CTSU PROCESS CHECKLIST

CTSU CONTACT INFORMATION

CTSU Web Site:

http://www.ctsu.org

(Members' area is password-protected)

CTSU Central Regulatory Office:

Coalition of National Cancer Cooperative Groups 1818 Market Street, Suite 1100

Philadelphia, PA 19103

CTSU Regulatory Office Fax: 215-569-0206

CTSU Regulatory Office Email: CTSURegulatory@ctsu.coccg.org

Link to

Fill out

CTSU Help Desk Phone: 1-888-823-5923 (9:00am-8:30 pm, M-F, ET)

CTSU Help Desk Email: <u>CTSUContact@westat.com</u> CTSU Regulatory Help Desk: 866-651-CTSU (2878)

Oncology Patients Enrollment Network (OPEN): https://open.ctsu.org CTSU Patient Registrar: 1-888-462-3009 (9:00am-5:00pm, M-F, ET) CTSU Registrar Cell Phone: 301-704-2376 (For patient enrollments that must be completed within approximately 1 hour. Please use 1-888-

462-3009 for ALL other CTSU enrollments.)
CTSU Patient Registrar Fax: 1-888-691-8039

Identity and Access Management (IAM)	
the CTEP-IAM through www.ctsu.org (under the Register to	ab)
online registration form	

Await CTEP-IAM/CTSU confirmation emails *change temporary password to permanent password (new members allow 2 business days to receive password)

SELECT AND DOWNLOAD PROTOCOL AND ASSOCIATED MATERIALS

☐ Protocol in full text	☐ Patient Enrollment Forms
☐ Amendments	□ Adverse Event Forms
☐ Pharmacy Forms	Education and Training Materials
☐ Case Report Forms	☐ Safety Updates (Drug Safety Notifications
Site Registration Documents	database is searchable by drug &/or protocol)

CONSULT PROTOCOL-SPECIFIC NOTES TO DETERMINE IF ANY MATERIALS FOR THE PROTOCOL MUST BE ORDERED FROM THE CTSU (e.g., Quality of Life booklets) AND ORDER, IF NECESSARY.

DOCUMENTS, SUCH AS THE PROTOCOL CONSENT FORMS, MUST BE SUBMITTED FOR LOCAL IRB APPROVAL.

PROTOCOL-SPECIFIC SITE REGISTRATION

Select and print the following documents from the site registration category of the protocol-specific web page:

- ☐ CTSU IRB Certification Form
- ☐ IRB Submission Application Template
 - (This is a tool to format your document for IRB review)
- ☐ IRB/Regulatory Approval Transmittal Form
- ☐ Other protocol-specific documents needed for IRB approval

Consult the registration/randomization section of the CTSU instructions for a complete list of required regulatory documents.

CTSU Investigator Verification demonstrated by:

- PI has current FDA 1572 Form, CV, Financial Disclosure Form, and Supplemental Investigator Data Form on file at PMB
- ☐ Physicians other than PI who enroll patients have current documentation (see above) on file with the PMB
- All enrolling physicians are listed as active in the PMB database
- ☐ All enrolling physicians are members of a Cooperative Group/CTSU
- ☐ All enrolling physicians are CTSU members

Treating physicians are strongly encouraged to submit investigator registration documentation to the NCI/PMB Physician database, complete CTEP-IAM registration form, and be active in a Cooperative Group.

Fax, email, or mail the following documents to the CTSU Central Regulatory Office:

- ☐ CTSU IRB Certification Form or IRB Approval Letter
- ☐ IRB/Regulatory Approval Transmittal Form
- Copy of IRB approved informed consent: consents should follow the consent outlined in the protocol (if applicable)
- ☐ Any protocol-specific requirements

The CTSU members' web site will provide a complete list of documents required for each protocol.

PATIENT ENROLLMENT/REGISTRATION

Download the following documents to assist with screening patients for eligibility:

- ☐ Time and Event Schedule
- Protocol Card, which summarizes eligibility criteria, required laboratory tests or procedures, and schema

NOTE: Always consult the latest version of the protocol as the ultimate authority.

Ensure the following:

- ☐ Informed consent is obtained
- ☐ Pretreatment evaluations are complete
- ☐ Eligibility criteria are satisfied
- ☐ The CTSU has received and approved required documents to date
- ☐ Site registration approval has been confirmed (i.e., site registration status is "Approved")

Enroll the patient via the mechanism described in the CTSU Logistical Appendix of the protocol:

- Oncology Patient Enrollment Network (OPEN)
- ☐ Inform the CTSU Registrar Office that a patient enrollment is forthcoming and submit the following:
 - ☐ CTSU Patient Enrollment Transmittal Form
 - ☐ Protocol-Specific Eligibility Checklist
 - Other forms or documents as required by the protocol
 - ☐ Await the following information from the CTSU via phone. fax. and/or e-mail:
 - ☐ Patient Identification Number
 - ☐ Randomization, as appropriate

Data Submission

- ☐ CRFs
- □ AdEERS
- ☐ After enrollment, all CRFs must be submitted to the location and in the matter outlined in the protocol document.