



5.2.1 Status of Study

Some actions update the Study status automatically, while some Status values are set by a user with appropriate permissions using the Set Study Status drop-down list on the Build Study page. These Status values also apply to Sites.

| Status | Use to | Comments |
|--|---|--|
| Design (also displayed in OpenClinica as Pending) | Build a Study | <ul style="list-style-type: none">• When you create a Study, the status is automatically set to Design.• Subjects cannot be enrolled in a Study if the status is Design (the Add Subject button is unavailable).• Once all the Build Study tasks are complete, for data entry to begin, the status must be changed to Available. |
| Available | Provide access to the Study to users (for Subject enrollment, data entry, editing, etc.) as the last step of building a Study . | <ul style="list-style-type: none">• Subjects cannot be enrolled in a Study until the status is set to Available. |
| Frozen | Prevent Site users from signing, entering, and editing data, but allow Study level users to edit data as needed to close Notes and Discrepancies. | <ul style="list-style-type: none">• Site users can view data but cannot enter or edit data.• Investigators cannot sign Events or Case Books.• Study-level users can view data and can close Discrepancies. Closing Discrepancies may involve editing data, which they <i>can</i> do via Notes and Discrepancies if they click the icon to View within record for CRFs having a status of Completed. It should be noted that this also allows users to change values for other items on the record that may not have an associated discrepancy. Your internal procedures should explicitly state what can/cannot be edited.• As always, all data changes are tracked in the Audit Log. |
| Locked | Prevent all users from entering or editing data. | <ul style="list-style-type: none">• Neither Site nor Study level users can sign CRFs, enter or edit data, or create or edit Notes and Discrepancies.• Viewing, printing, and extracting data are permitted. |

| | | |
|----------------|---|---|
| Removed | Make the study inaccessible to end users. | <ul style="list-style-type: none">• This status is set automatically when a Study is Removed.• Only Administrators can remove a Study. |
|----------------|---|---|

Functional approval by Laura Keita. Signed on 2014-09-15 10:54AM

Approved for publication by Ben Baumann. Signed on 2014-09-15 3:51PM

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