2.3.4 Electronic Signatures in OpenClinica

In OpenClinica, if your user Role has appropriate permission, you can sign a Study Event or an entire casebook for a Subject.

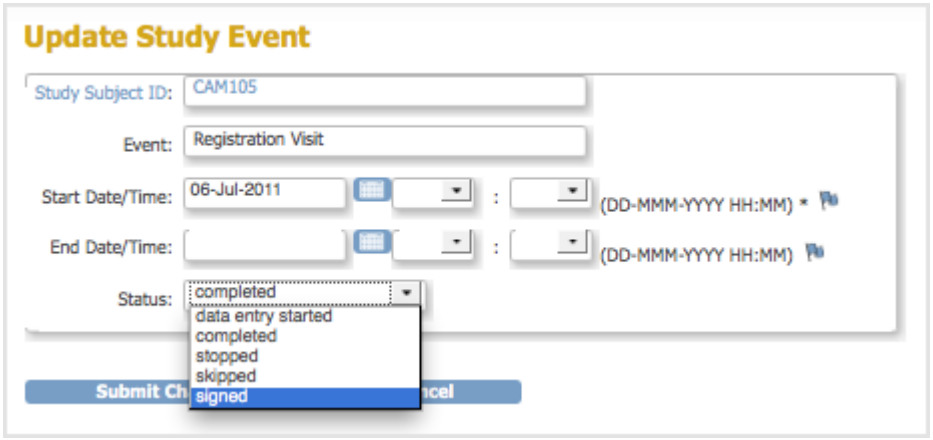
The OpenClinica electronic signature process complies with the FDA Code of Federal Regulations (CFR) Title 21 Part 11.

This page is not approved for publication.

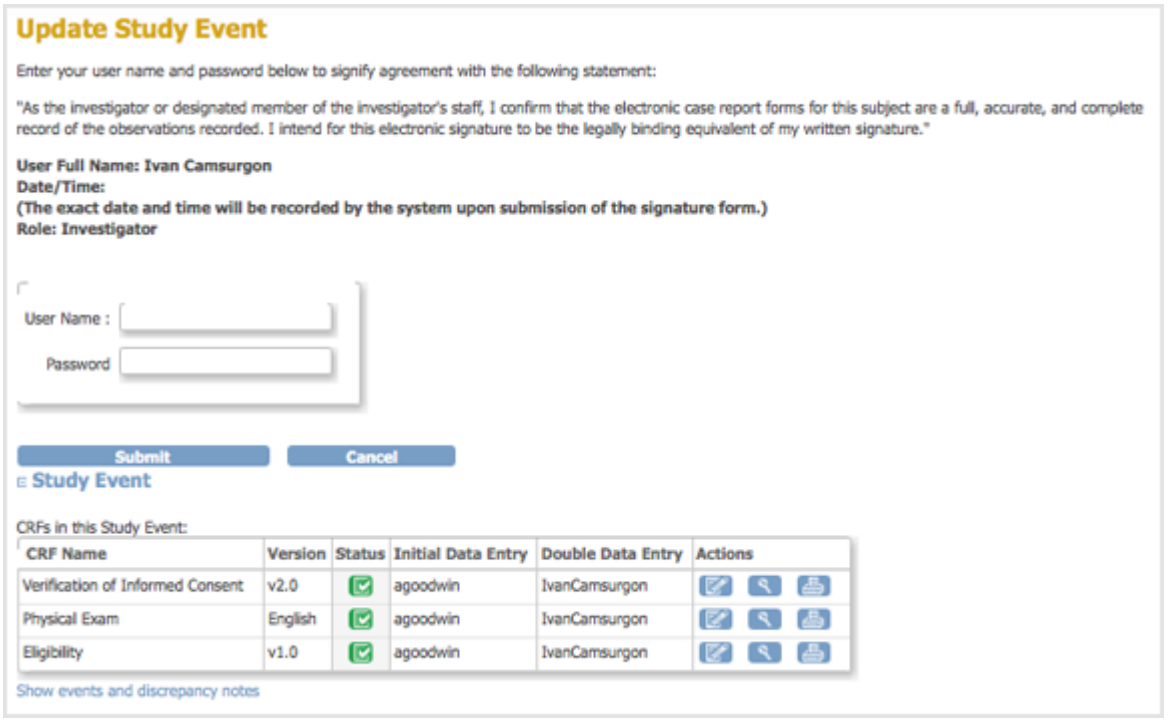
2.3.4.1 Sign an Event

When you sign an Event, you provide your approval of all CRF data for the Event for the Subject. To sign an Event:

