Data Management System
User's Manual

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Data Management System Users Manual

1. **Introduction**

   The Data Management System is a modular system designed to streamline study work flow and facilitate data collection and entry in a multi-site setting. The system is comprised of several modules covering a broad range of activities which include data entry, data and biospecimen tracking, patient randomization and reporting. While data can be captured on paper and entered at a later time, the system was designed to facilitate direct entry of data at the time of the patient evaluation and is the recommended method for data capture.

   All data systems are located in a private and secure area of the PALF website. Access is limited to project personnel who utilize these systems. A valid username and password are required. Valid usernames and passwords are assigned by the Data Coordinating Center. Personnel who require permission to access the PALF Data Management System should contact the Data Coordinating Center to request access. Username and passwords are to be kept private and are not to be shared. If you feel your username and/or password has been compromised submit a help center request via the Help Center to request a new username and password.

2. **System Requirements and Recommendations**

   2.1. Browser Support

   The following browsers have been tested and are supported by the PALF Data Management System. The recommended browsers are highlighted in blue in the table below and links to download or update the supported browsers are also provided.

   Note: Browsers not listed below or older versions of supported browsers have not been tested and may result in access restriction and functionality issues. Contact the DCC to check compatibility of a browser or version of a browser that is not listed below.

Browsers	Supported Versions	Download Links
Microsoft Internet Explorer	6	http://www.microsoft.com/windows/Internet-explorer/default.aspx
Microsoft Internet Explorer	7 or higher	http://www.microsoft.com/windows/Internet-explorer/default.aspx
Mozilla Firefox	3.5.5 or higher	http://www.mozilla.com/en-US/firefox/
Apple Safari	4.0 or higher	http://www.apple.com/safari/download/
Opera	9.64 or higher	http://www.opera.com/download/
Google Chrome	3.0 or higher	http://www.google.com/chrome/index.html?hl=en&brand=CHMA&utm_campaign=en&utm_source=en-ha-na-us-bk&utm_medium=ha

   2.2. Javascript

   Javascript is required and must be enabled in the browser in order to access the PALF Data Management System. If Javascript is not enabled or is not present, access to the system will be restricted. Below are step by step instructions to enable Javascript in the recommended browsers.

   Microsoft Internet Explorer 7, 8 & 9
   - Select the **Tools** option from the browser's toolbar.
   - Select **Internet Options** from the drop-down menu.

- A new window will appear, select the tab titled **Security** at the top of this new window.
- Click the **Internet** zone.
- If you do not have to customize your Internet security settings, click Default Level.
- If you have to customize your Internet security settings, follow these steps:
  - Click Custom Level.
  - In the Security Settings – Internet Zone dialog box, scroll and click Enable for Active Scripting in the Scripting section.
- Click **OK**

Mozilla Firefox 3.5.5
- Select the **Tools** option from the browser's toolbar.
- Select **Options** from the drop-down menu.
- Choose the **Content** tab.
- Check **Enable JavaScript**.
- Click **OK**

2.3. Cookies

Browser cookies are required and must be enabled in the browser in order to access the PALF Data Management System. If Cookies are not enabled or are not present, access to the system will be restricted. Below are step by step instructions to enable Cookies in the recommended browsers.

Microsoft Internet Explorer 7, 8 & 9
- Select the **Tools** option from the browser's toolbar.
- Select **Internet Options** from the drop-down menu.
- A new window will appear, select the tab titled **Privacy** at the top of this new window.
- Move the settings slider to **Low** or **Accept All Cookies**
- Click **OK**

Mozilla Firefox 3.5.5
- Select the **Tools** option from the browser's toolbar.
- Select **Options** from the drop-down menu.
- Choose the **Privacy** tab.
- Make sure the Firefox will: **Use custom settings for history is selected**.
- Check **Accept cookies from sites**.
- Click **OK**

2.4. Adobe Reader

Adobe Reader 7 or greater is required in order to print forms from the Data Management System. It is not required to enter data or perform updates. To update or download Adobe Reader for free follow this link: http://www.adobe.com/products/reader/ .

2.5. Microsoft Excel/Open Office

Microsoft Excel 2003, 2007, 2010 (http://office.microsoft.com/en-us/excel/) or Open Office (http://www.openoffice.org) is required in order to view downloaded reports from the Data Management System. It is not required to enter data or perform updates.

2.6. Screen Resolution

When accessing the PALF Data Management System a screen resolution of 1024 x 768 or higher is recommended. Although, the system will function at all resolutions this is recommended to minimize scroll bars.

2.7. Browser Refresh and Back Buttons

When using the Data Management System it is recommended that you minimize the use of the Back and Refresh buttons of your browser. While the system is equipped to handle these functions, the navigation system built into the Data Management System allows greater flexibility and a more efficient means to navigate within the Data Management System.

2.8. Apple Mac users

The Data Management is fully compatible with Apple Mac operating systems. However, your selected browser will need to be configured to use Adobe Reader and not the built-in Apple 'Preview'/WebKit PDF application to print forms. Installing Adobe Reader will automatically set Adobe Reader as the plug-in to use for PDFs in Safari. However, the Adobe Reader plug-in is currently not compatible with the Safari 5.1 browser that ships with Mac OS X 10.7 and 10.6 as stated in Compatibility Advisory Regarding Adobe Reader plug-in and Acrobat plug-in with Safari 5.1. A work around is to use the Google Chrome browser or you can download Adobe's Firefox plug-in from Adobe Labs and use Mozilla's Firefox browser. Adobe has stated they are working on a fix for this issue.

Also, to view Excel reports from the Data Management System you will need an appropriate application (see 2.5 above).
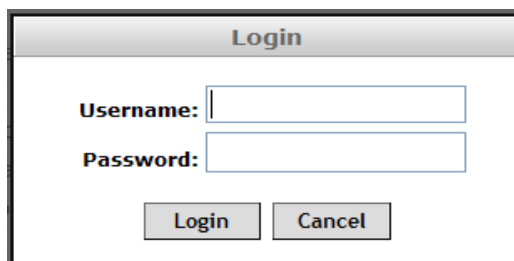
3. System Menus

3.1. Data Systems Main Menu

To access the Data Systems Main Menu, enter the researcher portal through the PALF project website at http://www.palfstudy.org and select 'Data System'. The Main Menu provides access to Data Management System and Sample Tracking System modules. Each module is username and password protected.

3.1.1. Accessing the System

Access to the Data Management System and Sample Tracking System modules will require an additional user login. The username and password provided to access the researcher portal of the PALF project website will be used to access the Data Management System and Sample Tracking System modules. Usernames are not case sensitive, but passwords are case sensitive. After entering the information click 'Login' to access the selected module or 'Cancel' to return to the Data Systems Main Menu.
 Note: if you incorrectly enter your login several times in succession your account will be locked and you will need to submit a ticket to the Help Center to unlock your account.
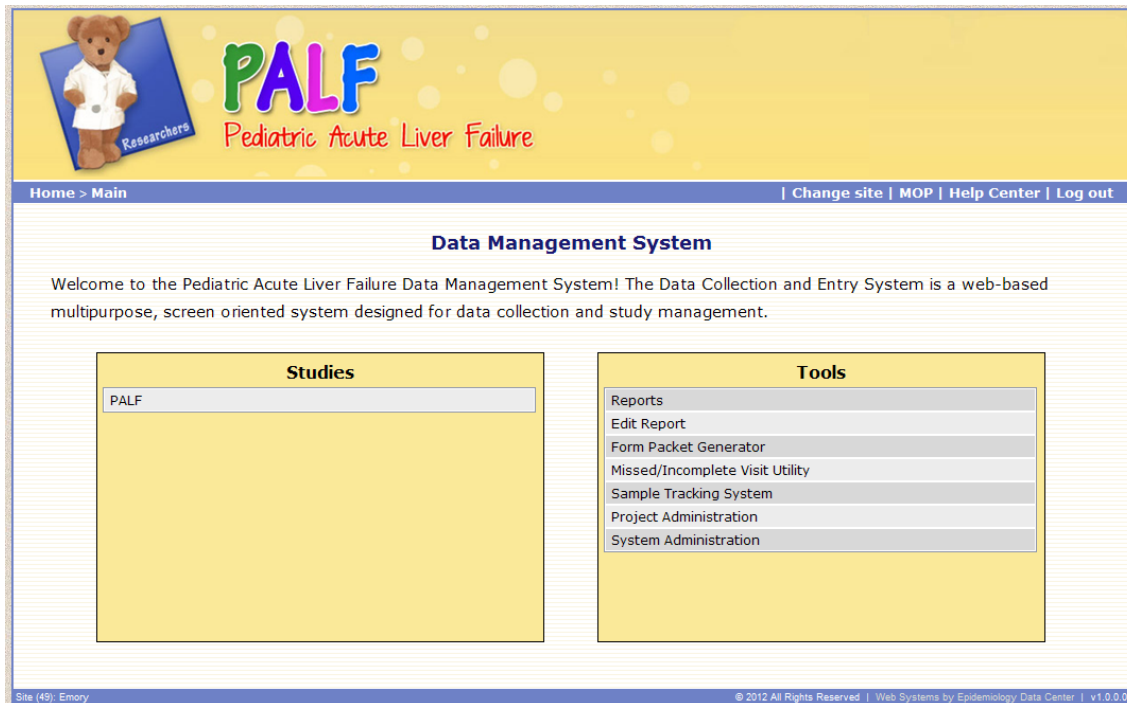

