2.7 Remove, Restore, and Delete Study Events and CRFs for a Subject

If your User Type and Role have appropriate permissions, you can remove and restore Study Event CRFs and Events, as well as delete Study Event CRFs and Events.

Approved for publication by Ben Baumann. Signed on 2014-03-24 8:07AM

Not valid unless obtained from the OpenClinica document management system on the day of use.

2.7.1 Remove and Restore Study Event CRFs for a Subject

You can remove a Study Event CRF if you want to prevent the information in it from being changed, but still want to access the information and potentially restore it for future use. You cannot remove a Study Event CRF when the Study Event status is "scheduled" or "not scheduled." To remove a Study Event CRF for a Subject:

1. In the Subject matrix, click the View icon in the Actions column.
   The View Subject page opens.
2. Click the Remove icon for the Study Event CRF you want to remove.
   The Remove CRF from Event page opens.
3. Click Remove Event CRF.
4. Click OK in the confirmation dialog box.
   The View Subject page opens, reflecting the removal of the Study Event CRF for that Subject.

After you remove a Study Event CRF:

- You cannot change data in the Study Event CRF.
- You can create Discrepancy Notes for Items in the Study Event CRF.
- The Study Event CRF status is "invalid" .

After a Study Event CRF has been removed, you can restore it so that you can enter data in it:

1. In the Subject matrix, click the View icon in the Actions column.
   The View Subject page opens.
2. Click the Restore icon for the Study Event CRF you want to restore.
   The Restore CRF to Event page opens.
3. Click Restore Event CRF.
4. Click OK in the confirmation dialog box.
   The View Subject page opens. The Study Event CRF status is no longer "invalid."

Note: Study Event CRFs that are removed and then restored maintain their original status once

restored. For example, when a completed CRF is removed and then restored, it is in the completed status after its restoration.

2.7.2 Delete Study Event CRFs for a Subject

If you no longer need the data in an Event CRF, you can delete that Event CRF. This is most often used when one Subject's data has ben entered into another Subject's form. Unlike the Remove action, once a Study Event CRF has been deleted, that data cannot be restored.

You cannot delete a Study Event CRF if the Event status is "scheduled" or "not scheduled."

To delete a Study Event CRF for a Subject:

1. In the **Subject Matrix Actions** column, click .
   The View Subject page opens.

2. For the Study Event CRF you want to delete, in the Actions column, click .
   The Delete CRF from Event page opens.

3. Click **Delete Event CRF**.
   A confirmation box displays.
4. To confirm the deletion, click **OK**.
   The View Subject page opens, reflecting the deletion of the Study Event CRF for that Subject.

After you delete a Study Event CRF:

- The CRF is cleared of all data and is available for re-entry.
  - All Notes and Discrepancies associated with the Event CRF are set to auto-closed and attributed to the username of the person who deleted the Event CRF.
  - All Rules that had executed based on the deleted data are reset.
  - All fields that have show/hide functionality are reset to their original state, whether show/hide is done in a Rule or using Simple Conditional Display.
- The Study Event CRF status is "data entry started."
  The status is set to "data entry started" because data entry was started on this form, and there is provinence data associated with that Event CRF (e.g., the audit log and any auto-closed Notes and Discrepancies).

2.7.3 Remove and Restore Study Events for a Subject

You can remove a Study Event if you want to prevent the information in it from being changed, but still want to access the information and potentially restore it for use in the future. You cannot remove a Study Event when its Event status is "not scheduled." To remove a Study Event for a Subject:

1. In the Subject matrix, click the View icon in the Actions column. The View Subject page opens.
2. Click the Remove icon  for the Study Event. The Remove Event from Study page opens.
3. Click Remove Event from Study.
4. Press OK in the confirmation dialog box that displays. The View Subject page opens, reflecting the Study Event's removal for that Subject.

After you remove a Study Event for a Subject:

- The original status of the Study Event (for example, Signed or Completed) will still be reflected in the user interface. For example, the View Subject page and Printable HTML Casebook will list the Study Event as Signed, Completed, etc., but the audit log will list the Removal event and the actions available for the Study Event will change after it has been removed.
- The status for all CRFs in the Study Event that have been started will be "invalid" .
- Data in CRFs for the Study Event cannot be changed.
- Discrepancy Notes can be created for Items in CRFs for the Study Event.

You can restore a Study Event that has been removed for a Subject:

1. In the Subject matrix, click the View icon in the Actions column. The View Subject page opens.
2. Click the Restore icon for the Study Event you want to restore. The Restore Event from Study page opens.
3. Click Restore Event to Study.
4. Press OK in the confirmation dialog box. The View Subject page opens, reflecting that the Study Event was restored for that Subject.

- After restoring a Study Event, the status of the CRFs for that Study Event for the Subject are no longer "invalid."

2.7.4 Delete Study Events

Delete a Study Event to reset the Study Event Status from "scheduled" to "unscheduled." You can delete a Study Event only when the Study Event status is "scheduled."

To delete a Study Event:

1. In the Subject matrix, click the View icon in the Actions column.
   The View Subject page opens.
2. Click the Delete icon in the Actions column for the Study Event CRF.
   The Delete Event from Study page opens.
3. Click Delete Event from Study.
4. Click OK in the confirmation dialog box.
   The View Subject page opens, showing the Study Event Status as "unscheduled."