institution in which the patient has been seen (for any reason), document which institution maintains follow-up records for future contacts.
- Contact local (county, state or province) vital statistic departments to see if the patient has died.
- Contact Social Security Administration (1-800-772-1213) with social security number; they can give the date of death but not the cause.
- Utilize the criss-cross directory in the public library. This lists by address.
- Document changes in phone numbers and addresses (patient and contacts), include the date that the change was discovered.
- Document the contact name and phone number that you called in the chart note, even if you were not successful. This will prevent approaching unproductive contacts repeatedly.
- Contact the Voter's registration office. State laws apply.
- A commercial mechanism is Find People Fast (1-800-829-1807). This firm will attempt to locate individuals using the social security number or last address within 7 years. Cost with social security number: $25, with address: $30.

  Check the on-line obituary section of the local newspaper where the patient resides and/or the city where the patient was born or has family.

Prepared by the NSABP CRA Committee
Revised 9-26-2003 CFB
Revised 2-2004 CTN & CRA Committees
Revised 4-2010 CTN & CRA Committees

CRA HELPFUL HINTS

What do you mean from A-Z?

- ACRP= Association of Clinical Research Professionals
- ASCO= American Society of Clinical Oncology
- ASH= American Society for Hematology
- CCRA= Certified Clinical Research Associate (ACRP)
- CCRC= Certified Clinical Research Coordinator (ACRP)
- CCRP= Certified Clinical Research Professional (SoCRA=Society of Clinical Research Associates)
- CDC= Center for Disease Control
- CFR= Code of Federal Regulations
- CLIA= Clinical Laboratory Improvement Amendments
- CI= Confidence Interval
- CME= Continuing Medical Education
- COI= Conflict of Interest
- CR= Complete Remission
- CRA= Clinical Research Associate
- CRC= Clinical Research Coordinator
- CRF= Case Report Form
- CTCAEv4.0= Common Toxicity Criteria for Adverse Events version 4.0
- CTEP= Cancer Therapy Evaluation Program (NCI)
- CTEP-AERS= CTEP Adverse Event Reporting System
- CTMB= Clinical Trials Monitoring Branch
- CTSU= Clinical Trials Support Unit
- CEU= Continuing Education Unit
- CV= Curriculum Vitae
- DFS= Disease Free Survival
- DHHS= Department of Health & Human Services
- DSMB= Data Safety Monitoring Board
- EDC= Electronic Data Capture
- EFS= Event Free Survival
- FDA= Food and Drug Administration
- FDA-1572= FDA form for Statement of Investigator
- FWA= Federalwide Assurance
- GCP= Good Clinical Practice

- HIPAA= Health Insurance Portability and Accoutability Act
- HHS= Health and Human Services (Department of)
- HR= Hazard Ratio
- IB= Investigator's Brochure
- ICF= Informed Consent Form
- IND= Investigational New Drug
- IRB= Institutional Review Board
- IND= Investigational New Drug
- JCAHO= Joint Commission of Accreditation of Health Care Organizations
- LOA= Letter of Agreement
- LAPS= Lead Academic Participating Sites
- MedDRA= Medical Dictionary for Regulatory Activities
- MM= Main Member
- NCCF= National Childhood Cancer Foundation
- NCI= National Cancer Institute
- NCORP= NCI Community Oncology Research Program
- NIH= National Institutes of Health
- NOS= Not otherwise specified
- NRG Oncology= Legacy Groups NSABP, RTOG, GOG
- OHRP= Office for Human Research Protection
- ONS= Oncology Nursing Society
- OS= Overall Survival
- PD= Progressive Disease
- PFS= Progression Free Survival
- PID= Patient ID
- PR= Partial Response
- PHI= Protected Health Information
- PI= Principal Investigator
- PMB=Pharmaceutical Management Branch
- QOL= Quality of Life
- RECIST= Response Evaluation Criteria in Solid Tumors
- SAE= Serious Adverse Event
- SOP= Standard Operating Procedures
- WBI= Whole Breast Irradiation

BRING THIS DIARY AND STUDY MEDICATION BOTTLE(S) TO EACH CLINIC VISIT, OR AS DIRECTED BY **RESEARCH NURSE.**

Name _____ MR# _____ 9455 PART 2 Cycle # _____

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Version date of this diary: 1/27/2014
Year Date															
Trametinib _____mg; take _____# pills each day. Take trametinib by mouth on an empty stomach, either 1 hr before or 2 hrs after a meal. You will take the medication once per day, at the same time each day. If you miss a dose of your medication, you should take it as soon as you remember that day up to 6 hrs past the scheduled time. If more than 6 hrs has passed since the scheduled time, DO NOT take the missed dose.	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	Please inform your research nurse and study doctor of any new medications you are taking.
	time	time	time	time	time	time	time	time	time	time	time	time	time	time	
GSK2141795 _____mg; take _____# pills each day. GSK2141795 must be taken 1 hour after a meal and two hours before the next meal. It is recommended that you take trametinib in the morning and GSK2141795 in the evening, however this is not required. You will take the medication once per day, at the same time each day. If you miss a dose of your medication, you should take it as soon as you remember that day up to 6 hours past the scheduled time. If more than 6 hours has passed since the scheduled time, DO NOT take the missed dose.	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	
	time	time	time	time	time	time	time	time	time	time	time	time	time	time	
FATIGUE															**Comments:**
Mild															
Moderate															
Severe															
NAUSEA/VOMITING															
Nausea															
Vomiting (# of times)despite anti-nausea medicine															
Loss of appetite															
Upset stomach															
BOWEL HABITS baseline _____	Diarrhea is defined as "The frequent passage of abnormally watery stool" may have abdominal cramping. It is NOT soft stool or frequent soft stool. **Keep count of how many stools you have on your symptom Diary.**														
Diarrhea															

