



Pediatric Heart Transplant Society

## Form Status, Data Corrections, and System Generated Forms Training Guide

Updated 10/08/2018

There are three possible status's that a form can have: 1) Not Started, 2) In Progress, and 3) Complete. This document will detail the differences in status.

### Not Started

Only system generated forms can be saved in the system in the status of 'Not Started'. All forms added by the user, once saved, will be in an 'In Progress' status. A status of 'Not Started' is indicated by a gray box on the left of the form on the patient summary.

|  |  |   |
|--|--|---|
| Not Started  | <b>Post Transplant Annual Followup</b> | Date of Followup <b>04/03/2013</b>      |
| Followup Anniversary: <b>Year 1 (Followup Window: 1/3/2013 - 7/2/2013)</b> |  | Updated By System, 12/2/2017 2:00:11 AM |

All 'Not Started' forms will also appear on the Site Dashboard in the 'Pending & In Progress Forms' grid.

### In Progress

All forms except for the Screening Log can be saved as 'In Progress'. Once a form is saved as In Progress the user can return to the form later to finish and submit the form.

|                       |
|-----------------------|
| <b>Save for Later</b> |
|-----------------------|

A status of 'In Progress' is indicated by a blue box on the left of the form on the patient summary. All 'In Progress' forms will also appear on the Site Dashboard in the 'Pending & In Progress Forms' grid.

|             |                |   |
|-------------|----------------|---|
| In Progress | <b>Listing</b> | Date of Listing <b>10/05/2011</b>         |
|             |                | Updated By slende, 10/19/2017 10:52:08 AM |

### Complete

Once a form has been completed, to can be submitted using the 'Validate & Save' button at the bottom of the form.

|                            |
|----------------------------|
| <b>Validate &amp; Save</b> |
|----------------------------|



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The system will check for incomplete questions and indicate so with a red box under the question.

**Required**

The user can then answer any additional questions that are missing and resubmit the form. A status of 'Complete' is indicated by a green box on the left of the form on the patient summary.

Complete

Patient Enrollment

Date of Birth 10/09/2013

Primary Etiology: Cardiac Tumor

Updated By slende, 10/8/2018 3:07:23 PM

### Editing 'Completed' Forms

The users will always have full control of their hospital's data. If a correction is needed, even if the form is in a 'Complete' status, the user may still edit the data and re-submit the form.

### Editing events from previous versions of the forms

Initial data forms were created in 1993. Major revisions followed in 1996, 1999, 2005, 2010, and 2015. All current and previous data collection forms are available on the PHTS website (<http://www.uab.edu/medicine/phts/forms-and-manuals>).

By default, all data pre-populated from the paper form submission into the web based data entry system was pre-populated with a status of 'Complete'. Because of the form revisions and questions added with each revision, all forms pre-populated have some questions blank. While these forms are in a 'Complete' status now, if a user edits the forms, they system will require all additional questions that are blank to then be addressed. For example, if a user edits a data point on an event from 2012 and a question was added in 2015, the system will require all questions added in the 2015 revision to be answered.

Users are NOT expected to answer questions for an event if the event occurred before the question was added. Since the system requires an answer, the user may select 'Not Done' or 'Unknown' for these instances. In the current form manual (available here: <http://www.uab.edu/medicine/phts/forms-and-manuals/2015-forms>) the year of the form revision is listed after each question to indicate when PHTS started collecting that specific data element. For questions that were added pre-launch of the web based system on the paper form revisions, the year of the form revision is listed. For questions added post launch of the web based system, the specific date of the addition is listed.



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### Data Validation

Twice a year PHTS creates a “Data Build”. In brief, all of the data in the database is taken and saved as a separate copy from the database. This dataset is used for research projects and Quality Assurance reports. Throughout the year, sites continue to enter data and make corrections to data entered previously. Each time the Data Build is created, an entire copy of the database is used rather than just adding data entered since the last build was created. Therefore, when it is discovered a correction is needed, no matter how old the correction is, the correction should always be made because that correction will be included in the next Data Build.

### System Generated Forms

While majority of the functions in the system are user driven, there are a handful of forms the system will automatically generate. All system generated forms will generate in a ‘Not Started’ status and appear in the ‘Pending & In Progress Forms’ grid on the Site Dashboard. For all system generated forms, the system will first check to see if the form has already been entered and if not, will generate a new form.

#### System generated forms include:

- **Listing Form (Form 1) and Relisting Form (Form 1RL):** On the Patient Enrollment Form, the user will indicate if the patient’s listing is a first listing for transplant or if the patient is being relisting. The user will then enter the listing/relisting date. The system will generate either the listing form or relisting form depending on the answer to this question.
- **Donor (Form 2) and Initial Immunosuppression (Form 3):** Each Transplant Form (Form 1t) submitted is required to have a Form 2 and Form 3 submitted for the corresponding transplant. Once a Form 1t is submitted, the system will automatically generate a Form 2 and Form 3. However, if the Form 2 or Form 3 is added and completed first, the transplant will not automatically generate.
- **MCSD Forms:** The listing, transplant, and relisting forms ask in the status details if the patient was on MCSD support at time of listing. If yes, the system will generate an MCSD form if one has not already been started.
- **Post Transplant Annual Follow-up (Form 8):** Form 8s are due at the time of the transplant anniversary. For patients with a transplant date pre-launch of the web based system (October 2015), the follow-up window is + or – 180 days of the transplant anniversary. For patients with a transplant date post launch of the web based system the follow-up window is + or – 90 days of the transplant anniversary. The system will generate a form 8 in a ‘Not Started’ status every year on the transplant anniversary if a form has not already been started until the patient has a censor point entered. While the database began in 1993, Form 8s were not introduced into data collection until January 1, 1996 in the first form revision.



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- **Pre Transplant Annual Follow-up (Form 12):** Form 12s are due at the time of the listing anniversary. For patients with a listing date pre-launch of the web based system (October 2015), the follow-up window is + or – 180 days of the listing anniversary. For patients with a listing date post launch of the web based system the follow-up window is + or – 90 days of the listing anniversary. The system will generate a form 12 in a 'Not Started' status every year on the listing anniversary if a form has not already been started until the patient has a transplant form or censor point entered.
- **Pre Transplant Annual Follow-up (Form 12):** All patients that pass away pre transplant are required to have a form 12 with an event date within 10 days of the death date. If the system does not find a form 12, one will be generated automatically.