

Jefferson Kimmel Cancer Center Network Policy and Procedure Manual

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Jefferson Kimmel Cancer Center Network

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Jefferson Kimmel Cancer Center Network

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Section 3.0 New Coordinator Training Orientation

3.1 *Campus Keys: A Thomas Jefferson University (TJU) Unique Identifier*

JKCCN Contact: Vicki Squire, RN

A TJU campus key and password are required to access the following applications:

- Jefferson Remote Access Portal (RAP) <https://connect.tjuh.org>
- Within RAP, links to the Electronic adverse event reporting system (eSAEy) and the Electronic unanticipated problem reporting system (eazUP)
- Jefferson Kimmel Cancer Center Network (JKCCN) Consent Form Repository <http://www.kimmelcancercenter.org/kcc/JKCCN/file-repository/>

The following information is necessary to establish a campus key and should be submitted to Vicki Squire:

- Name
- Email address
- Work phone
- Home zip code
- Date of birth

It usually takes Jefferson's Information Technology Department two weeks to process your campus key. They will call you to inform you of your campus key and initial password.

Please note: The remote access portal is the first point of entry to get to the eSAEy and eazUP applications; this is a two-step process. The remote access portal requires a password change every 3 months, but there is not an automatic notification process in place for alerting you to this requirement. If you are denied access, it will most likely be due to the need to change your password. To change your password go to the following link:

<http://campuskey.tjuh.net/selfchangepwd.jsp>

The same password works for RAP, eSAEy, eazUP, and the JKCCN consent form repository.

Your campus key will always remain the same.

3.2 *IRB Training in Human Subjects Protection*

All personnel working on any aspect of clinical research must complete IRB training before participating in any aspect of clinical research, especially the consent process. Initially, two certifications must be completed: 1) Training in human subjects' protection, and 2) HIPAA training.

For more information, please see the [Regulatory/IRB](#) section.

3.3 *Introduction to CTEP/CTSU*

JKCCN Contacts: Joshua Schoppe and Kelly Shipman

Thomas Jefferson University Hospital is a member of three federally-funded cooperative cancer research groups: **Eastern Cooperative Oncology Group (ECOG)**, **National Surgical Adjuvant Breast and Bowel Project (NSABP)**, and **Radiation Therapy Oncology Group (RTOG)**. The three groups research new anti-cancer regimens to treat a variety of disease sites through the utilization of different modalities, including surgery, chemotherapy, and radiotherapy.

The division of the National Cancer Institute (NCI) that funds cooperative research groups is called the Clinical Trials Evaluation Program (CTEP). In order to take part in the cooperative research group program each clinical research associate, must obtain a CTEP Associate ID # by setting up a CTEP Identity and Access Management (IAM) account. Having this ID # will allow you to take full advantage of the tools and information these groups have to offer. This ID # will be necessary to set up log-in and password information for the website of the Clinical Trials Support Unit (CTSU), which provides expanded access to NCI-funded phase 3 clinical trials.

Link to obtain CTEP ID #: <https://eapps-ctep.nci.nih.gov/iam>

New Accounts:

- Click the Request New Account link at the bottom right.
- Follow the application instructions through four steps. A unique e-mail address is required.
- You will be asked to select three security questions, and one must be answered any time a temporary password is changed.
- When you receive your CTEP-IAM approval email, click the link provided in the email and activate your account by changing your temporary password to a permanent password.

Several resources are available on the CTSU website within the “Education and Resources” tab.

For additional information, contact the CTEP Registration Help Desk by phone at 301-496-9910 (Monday through Friday 8.30am to 4.30pm) or by e-mail at ctepreghelp@ctep.nci.nih.gov.

For more information, please see the [CTSU](#) section.

3.4 *Eastern Cooperative Oncology Group (ECOG)*

A multi-disciplinary organization devoted to the prevention, treatment, and cure of adult malignancies.

For more information, please see the [ECOG](#) section.

JKCCN Contact: Joshua Schoppe

3.5 *National Surgical Adjuvant Breast and Bowel Project (NSABP)*

A national cooperative group conducting clinical trials for treatment and prevention of breast and colorectal cancer.

For more information, please see the [NSABP](#) section.

JKCCN Contact: Vicki Squire

3.6 *Radiation Treatment Oncology Group (RTOG)*

A national cooperative group conducting clinical trials to evaluate new forms of radiotherapy delivery and to test new systemic therapies in conjunction with radiotherapy.

For more information, please see the [RTOG](#) section.

JKCCN Contact: Kelly Shipman

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Section 4.0 JKCCN Accrual

Monthly Log

Contact: Rita Carlino

At the end of every month from Rita Carlino, Program Coordinator for the Jefferson Kimmel Cancer Center Network will send an e-mail that asks for your institution's past month's accrual. Please provide the following information:

- The number of patients accrued for each disease site
- The race and gender for each patient accrued

Note: Please also include patients enrolled to clinical trials that are not open through Jefferson.

Submission of the Monthly Log is expected to be sent in even if zero patients have been accrued during the past month.

Upon completion of the Log, please fax or e-mail your reply to Rita Carlino by the date indicated in her e-mail. No cover page is necessary.

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Section 5.0 Cancer Trials Support Unit (CTSU)

The **CTSU** is a service of the National Cancer Institute that provides for clinicians across the US and Canada access to cancer treatment trials.

Participation is open for members and affiliates of the following Cooperative Groups:

ACOSOG	GOG
CALGB	NSABP
NCCTG	RTOG
NCIC CTG	SWOG
ECOG	

CTSU Administrator for the JKCCN: Joshua Schoppe

CTSU Data Administrator for the JKCCN: Kelly Shipman

5.1 CTSU Membership

Membership Registration is facilitated by the Cancer Therapy Evaluation Program Identity and Access Management (CTEP-IAM) System. This is required for all investigators who treat patients and prescribe medications as well as all key clinical trial personal. The purpose of the CTEP-IAM is to provide a central validation of all staff involved in the conduct of CTEP-sponsored trials, to facilitate identification of personnel found on multiple Group rosters, to provide access to other CTSU and CTEP databases and programs and to track/support regulatory compliance for Group Administrators and CTSU regulatory staff. More information on CTSU membership, please use the following link: https://www.ctsu.org/RegProced_ir-ar.asp

Accessing Protocols and Documents: Requires Password. You can search by cancer type, protocol ID number, and by lead cooperative group.

Link to CTSU website: <http://members.ctsu.org>

5.2 *Enrolling Patients to CTSU Protocols*

- Required components prior to patient enrollment: Enrolling physician must be registered and credentialed with the CTSU, all required Site Registration materials must be received and approved by the CTSU, patient informed consent must be obtained, all protocol-specific pretreatment evaluations must be performed and eligibility criteria must be satisfied
- FAX the Patient Enrollment Transmittal Form and protocol-specific enrollment forms (Eligibility Checklist and Registration Form) to the CTSU at 1-888-691-8039. The CTSU Registrar Office is open Monday – Friday from 9am – 5:30pm.
- CTSU Patient Registrars will:
 - Confirm the regulatory requirements are met
 - Verify completeness of faxed enrollment forms
 - Contact sponsoring Group to register the patient
 - Obtain Patient Identification Number and randomization assignment
 - Convey patient ID# and randomization assignment to site
- **For patient enrollments that must be completed within approximately 1 hour, please call the CTSU Cell Phone: 301-704-2376**

5.3 *Submitting Data through the CTSU*

- Instructions are always specified in protocol
- For the majority of studies, data forms (CRFs) are to be submitted to the Group leading the trial, using the methods outlined in the CTSU Logistical Appendix of each protocol document.
- Some protocols require collection of special materials: tumor blocks, slides, and/or copies of X-ray films. Read the protocol and send materials as instructed
- Queries are usually generated by and sent to sites by the Lead Group. Query responses should be submitted back to the Lead Group in the manner specified in the query letter or protocol document

5.4 *Education and Promotion*

Information on CTSU procedures, protocol-specific materials, audit resources, and other helpful resources can be found by visiting the “Education and Resources” tab on the CTSU member website.

