


Public reporting burden for this collection of information is estimated to average 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 (0925-0753). 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.



Complete this form and upload to the Regulatory Submission Portal. Select the Enrollment/Transfer document type. For more information contact the CTSU Help Desk at 1-888-823-5923 or CTSUContact@westat.com.

Requests will be reviewed within 5 business days of receipt.

Notifications will be sent to the Receiving Site, Lead Protocol Organization, and the Pharmaceutical Management Branch.

Patient ID#: \_\_\_\_\_ Group/Protocol Number: \_\_\_\_\_

Case Status:  Active Trt  F/up Is the transfer occurring between registration steps? Yes / No

**Transferring Site/Investigator\* Information:** (Please submit the form to receiving site (if applicable) after completion of this section.)

Site Name: \_\_\_\_\_ CTEP Code: \_\_\_\_\_

Treating Investigator Name: \_\_\_\_\_ CTEP ID#: \_\_\_\_\_

Treating Investigator Signature: \_\_\_\_\_

**Receiving Site/Investigator\* Information:**

Site Name: \_\_\_\_\_ CTEP Code: \_\_\_\_\_

Credited Organization (For follow-up credit): \_\_\_\_\_

Treating Investigator Name: \_\_\_\_\_ CTEP ID#: \_\_\_\_\_

Treating Investigator Signature: \_\_\_\_\_

\*By signing this form the receiving site takes responsibility for **all** outstanding data from the originating site. Please review the Transfer checklist.  
\*Completion of this form is required for transfers between investigators located at the same site.

**Level of responsibility being transferred to receiving site or investigator:**

- Full: (All responsibility for the patient is transferred to receiving institution)
- Partial: (Temporary transfer of subject to another site; please indicate the level of responsibility at the receiving site)

Data Share: (For transfers for studies in Rave, if supported by the LPO; sites may elect to share data. Indicate length of time required for data sharing.)

Contact Person: \_\_\_\_\_

Phone #: \_\_\_\_\_ Email Address: \_\_\_\_\_

Complete this form and submit to the CTSU Help Desk by e-mail at [ctscontact@westat.com](mailto:ctscontact@westat.com) or by fax to 1-888-691-8039. For more information, contact the CTSU Help Desk at 1-888-823-5923 or [CTSUSUContact@westat.com](mailto:CTSUSUContact@westat.com).

Requests will be reviewed within 3 business days of receipt.

Office Use Only:

Receiving site approved for registration:

Date: \_\_\_\_\_ Int. \_\_\_\_\_

LPO Authorization:

Date: \_\_\_\_\_ Int. \_\_\_\_\_

Receiving Investigator eligible:

Date: \_\_\_\_\_ Int. \_\_\_\_\_

PMB Copied:

Date: \_\_\_\_\_ Int. \_\_\_\_\_

## Patient Transfer and Investigator Update Checklist

*Transferring sites that are having difficulty locating a receiving site are encouraged to contact the CTSU or the Lead Protocol Organization for assistance in locating a participating site. If processing of the transfer request is urgent please note this on the fax cover sheet and notify the CTSU Help Desk at 1-888-823-5923.*

The following information must be provided to CTSU for patient transfers and physician updates:

- ✓ Patient ID
- ✓ Protocol/Study ID
- ✓ Date of Request
- ✓ Transfer Effective Date
- ✗ ~~Level(s) of responsibility being transferred to the receiving site:~~
  - ~~Full (all responsibility for the patient is transferred to the receiving site)~~
  - ~~Partial, (temporary responsibility for the patient is transferred to the receiving site; dependent on the agreement between the sites data management responsibilities may be retained by the originating site.)~~
- ✓ Name of transferring institution and its CTEP Code
- ✓ Name of transferring investigator and his/her CTEP IID
- ✓ Name of the receiving institution and its CTEP Code
- ✓ Name of the receiving treating investigator and his/her CTEP IID
- ✓ Signature of transferring institution treating investigator (if available)
- ✓ Signature of receiving institution treating investigator
- ✓ Name, phone number and email address of individual completing the request
- ✓ Status of the patient case
- ✗ ~~If the transfer is occurring between patient registration steps (needed to update OPEN)~~
- ✗ ~~If a large subset of subjects is being transferred or the investigator is being updated, a single transfer form with an attached list can be submitted to CTSU. Please ensure the list includes all applicable patient records.~~

The following regulatory requirements must be verified by the CTSU Patient Transfer Coordinator:

- ✓ The receiving site has an active Institutional Review Board (IRB) approval status for the study
- ✓ The receiving treating investigator (physician of record) has an active CTSU membership

The Study PI for the protocol must have an active status

### Transferring Site Responsibilities

- ✓ All outstanding CRFs should be submitted prior to the transfer.
- ✓ Copies of all CRFs and subject records, as appropriate, must be submitted to the receiving site prior to the transfer.
- ✓ A listing of any outstanding queries or forms that cannot be resolved prior to transfer should be submitted to the receiving site.
- ✓ Transferring sites will be subject to audit for visits up to the point of transfer.

### Receiving Site Responsibilities

- ✓ Receiving sites are responsible for all queries upon acceptance of the transfer.
- ✓ Receiving sites are responsible for all delinquent forms upon acceptance of the transfer.
- ✓ Patients should be reconsented per local institutional and IRB policies.
- ✓ Receiving sites may be subject to audit of cases after the time of subject transfer.
- ✓ For transfers received from a lead Group site and that were not processed in OPEN, the site must submit the CTSU Patient Enrollment Form and copies of the enrollment confirmation with the transfer form to CTSU to establish a subject record.
- ✓ Sites must select a credited Organization for follow-up payments and audit.