The site number and name will be displayed in the lower left side of the footer.
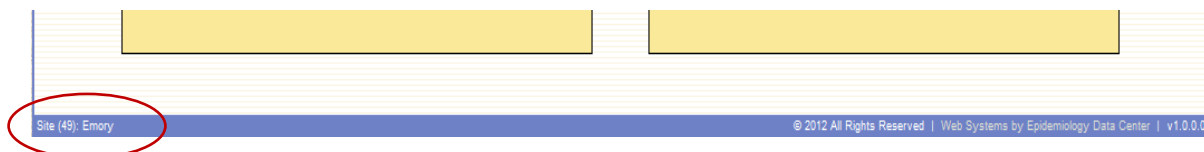
3.2. Data Management System Menu

From the Data Management System Menu you can access the Studies Menu and the Tools Menu (See Appendix B for a description of each of the Data Management System Tools). To access the Forms Menu select the study from the list.


3.3. Forms Menu

The Forms Menu consists of two panels. On the left panel is a list of all available forms for the study. To enter one of the forms either highlight and left click with your mouse or tab to and press the enter key to open that form for entry. To start a "Biochemistries Battery" select "Biochemistries" in the form list by either highlighting and left clicking with your mouse or tabbing to and pressing the enter key. To enter an individual biochemistry form click the expand symbol ⊞ next to "Biochemistries and select the specific form.

On the right panel you can search for a specific patient by entering their Patient ID or Screening ID and clicking the 'Search' button. If the Patient ID or Screening ID are valid you will be directed to that patient's Form List page.

From the form menu you can also access the study reports.
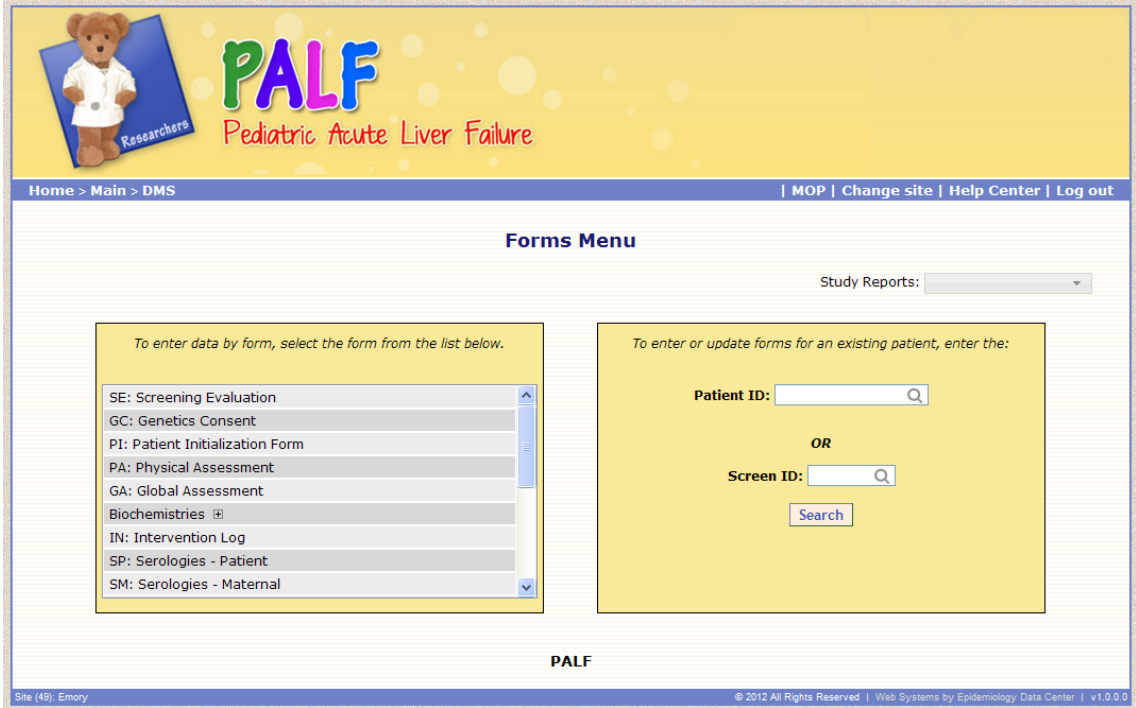
3.4. Patient Form List

The Patient Form List page displays all the available forms and provides links to enter a new form, update an existing form, verify a form, or print a study form. You can also access patient reports.
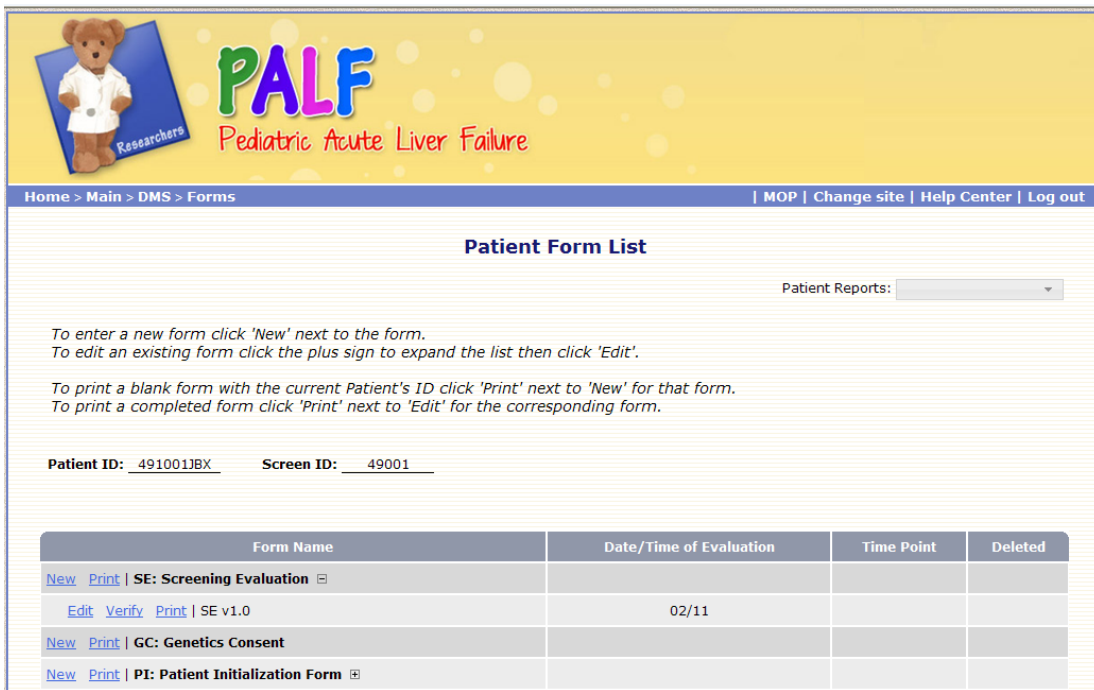
a)   To enter a new form: click the 'New' link to the left of the form.