CTEP-IAM Fact Sheet: https://members.ctsu.org/CTEP-IAM_FactSheet.pdf

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Section 6.0 Eastern Cooperative Oncology Group (ECOG)

Main Institution: Mayo Clinic (Rochester, MN)

Affiliate Institutions:

Albert Einstein Medical Center

Aria Health

Ephrata Community Hospital- Ephrata Cancer Center

Pocono Medical Center- Hughes Cancer Center

Hematology and Oncology Associates of NEPA, PC

Jennersville Regional Hospital

Thomas Jefferson University Hospital

Principal Investigator: William Tester, MD

Program Coordinator: Joshua Schoppe

Regulatory Contact: Rolma Mancinow

ECOG Coordinating Center

Address: Frontier Science, 900 Commonwealth Avenue, Boston, MA 02215

Phone: 617-632-3610

Fax: 617-632-2990

Link to ECOG website: <http://www.ecog.org>

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Section 7.0

Radiation Therapy Oncology Group (RTOG)

Main Institution: Thomas Jefferson University Hospital, RTOG Institution # 601

Affiliate Institutions:

190 Pocono Cancer Center
0608 Hudson Valley Oncology Associates
0610 Sparta Cancer Center
2213 Northeast Radiation Oncology Center
5101 Albert Einstein Medical Center

Principal Investigator: Maria Werner-Wasik, MD 215-955-7679

Contact: Kelly Shipman

Regulatory Contact: Rolma Mancinow

RTOG Headquarters

Address: 1818 Market Street, Suite 1600, Philadelphia, PA 19103

Phone: 215-574-3189 or 1-800-227-5463, x4189

Fax: 215-928-0153

Link to RTOG website: <http://www.rtog.org>

For questions regarding data submission, please call the RTOG Data Management Main Telephone number at 215-574-3214.

Orientation: A comprehensive orientation for Research Associates (RAs) is held every few months at RTOG headquarters in Philadelphia, as well as periodically at RTOG semi-annual meetings. An orientation schedule is listed on the RTOG website at <http://rtog.org/members/RAcorner.html>.

RTOG Audits: Please e-mail Kelly Shipman to view a Powerpoint presentation pertaining to RTOG audits.

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Section 8.0

National Surgical Adjuvant Breast and Bowel Project (NSABP Treatment Trials)

Main Institution: Kimmel Cancer Center at Jefferson, #717

Affiliate Institutions:

717-03 Mercy Fitzgerald Hospital
717-04 Aria Health
717-05 Riddle Memorial Hospital
717-07 Ephrata Community Hospital- Ephrata Cancer Center
717-08 Mercy Suburban Hospital-Norristown Regional Cancer Center
717-09 Associates in Hematology-Oncology, PC
717-10 Underwood Memorial Hospital
717-11 Sacred Heart Hospital
717-12 Pocono Medical Center- Hughes Cancer Center
717-13 Montgomery Hospital Medical Center
717-14 Hematology and Oncology Associates of NEPA, PC
717-15 Jennersville Regional Hospital
717-16 Sparta Cancer Center

Principal Investigator: Scott D. Goldstein, MD 215-955-5869

Program Coordinator: Vicki Squire, RN

Regulatory Contact: Rolma Mancinow

NSABP Biostatistical Center

Address: One Sterling Plaza, 210 North Craig St. Ste 500, Pittsburgh, PA 15213

Fax for case report forms: 412-622-2111

NSABP Clinical Coordinating Section

Phone: 800-477-7227

Email: ccs@nsabp.org

Nurses answer clinical questions related to protocol eligibility, treatment modifications, adverse events and other protocol logistics.

Link to NSABP Homepage: <http://www.nsabp.pitt.edu>

Jefferson Kimmel Cancer Center Network

Section 9.0

Jefferson Oncology Group (JOG)

The Jefferson Oncology Group (JOG) is a cancer research consortium comprised of members of the Jefferson Kimmel Cancer Center Network and their affiliated physicians.

Group Chairperson: Rita Axelrod, MD 215-955-1965

JKCCN Contacts: Vicki Squire and Joshua Schoppe

- New JOG Trials are announced in the JKCCN E-News published bi-weekly. On the same day, site investigators receive an email announcing the new JOG trial.
- Most sponsors need to establish US sites early in their timeline leading to trial activation, so usually the announcement of a new JOG trial and polling for Network interest will be done in advance of study activation by 2 to 3 months.
- To ensure your site is selected, response to the announcement by the deadline stated in the E-newsletter is crucial.

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Section 10.0
STAR Prevention Trial
(National Surgical Adjuvant Breast and Bowel Project)

Closed to Accrual November 4, 2004

Principal Investigator: Edith Mitchell, MD 215-955-8874

Program Coordinator: Vicki Squire, RN

Sites:

JEF 01- Kimmel Cancer Center at Jefferson

JEF 03- Riddle Memorial Hospital

JEF 05- Underwood Memorial Hospital

JEF 09- Mercy Fitzgerald Hospital

JEF 10- Aria Health

JEF 11- Ephrata Cancer Center

JEF 12- Sacred Heart Hospital

For questions concerning data submission call: 412-383-1100

Link to NSABP Homepage: www.nsabp.pitt.edu

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Section 11.0 Quality Assurance Program (Cooperative Group Research)

11.1 Purpose

- To promote continuous audit readiness
- To mutually establish action plans for performance improvement, as needed

11.2 Functions

Consent Quality Review

- Consents are reviewed to ensure agreement with cooperative group's template
- If discrepancies are noted, institutions are immediately notified and advice is given regarding informing patients

Patient Registration

- To ensure consent process is done in accordance with federal regulations and local IRB policy
- To enter patients into TJUH database by JKCCN, so that Network institutions can submit Serious Adverse Events for enrolled patients

Data Quality & Timeliness

- Quarterly and as needed, information on delinquent data is gathered by JKCCN and sent to institutions via e-mail
- Data Clarification Forms/queries from the cooperative groups are sent to Network sites for resolution

On-site Monitoring

- Periodic site visits to ensure research is conducted in accordance with federal, state, sponsor, and local IRB policies
- Review 20% of enrollment at each site and visit each site 2 times per year, or more often as needed

Jefferson Kimmel Cancer Center Network

Section 12.0 Regulatory/IRB

12.1 IRB Training in Human Subjects Protection

Two IRB training certifications must be completed before any clinical research participation is initiated: 1) Training in Human Subjects Protection, and 2) HIPAA training.

Link to IRB training: http://www.jefferson.edu/ohr/irb_training/

Certifying Exam

- To be taken every 3 years

This module consists of a mini-course with a comprehensive test. Set aside 2-3 hours for this if you are new to clinical research.

Annual training

- To be taken every 2 years (in between the certifying exam)

This module takes less than one hour to complete.

HIPAA training

- To be taken once

This module takes less than one hour to complete.

Step-by-step instructions to complete IRB training: Select the box “New User”. This link will take you to a page where you can enter your campus key and password (if you do not have a campus key and password, please contact Vicki Squire). You will then be prompted to complete any training you are missing. If you are a new user, you must complete the certifying exam and the HIPAA exam to be compliant with the IRB regulations.

Please remember the system is CASE SENSITIVE.

It is important to print your training certifications and keep them on file.

12.2 Disclosure of Conflicts of Interest

A completed Disclosure of Conflicts of Interest form is required each fiscal year (July 1st to June 30th) by University Policy. Additionally, government regulations require that this type of certification is on file for all individuals who are listed as investigators and clinical research personnel on research projects and/or protocols at Thomas Jefferson University.

The TJU IRB will not accept any clinical trial application (addendums, annual reviews or amendments) from your institution until all personnel have completed and submitted the disclosure form.

