

Terumo Heart, Inc. DuraHeart US BTT Study

Investigator Sign-off Instructions

Investigator Destination

See the CDP User Instructions Chapter 6, Investigator Signs Forms for complete details. The complete CDP User Instruction manual can be accessed by clicking on the Help Destination within CDP.

After the study coordinator has filled out the i-CRF, the investigator (i.e. a user with the role of “Investigator”) can sign individual i-CRFs or a batch of i-CRFs. Once logged in, the investigator will see a message regarding the number of forms to be signed.

Important Messages:

- * There are currently no messages.
- * There are [57 Form\(s\)](#) which are pending an Investigator's signature.

The Investigator can navigate to the Investigator Center through the Investigator Center link in the destinations or click on the hyperlink within the message regarding the number of forms pending signature. The Investigator Center will display all i-CRFs that are pending signature ordered by patient and i-CRF along with the CRF certification statement:

Forms Requiring an Investigator Signature

CRF Certification Statement

I have reviewed all the data contained on this CRF and certify that it is an accurate, complete and true reflection of the patient's records.

Entering your Password below applies your electronic signature to the selected CRFs. This is the equivalent of applying your handwritten signature to a paper CRF.

Password:

Sign Checked Forms

Warning: Any attempt to sign this CRF by anyone other than the person listed above will be viewed as fraud under 21 CFR Part 11.

Site: Training Site 01

Patient ID	Form	Form Status	Sign Form
TRAIN01-001	? Baseline Form (Visit Date: 12/02/2009)	Complete/DCF Pending	<input type="checkbox"/>
	Surgical Procedure Form - Initial Implant (Surgery Start Date: 11/11/2009)	Pending	<input type="checkbox"/>
	Adverse Event Form (Calculated Field for Display: 002, 1, 06/08/2009)	Pending	<input type="checkbox"/>
	? AE Form - Major Infection (Calculated Field for Display: , ,)	Pending	<input type="checkbox"/>
TRAIN01-002	Inclusion/Exclusion Form (Visit Date: 02/09/2009)	Pending	<input type="checkbox"/>
	? Medical History Form	Pending	<input type="checkbox"/>
	? Post-implant Form - Day 1	Pending	<input type="checkbox"/>
	Adverse Event Form (Calculated Field for Display: 001, 1, 03/02/2009)	Pending	<input type="checkbox"/>
	? Adverse Event Form (Calculated Field for Display: 001, 2,)	Pending	<input type="checkbox"/>
	? AE Form - Device Malfunction (Calculated Field for Display: , ,)	Pending	<input type="checkbox"/>

Only forms that require signature will display in this listing. Forms with a question mark prior to the form name contain unresolved queries and/or DCFs. The Form Status indicates whether the form was previously submitted but has since been resubmitted (Complete/DCF Pending) or the form has never been signed by the investigator (Pending). The monitored status of the form will not be displayed in this listing.

The investigator can review the data entered into a specific form by clicking on the form name. The investigator can sign the form while viewing the form by entering their password in the Password field near the bottom of the data entry screen, and then clicking the [Sign/Submit Forms] button (see image below).

VITAL SIGNS PROCEDURAL INFORMATION REASON FOR PROCEDURE LVAD IMPLANT INFORMATION
INTRAOPERATIVE PHARMACOLOGIC THERAPY INTRAOPERATIVE BLOOD TRANSFUSION NARRATIVE

CRF Certification Statement
I have reviewed all the data contained on this CRF and certify that it is an accurate, complete and true reflection of the patient's records.
Entering your Password below applies your electronic signature to the CRF. This is the equivalent of applying your handwritten signature to a paper CRF.
THI Investigator's Credentials:
Password: **Sign/Submit Form**
Warning: Any attempt to sign this CRF by anyone other than the person listed above will be viewed as fraud under 21 CFR Part 11.

Please review and sign the following forms individually:

Inclusion/Exclusion,
Surgical Procedure,
AE (all types),
Death Form,
Protocol Deviation

To sign a batch of reviewed forms, the investigator exits the viewing of any one form and chooses which forms to sign by clicking in the Sign Form box in the last column (as pictured above). The investigator then enters their password in the Password of the CRF certification section and then clicks the [Sign Checked Forms] button.

After the investigator electronically signs the forms the status of the form will be Complete.

Terumo Heart recommends that an investigator waits until after a form is monitored before signing.