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. $\langle n \rangle$
- 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.



Site Initiated Data Update Form Protocol: 8121

| PATIENT INITIALS: | PATIENT NUMBER: | INVESTIGATOR NAME: |
|-------------------|-----------------|--------------------|
| CRF NAME: | VISIT/CYCLE #: | WEEK #: |

Instructions:

- Use this form to submit data updates to a single CRF.
- A separate Data Update Form must be completed for each CRF that needs to be updated.
- Enter one update per row in the table below.
- Fax completed form to the CTSU (DO NOT submit amended CRF unless form is re-submitted to include investigator signature).
- Data Update Form must be accompanied by a CTSU Data Transmittal Form.
- Submit future updates to the same form on a new Data Update Form, do not re-submit an updated Data Update Form.
- Please retain a copy of this signed and dated Data Update Form for patient record.

| Field/Question | Current Value | Correct/Updated Value |
|----------------|---------------|-----------------------|
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| Investigator or designee | Signature: | Date: |
|--------------------------|------------|-------|
| | | |

Contact the CTSU Helpdesk with any questions: (888) 823-5923 or CTSUContact@Westat.com