An e-mail reminder to complete this form will be sent every year at the end of May.

The Disclosure of Conflicts of Interest form can either be completed online or by sending a printed copy to Rolma Mancinow at the JKCCN office.

Link to University Counsel Website:

http://www.jefferson.edu/universitycounsel/compliance_conflict.htm

12.3 Adverse Event Reporting

Serious Adverse Event versus Adverse Event (Specified in protocol)

Serious Adverse Events*	Adverse Events (Toxicities)
Expedited vs. Regular Reporting: <ul style="list-style-type: none"> - Specified in Protocol - When in doubt as to regular vs. expedited: call sponsor or cooperative group 	Reporting to sponsor is usually due at the end of a cycle of treatment Reporting requirements are usually outlined on protocol case report forms
Expedited reporting: <ul style="list-style-type: none"> - Reporting within 24 hours of notification of the event 	
Regular reporting: <ul style="list-style-type: none"> - Time frame specified in protocol 	
Actions to take within protocol parameters for reporting serious adverse events: <ul style="list-style-type: none"> - JOG Trials- complete sponsor SAE Form and call JKCCN Office - Cooperative Group Trials- complete ADEERS and request copy of ADEERS sent to: <u>jkccn@kimmelcancercenter.org</u> 	
Thomas Jefferson University IRB Notification: <ul style="list-style-type: none"> - Submit an OHR-10 - Enter eSAEy system via Remote Access Portal <u>https://connect.tjuh.org</u> 	

***NOTE: All hospitalizations and deaths occurring during and within 30 days of protocol treatment are considered serious adverse events by the TJU IRB and require reporting via the eSAEy system.**

Please see the following pages for more detailed TJU IRB guidelines (taken from *Office of Human Research, Division of Human Subjects Protection Internal Policy*, Thomas Jefferson University and Hospitals, 2008).

**Office of Human Research
Division of Human Subjects Protection Internal Policy**

**100 General Administration (GA)
Policy GA 120: Policy and Procedure for Reporting and Reviewing Unanticipated
Problems Involving Risks to Subjects or Others**

1. PURPOSE

The purpose of this policy is to ensure prompt reporting to the IRB of Serious Adverse Events (SAEs) and Unanticipated Problems (UAPs) by principal investigators. Regulatory requirements of both DHHS (45 CFR 46.103(b)(5)) and FDA (21 CFR 56.108(b)(1)) require that "each IRB shall follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head of any unanticipated problems involving risks to subjects or others."

An unanticipated problem is one that is not described in the protocol or consent form.

2. PROBLEMS TO BE REPORTED TO THE IRB

The following must be reported to the IRB:

- An Adverse Event (AE) is any unfavorable and unintended sign including an abnormal laboratory finding, symptom or disease, temporally associated with the use of a medical treatment or procedure that may or may not be considered to be related to the medical treatment or procedure.
- Serious Adverse Events (SAE) are defined as any untoward occurrence that results in any of the following:
 - Death
 - A life-threatening adverse experience
 - Inpatient hospitalization or prolongation of an existing hospitalization
 - Persistent or significant disability or incapacity
 - Congenital anomaly or birth defect
- An Unanticipated Adverse Device Effect is any serious adverse effect on health or safety or any life-threatening problem or death caused by or associated with a device, if not identified in the device brochure, protocol, or consent form.
- Unanticipated Problems posing risks to subjects or others are unforeseen and indicate that participants or others are at increased risk of harm. Examples include but are not limited to the following:
 - An interim analysis of the data suggesting or indicating additional risk associated with a study procedure or test article.
 - A report (journal article or abstract, etc.) that shows that the risks or potential benefits of the research might now be different from those initially presented to the IRB.
 - A breach of confidentiality.

**Office of Human Research
Division of Human Subjects Protection Internal Policy**

- Change in FDA labeling or withdrawal from marketing of a drug, device, or biological used in a research protocol.
- Change made to the research without prior IRB review to eliminate an apparent immediate hazard to a subject.
- Incarceration of a subject in a protocol not approved to enroll prisoners.
- An event that requires prompt reporting to the sponsor.
- Sponsor imposed suspension for risk.
- Complaint of a subject when the complaint indicates unexpected risks or cannot be resolved by the research team.
- A change to a protocol or procedure that is not pre-approved by the IRB.
- Protocol violation (an accidental or unintentional change to the IRB-approved protocol) that may harm subjects or others or that indicates that subjects or others may be at increased risk of harm.
- Other unanticipated information that indicates participants or others might be at increased risk of harm.

Some events do not qualify as AEs, SAEs or Unanticipated Problems posing risks to subjects or others. Most of these are events or circumstances encountered in the usual course of receiving medical attention. Examples of these are pain or minimal bleeding/bruising at the time of venipuncture, drowsiness after sedation, boredom while waiting for the scheduled visit or procedure, or other similar scenarios.

3. REVIEW OF SAEs AND UAPs

Electronically submitted on-site SAE reports are forwarded to two IRB reviewers, a pharmacist and a physician, who may either accept the report and forward it to the Adverse Events Coordinator in the DHSP, or request clarifications or changes prior to forwarding to the AE Coordinator. If the SAE requires amendment to the protocol or consent, an OHR-12 must be submitted for IRB review. Once accepted, the SAE information is incorporated into the Division of Human Subjects Protection AE Database and, if no protocol or consent form changes are required, a synopsis is presented to the convened IRB at the time of continuing review.

Reports of unanticipated problems will be reviewed by the Director or Associate Director, DHSP, to determine whether the problem meets the definition of an "unanticipated problem involving risks to subjects or others" before deciding what, if any, action should be taken.

If this pre-review indicates that the event reported does not meet the definition of an "unanticipated problem", then no further action is required and the report is filed in the DHSP.

**Office of Human Research
Division of Human Subjects Protection Internal Policy**

If the unanticipated problem involves failure to follow federal or institutional human subjects regulations, further action may involve a non-compliance investigation/hearing.

If the pre-review determines that the problem reported represents an unanticipated problem involving risks to subjects or others, the Director/Associate Director, DHSP, will present the unanticipated problem to a convened IRB or assign a reviewer based on expertise and experience who will present the information to the Board. Immediate actions may also be necessary to eliminate any immediate hazards to subjects or others. If this is the case, the Director/Associate Director, DHSP, will notify the Board of the actions taken.

4. ACTIONS for CONSIDERATION BY THE CONVENED IRB

The convened IRB will consider the following actions during its deliberations:

- Modification of the protocol
- Modification of the information disclosed during the consent process
- Providing additional information to past subjects
- Notification of current subjects when such information might relate to their willingness to continue participation in the study
- Requirement that current subjects be re-consented
- Modification of the continuing review schedule
- Monitoring of the research and/or consent process by the DHSP QA/QI program
- Suspension of the research
- Termination of the research
- Referral to other organizational entities for further investigation

5. REPORTING OF ADVERSE EVENTS AND UNANTICIPATED PROBLEMS

On-site Adverse Events: On-site AEs and SAEs should be reported using the electronic AE reporting system (eSAEy) accessed at <http://www3.kimmelcancercenter.org/clinicaltrials/ae/>.

On-site SAEs that are deemed to be possibly or definitely related to the study article should be reported within 48 hours of knowledge of the event, except that death should be reported within 24 hours (one working day). Unrelated SAEs should be reported within 5 working days.

Off-site AEs/SAEs: Off-site AEs/SAEs or IND safety reports that require a change to the protocol and/or consent form should be submitted for review within 5 working days of knowledge of the event and be accompanied by a completed OHR10 off site report form and an OHR-12 form to effect the required amendment. Off-site AEs/SAEs or IND safety reports that do not require a change in the protocol or consent should not be reported to the IRB. A summary or itemized listing of these events should be included with the continuing review for the study.

