Public reporting burden for this collection of information is estimated to vary from 5 to 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx). Do not return the completed form to this address.

## Filling out PDF Forms

This PDF form contains "roll-over or double-click" help functionality.

This form allows you to enter data directly onto the screen. After completing the form, you are able to print the document so that you can fax/mail the document.

To fill out a form:

- 1. Select the hand tool.
- 2. Position the pointer inside a field, and click to type text.
- 3. After entering text or selecting a check box, do one of the following:
  - Press tab to accept the form field change and go to the next form field.
  - Press Shift+Tab to accept the form field change and go to the previous form field.
  - Press Enter (Windows) or Return (Mac OS) to accept the form field change and deselect the current form field.
- 4. Once completed, print the form.



## CTSU Data Transmittal Form Instructions for PACCT1

- All CRF's, reports etc should be faxed to <u>301-545-0406</u>.
- All submitted documents <u>must</u> include the new bar-coded transmittal form. Forms will not be processed properly if the transmittal is not included.
- Transmittal forms are now study specific for certain studies on the CTSU menu. It is **crucial** to select the appropriate form for your study when submitting documents.
- Complete 1 transmittal form for each patient and protocol. Be sure to include your contact information in case of questions.
- Be sure patient ID and protocol number are present on the top of each submitted page. If this is not done, you will be asked to resubmit.
- Please remove all patient identifiers or HIPAA protected information.
- Do not fax more than 50 pages in a single transmission. This may cause the system to malfunction, potentially losing pages.
- Be sure to complete the transmittal form in its entirety. If the transmittal form is not complete and correct for each submitted form(s), the documents may be returned.
- Please check your fax machine to be sure faxes were successfully sent.

Please contact CTSU Help Desk at 1-888-823-5923 if you have any questions or have problems faxing



## **TAILORX/PACCT1**

## CTSU DATA TRANSMITTAL FORM

Please FAX to: 1-301-545-0406

Call 1-888-823-5923 if you are experiencing difficulty faxing

- Record only one patient and protocol per transmittal sheet.
- Ensure Patient ID and Protocol ID are recorded on each page of each item included.
- Ensure pages are in proper sequence (2-sided forms must be copied by site before faxing).
- Do not fax more than 50 pages in one submission.
- · Do not submit amended forms.

CTSU Data Clarification

Form
CTSU Unsolicited Data

**Modification Form** 

• Complete a TAILORx Unsolicited Data Modification Form to update data on previously submitted forms.

Date:(dd-mmm-yyyy)		Total # Pages Faxed: (including transmittal)	Patient ID#:
Site Name	e:		NCI Site Code:
			(Example TX001)
Site Addr	ess:		
Completed By:		Phone #	#
Email add	dress:		
		SU has questions or if data submission needs to	be re-submitted with corrective action.

PLEASE NOTE: Sites submitting items improperly will be contacted to take corrective action and re-submit data.

CRFs/ Reports/	Submitted	# of	Visit						
Documents		pages	Baseline	End TX	FUP	Sec Primary	Non Prot TX	Recurrence	Death
On Study Form									
Chemotherapy Form									
Radiation Therapy Form									
Follow Up Form									
Cross Registration Form									
Non-Protocol Therapy Form									
Second Primary Form									
Pre-Registration Form									
TAILORx Material Submission Form									
TAILORx Source Document Tracking Coversheet									
Path Report [with/without ERPR/Her2 reports included]									
ERPR Report <u>or</u> Her2/neu Report									
Physician Note									
Surgical Report									
Radiology Report									
Lab Report									
Mammogram Report									
CTSU Data Re-Submission Form			CTSU Help Desk Contact Information: 1-888-823-5923						

CTSU Help Desk Contact Information: 1-888-823-5923

Please submit documents as specified on this form; DO NOT add additional documents that are not present.

Provide the following forms directly to ECOG for the "Baseline", "3 Months", "6 Months", "12 Months", "24 Months", and "36 Months" reporting periods: Form 3112: TAILORX Assessment Compliance Form, Form 3113: TAILORX FACT-Cognitive Function Form, Form 3114: TAILORX FACT-Endocrine Systems Form, Form 3115: TAILORX FACT-Fatigue Scale Form, Form 3116: TAILORX FACT-General Form, Form 3117: TAILORX PROMS Fatigue Short Form, Form 3118: TAILORX Assessment of Survivor Concerns Form.

Provide the following form directly to ECOG as appropriate: Form 3018: ECOG Withdrawal of Consent.