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b) To print a blank form with the Patient ID inserted: click the 'Print' link to the left of the form.

c) To view existing forms: click the expand symbol ⊞ next to the specific form. This will display all of the forms previously entered for that patient. Information displayed:
   – Links for editing, verifying and printing an existing form
   – Version of the form
   – Date of evaluation
   – Time Point (if applicable)
   – Deletion status

d) To edit a form: click the 'Edit' link. This will open the form in update mode. (See section 6 for detail on updating a form).

e) To verify a form: click the 'Verify' link. This will open the form in verify mode. (See section 7 for detail on verifying a form).

f) To print a form: click the 'Print' link. This will open a printer friendly PDF version of the form that you can then print.

3.5. Study and Patient Reports

This utility will generate reports for all patients or for an individual patient. To generate a report go to the Forms Menu and click the Study Reports drop down menu to view the various study reports available.

After selecting a report, you may be prompted for additional information, such as the Study or Patient ID. After entering the information click 'OK' to generate the report. Reports for an individual patient can also be generated from the Patient Form List page.

3.6. Menu Navigation

The navigation bar is located at the top of each page, just under the PALF page header.

Home > Main > DMS > Forms > Patient | MOP | Change site | Help Center | Log out

The left hand side of the navigation bar shows the depth you are currently at in the system and provides a quick way to jump back to various pages.

Home – will return to the Pediatric Acute Liver Failure public website (http://www.palfstudy.org) and will log you out of the Data Management System.

Main – will return to the Data Systems Main Menu and log you out of the Data Management System. See Section 3.1 for details on the Data System Main Menu.

DMS – will return to the Data Management System page containing the Studies and Tools panels. See Section 3.2 for details on the Data System Main Menu.

Forms – will return to the Forms Menu. See Section 3.3 for details on the Forms Menu.

Patient – will return to the Patient Form List page for the current patient. See Section 3.4 for details on the Patient Form List.

The right hand side of the navigation bar has a log out, help center, change site and MOP links.

MOP – will display the manual of operations pop-up window which allows you to select a MOP for an individual form. If you are working in a form and you click this link the MOP for that form will be displayed.

Change Site – will display the change site pop-up which allows you to select a different site. This link is only available if you have access to more than one site's data.

Help Center – directs you to the PALF Website Help Center to report any issues encountered in the Data Management System. An additional log in using your PALF username and password will be required.

Log out – logs you out of the Data Management System and returns to the Main Menu. It is important to properly log out of the Data Management System when you are finished with a session. Proper logout practices are particularly important when a computer is shared between users. The log out procedure forces the data management system to clear all user specific information that is retained by the system when a session is in progress. Improper logout procedure can result in records being locked by the system (records will be released after 30 minutes).

4. Data Collection Forms Overview

The following rules and descriptions apply to both form entry and form updating.

4.1. Form Activity Notifications

When the system is performing an action on a form it will notify you by displaying an animated activity icon (or "processing"). This icon is seen while saving data to or retrieving data from the database. While this icon is seen the system is processing and you should allow the system to finish.

4.2. Field Navigation

To advance from one field to the next field, use the **TAB** key or the mouse. The **TAB** key will visit each field on a form according to a preprogrammed order.
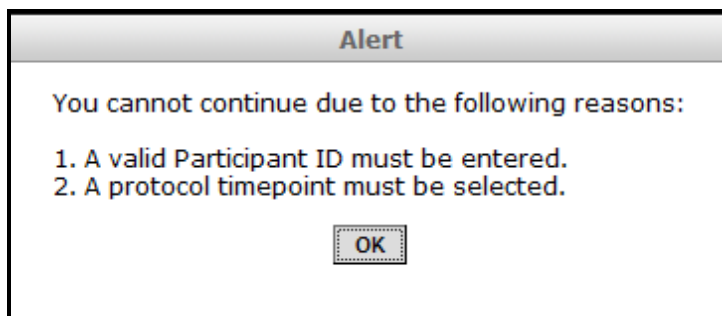
Keyboard navigation techniques:

    a. Navigation from field to field: the **TAB** key can be used to move from one field to next field, and **SHIFT+TAB** moves in reverse order. Use the **Arrow Keys** to move between elements in a group (such as a group of radio buttons).

    b. Buttons (e.g. Next, Submit, etc.): selectable with either the **ENTER** or **SPACE BAR** Key.

    c. Check boxes: **SPACE BAR** will select or deselect a check box.

    d. Radio Button groups: **TAB** moves from one radio button group to the next group, and **Arrow keys** move from one radio button to another within a group.

    e. Text fields: **TAB** moves to the input field.

    f. Drop down lists: you can navigate a drop-down list with the **Arrow keys** and open it with **Alt + Down Arrow**. You can also type the first character of a drop-down value to jump directly to that answer.
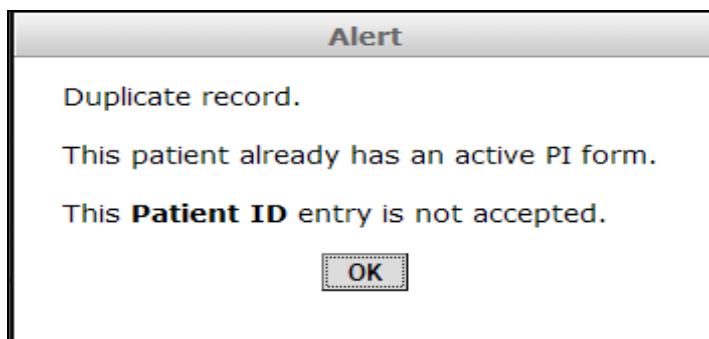
4.3. Required Fields

Each form has one or more data fields that uniquely identify records entered for that form. Valid data must be entered in these fields. Most often these fields are located at the top of the entry screen.

Required fields must be completed before data are submitted to the database. On submit the user will receive a specific pop-up message if a required field is left blank and that field will have a red border.

> **Alert**
>
> You cannot continue due to the following reasons:
>
> 1. A valid Participant ID must be entered.
> 2. A protocol timepoint must be selected.
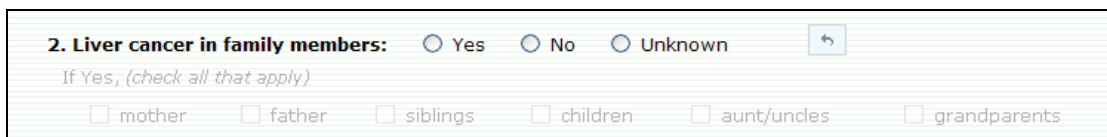>
> [OK]

4.4. Duplicate Records

A duplicate record check is performed on entry of the first page of a form. A duplicate record is identified according to the values entered in the required fields. If a duplicate record exists a pop-up message will be displayed.

> **Alert**
>
> Duplicate record.
>
> This patient already has an active PI form.
>
> This **Patient ID** entry is not accepted.
>
> [OK]

When you click the "OK" button, you will be returned to the form. Review and resolve the invalid entry and click the "Submit" button, or click 'Cancel' to return to the Patient Form List.

4.5. Field Dependencies

Within sections of forms, there are often fields that are dependent upon a previous field's response. In these cases, the dependent field(s) will be 'grayed out' and will not allow you to enter or update data.
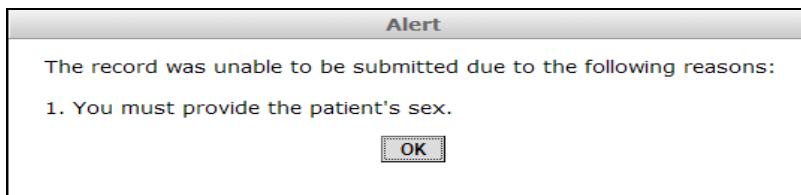

4.6. Invalid Values

Point of entry data checks are in place to identify certain types of data entry errors that may occur during the data entry process.

If a value entered in a field is invalid that field will immediately be shown with a red border. Upon hovering over the field with your mouse a notification will appear stating the reason for the red border.