**Office of Human Research
Division of Human Subjects Protection Internal Policy**

AE Grading: AEs should be categorized for severity using the Common Toxicities Criteria (CTC) version 3.0. This is incorporated into the eSAE reporting system. CTC version 3.0 can also be accessed at <http://ctep.cancer.gov/>.

Unanticipated Problems: Unanticipated problems that pose risk to subjects or others, and that are not AEs/SAEs should be reported within 10 working days using form OHR-20 along with an OHR-12 if an amendment is required.

Events that meet the reporting criteria in Policy GA 120 will be handled according to Policy GA 114, Reporting of Unanticipated Problems, Terminations, Suspensions and Non-compliance.

Approved by: (Signature on File)
Vice President for Research

Date: _____

(Signature on File)
Director, DHSP

Date: _____

Jefferson Kimmel Cancer Center Network

Section 13.0 Investigational Agent Handling



*Investigational Drug Service
Thomas Jefferson University Hospital
Department of Pharmacy*

March 2009

Pharmacists: Linda Sailor, PharmD
Rania Sadaka, PharmD

Address: 111 South 11th Street
2290 Gibbon
Philadelphia, PA 19107

Telephone: 215-955-6923
Beeper: 877-656-5774
Fax: 215-955-7946

Service email: ids-service.pharmacy@jeffersonhospital.org

General Information

The TJUH Department of Pharmacy operates an Investigational Drug Service (IDS). The Service manages all investigational drug studies for TJUH inpatients. IDS provides the service for a fee to physicians who are conducting outpatient investigational drug studies.

IDS provides many services ranging from preparation and dispensing of investigational agents, completion of accountability records, procurement and appropriate storage of medication. IDS can also prepare randomization schedules for studies, provide blinding of medication and conduct in-services to health care professionals to ensure proper study management.

IDS is staffed by 2 full-time pharmacists from the hours of 7 am through 4:30 pm Monday through Friday. The service provides coverage 24 hours/day, 7 days/week. Off-hour coverage is provided through Night Call along with our pharmacy residents. Night Call pharmacists and residents have been fully trained in the area.

TO OBTAIN DRUG: For some studies, IDS is considered the depot pharmacy for the Jefferson Kimmel Cancer Center Network. Study drug will only be shipped to IDS, which will then transfer to Network sites.

IDS requires the following information prior to drug shipment to network site:

- Signed patient informed consent
- Physician order for study medication
- Confirmation of patient enrollment/registration into specific study
- Contact name, telephone number and address of Network Site

A fax coversheet is available to facilitate this process (please contact IDS to obtain a copy of this form). Please allow sufficient time to ship medication. Provide date needed at network site on fax coversheet.

NOTE: Cooperative group studies do not typically provide a start-up supply of medication. Drug will not be shipped until enrollment/ registration is completed. Please keep this in mind when scheduling patients.

If you have any questions in regard to where drug must be obtained, you may either call the Jefferson Cancer Network or IDS for further assistance.

Drug Accountability Guidelines

POLICY: FDA regulations require investigators to establish a record of receipt, use and disposition of all investigational agents distributed by the Pharmaceutical Management Branch (PMB). The National Cancer Institute as a sponsor of investigational trials has the responsibility to assure the FDA that systems are in place by their investigators in their clinical trial program.

Investigators may practice and treat patients with investigational agents at more than one institution, however they must designate a single location as custodian to receive and manage the investigational agents. Simply stated there must be only one shipping address for a NCI designated physician. The Investigational Drug Service at TJUH is considered to be the central pharmacy for the Jefferson

Kimmel Cancer Center Network.

Procedures must be in place to maintain a satellite record for each agent transported to an affiliate institution. Transportation of NCI- supplied agents from a central location to a satellite must be done by institution staff or courier service. Secondary carriers such as Fed Ex or UPS must not be utilized. Please refer to the attached Transportation Policy and Procedure.

Industry-sponsored studies are not subject to the above regulations regarding transportation by staff and courier. Each industry-sponsored trial is handled on an individual basis, and study drug may be sent via FedEx for industry trials if Sponsor allows.

The entire procedure can be broken down into the following steps:

NOTIFICATION OF PATIENT ENROLLMENT

Once a patient has been identified at a satellite location, please complete the fax notification to IDS. Arrangements will be made to transport medication to the satellite location along with providing an estimated date of arrival.

TRANSPORT OF DRUG TO SATELLITE

Refer to the attached Transport Policy and Procedure. As stated in the policy, each shipment will be accompanied by a cover letter. Please inspect the shipment against the cover letter. If there are any discrepancies, please notify IDS immediately.

RECEIPT OF DRUG AT SATELLITE

Once drug has been inspected, complete a drug accountability record. IDS will provide an investigational drug accountability record with every shipment.

STORAGE OF DRUG AT SATELLITE

Investigational medication must be stored in a secure location where only authorized personnel have access. Store each investigational agent separately by protocol. Ensure proper temperature conditions are being maintained with valid documentation (ie; daily temperature logs).

COMPLETION OF INVESTIGATIONAL DRUG ACCOUNTABILITY RECORDS

The drug accountability record form (DARF) must be used for any transaction involving NCI-supplied agents from the PMB. This form may be downloaded from the CTEP web site.

The DARF can be broken down into 2 sections, upper portion and lower portion. The upper portion relates to specific information related to specific protocol and the treatment facility. The bottom portion is designed to record agent transactions (ie; receiving, dispensing). Please refer to the Pharmaceutical Management Branch Slideshow

http://ctep.info.nih.gov/branches/pmb/idh_slideshow.htm for specifics on how to complete DARF slides 16 through 29.

Some helpful hints to keep in mind for completing DARFS:

- Use black pen only
- Do not use white-out. If an error is made, place a single line through the error, date and initial
- Complete DARF in its entirety

RETURN OF UNUSED INVESTIGATIONAL MEDICATION & COMPLETED ACCOUNTABILITY RECORDS

Once a patient has completed treatment at the satellite location or the study has been closed to enrollment, return any unused medication to IDS (central location). The DARF must be completed indicating that drug has been returned to IDS. The balance on the DARF from the satellite location must equal zero showing that there are no supplies at the satellite. IDS will maintain the original DARF with the satellite maintaining a copy of the DARF.

Jefferson Kimmel Cancer Center Network

Section 14.0 Clinical Trial Payment

In order to receive appropriate payment for your enrolled patients, the JKCCN must receive notification when patients are enrolled at network affiliates. Notification is accomplished by faxing a completed JKCCN registration form to the JKCCN office at (215) 955-1020 at time of enrollment.

Payment for cooperative group (excluding RTOG) patient accruals

All cooperative group payments are sent to the JKCCN Office. JKCCN personnel process the checks and authorize payouts semi-annually. Each payment must first be tied to a patient accrual. To accomplish this:

- All registration forms must be received and databased
- Annual sub-award agreements must be signed by the network institutions and promptly returned to Jefferson's Office of Research Administration

JKCCN prepares invoices detailing each accrual and the corresponding payment for that accrual. Checks and invoices are sent to network institutions in care of its research coordinator via Fed-Ex.

Please address questions to Rolma Mancinow (ECOG) and Kelly Shipman (NSABP).

Payment for RTOG patient accruals

Payments for RTOG patients are sent directly to Network institutions by the Group who is given credit for those patients.

Payment for JOG patient accruals

As monies are received from the sponsor, payments are made to network institutions according to the "per patient" amount and milestones stated in the contract.

Procedure: Karen Gosik of the Kimmel Cancer Center will email an invoice to the study coordinator at the Network institution. The invoice should be printed on the Network institution's letterhead, signed by the Principal Investigator and sent to Karen Gosik.

Please address questions to Joshua Schoppe and Vicki Squire.

