

6.4 Administer CRFs

The Administer CRFs features allow you to create and manage defined CRFs used for data entry in OpenClinica. The features are the same as those found in the Study Setup and the Monitor and Manage Data modules (see <u>Create and Modify Case Report Forms</u>), except in the Administration module, you can also archive and unarchive CRFs, which is described here. When you archive a version of a defined CRF:

- That version of the CRF cannot have been used for entering Study Event data for Subjects.
- Any data already captured using that version of the CRF is maintained in the system, although you cannot modify it.
- Data already captured using that version of the CRF is included in data extracts you create.
- The version of the CRF can be unarchived.

To archive a version of a defined CRF:

1. From the Tasks menu, in the Administration module, select CRFs. The Administer Case Report Forms (CRFs) page opens.

Page 1 of 1						Find	Blank CRF Template		OpenClinic Library	a CRF Creat New	Create a New CRF	
CRF Name	Date Updated	Last Updated by	CRF_OID	Versions	Version_OID	Date Created	Owner	Status	Download	Actions		
Adverse Events	05-Jul-2011	agoodwin	F_ADVERSEEVENT	(original)		05-Jul-2011	agoodwin	available			3 (
				v1.0	F_ADVERSEEVENT_V10	05-Jul-2011	agoodwin	available		S 🔒 🛛	3 (
				v1.2	F_ADVERSEEVENT_V12	05-Jul-2011	agoodwin	available		S 🔒 🕽	3 (
Agent Administration	05-Jul-2011	agoodwin	F_AGENTADMINIS	(original)		05-Jul-2011	agoodwin	available			3 (
				v1.0	F_AGENTADMINIS_V10	05-Jul-2011	agoodwin	available		S 🔒 D		
Concomitant Medications	05-Jul-2011	agoodwin	F_CONCOMITANTM	(original)		05-Jul-2011	agoodwin	available			3 (
				v1.0	F_CONCOMITANTM_V10	05-Jul-2011	agoodwin	available		S 🔒 🛛	3	
Eligibility	05-Jul-2011	agoodwin	F_ELIGIBILITY	(original)		05-Jul-2011	agoodwin	available			3 (
				v1.0	F_ELIGIBILITY_V10	05-Jul-2011	agoodwin	available		S 🔂 D	3	
Physical Exam	05-Jul-2011	agoodwin	F_PHYSICALEXAM	(original)		05-Jul-2011	agoodwin	available			3 (
				English	F_PHYSICALEXAM_ENGLISH	05-Jul-2011	agoodwin	available		5 🔂 🕽	3 (
				Español	F_PHYSICALEXAM_ESPAOL	05-Jul-2011	agoodwin	available		S 🔂 D	3	
Verification of Informed	05-Jul-2011	agoodwin	F_VERIFICATION	(original)		05-Jul-2011	agoodwin	available			31	
				v2.0	F VERIFICATION V20	05-Jul-2011	accodivin	available				

2. For the version of the CRF you want to archive, click the Archive icon 🚯 in the Actions column.

The Confirm Archiving CRF Version page opens. For the example shown here, the Adverse Events CRF, version v1.0 is being archived.

CRF Name:	Adverse Events					
CRF Version:	v1.0					
Description:	Adverse events which captures multiple AE's. Each AE is its own section.					
		in 2011-04-04				
Revision Notes:	created agoodwin 2011-04-04					
Revision Notes: ubjects that are in the	created agoodwin 2011-04-04 middle of data entry for this CRF version are shown as fol	lowing:				
Revision Notes: ubjects that are in the Study Subject Labe	e middle of data entry for this CRF version are shown as fol Study Name	lowing: Study Event				

3. Verify the information, then click Archive CRF Version.

The Administer CRFs page opens. The version you archived now has an Unarchive icon in the Actions column, and its status is "locked."

Page 1 of 1						Find	Blank CRF Template		OpenClinic Library	a CRF	F Create a New CRF	
CRF Name	Date Updated	Last Updated by	CRF_OID	Versions	Version_OID	Date Created	Owner	Status	Download	Actions		
Adverse Events	05-Jul-2011	agoodwin	F_ADVERSEEVENT	(original)		05-Jul-2011	agoodwin	available		51		E
				v1.0	F_ADVERSEEVENT_V10	05-Jul-2011	agoodwin	locked		S 6	X	X
				v1.2	F_ADVERSEEVENT_V12	05-Jul-2011	agoodwin	available		S 6	X	X
Agent Administration	05-Jul-2011	agoodwin	F_AGENTADMINIS	(original)		05-Jul-2011	agoodwin	available				E
				v1.0	F_AGENTADMINIS_V10	05-Jul-2011	agoodwin	available		S 6	X	X
Concomitant Medications	05-3ul-2011	agoodwin	F_CONCOMITANTM	(original)		05-Jul-2011	agoodwin	available				6
				v1.0	F_CONCOMITANTM_V10	05-Jul-2011	agoodwin	available		S 6	X	X
Eligibility	05-Jul-2011	agoodwin	F_ELIGIBILITY	(original)		05-Jul-2011	agoodwin	available		S		6
				v1.0	F_ELIGIBILITY_V10	05-Jul-2011	agoodwin	available		٦ (X	X
Physical Exam	05-Jul-2011	agoodwin	F_PHYSICALEXAM	(original)		05-Jul-2011	agoodwin	available		S		E
				English	F_PHYSICALEXAM_ENGLISH	05-Jul-2011	agoodwin	available		5	X	X
				Español	F_PHYSICALEXAM_ESPAOL	05-Jul-2011	agoodwin	available		٦ (X	X
Verification of Informed	05-Jul-2011	agoodwin	F_VERIFICATION	(original)		05-Jul-2011	agoodwin	available		5		E
				v2.0	F VERIFICATION V29	05-Jul-2011	accodwin	available				

To unarchive a version of a defined CRF:

- 1. Click the Unarchive icon 😨 in the Actions column for the CRF you want to unarchive. The Confirm Unarchiving CRF Version dialog box opens.
- Verify the information, then click Unarchive CRF Version. The Administer CRFs page opens. The version of the CRF you unarchived has an Archive icon in the Actions column and a status of "available."

Approved for publication by Ben Baumann. Signed on 2014-03-24 8:47AM

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