For example, sex was not selected and this is a required field for the Screening Evaluation form.
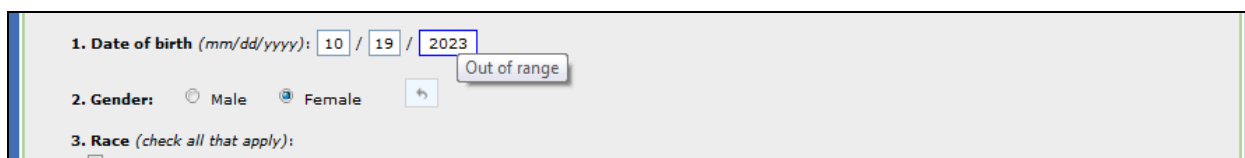

If you click the submit button a pop-up message will be displayed.

These invalid values must be resolved before data are submitted to the database. When you click the 'OK' button you will be returned to the form. Review and resolve the invalid entry and click the 'Submit' button, or click 'Cancel' to return to the Patient Form List.

4.7. Out of Range Values

Point of entry data checks are also in place to identify out of range values entered during the data entry process.

If a value entered in a field is flagged as 'out of range' that field will immediately be shown with a blue border. Upon hovering over the field with your mouse a notification will appear stating the reason for the blue border. Data items outlined in blue do not have to be resolved to submit the data to the database.

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Some 'out of range' values will be able to be indicated as correct during entry, verification or editing. To indicate that an out of range value is correct, check the box in the "result out of range but correct" column. The values indicated as correct during entry, verification or editing will automatically be bypassed and will not appear in the post processing edit report.

| Comprehensive Panel	Units	Time (If different from above)	Normal Range (LLN-ULN)	Not Done	Result out of range but correct
1. INR	4.2	:		☐	☑

4.8. Special Codes

Special codes are used principally to code different types of missing data. Special codes cannot be used for key fields. Special codes include: Missing, Not Applicable, Unknown, Refused/Prefer Not to Answer, and Not Done.

The Missing code is automatically inserted into a data field by the system when a field is left blank.
When dependent field(s) are not applicable a Not Applicable code is automatically inserted into the data field by the system.

Type of Data	Data Collector Codes for Paper Forms	Data Entry Codes
Missing or left blank	Field left blank or MISS	-1
Not applicable	NA	-2
Unknown	UNK	-3
Refused/Prefer Not to Answer	REF	-4
Not Done	ND	-5
Below the lower level of detection	BLD	-6
Above the upper level of detection	AUD	-7
Equivocal/Not Definitive	EQUIV	-8
Not assessable/Cannot determine	NAS	-9

4.9. Unsaved Data Alert

While entering or updating a form, if you attempt to navigate away from the form you will receive a pop-up alert message. The message will ask that you confirm that the new data you entered or updated will be lost. Clicking 'OK' will allow the browser to continue with your requested action and the unsaved data will be lost. Clicking 'Cancel' will cancel the requested action and return you to the form. You must click 'Submit' or 'Update' to save the data.
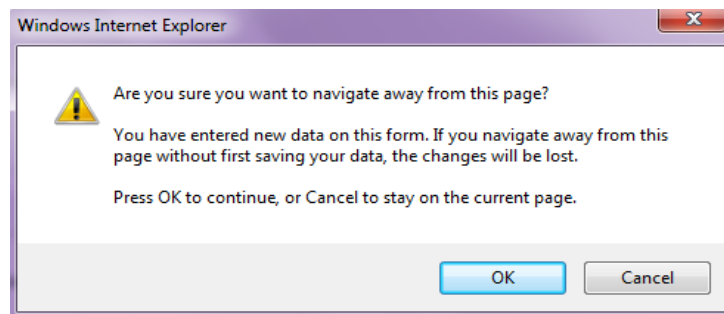
5. Entering a Form

Forms are either in single page or log format. 'Next' and 'Previous' buttons are provided on multi-page log forms. 'Submit (or Insert)' and 'Cancel' buttons are provided on all forms. Refer to Appendix A for a description of actions associated with each button.

Data for a given form may be entered in one or more entry sessions.

The PALF studies consist of coordinator completed, investigator completed, and patient completed data forms.

5.1. Coordinator and Investigator Completed Forms

Most of the coordinator and investigator completed forms are intended to be entered directly into the system by the coordinator/investigator. Coordinator/Investigator completed forms are entered via the Data Management System located on the Research side of the project website. Select "Data Management System" from the Data Systems Main Menu, select a study from the Data Management System menu and then select a form through the Forms Menu or through the Patient Form List (for a specific patient) by clicking the 'New' link next to the form that you would like to enter.

The Screening Evaluation (SE) will assign a Patient ID if the patient meets the eligibility criteria and consented to be in the study. The system will not allow you to enter any other forms until the patient has a SE form entered that indicates the patient met all eligibility criteria, has consented and has a system assigned Patient ID. All patients screened, regardless of whether they are eligible, will be assigned a Screen ID by the system on submission of the SE form.

5.1.1. Log Forms

Data collected regarding medications, interventions, procedures, diagnoses, infections, diagnostic tests (virals, autoimmune, metabolic), UNOS/TGLN, liver offers, and events will be entered in log format. This format allows the user to see the majority of the records entered during all modes (entry, verification, editing, and printing). The user will also be able to sort the records in ascending or descending order based on the column selected for sorting. The Intervention and Event logs have a slightly different format compared to the other logs and will have only limited information regarding the intervention/event displayed in the log table. A form page will be opened where the intervention/log data will be entered, verified or edited.

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Select the log form from the Forms Menu or Patient Form List page. If selecting a form from the Forms Menu select the Patient ID (the Patient ID will automatically be inserted if selecting the form from the Patient Form List page). If the patient already has records entered for the log, the previously entered records will be shown in the table. Deleted records will only be shown when the "Include deleted records" check box is checked.

Entry

To enter a new log record, enter all information in the last row of the table and click "Insert" to submit the record to the database.

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If the record is submitted, a notification message will be displayed indicating that the record has been successfully submitted to the database. The system will assign a system ID to uniquely identify the record for the patient.
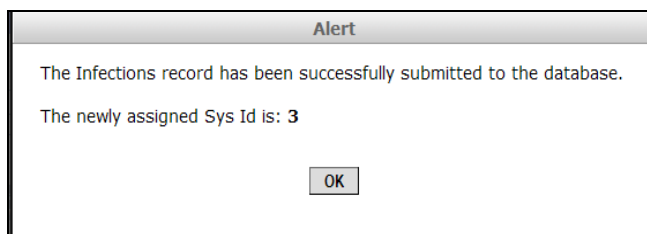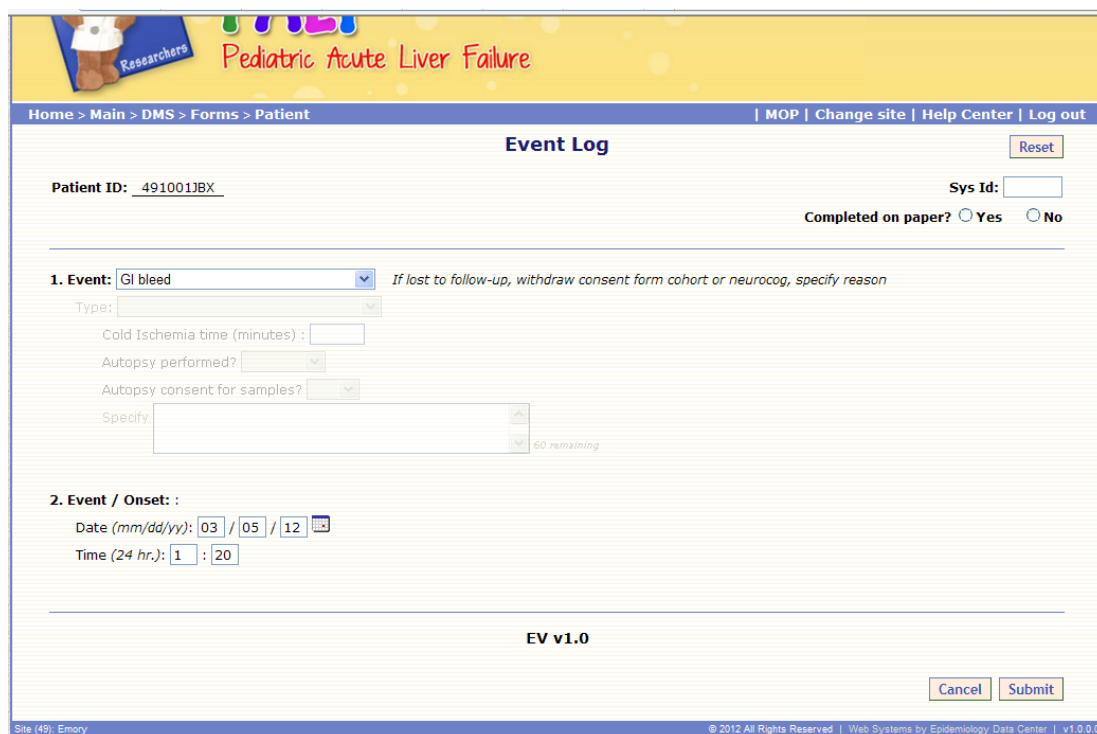
Enter another record or select "Back" to return to the Forms Menu/Patient Form List page.