Jefferson Kimmel Cancer Center Network

Appendix I: JKCCN Source Documents and Forms

- Study-specific source documents:
 - [NSABP B-42 Patient's Pill Diary](#)
 - [NSABP B-43 Screening Document](#)
 - [NSABP B-44-I \(BETH\) Screening Document](#)
- [Patient's Pill Diary](#)
- [Oral Medication Record \(for coordinator use\)](#)
- [Concomitant Medications Log – Baseline](#)
- [Concomitant Medications Log – Update](#)
- [JKCCN Toxicity Flowsheet](#)
- [JKCCN QA Review Checklist](#)
- [JKCCN Registration Form](#)
- [My Usernames and Passwords](#)
- [Consent Review Source Document](#)

NSABP B-42 Patient's Medication Diary

Today's date _____ Agent _____ Dosage _____

Patient Name _____ (or initials) Patient Study ID _____

Adherence to treatment:

a) _____ # of pills dispensed on (date)

b) _____ # of pills returned on (date)

c) _____ # of pills expected to be taken

$[(a) - (b)] / (c) \times 100 =$ _____ % adherence to treatment

By patient report (every 6 months):

- *What percentage of the patient's study pills did she take?*

- All (100%)
- Almost all (approximately 90%)
- About three-fourths (approximately 75%)
- About half (approximately 50%)
- About one-fourth
- Only a few (less than 25%)
- None

- *How was this percentage determined?*

- Patient estimate
- Pill count
- Both

Comments: _____

Research Nurse/Coordinator's Signature and Date:

NSABP B-43 Eligibility Checklist – SCREENING

Patient Name: _____ Date of Birth: _____

Conditions for Patient Eligibility

A patient can not be considered eligible for this study unless all of the following conditions are met.

1. _____ The patient is female.
2. _____ The patient is 18 years of age or older.
3. _____ The patient has a life expectancy of at least 10 years, excluding her diagnosis of breast cancer.
4. _____ The patient has an ECOG performance status of 0 or 1. **Performance Status:** _____
5. _____ The patient of reproductive potential is willing to be on non-hormonal birth control during the study and for 6 months after completion of trastuzumab.
6. _____ The patient has signed and dated IRB/EC-approved consent forms that conform to the guidelines of the local regulatory authority and of the institution. The consent forms include a consent form for pre-entry central HER2 testing and a consent form for participation in the BETH trial (see Section 14.1).
7. _____ The patient has consented to submit tumor samples from her breast surgery for HER2 testing.
8. _____ On histologic examination, the tumor must be ductal carcinoma in situ (DCIS). (Patients with mixed DCIS and lobular carcinoma in situ [LCIS] are eligible.)
9. _____ The patient's DCIS must be HER2-positive as *determined by central testing* (see Sections 6.1 and 6.2 for details).
10. _____ The patient's estrogen and/or progesterone receptor status must be determined prior to randomization. (Patients who have DCIS that is hormone receptor positive or negative are eligible.)
11. _____ All DCIS has been resected by lumpectomy.
12. _____ The margins of the patient's resected specimen are histologically free of DCIS. For patients in whom pathologic examination demonstrates DCIS present at the line of resection, re-excision(s) may be performed to obtain clear margins. (Patients who require mastectomy are not eligible.)
13. _____ If axillary staging is performed, nodal staging is pN0, pN0(i-), pN0(i+) which is defined as isolated tumor cells $\leq 0.2\text{mm}$, regardless of the method of detection, i.e., IHC or H&E, pN0(mol-), or pN0(mol+). **Note: Axillary staging is not required.** (Refer to AJCC Staging Criteria in the Treatment Trial Information section in the Members' Area of the NSABP Web site for TNM nomenclature and staging information.) **Nodal staging:** _____
14. _____ The interval between the last surgery for excision of DCIS (lumpectomy or re-excision of lumpectomy margins) and randomization is no more than 120 days.
Date of surgery: _____ **Randomization date:** _____

Conditions for patient ineligibility

Any patient with one or more of the following conditions will be ineligible for this study.

1. _____ Invasive (including microinvasion staged as T1mic) breast cancer. (Patients with DCIS "suspicious" for microinvasion, but not confirmed, are eligible.)
2. _____ Nodal staging of pN1 (including pN1mi). (Note: Axillary staging is not required.)
3. _____ DCIS is present in more than one quadrant (multicentric).

4. _____ Masses or clusters of calcification that are clinically or mammographically suspicious unless biopsied and proven to be benign. (If DCIS is found, the patient is eligible if the DCIS was in the same quadrant of the ipsilateral breast and was resected with clear margins.)
5. _____ Contralateral breast cancer (including DCIS).
6. _____ Whole breast irradiation administered before randomization. (Partial breast irradiation is prohibited.)
7. _____ Prior history of breast cancer, including DCIS. (Patients with a history of LCIS are eligible.)
8. _____ Prior anthracycline chemotherapy for any malignancy.
9. _____ Cardiac disease that would preclude the use of the drugs included in the B-43 treatment regimens. This includes but is not confined to:

Active cardiac disease

- Angina pectoris that requires the use of anti-anginal medication;
- Ventricular arrhythmias except for benign premature ventricular contractions (PVCs) controlled by medication;
- Conduction abnormality requiring a pacemaker;
- Supraventricular and nodal arrhythmias requiring a pacemaker or not controlled with medication; and
- Clinically significant valvular disease

History of cardiac disease:

- Myocardial infarction documented by elevated cardiac enzymes or persistent regional wall abnormalities on assessment of LV function;
- Documented congestive heart failure; or
- Documented cardiomyopathy

10. _____ Uncontrolled hypertension, i.e., systolic BP greater than 180 mm/Hg and/or diastolic BP greater than 100 mm/Hg. (Patients with hypertension that is well controlled on medication are eligible.)
Blood pressure: _____
11. _____ Other nonmalignant systemic disease that would preclude a patient from receiving trastuzumab or radiation therapy or would prevent prolonged follow-up.
12. _____ Other malignancies unless the patient is considered to be disease-free for 5 or more years prior to randomization and is deemed by her physician to be at low risk of recurrence. Patients with the following cancers are eligible if diagnosed and treated within the past 5 years; carcinoma in situ of the cervix, carcinoma in situ of the colon, melanoma in situ, and basal cell and squamous cell carcinoma of the skin.
13. _____ Pregnancy or lactation at the time of study entry. (*Note: Pregnancy testing according to institutional standards should be performed for women of childbearing potential.*)
14. _____ Administration of any investigational agent within 30 days before study entry.
15. _____ Psychiatric or addictive disorders or other conditions that, in the opinion of the investigator, would preclude the patient from meeting the study requirements.

Form Completed By: _____ **Date:** _____

Investigator's Signature: _____ **Date:** _____

NSABP B-44-I (BETH) Eligibility Checklist – SCREENING

Patient Name: _____ Date of Birth: _____

Conditions for Patient Eligibility:

A patient cannot be considered eligible for this study unless all of the following conditions are met.