★**If Diarrhea occurs notify treating physician and / or research nurse before starting Imodium. If instructed by MD/CRN to take Imodium, follow instructions closely (refer to pt education material). Indicate on diary # of Imodium pills.**

Name _____ MR# _____ 9455 PART 2 Cycle # _____

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Version date of this diary: 1/27/2014
Year Date															
Imodium 4 mg (Only 1st dose)															
Imodium 2 mg															
Constipation															
SKIN REACTION *TAKE PICTURE at on set*															
Itching															
Rash (bumps, skin coloring etc)															
Cracking or peeling of the hands and/or feet															
Nail changes															
Use of any topical agents "creams"															
Vision changes:	**Notify your treating physician and research nurse if you are experiencing visual changes or concerns**														
Trouble focusing															
Vision blurry															
Pain															
Hypertension *greater than 140/90*															
CARDIOVASCULAR															
Abnormal heartbeat															
Chest pain															
Dizziness															
Fainting															
Shortness of breath (Dyspnea)															
Swelling of feet & ankles															
INFECTIONS:															
Temperature:															
Symptoms (cold, UTI)															
EMOTIONAL															
Depressed															
Anxious															
Other symptoms															

Name _____ # _____ 9455 PART 2 Cycle # _____

Day	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
Year Date															
Trametinib _____mg; take _____# pills each day. Take trametinib by mouth on an empty stomach, either 1 hr before or 2 hrs after a meal. You will take the medication once per day, at the same time each day. If you miss a dose of your medication, you should take it as soon as you remember that day up to 6 hrs past the scheduled time. If more than 6 hrs has passed since the scheduled time, DO NOT take the missed dose.	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	Please inform your research nurse and study doctor of any new medications you are taking.
	time	time	time	time	time	time	time	time	time	time	time	time	time	time	
GSK2141795 _____mg; take _____# pills each day. GSK2141795 must be taken 1 hour after a meal and two hours before the next meal. It is recommended that you take trametinib in the morning and GSK2141795 in the evening, however this is not required. You will take the medication once per day, at the same time each day.	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	# pills	If you miss a dose of your medication, you should take it as soon as you remember that day up to 6 hours past the scheduled time. If more than 6 hours has passed since the scheduled time, DO NOT take the missed dose.
	time	time	time	time	time	time	time	time	time	time	time	time	time	time	
FATIGUE															**COMMENTS:**
Mild															
Moderate															
Severe															
NAUSEA/VOMITING															
Nausea															
Vomiting (# of times)despite anti-nausea meds															
Loss of appetite															
BOWEL HABITS baseline _____	Diarrhea is defined as "The frequent passage of abnormally watery stool" may have abdominal cramping. It is NOT soft stool or frequent soft stool. **Keep count of how many stools you have on your symptom Diary.**														
Diarrhea															
★**If Diarrhea occurs notify treating physician and / or research nurse before starting Imodium. If instructed by MD/CRN to take Imodium, follow instructions closely (refer to pt education material). Indicate on diary # of Imodium pills.** See pt education material															
Imodium 4 mg (Only 1st dose)															
Imodium 2 mg															
Constipation															

Name _____ # _____ 9455 PART 2 Cycle # _____

Day	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
Year Date															
SKIN REACTION *TAKE PICTURE at on set*															
Itching															
Rash (bumps, skin coloring etc)															
Cracking or peeling of the hands and/or feet															
Nail changes															
Use of any topical agents "creams"															
Vision changes:	**Notify your treating physician and research nurse if you are experiencing visual changes or concerns**														
Trouble focusing															
Vision blurry															
Pain															
Hypertension *greater than 140/90*															
CARDIOVASCULAR															
Abnormal heartbeat															
Chest pain															
Dizziness															
Fainting															
Shortness of breath (Dyspnea)															
Swelling of feet & ankles															
INFECTIONS:															
Temperature															
Symptoms (cold, UTI)															
EMOTIONAL															
Depressed															
Anxious															
Other symptoms															

Patient signature: _____ **DATE:** _____

Pill Count: **Trametinib** **Patient has taken** _____ **pills this cycle. Pt has missed** _____ **# of pills, as indicated on diary.**

GSK2141795 **Patient has taken** _____ **pills this cycle. Pt has missed** _____ **# of pills, as indicated on diary.**

This diary & pill log was reviewed with pt by the **Research Nurse/CRA** _____ DATE: _____

EMERGENCY CALL- IN FACT SHEET

If you need to call a doctor after regular office hours, it is very important for you to let the doctor answering your call know that you are a study patient, the name of your doctor, what you are receiving treatment for, the name of the study you are on, the names of the chemotherapy drugs you are receiving, and when you were last given a treatment. The research nurses have developed this sheet to help you remember this information.