Intervention/Event Logs
For Interventions and Events Logs, select the "New" link in the last row of the table.

Enter the information for the intervention/event in the intervention/event form page. Click "Submit" to submit the record to the database or "Cancel" to cancel the entry and return to the log table.

If the record is submitted, a notification message will be displayed indicating that the record has been successfully submitted to the database. The system will assign a system ID to uniquely identify the record for the patient.

Select either "Enter Another" to enter another intervention/event, "Forms Menu" to go to the Forms Menu page, "Patient Form List" to go to the Patient Forms List page or "Event/Intervention Logs List" to return to the Event/Intervention log list page.

Note: Only limited information regarding a particular intervention/event is displayed in the log table. To see all information related to a particular intervention/event click the "Edit" link.

Verify

To verify a log record click the "Verify" link and verify that the information entered is correct.

The record being verified will be displayed in pink. After any necessary changes are made and all information has been verified to be correct, click the "confirm" link to submit any changes to the database and set the record's status to verified, or click "Cancel" to return to the log table.

Intervention and Event Logs

For Intervention and Event Logs, select the "Verify" link in the last row of the table.

Review the information entered for each data field. Make corrections as necessary. At the end of the form check the "Check to confirm verification of data" checkbox when all data for the form have been verified to match the information on the paper source.

Click the "Verify" button to submit any changes made to the form to the database and to change the form's status to verified. A confirmation message will be displayed indicating that the form has been verified.

Editing

To edit a log record, click the "Edit" link. The record being edited will be displayed in pink. Make the necessary changes to the data and click "Update" to submit the changes made to the database or click "Cancel" to return to the log table.

Intervention and Event Logs
For Intervention and Event Logs, select the "Edit" link in the last row of the table.

Update data entered for that form, delete the form, or restore the form (if previously deleted). Click the "Update", "Delete" or "Restore" button to update the record.

Delete and Restore
To delete or restore a log record, click the "Delete" or "Restore" link. The user will be asked to confirm or cancel the action. Select "Confirm" to delete/restore the record or "Cancel" to cancel the action and return to the log table.

Sorting
To sort a table in ascending or descending order, click the column heading for the field by which you want the data to be sorted. An arrow will appear indicating the current sort order for the column (up arrow= ascending and down arrow=descending). To reverse the order of the column click on the column heading again and the direction of the sort order will be reversed. A table can be sorted by any column except the last column of the table containing the links for edit, verify, delete, restore and insert.

System ID △	Intervention	Date Started (mm/dd/yy)	Time Started (24 hr.)	Date Stopped (mm/dd/yy)	Time Stopped (24 hr.)	Volume/Amount Given (ml)	Completed on paper?	Deleted	
1	(14) Vitamin K	03/05/12	_:_	-3/-3/-3	_:_		Yes		Edit | Verify
									New

Print/Cancel
Click the "Print" button below the last row of the table to Print all of the log records currently entered. Records will be printed in order by System ID.

Note: Only non-deleted records will be printed and records will not print seperately.

Once all records have been entered, verified, edited, deleted, restored or printed, click the "Cancel" button below the last row of the table to return to the Forms Menu or Patient Form List.

5.1.2. Biochemistries Battery

The Comprehensive Metabolic Panel, CBC with Differential Panel, Blood Gases and Procedural Labs are part of the Biochemistries battery. The battery allows the user to enter one or more of these forms in succession without the need to re-enter the key information (Patient ID, date of sample, time of sample, and time point).

To begin a biochemistries battery session, click on "Biochemistries" on the Form Menu page or the 'New' link to the left of "Biochemistries" on the Patient Form List page.

The key field information bar will be displayed at the top of the page under the navigation bar. Enter the appropriate key information and click on one of the biochemistries form names displayed in the key field information bar.
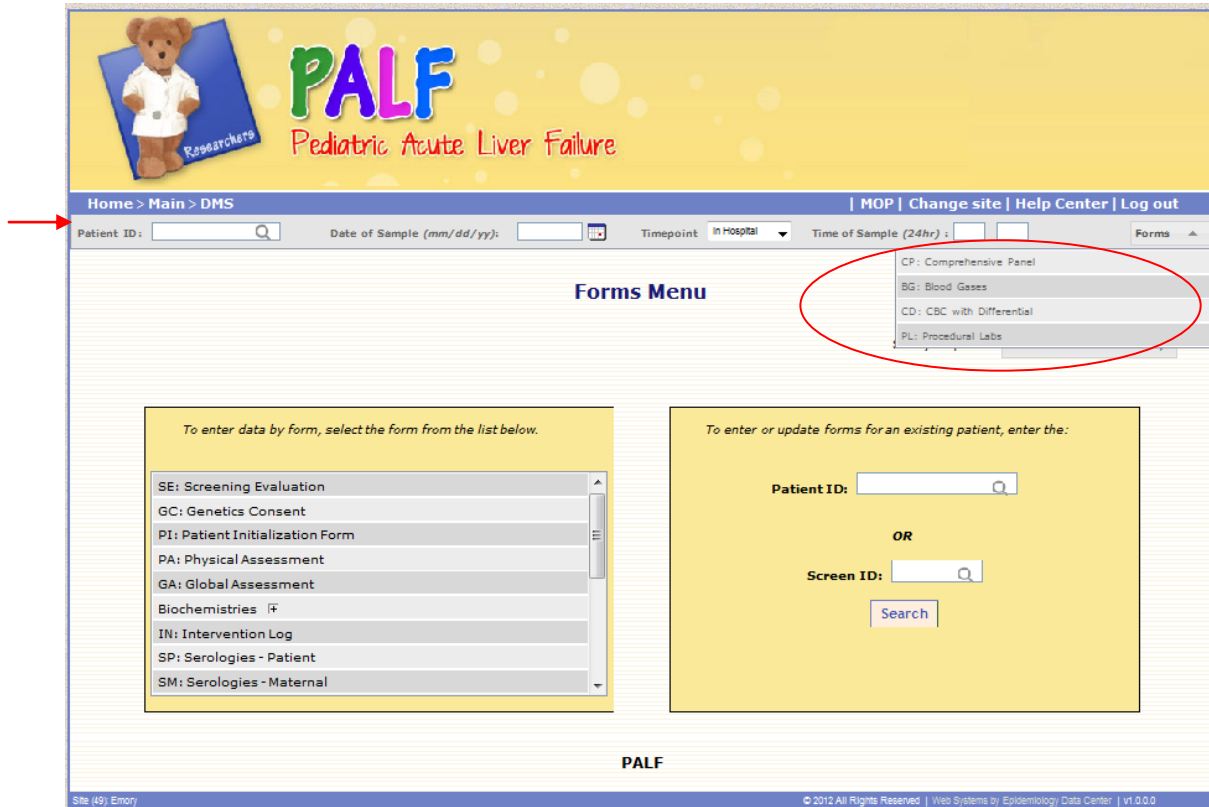
The form will be opened for entry and the key fields filled in with the information entered into the key field information bar. To modify the key fields on the form, change the information in the key field information bar.
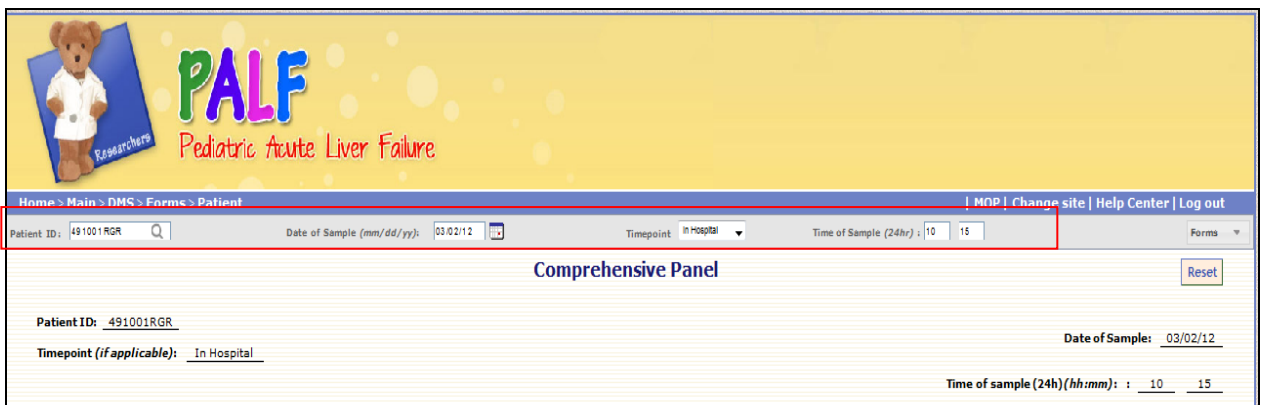
Click "Submit" to submit the record to the database or "Cancel" to cancel the entry and return to the Forms Menu/Patient Form List page.