1. _____ The patient is female.
2. _____ The patient is 18 years of age or older.
3. _____ The patient has a life expectancy of at least 10 years, excluding her diagnosis of breast cancer.
4. _____ The patient has an ECOG performance status of 0 or 1 (see Appendix D).
5. _____ The patient is willing to be on non-hormonal birth control during the study and for 6 months post-treatment.
6. _____ The patient has signed and dated IRB/EC-approved consent forms that conform to the guidelines of the local regulatory authority and of the institution. The consent forms include a consent form for pre-entry central HER2 testing and a consent form for participation in the BETH trial (see Section 14.1).
7. _____ The patient has consented to submit tumor samples from her breast surgery for HER2 testing.
8. _____ If the patient has had breast reconstruction, tissue expansion is not planned within 2 weeks before first dose of bevacizumab, during bevacizumab treatment, and until 6 weeks following the last dose of bevacizumab.
9. _____ The tumor is unilateral invasive adenocarcinoma of the breast on histologic examination.
10. _____ The breast cancer is HER2-positive based on the test results as follows:
 - a. **Local testing** (if available) should demonstrate that the tumor is IHC 2+ or 3+ or is considered to be HER2-positive for gene amplification by FISH, CISH, or other in situ hybridization (ISH) method. (If local ISH test results are considered equivocal, the tumor can be submitted for central HER2 testing).
 - b. **Central testing** (a requirement for ALL patients) must demonstrate that the tumor is HER2-positive, which is defined as FISH-positive and/or IHC 3+.
11. _____ All of the following staging criteria (according to the 6th edition of the AJCC Cancer Staging Manual) have been met:
 - a. By pathologic evaluation, primary tumor must be pT₁₋₃ **Primary tumor:** _____
 - b. By pathologic evaluation, ipsilateral nodes must be pN₀, pN₁ (pN_{1mi}, pN_{1a}, pN_{1b}, pN_{1c}), pN_{2a}, pN_{3a}, or pN_{3b}
Ipsilateral nodes: _____
 - c. **If pN₀**, at least one of the following criteria must be met:
 - i. Pathologic tumor size > 2.0 cm; **Tumor size:** _____
 - ii. ER negative *and* PgR negative; **ER neg:** _____ **PgR neg:** _____
 - iii. _____ Histologic and/or nuclear grade 2 (intermediate) or _____ 3 (high); **or**
 - iv. Age < 35 years **Age:** _____
12. _____ The patient underwent either a _____ total mastectomy or _____ breast conserving surgery (lumpectomy).
13. _____ If the patient underwent lumpectomy, the margins of the resected specimen must be histologically free of invasive tumor and ductal carcinoma in situ (DCIS) as determined by the local pathologist. If pathologic examination demonstrates tumor at the line of resection, additional operative procedures may be performed to obtain clear margins. If tumor is still present at the resection margin after re-excision(s), the patient must undergo total mastectomy to be eligible. (Patients with margins positive for lobular carcinoma in situ [LCIS] are eligible without additional resection.)
14. _____ If the patient underwent mastectomy, margins must be free of gross residual tumor. Patients with microscopic positive margins are eligible (see Section 8.8 for radiation therapy [RT] requirements).
15. _____ The patient completed one of the following procedures for evaluation of pathologic nodal status:

- a. ____ Sentinel lymphadenectomy followed by removal of additional non-sentinel lymph nodes if the sentinel node (SN) is positive;
 - b. ____ Sentinel lymphadenectomy alone if pathologic nodal staging based on sentinel lymphadenectomy is pN₀, pN_{1mi} or pN_{1b}; or
 - c. ____ Axillary lymphadenectomy without SN isolation procedure.
16. ____ The interval between the last surgery for breast cancer (treatment or staging) and randomization is at least 28 days but no more than 84 days. **Date of surgery:** ____ **Randomization date:** ____
17. ____ The patient must have ER analysis performed on the primary tumor prior to randomization. If ER analysis is negative, the PgR analysis must also be performed. **Date of ER analysis:** ____
18. ____ The most recent postoperative blood counts, performed within 6 weeks prior to randomization, met the following criteria:
- a. ANC must be $\geq 1200/\text{mm}^3$ ($1.2 \times 10^9/\text{L}$); **ANC:** ____
 - b. Platelet count must be $\geq 100,000/\text{mm}^3$ ($100.0 \times 10^9/\text{L}$); **Platelets:** ____
 - c. Hemoglobin must be $\geq 10\text{g/dL}$. **Hemoglobin:** ____
19. ____ The following criteria for evidence of adequate hepatic function must be met based on the results of the most recent postoperative tests performed within 6 weeks prior to randomization:
- a. Total bilirubin must be \leq upper limit of normal (ULN) for the lab unless the patient has a bilirubin elevation $>$ ULN to $1.5 \times$ ULN due to Gilbert's disease or similar syndrome involving slow conjugation of bilirubin; *and* **Bilirubin:** ____
 - b. Alkaline phosphatase must be $\leq 2.5 \times$ ULN for the lab; *and* **Alkaline phosphatase:** ____
 - c. AST must be $\leq 1.5 \times$ ULN for the lab. **AST:** ____
 - d. *Alkaline phosphatase and AST may not both be $>$ the ULN.* For example, if the alkaline phosphatase is $>$ the ULN but $\leq 2.5 \times$ ULN, then the AST must be \leq the ULN. If the AST is $>$ the ULN but $\leq 1.5 \times$ ULN, then the alkaline phosphatase must be \leq ULN.
20. ____ If the patient's AST or alkaline phosphatase is $>$ ULN, she is eligible for inclusion in the study if liver imaging (CT, MRI, or PET scan performed within 3 months prior to randomization) does not demonstrate metastatic disease and the requirements in criterion # 18 are met.
21. ____ If the patient's alkaline phosphatase is $>$ ULN but $2.5 \times$ ULN, she is eligible for inclusion in the study if a bone scan or PET scan (performed within 3 months prior to randomization) does not demonstrate metastatic disease.
22. ____ The patient has met the following criteria for renal function, based on the results of the most recent postoperative tests performed within 6 weeks prior to randomization:
- a. Serum creatinine is \leq ULN for the lab. **Serum creatinine:** ____
 - b. Measured or calculated creatinine clearance is > 60 mL/min (see Section 8.5.1 for instructions regarding calculation of creatinine clearance). **Creatinine clearance:** ____
23. ____ The patient's urine dipstick indicates 0-1+ protein. If dipstick reading is $\geq 2+$, collect a 24-hour urine specimen, which must demonstrate < 1.0 g of protein per 24 hours. (Eligibility must be based on the most recent postoperative test(s) performed within 6 weeks prior to randomization.) **Urine:** ____
24. ____ LVEF assessment must be performed within 3 months prior to randomization. It is preferred that LVEF assessment be performed by 2-D echocardiogram; however, MUGA scan may be substituted based on institutional preferences. **The LVEF must be $\geq 55\%$ regardless of the cardiac imaging facility's lower limit of normal (LLN). (The same method should be used throughout the study; all assessments should be performed at the same cardiac imaging facility used at baseline.)**
LVEF: ____

Note: Since the pre-entry LVEF serves as the baseline for comparing subsequent LVEF assessments to determine if trastuzumab and bevacizumab therapy can be administered, it is critical that this baseline study be an accurate assessment of the patient's LVEF. *If the baseline LVEF is $> 70\%$, the investigator is encouraged to have the accuracy of the initial LVEF result confirmed and to consider repeating the test if the accuracy is uncertain.*

25. _____ The ECG (performed within 3 months prior to randomization) has not demonstrated any of the following conditions:
- Ventricular arrhythmias except for benign premature ventricular contractions;
 - Supraventricular and nodal arrhythmias requiring a pacemaker or not controlled with medication; and
 - Conduction abnormality requiring a pacemaker.

Conditions for Patient Ineligibility:

Patients with one or more of the following conditions are ineligible for this study.