1. Follow the instructions in Manually Change Event Status, and set the status to "signed."



2. Click Submit Changes.
   The Update Study Event page displays links to all information for the Subject for the Study; click a link to review the information. It also presents a statement about what signing the Subject record signifies.

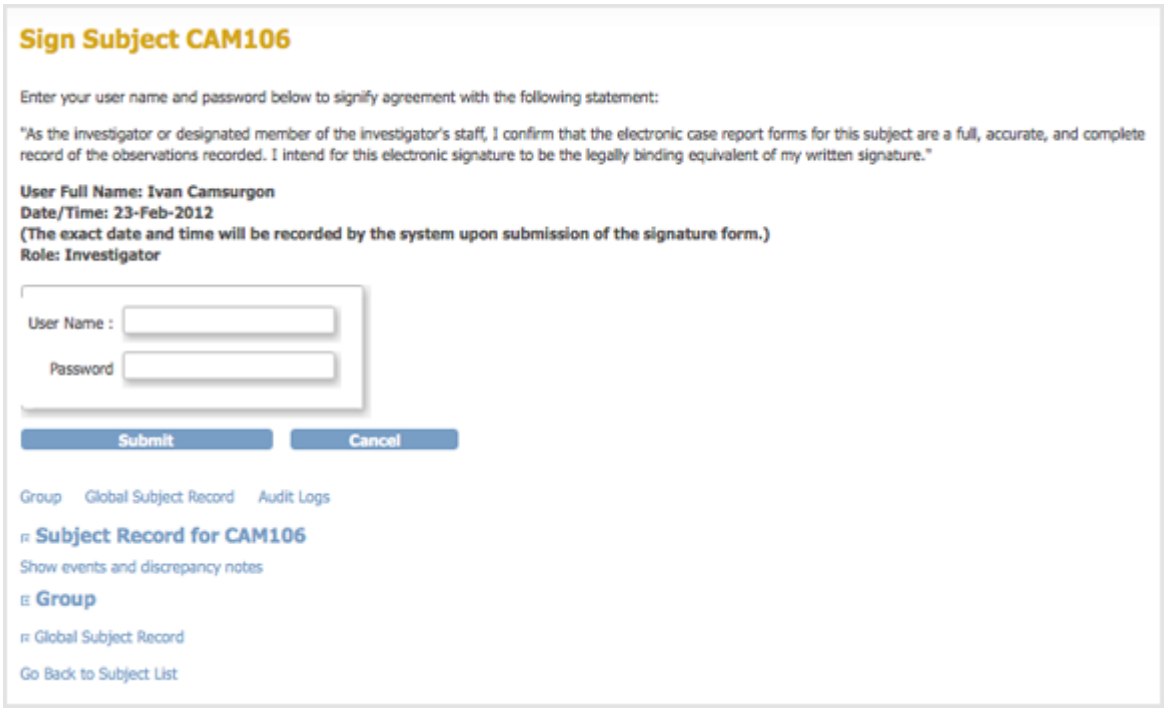


3. Enter your user name and password in the appropriate fields.
4. Click Submit.
   The View Subject page opens, showing the status for the Event as "signed."

2.3.4.2 Sign a Casebook (Entire Subject Record)

When you sign a Subject casebook, which is also referred to as the complete Subject record, you provide your approval of all CRF data for all Study Events for the Subject.

1. To sign the casebook, no Events for that Subject can have a status of "scheduled" or "data entry started." When that is true, the Sign icon is listed in the Actions column for that Subject. Click the Sign icon.
2. The Sign Subject page opens, showing links to all information for the Subject for the Study; click any link to review the information. The page also presents a statement about what signing the Subject record signifies.



3. Enter your user name and password in the appropriate fields.
4. Click Submit.
   The Subject Matrix opens, showing the status for all Events as signed.