NHS
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GD User guide to signing off SOPs on OpenClinca

When an SOP is released or ratified, you will be required to record you have read it on OpenClinica. OpenClinica is data repository that is accessed using a web browser (Firefox is recommended). We have two instances of OpenClinica known as the test site and the live site, the SOP training record is housed on the test site. The test site can be assessed using the following link: https://papworth-test.eclinicalhosting.com/OpenClinica/pages/login/login

Log in using the username and password you have been provided with. If you are unsure of your login details please contact the Data Management Team papworth.openclinica@nhs.net

Once you have logged into OpenClinica verify you are on the correct Study/Site by referring to the top left of the page, it should read **Standard Operating Procedures** followed by your staff group. If it does not, select Change Study/Site and select this from the list.

Staff members are listed as Study Subjects. Find yourself by either using the Subject Matrix or searching in Study Subject ID box. Every staff member has their own row. The events are shown across the top. The events divide the SOPs into groups of 10, to locate a SOP determine which event it falls into then open the event by clicking the icon for the appropriate group of 10, then clicking

View/Enter Data. The icon will be either ▦ (if you've not reviewed any SOPs in the group) or ▥ (if you've previously reviewed at least one SOP in the group).
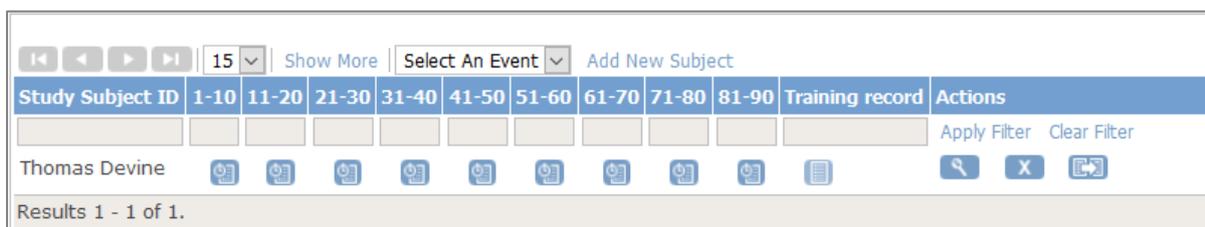
Once you have opened the event you will see all the CRFs within. Each CRF represents a SOP; the current version number is also shown on this page. If a SOP does not appear to you on this page, then you are not required to read it.

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
SOP 001	v8.0	▤			▦ ✎ 🖨
SOP 002	v7.0	▤			▦ ✎ 🖨
SOP 003	v8.0	▤			▦ ✎ 🖨
SOP 005	v3.0	▤			▦ ✎ 🖨
SOP 009	v5.0	▤			▦ ✎ 🖨

View this Subject's Record	Exit
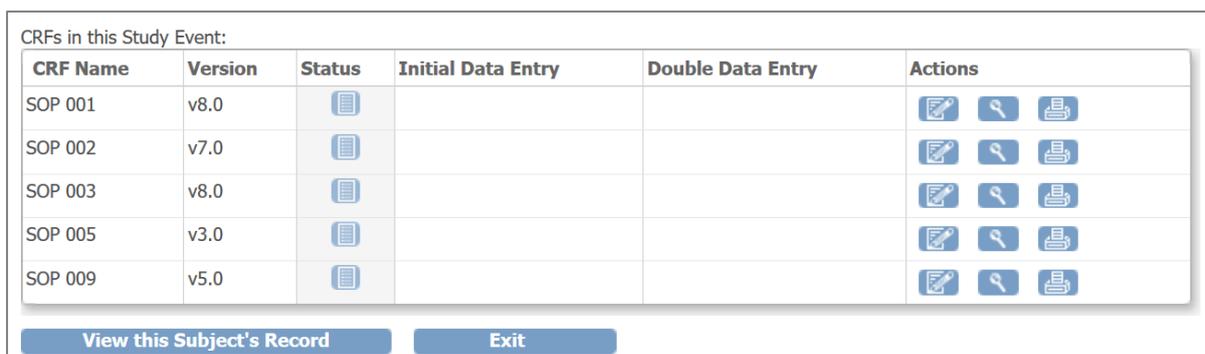
To sign off a SOP click the Enter Data symbol to open the appropriate CRF.
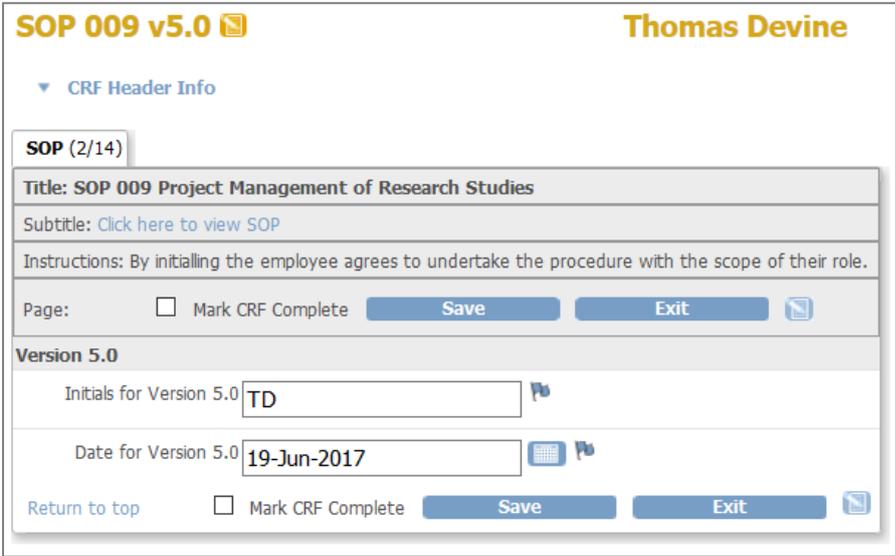
There are two fields to complete on this page, initials and date. Enter your initials and the date you read the SOP in the required fields; the date picker icon to the right of the date field lets you select a date and saves typing. You can read the SOP directly from here by following the link under the SOP title. You should not mark the CRF as complete.

Once you have entered your initials and date click **Save**.

Once you signed off an SOP for the first time the status symbol will change colour to orange. This will always remain orange; when a new version of the SOP is released it will not revert back to blue. It is therefore important you look out for any e-mails notifying you of ratified SOPs. Except for the colour change, the rest of the process is the same for resigning a new version.

If you have any queries or issues please contact the Data Management Team
papworth.openclinica@nhs.net