15.3.4 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.
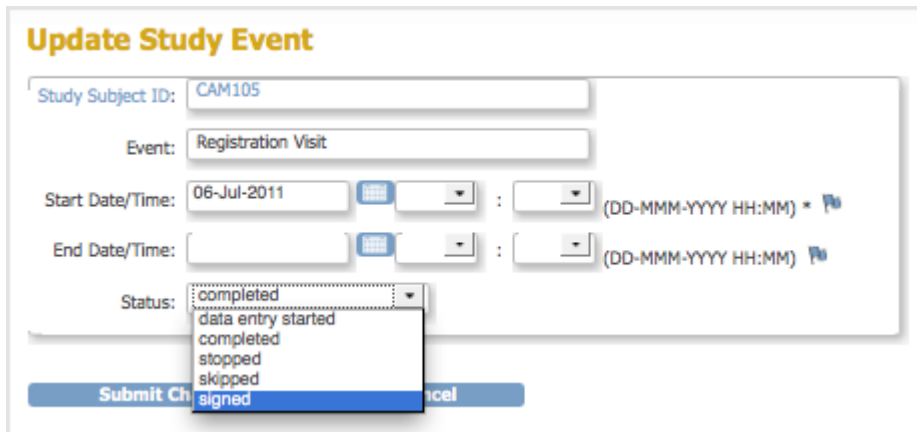
The OpenClinica electronic signature process complies with the FDA Code of Federal Regulations (CFR) Title 21 Part 11.

> This page is not approved for publication.

15.3.4.1 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.

Update Study Event

Enter your user name and password below to signify agreement with the following statement:

"As the investigator or designated member of the investigator's staff, I confirm that the electronic case report forms for this subject are a full, accurate, and complete record of the observations recorded. I intend for this electronic signature to be the legally binding equivalent of my written signature."

User Full Name: Ivan Camsurgon
Date/Time:
(The exact date and time will be recorded by the system upon submission of the signature form.)
Role: Investigator

User Name :

Password

[Submit] [Cancel]

⊏ **Study Event**

CRFs in this Study Event:

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
Verification of Informed Consent	v2.0	☑	agoodwin	IvanCamsurgon	
Physical Exam	English	☑	agoodwin	IvanCamsurgon	
Eligibility	v1.0	☑	agoodwin	IvanCamsurgon	

Show events and discrepancy notes

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."

15.3.4.2 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.

Sign Subject CAM106

Enter your user name and password below to signify agreement with the following statement:

"As the investigator or designated member of the investigator's staff, I confirm that the electronic case report forms for this subject are a full, accurate, and complete record of the observations recorded. I intend for this electronic signature to be the legally binding equivalent of my written signature."

User Full Name: Ivan Camsurgon
Date/Time: 23-Feb-2012
(The exact date and time will be recorded by the system upon submission of the signature form.)
Role: Investigator

User Name :
Password

Submit   Cancel

Group   Global Subject Record   Audit Logs

⊓ Subject Record for CAM106
Show events and discrepancy notes
⊟ Group
⊓ Global Subject Record
Go Back to Subject List

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.