A check mark will appear in front of the forms that have been entered with the keys entered into the key field information bar. To enter another form with the same key fields click on the next form in the form list in the key field information bar.

Note: If one or more of the key fields are changed in the bar the system will recognize this as a new battery of forms.

A form already entered in the battery, can be opened in edit mode by clicking on the name of the form. The user will be provided a notification indicating a form with those keys have already been enter and whether the user would like to view the record. If "Yes" the form will be opened in edit mode and if "No" the user will be returned to the entry screen.

To exit the battery mode, select "Forms" or "Patient" on the left hand side of the navigation bar.

5.2. Patient Self-Assessment Battery (For Patient Direct Entry Only)

The patient self-assessment forms are entered via the Data Management System located on the Research side of the project website. Select "Data Management System" from the Data Systems Main Menu, select a study from the Data Management System menu, and then "Start Patient Self-Assessment Battery (for patient direct entry only)" from the Forms Menu or enter the Patient ID and click search and from the Patient Form List click "Start Patient Self-Assessment Battery (for patient direct entry only)".

This utility is to be used only when the patient/parent is completing the self-assessment forms (English only – other languages are to be completed via a paper copy) on the computer and the data is entered directly into the database. This utility should <u>NOT</u> be used if the forms are completed on paper (entry of paper forms should be done by the coordinator from the Forms Menu or Patient Form List). **Note that the PedsQL Generic and Multidimensional (5-7 years) patient forms are not available in the self-assessment battery. These forms are completed via interview by the coordinator with the patient and should be entered by the coordinator from the Form Menu or Patient Form List).**

The utility selects all the self-assessment forms that should be completed by the patient/parent according to the protocol timepoint and the patient's current age (prepopulated by the system if available) entered by the coordinator. The patient/parent can then complete the self-assessment forms in succession without interruption between the forms. However, if the patient/parent is interrupted while completing the battery of forms, the system will allow the patient/parent to interrupt the session and return to it at a later time on that same day.

Note: The self-assessment forms selected will only be available to be completed using the self-assessment battery utility during the day the session is initiated. If the self-assessment battery session was started prior to the current date the following alert will be displayed and the "Start Patient/Start Parent" buttons will be inactivated.
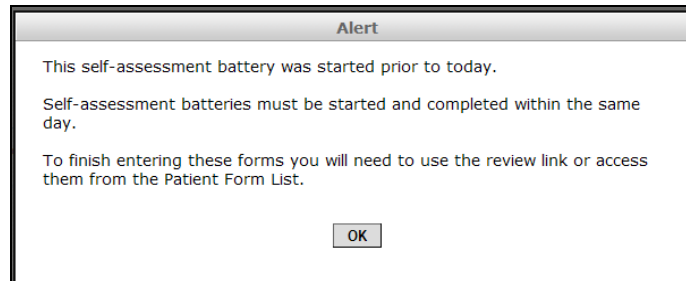
The coordinator must enter the Patient ID, current patient age (will be prepopulated by system if available) and protocol timepoint.
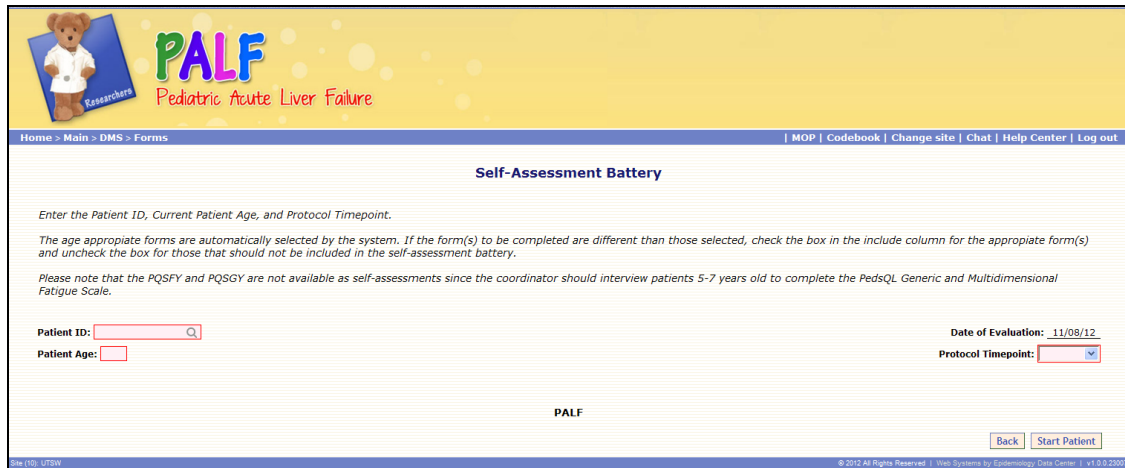
A table will be displayed showing all self-assessment forms. Those self-assessment forms that need to be completed based on the protocol timepoint and patient age entered will be checked in the include column. The table will also display how much of the each form is currently completed and whether the form is to be completed by the patient or parent. To include or exclude a form from the battery either check or uncheck the checkbox in the include column.

If some self-assessment forms are to be completed by the parent and some are to be completed by the patient, the coordinator will be responsible to initiate a separate self-assessment battery session for both the parent and patient. The coordinator will be asked to log back into the Data Management System at the end of each session.

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Click the "Start Parent/Start Patient" button to begin the Self-Assessment Battery. The window will close to lock out parent/patient access to the Data Management System. A new window with limited functionality will be opened with the self-assessment(s). **Note that the parent/patient will not be able to access the research side of the PALF website.**

Once the parent/patient is finished they will be shown a "Thank you" message that asks them to notify the coordinator that they have finished. The coordinator should click the "Next" button to close the self-assessment window.

The coordinator will then be prompted to enter their username and password in order to log back into the Data Management System and will then get a message that the self-assessment battery has been successfully submitted to the database.

The coordinator will be returned to the patient self-assessment battery entry criteria page with the table showing all the self-assessment forms. The "percent complete" column will show how much of each form is currently complete. The coordinator can review each of the forms by clicking on the "Review" link in the Review column. When the "Review" link is clicked the form will be opened in a **coordinator use only mode** and all missing data in the form will by highlighted in blue to assist the coordinators in the review process. The coordinator can review the questionnaire with the parent/patient and update missing or other responses the parent/patient requests to change. ***The parent/patient should not be given access to the Data Management System in the coordinator use only mode.*** If it is necessary to put the parent/patient back into the patient self-assessment battery to complete the forms click the "Start Patient/Start Parent" button in the patient self-assessment battery entry criteria page or to begin the second self-assessment session with either the parent/patient click the appropriate start button.