Tell the doctor answering your call your name: _____
(Your name)

I am a patient of: _____
(Your doctor's name)

I am being treated for: _____
(The type of cancer you have)

I am being treated on the study: _____
(Study name and number)

My last treatment was on: _____
(The date of your last chemotherapy treatment)

The chemotherapy I received was: _____
(Chemotherapy name)

I am having a problem with: _____
(Explain your problem)

Prophylactic (prevention) and Symptoms Management:
NCI 9455

- **DIARRHEA:** Diarrhea is defined as "The frequent passage of abnormally watery stool" and may have abdominal cramping, not soft stool or frequent soft stool. Keep count of how many stools you have on your symptom Diary.

DIARRHEA is a common occurring toxicity associated with Trametinib and GSK2141795 study drug.

PLEASE have at home this over the counter (OTC) medication **Imodium (loperamide). Only take if instructed by MD or research nurse**

Diet: Stop all lactose containing products (dairy): eat small meals, such as the BRAT diet (banana, rice, apples, and toast)

Hydrate: drink 8-10 large glasses of clear liquids per day (e.g. Gatorade or broth)

If Diarrhea occurs notify treating physician and / or research nurse. Remember if after hours call 828-0951 for the Hem/Onc physician on call. Tell him you are on a phase II clinical trial and you have Imodium medications at home; but was instructed not to take until notifying the physician. If instructed to start Imodium, follow these instructions below.

- Initial dose Imodium 4 mg (two pills), followed by 2 mg every 4 hours or after every unformed stool: Maximum of 16 mg /day. Continue until diarrhea –free for 12 hours.
- If diarrhea greater 48 hours take Imodium 2 mg every 2 hours; maximum 16 mg /day. Notify the physician (Have your local pharmacy phone number handy); the physician may prescribe a second-line of therapies for you.
- Continue with the above diet and hydration recommendation.
- Patients who have any worsening of **fatigue, nausea, vomiting, right upper quadrant abdominal pain or tenderness, fever, rash, shortness of breath while taking anti-diarrhea meds contact your physician or physician on call ASAP – to avoid dehydration. You may need to have IV hydration.**
- Document all of the above on your symptom diary.

- **RASH**: remember to document on your symptom diary and try to take a picture.

Prevention and Prophylaxis: Rash prophylaxis is recommended for the first 6 weeks of study treatment.
avoid unnecessary exposure to sunlight

- Apply broad-spectrum sunscreen (containing titanium dioxide or zinc oxide) with a skin protection factor (SPF) ≥15 at least twice daily
- Use thick, alcohol-free emollient cream (e.g. glycerin and cetomacrogol cream) on dry areas of the body at least twice daily
- Topical steroids and antibiotics should be applied at least twice daily, starting on Day 1 of study treatment, to body areas such as face, chest and upper back.
- Use mild-strength topical steroid (hydrocortisone 1% cream) or topical antibiotics (clindamycin) or oral antibiotics (doxycycline)

Symptomatic Care: Patients who develop rash/skin toxicities should be seen your physician and research nurse for symptomatic /supportive care management.

- **Pruritic lesions defined as: symptoms of generalized itching, without rash it is a distressing symptom that can cause discomfort and threaten the effectiveness of the skin as a major protective barrier.**
  - Cool compresses and oral antihistamine therapies.
- **Fissuring lesions defined as: A linear discontinuation of the epithelial lining with a sharply demarcated margin, which can extend in to the dermis.**
  - Monsel's solution, silver nitrate, or zinc oxide cream.
- **Desquamation defined as the shedding of the outer layers of the skin**
  - Thick emollients and mild soap.
- **Paronychia defined as inflammation involving the folds of tissue around the fingernail.**
  - Antiseptic baths, OTC (local) potent corticosteroids in addition to antibiotics; if no improvement, consult treating MD and research nurse.
- **Infected lesions:**
  - Appropriate bacterial/fungal culture-driven systemic or topical antibiotics.

PATIENT CONTACT FORM

Date: _____

Patient's Name: _____

Address: _____

_____

Home Phone: _____ Cell Phone: _____

Work Phone: _____ E-mail Address: _____

Spouse's Name: _____

Please provide the names & addresses of three (3) people (other than spouse) who can always reach the patient. Include at least one (1) from patient's hometown, if out of state.

1. _____
First Name Last Name Relationship to Patient

_____
Street City/State Zip Phone

_____
Name of Spouse E-mail address

2. _____
First Name Last Name Relationship to Patient

_____
Street City/State Zip Phone

_____
Name of Spouse E-mail address

3. _____
First Name Last Name Relationship to Patient

_____
Street City/State Zip Phone

_____
Name of Spouse E-mail address