- _____ Inflammatory breast cancer.
- _____ Definitive clinical or radiologic evidence of metastatic disease. (Chest imaging [mandatory for all patients] and other imaging [if required] must have been performed within 3 months prior to randomization.)
- _____ Synchronous contralateral breast cancer (invasive or noninvasive).
- _____ History of ipsilateral invasive breast cancer regardless of treatment or ipsilateral DCIS treated with excision and RT.
- _____ History of non-breast malignancies within the 5 years prior to study entry, except for the following: carcinoma in situ of the cervix, carcinoma in situ of the colon, melanoma in situ, and basal cell and squamous cell carcinomas of the skin.
- _____ Previous therapy with anthracyclines, taxanes, carboplatin, trastuzumab, or bevacizumab for any malignancy.
- _____ RT, chemotherapy, and/or targeted therapy, administered for the currently diagnosed breast cancer prior to randomization.
- _____ Continued therapy with any hormonal agent such as raloxifene or tamoxifen (or other SERM) or an aromatase inhibitor. (Patients are eligible if these medications are discontinued prior to randomization.)
- _____ Any sex hormonal therapy, e.g., birth control pills, ovarian hormone replacement therapy, etc. as described in Section 8.10.4. Patients are eligible if these medications are discontinued prior to randomization.
- _____ Cardiac disease (history of and/or active disease) that would preclude the use of the drugs included in the treatment regimens. This includes but is not confined to:
Active cardiac disease
 - angina pectoris that requires the use of anti-anginal medication;
 - ventricular arrhythmias except for benign premature ventricular contractions;
 - supraventricular and nodal arrhythmias requiring a pacemaker or not controlled with medication;
 - conduction abnormality requiring a pacemaker;
 - valvular disease with documented compromise in cardiac function; and
 - symptomatic pericarditis.
- _____ Uncontrolled hypertension defined as systolic blood pressure (BP) > 150 mmHg or diastolic BP > 90 mmHg, with or without anti-hypertensive medication. (BP must be assessed within 28 days prior to randomization.) Patients with initial BP elevations are eligible if initiation or adjustment of BP medication lowers pressure to meet entry criteria. (*See Appendix E for BP management requirements.*)
Blood Pressure: _____
- _____ History of hypertensive crisis or hypertensive encephalopathy.
- _____ History of TIA or CVA.
- _____ History of any arterial thrombotic event within 12 months before randomization.
- _____ Symptomatic peripheral vascular disease.
- _____ Intrinsic lung disease resulting in dyspnea.

17. ____ Unstable diabetes mellitus.
18. ____ Active infection or chronic infection requiring suppressive antibiotics.
19. ____ Any significant bleeding within 6 months before randomization, exclusive of menorrhagia in premenopausal women.
20. ____ Non-healing wound, skin ulcers, or incompletely healed bone fracture.
21. ____ Major surgical procedure, open biopsy, or significant traumatic injury within 28 days prior to planned start of study therapy. (Note: Placement of a vascular access device is not considered a major surgical procedure. See Sections 8.2 and 8.4 for instructions regarding initiation of therapy after device placement.)
22. ____ Anticipation of need for major surgical procedures during study therapy and for at least 3 months following completion of bevacizumab.
23. ____ Gastroduodenal ulcer(s) documented by endoscopy to be active within 6 months before randomization.
24. ____ History of GI perforation, abdominal fistulae, or intra-abdominal abscess.
25. ____ Known bleeding diathesis or coagulopathy.
26. ____ Requirement for therapeutic doses of coumadin or equivalent.
27. ____ Sensory/motor neuropathy \geq grade 2, as defined by the NCI CTCAE v3.0.
28. ____ Conditions that would prohibit administration of corticosteroids.
29. ____ Chronic daily treatment with corticosteroids (dose of > 10 mg/day methylprednisolone equivalent) (excluding inhaled steroids).
30. ____ History of hypersensitivity reaction to drugs formulated with polysorbate 80.
31. ____ Pregnancy or lactation at the time of study entry. (*Note: Pregnancy testing must be performed within 14 days prior to randomization according to institutional standards for women of child-bearing potential.*)
32. ____ Other malignant systemic disease that would preclude the patient from receiving study treatment or would prevent required follow-up.
33. ____ Psychiatric or addictive disorders or other conditions that, in the opinion of the investigator, would preclude the patient from meeting the study requirements.
34. ____ Use of any investigational product within 4 weeks prior to enrollment in the study.
35. ____ Pregnancy at time of study entry.

Form Completed By: _____ **Date:** _____

Investigator's Signature: _____ **Date:** _____

**Oral Medication Record
(for coordinator use only)**

Today's date: _____ **Agent:** _____ **Dosage:** _____

Patient Name: _____ *(or initials)* **Patient Study ID:** _____

Protocol: _____

Adherence to treatment:

a) _____ # of pills dispensed on (date)

b) _____ # of pills returned on (date)

c) _____ # of pills expected to be taken

$[(a) - (b)] / (c) \times 100 =$ _____ % adherence to treatment

Comments: _____

Research Nurse/Coordinator's Signature and Date:

Concomitant Medications and OTC Supplements – Baseline

Today's date: _____ Patient Name: _____ (or initials)
 Patient Study ID: _____ Protocol: _____

Product Name and/or Generic Name and Dose	Indication	Start Date	End Date (or indicate if ongoing)
		_ / _ / _	_ / _ / _ <input type="checkbox"/> ongoing
		_ / _ / _	_ / _ / _ <input type="checkbox"/> ongoing
		_ / _ / _	_ / _ / _ <input type="checkbox"/> ongoing
		_ / _ / _	_ / _ / _ <input type="checkbox"/> ongoing
		_ / _ / _	_ / _ / _ <input type="checkbox"/> ongoing
		_ / _ / _	_ / _ / _ <input type="checkbox"/> ongoing

Form Completed By: _____ Date: _____

Research Nurse/Coordinator's Signature: _____ Date: _____

Concomitant Medications and OTC Supplements – Update (Cycle # ____)

Today's date: _____ Patient Name: _____ (or initials)
Patient Study ID: _____ Protocol: _____

Product Name and/or Generic Name and Dose	Indication	Start Date	End Date (or indicate if ongoing)
		__/__/__	__/__/__ <input type="checkbox"/> ongoing
		__/__/__	__/__/__ <input type="checkbox"/> ongoing
		__/__/__	__/__/__ <input type="checkbox"/> ongoing
		__/__/__	__/__/__ <input type="checkbox"/> ongoing
		__/__/__	__/__/__ <input type="checkbox"/> ongoing
		__/__/__	__/__/__ <input type="checkbox"/> ongoing

Form Completed By: _____ Date: _____

Research Nurse/Coordinator's Signature: _____ Date: _____

PATIENT _____
 STUDY _____

ECOG PERFORMANCE SCORE _____
 PATIENT'S SEQUENCE NO. _____

CYCLE _____
 DATE _____

Jefferson Kimmel Cancer Center Network Toxicity Flowsheet

Date	Brief Discription of Event ♦	CTC Grade ♣	Attribution (related to therapy)	Action (check all that apply)	Outcome	Signature	<p style="text-align: center;">Common symptoms to review</p>	
Date: <input type="checkbox"/> New <input type="checkbox"/> F-U		<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> Unrelated <input type="checkbox"/> Unlikely <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Definite	<input type="checkbox"/> none required <input type="checkbox"/> dose reduced* <input type="checkbox"/> dose held* <input type="checkbox"/> AdEERS <input type="checkbox"/> IRB notified	<input type="checkbox"/> resolved <input type="checkbox"/> ongoing			Allergic reaction
								Neutrophils (ANC)
								Hemoglobin
								Platelets
								Metabolic
								Fatigue
								Fever
								Nausea
								Vomiting
								Diarrhea
								Constipation
								Mucositis
								Anorexia
								Rash/Desquamation
								Pain
							Peripheral Neuropathy	
							Dyspnea	
							Cough	
							Alopecia	
							Hot Flashes	
							Ammenorhea	

* Details of any type of dose adjustment must appear elsewhere in a source document

♦ In follow-up continue to capture event on this flowsheet until return to baseline

♣ CTC Version per protocol

JKCCN Quality Assurance Review

Institution: _____

Coordinator: _____

Study #: _____

Pt. Initials: _____

Sequence #: _____

1. Consent Process

	Main Consent	Tissue Consent	Addendum Consent
a. Valid consent used TJU consent used? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
b. Questions answered, if any	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
c. Signed and dated (all signature lines dated and complete)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
d. Each page initialed and dated	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
e. Consent process documented in Progress note? <input type="checkbox"/> Yes <input type="checkbox"/> No Consent review source document? <input type="checkbox"/> Yes <input type="checkbox"/> No			
f. Re-consent process executed? 1. Valid consent used 2. Questions answered, if any 3. Signed and dated (all signature lines dated and complete) 4. Each page initialed and dated	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Version date used: _____ Date of re-consent: _____ <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Version date used: _____ Date of re-consent: _____ <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	