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Note: If a battery cannot be completed an alert message will be displayed with the reason why the form(s) are not available for entry.

When finished click "Back" to return to the Form Menu or Patient Form List page.

6. Edit, Delete or Restore a Form

To update, delete or restore a form, click the expand symbol ⊞ next to the specific form in the Patient Form List.

Click the 'Edit' link to open the form. You may then update data entered for that form, delete the form, or restore the form (if previously deleted). Refer to Appendix A for a description of the actions associated with the 'Update', 'Delete', and 'Restore' buttons.

7. Verify a Form

A visual verification module has been implemented for all data forms associated with the IT trials, and must be used when data are not directly entered into the data system. Direct entry is defined as data entered directly into the database without use of a paper source.   When data are collected on paper forms and then entered into the data system, the visual verification process must be performed. The verification process should identify data entry errors.

Additional Question on Entry

Each form will now include the question "Completed on paper?" to indicate whether the original form was completed on paper. The question will be located under the date of evaluation on most forms (log forms will have an additional column for this question).

If the date of evaluation is equal to the current date, the user must indicate whether the form was completed on a paper source prior to entry. If the date of evaluation is not equal to the current date this question is automatically set to "Yes". This question is a required field and must be answered before the form can be submitted to the database.

To verify a record from the Form Menu page enter the Patient ID and click "Search". Click the expand symbol ⊞ next to the specific form to be verified. Click the "verify" link next to the form to be verified.

Review the information entered for each data field. Make corrections as necessary. At the end of the form check the "Check to confirm verification of data" checkbox when all data for the form have been verified to match the information on the paper source.

Click the "Verify" button to submit any changes made to the form to the database and to change the form's status to verified. A confirmation message will be displayed indicating that the form has been verified.

Note: Post processing data quality control checks will only be applied to verified records.

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Appendix A: Button Controls

Cancel *Cancel Button*

The Cancel button is located in the lower right corner of each non patient self-assessment form. For patient self-assessment forms the cancel button is located in the lower left corner.

If the Cancel button is clicked during entry of a single page form, and data have been entered on the form, you will receive the Unsaved Data Alert (see section 4.9). If you are entering a multi-page form and you click 'Cancel' you will receive a pop-up question asking if you wish to save what you have currently entered. If you click 'Yes' all data currently entered on the form will be saved so that you may return later to complete the form. Otherwise, if you click 'No' all of the data will be lost. Regardless of your choice, you will be returned to the page from which you selected the form, either the Forms Menu or the Patient Form List.

Delete *Delete Button*

The Delete button is located in the upper left corner of every form during edit mode. The Delete button is used to delete records from the database. Records that are deleted from the database may be restored at a later date.

Clicking the Delete button will produce a pop-up message asking you to confirm the action. If you click 'Confirm' the form will be deleted and you will receive a pop-up confirming this. After the confirmation pop-up you will be returned to the Patient Form List. Otherwise, if you click 'Cancel' the form will not be deleted and you will not be redirected.

Warning
Are you sure you want to delete this Baseline Evaluation - Coordinator (Adult) form?
Confirm   Cancel

Notification
The Baseline Evaluation - Coordinator (Adult) form has been deleted.
OK
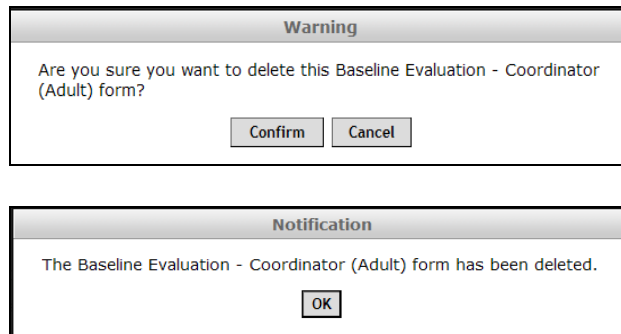
Once a form is deleted you may still access it from the Patient Form List. However, the form will not be editable. If you want to edit the form you must restore it first (See section 6). A deleted form will have the words "deleted" in red next to the Patient ID; the printed version will include this as well.

<< Previous   **Next >>**   *Next and Previous Buttons*

The Next and Previous buttons are used in multi-page forms to move back and forth between pages. They are located at the bottom left corner of multi-page forms. Each time you click 'Next' data on that current page is validated. If there are any invalid values or 'out of range' values you will receive the appropriate pop-up. Some validation issues must be resolved to move to the next page. Otherwise, if validation passes you will be moved to the next page.

Reset   *Reset Button*

A reset button is located in the upper right hand corner of each form, except for patient self-assessment forms. Clicking the reset button will reset the current form to its default state. Hence, all data and selections on the form are cleared. In the case of multi-page forms, data fields on all pages are cleared and you are returned to page one of the form.

Restore   *Restore Button*

The Restore button is located in the upper left corner of every deleted form.

Clicking the Restore button will produce a pop-up message confirming that the form has been restored. After the confirmation message you will be returned to the form in an editable state.

> **Notification**
>
> The Symptom Assessment (Adult) form has been restored.
>
> OK
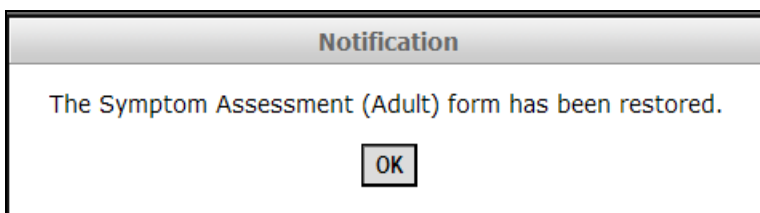
Submit   *Submit Button*

The Submit button is located in the lower right corner. In the case of multi-page forms and patient self-assessment forms the Submit button is only found on the final page.

When the Submit button is clicked the system will run through validation checks to confirm that data are okay to be submitted to the database. The validation checks look for required fields (see section 4.3), invalid values (see section 4.6), 'out of range' values (see section 4.7) and duplicate records (see section 4.4). Once all of these checks are passed you will receive a pop-up notice that the data have been saved in the database. The data have not been saved until you see this pop-up:

> **Notification**
>
> The Special Visit Form (Adult) form has been successfully submitted to the database.
>
> Would you like to print the form?
>
> Yes   No
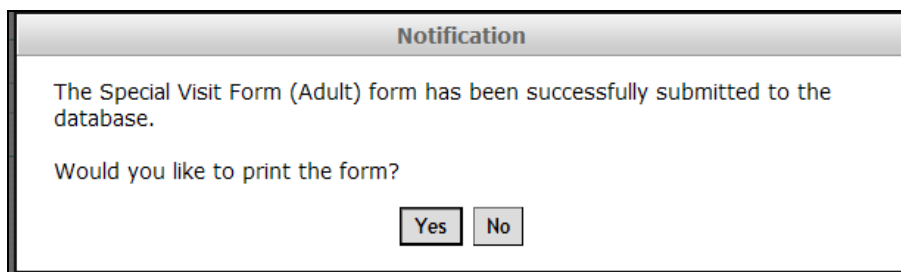
The pop-up also asks if you would like to print the form that was just submitted to the database. If you click 'Yes' a separate window will open with a PDF version of the form for printing and the original window will return to an un-editable version of the form with the bottom right corner of the form containing the buttons 'Enter Another', 'Forms Menu', and 'Patient Forms List'. Otherwise, if you click 'No' you will return to an un-editable version of the form with the bottom right corner of the form containing the buttons 'Enter Another', 'Forms Menu', and 'Patient Forms List'.

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Enter Another — Clicking this will open a fresh copy of the current form so that you may enter another one.

Forms Menu — Clicking this will take you back to the Forms Menu (see section 3.3).

