

GD009

User Access Guidelines

It is vital to track all users who have access to clinical study data. Good Clinical Practice Guide (2012) states :“There should be a formal and documented mechanism for the granting of the correct level permission access code and revoking access (for example, when someone leave an organisation or ceases to work on that clinical trial) to ensure adequate security and control of the system.” While access codes may no longer be the best method, controlling who can access, and what they can access is essential, and requires documenting.

1. OpenClinica

- a. This is the preferred data repository, and it has 9 different roles, which can be set for an individual site or for the whole study. The details of these are in Appendix A.
- b. To document the user access, the eForms Database Access form (FRM052) must be used. See GD023 eForms system for study documents for further details. If eForms is not being used for a study, then the study specific spreadsheet should be stored in appropriate N: drive subdirectory for the study, and in a folder for data management, see Sponsor / Investigator File Checklist FRM021 for correct location.

2. Excel

- a. Excel should only be used for small non CTIMP studies, and has no in built roles. The management of the access and security should be covered in the Data Management Plan (DMP) and the Database access form (FRM052) should document user access.

3. Other

- a. If other data repositories are used, where possible roles should be used, and the user access should be recorded in a similar manner to OpenClinica, and/or recorded in the DMP.

4. Multi-site studies

- a. For studies with multiple sites, users must only be given access to the sites where they are authorised. For Papworth staff, depending upon their role requirements, if documented in FRM052 they can be given access to all or multiple sites.
- b. After giving access to a site user, it must be confirmed that they have only be given access to the correct sites. This should be done either by a second member of the data team, or the same member who added the user. If it is the same user, this cannot be done on the same day. Once verified, FRM052 must be updated. The method of verification will depend on the data repository.

Appendix A – OpenClinica Roles

The following tables summarize the modules and features available to each of the User Roles at the Study and Site levels. These are from OpenClinica 3.x.

Summary of Available Modules and Features for User Roles at the Study Level

User Role	Modules and Main Features
Data Manager	Submit Data: Add and Manage Subjects View, Schedule, and Enter Data into CRFs for Events No Waiting to Perform Double Data Entry After Initial Data Entry Import Data Notes and Discrepancies Monitor and Manage Data: Study Audit Log and Source Data Verification Manage Groups Create, Edit, and Manage CRFs Rules Extract Data Study Setup: View and Build Study Assign Users
Study Director	Submit Data: Add and Manage Subjects View, Schedule, and Enter Data into CRFs for Events No Waiting to Perform Double Data Entry After Initial Data Entry Import Data Notes and Discrepancies Monitor and Manage Data: Study Audit Log and Source Data Verification Manage Groups Create, Edit, and Manage CRFs Rules Extract Data Study Setup: View and Build Study Assign Users
Data Specialist	Submit Data: Add and Manage Subjects View, Schedule, and Enter Data into CRFs for Events Import Data Notes and Discrepancies Sign Subject data Extract Data

Monitor	Monitor and Manage Data: View Subjects View Events Study Audit Log and Source Data Verification Notes and Discrepancies Extract Data
Data Entry Person	Submit Data: Add and Manage Subjects View, Schedule, and Enter Data into CRFs for Events Import Data Notes and Discrepancies

Summary of Available Modules and Features for User Roles at the Site Level

User Role	Modules and Main Features
Investigator	Submit Data: Add and Manage Subjects View, Schedule, and Enter Data into CRFs for Events Import Data Notes and Discrepancies Sign Subject Data Extract Data
Monitor (site)	Monitor and Manage Data: View Subjects View Events Study Audit Log and Source Data Verification Notes and Discrepancies Extract Data
Clinical Research Coordinator	Submit Data: Add and Manage Subjects View, Schedule, and Enter Data into CRFs for Events Import Data Notes and Discrepancies
Data Entry Person	Submit Data: Add and Manage Subjects View, Schedule, and Enter Data into CRFs for Events Import Data Notes and Discrepancies (Same as Clinical Research Coordinator; use to differentiate office job titles for similar job function if necessary.)