2. Eligibility

- a. Complete Checklist Yes No Comments: _____
- i. Cooperative group checklist used Yes No
- ii. JKCCN checklist used Yes No
- b. Checklist signed and dated Yes No Comments: _____
- c. Source Documents complete Yes No
- d. Source documents signed and dated Yes No
- e. Stratification factors documented Yes No
- If yes, note here: _____

3. Treatment

- a. Verification of correct BSA and initial dosage Yes No
Height: _____ Weight: _____ BSA: _____
- b. Correct drug sources Yes No
- c. Dose adjustment as per protocol Yes No N/A
If yes, explain:

(Treatment cont'd)

d. For NSABP trials, all lab results reviewed and documented before chemo hung all cycles Yes No N/A
If no, explain:

e. Use of AE flowsheet (JKCCN or site-specific) all cycles Yes No
If no, explain:

f. Complete physician notes (PS, AE's, SAE's, dose adjustment) all cycles Yes No
If no, explain:

g. Serious adverse events (SAE's)? Yes No
If yes, documented and reported per protocol to AdEERS? Yes No
TJU IRB? Yes No
Comments:

h. Oral Medication compliance documented Yes No
Pill Count? Yes No
Patient Diary? Yes No
Comments:

i. Timely Data Submission (within 3 months) Yes No
Comments:

4. Study medication logs and supplies

a. Use of current NCI logs (DARFs) Yes No
b. Complete Yes No
Comments:

c. Accurate Yes No
Comments:

d. Corrections initialed and dated Yes No
e. Returned/destroyed drug per protocol Yes No
Comments:

Comments:

Workspace/Notes

<p>Treatment Cycles</p> <p>Cycle # ___ Dates _____</p> <p>Cycle # ___ Dates _____</p> <p>Cycle # ___ Dates _____</p> <p>Cycle # ___ Dates _____</p> <p>Cycle # ___ Dates _____</p> <p>Cycle # ___ Dates _____</p> <p>Cycle # ___ Dates _____</p> <p>Cycle # ___ Dates _____</p> <p>Cycle # ___ Dates _____</p> <p>Cycle # ___ Dates _____</p> <p>Cycle # ___ Dates _____</p> <p>Cycle # ___ Dates _____</p> <p>Cycle # ___ Dates _____</p>	<p>BSA Calculation</p> <p>Parameter for dose change:</p> <p>_____</p> <p>_____</p>
<p>Dose Delays:</p> <p>Cycle # ___ Dates _____ Reason _____</p> <p>Cycle # ___ Dates _____ Reason _____</p>	
<p>Dose Modifications:</p> <p>Cycle # ___ Dates _____ Reason _____</p> <p>Cycle # ___ Dates _____ Reason _____</p>	

Items for follow-up and action plan

Deviation	Action Plan

JKCCN Coordinator Signature: _____ Date: _____

Site Coordinator Signature: _____ Date: _____

Please submit this form to the JCN in a timely fashion.

* Indicates Required Field

Clinical Trial Patient Registration Form

Unique Patient Identifiers	
Institution:* _____	- Since patient names can be duplicated (i.e. John Smith), these values are how we uniquely identify patients.
Med Rec #:* _____	Please verify this data is complete and accurate .

Patient Information			
Last Name: * _____ MI: _____ First: * _____ Birth Date: * _____ (ex: mm/dd/yyyy)	<p style="text-align: center;">(should be self-reported by patient)</p> <table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> Race* <input type="checkbox"/> White <input type="checkbox"/> Black or African American <input type="checkbox"/> Asian <input type="checkbox"/> American Indian/Alaska Native <input type="checkbox"/> Native Hawaiian/Pacific Islander <input type="checkbox"/> More Than One Race <input type="checkbox"/> Unknown </td> <td style="width: 50%; vertical-align: top;"> Ethnicity* <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Unknown Gender* <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown </td> </tr> </table>	Race* <input type="checkbox"/> White <input type="checkbox"/> Black or African American <input type="checkbox"/> Asian <input type="checkbox"/> American Indian/Alaska Native <input type="checkbox"/> Native Hawaiian/Pacific Islander <input type="checkbox"/> More Than One Race <input type="checkbox"/> Unknown	Ethnicity* <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Unknown Gender* <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown
Race* <input type="checkbox"/> White <input type="checkbox"/> Black or African American <input type="checkbox"/> Asian <input type="checkbox"/> American Indian/Alaska Native <input type="checkbox"/> Native Hawaiian/Pacific Islander <input type="checkbox"/> More Than One Race <input type="checkbox"/> Unknown	Ethnicity* <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Unknown Gender* <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown		

Clinical Trial Information	
Trial #: * _____ (IRB #, Coop Group #, or JOG #)	Enrolling MD: * _____
Trial Arm: * _____	Other MD: _____ (multi-modality, surgical, etc) (optional)
Cohort: _____ (if applicable)	Disease Site: * _____
Sequence #: * _____	Date Enrolled: * _____ (ex: mm/dd/yyyy)
Notes: (optional) _____	TJU Consent: * <input type="checkbox"/> Yes <input type="checkbox"/> No

Late Registration	
- if this form is being submitted more than one month past the "Date Enrolled" above, please include the patient status and any other applicable information	
Patient Status: * <input checked="" type="checkbox"/> Alive <input type="checkbox"/> Expired	Date Off Drug: _____ (ex: mm/dd/yyyy)
Date Expired: _____ (ex: mm/dd/yyyy)	Date Off Study: _____ (ex: mm/dd/yyyy)

Name of Submitter: * _____

Phone #: * _____

MY USERNAMES & PASSWORDS

Group: _____

Username: _____

Password: _____

Group: _____

Username: _____

Password: _____

Group: _____

Username: _____

Password: _____

Group: _____

Username: _____

Password: _____

Group: _____

Username: _____

Password: _____

Group: _____

Username: _____

Password: _____

Group: _____

Username: _____

Password: _____

Jefferson Kimmel Cancer Center Network

CONSENT REVIEW SOURCE DOCUMENT

Patient Name _____ Study #: _____

Protocol: _____ Consent Version date: _____

Consent Expiration Date: _____

The following were discussed with the patient:	Yes	No	N/A
1. Purpose of the study/who are the participants			
2. Study design (schedule of the trial)			
3. Schedule of study tests			
4. Study specific questionnaires			
5. Potential side effects			
6. All trial medications disclosed			
7. Follow-up schedule after active treatment			
8. Confidentiality			
9. Pregnancy statement reviewed			
10. Pregnancy while on the trial			
11. Voluntary participation /withdrawal			
12. Alternative options to the clinical trial			
13. Potential benefits of a clinical trial			
14. The screening process			
15. The randomization process			
16. Potential re-consenting upon new findings			
17. Blinding / un-blinding			
18. Clinical trials phone numbers			
19. Contacts for patient after hours / weekends			
20. Contact clinical trials if hospitalized / ER visit			
21. No payment for being in the study			
22. Any compensation for illness/injury			
23. Insurance/Payment			
24. All patient questions answered			
25. Copy of consent given to patient			
26. All sub-studies discussed with patient and related questions in consent form answered (i.e., PK, PG, blood & tumor samples for research, etc.)			
27. Consent form addendum signed			
28. Short form consent signed			
29. Translated consent signed			
30. Translator required: Name of translator:			
	Language:		

Remarks: _____

Signature: _____ Date: _____

Jefferson Kimmel Cancer Center Network

CONSENT REVIEW SOURCE DOCUMENT

(Amendment/Additional information)

Patient Name _____ Study #: _____.

Protocol: _____ Amendment #: _____.

Consent Version date: _____.

The following were discussed with the patient:	Yes	No
Changes to the consent		
All questions answered		
Copy of consent given to patient		
Translated consent signed		
Translator required		
Name of Translator _____	Language: _____	

Comments:

Signature: _____ Date: _____.