Patient Form List — Clicking this will take you back to the current Patient's Form List (see section 3.4).

Event Logs List — Clicking this will take you back to the log list

↶ *Undo Button*

In order to reset (deselect) all members within a radio button group, click the undo button icon next to the question to reset every radio button in that group and any dependent questions to the default state.

Update *Update Button*

The Update button is located in the lower right corner of every form opened in Edit mode. In the case of entering multi page forms and patient self-assessment forms the Update button will not be seen until the final page.

When the Update button is clicked the system will run through all of its validation checks to be sure the data is okay to be submitted to the database. It will look for required fields (see section 4.3), invalid values (see section 4.6), 'out of range' values (see section 4.7) and duplicate records (see section 4.4). Once all of these checks are passed, you will receive a pop-up notice that the data has been updated in the database. Until you see this pop-up the changes to the data have not been saved.

Notification

The Baseline Evaluation - Patient (Adult) form has been updated.

Would you like to print the form?

[Yes] [No]
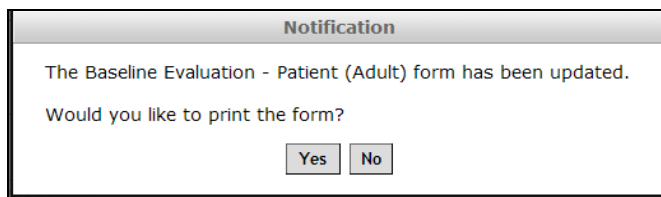
The pop-up also asks you if you would like to print the form that you just updated in the database. If you click 'Yes' a separate window will open with a printer friendly PDF version of the form for printing and the original window will return to the Patient's Form List . Otherwise, if you click 'No' you will be returned to the Patient's Form List.

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Appendix B: Data Management System Tools

Reports

This utility will generate reports for all patients or for an individual patient (see section 3.5 for more details)

Edit Report

This utility will provide a site's non-dynamic edit report for a study. A post process edit routine will be run according to a set schedule to facilitate timely resolution of data collection and entry issues. If the edit report has not yet been posted a message will be displayed indicating that the edits are in progress and to check back later.

To display the edit report for your site for a specific study, enter the Data Management System located on the Research side of the project website. Select "Data Management System" from the Data Systems Main Menu, select 'Edit Report' under "Tools" from the Data Management System menu. Select the study that you want the Edit Report for and click "OK" to display the Edit Report.

| ID	Form	Timepoint	Date of Evaluation	Page Number	Line Number	Variable Name	Variable Label	Variable Value	Edit Type	Edit Reason	Bypass	Will Never Be Obtained	Coordinator Comment
010001YQP		Baseline	01/14/2011	3	2	RACEW	Race: White	0	Logic Check	Race on BP form does not match SL form	☐	☐	
010001YQP	BP	Baseline	01/14/2011	3	2	RACEO	Race: Other	Yes	Logic Check	Race on BP form does not match SL form	☐	☐	
010002DXU	BC	Baseline				sdate	Sample Date	02/08/11	Logic Check	Sample date does not match date of evaluation	☐	☐	
010002DXU	BP	Baseline	01/18/2011	5	3	DOEBP	Date of Evaluation: BP	01/19/11	Logic Check	Check dates of evaluation on BC and BP forms	☐	☐	

The following information will be displayed in the edit report.

Edit Report Column Name	Description
ID	Patient ID
Form	Short form name (example: Quality of Life=QL).
Timepoint	Timepoint associated with form, if applicable.
Date and time of evaluation	Evaluation date and time associated with the form.
System ID	System ID number assigned to the log entry associated with the data item in question.
Variable Name	Database variable name associated with the data item in question.
Variable Label	Descriptive label associated with data item in question.
Variable Value	The current value recorded in database for the data item in question. Special codes are used to distinguish between different types of missing data in the database (see section 4.8)

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Edit Report Column Name	Description
Edit Type	There are five primary types of edits requests: 1) Cannot be missing: update field to the appropriate value 2) Cannot be NA: review and confirm item is to be recorded as not applicable 3) Out of range: data item is outside the low/high range set in the database; confirm value is correct. 4) Dependency Mismatch: based on an answer given for a 'Parent' or 'Child' (skip/dependency type question) an appropriate response was not given for one or the other 5) Logic check: based on what we expect for a particular item or data across forms, a confirmation of the data is necessary
Edit Reason	Provides additional information to clarify the edit request. May include information about other data items which affect the current data item in question.
Bypass	This box should be checked by the coordinator if they have verified the data to be correct. The coordinator must also provide a reason for the bypass, except for 'Out of Range' edits, in the 'Coordinator Comments' column. The bypass box will not be an option for missing values. It is expected that a missing field will be updated to a valid value or an appropriate special code (e.g. not done, unknown, prefer not to answer). All bypass requests will be reviewed by the DCC.
Will Never Be Obtained	When a patient does not answer a question and you know that the response will never be available, you can check "will never be obtained" on the edit report. This checkbox will only apply to missing responses on self-assessment questionnaires.
Coordinator comment	To provide further details to the DCC regarding an edit or bypass.

To print and/or save the edit report click the "Print" button which will open a PDF version of the edit report in a separate pop-up window in your browser.

To submit a bypass request to the DCC for any item which has been verified and the data found to be correct, check the bypass check box for the edit you wish to bypass and provide a reason for the bypass in the "Coordinator Comments" column and then click "Update". The bypass request(s) have not been saved until you see this pop-up:
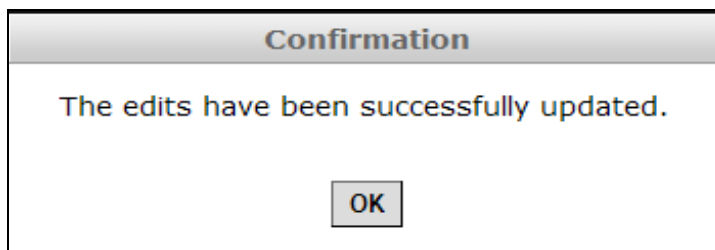
Direct link from Edit report to the record

To open a form that has an edit displayed on the report, click on the "Edit Form" link above the coordinator comment box in the Edit Report. The form will open in edit mode to allow the user to make a change to the record, if appropriate. Click the "Update" button to submit changes made to the record or the "Cancel" button to leave the form without saving any changes to the database. The user will then be returned to the edit report to address other edits in the report.

The user also now has the ability to print the form containing the edit in question by clicking the "Print Form" link above the coordinator comment box. Once printed simply close the PDF to return to the Edit report.

Edits will remain in the report, regardless of whether they are resolved, until the next edit report is generated (edit reports are routinely generated on Tuesdays and Thursdays).

ID	Form	Timepoint	Date of Evaluation	Page Number	Line Number	Variable Name	Variable Label	Variable Value	Edit Type	Edit Reason	Bypass	Will Never Be Obtained	Coordinator Comment
													Edit Form | Print Form
0001YQP	BC	Baseline	01/14/2011				Samples Obtained	Yes	Logic Check	BC form indicated that samples were obtained, however no baseline samples have been entered into the Sample Tracking System	☐	☐	
													100 remaining

Note: Edits that are related to more than one record will not have "Edit Form" or "Print Form" links.

Form Packet Generator

The Form Packet Generator is a tool provided to print all or some of the data forms required at specific visits with key fields, such as Patient ID, date of evaluation, and timepoint prefilled on the printed forms. See the PALF Form Packet Generator Guide for further details.

Missed/Incomplete Visit Utility

This administrative utility is used to track missed or partially completed visits.

For a missed visit enter the Patient ID, study associated with the visit, and timepoint. Click the "Missed" radio button and select a reason for the missed visit from the "Reason for Missed/Incomplete Visit" from the drop down box. If the visit was a "Special Visit" provide the primary reason for the special visit and date of the special visit. Click "Submit" to save the notification to the database.

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For an incomplete visit provide the same information described above and in addition check those forms which were not completed at the time of the visit. Click "Submit" to save the notification to the database.

Sample Tracking System
This web-based system is used to initialize barcodes, enter and edit information for samples collected, and generate shipping manifests at the time of shipment. See the Sample Tracking System User Manual for further details.