OpenClinica User Agreement

OpenClinica is an electronic data capture tool and is provided by the Research Information Solutions and Innovation (RISI) Services within The Research Institute of Nationwide Children's Hospital (NCH).

By logging onto any NCH provided OpenClinica site, the user is agreeing to the following:

1. If the project for which OpenClinica will be used involves *human subjects research* (per the U.S. Department of Health and Human Services [DHHS] Code of Federal Regulations definition[1]), it has been submitted to the Institutional Review Board (IRB) for review or exemption and has been APPROVED before the project is moved to production and data collection can commence.

2. The user understands that PHI cannot be shared with any external party without a Materials Data Transfer Agreement (MDTA) or contract in place.

3. Users will not share their login credentials with other study personnel working on the project. Login credentials are easily obtained through RISI. The user must immediately notify an OpenClinica administrator if they notice suspicious activity with their account or if they have been locked out.

4. The user understands that the OpenClinica project will be actively maintained per the timeframe described in the user's approved IRB protocol, or other timeframe agreed upon by all parties prior to study initiation. The OpenClinica project will be archived after this time. Once archived, the data will remain in the database and the study can be reopened as necessary at the request of the PI for the project with the appropriate approvals.

5. The user understands that any data exported from OpenClinica that contains PHI needs to be encrypted or put on an encrypted device.

6. The user understands that an OpenClinica administrator will be responsible for:
    a. Adding all new users to OpenClinica and assigning access rights
    b. Approve and migrate all new projects into production
    c. Audit user access and data collection annually based on date of Production.

7. The user understands that the Principal Investigator of the study will be responsible for (all annual dates are based on the date the project went into Production):
    a. An annual review of system activity within the database
    b. An annual review of the users who have access to the database
    c. Provide RISI with documentation of IRB approval annually.

8. The user understands that additional requirements are needed to make an OpenClinica database compliant with part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures (21 CFR Part 11). If data related to an IND is collected in this database it is the user's responsibility to inform RISI.

9. FOR NCH EMPLOYEES ONLY, the user has read and agrees to comply with Nationwide Children's Technology Acceptable Use Policy, ADMIN XIV-6.

10. Any publications resulting from the user of OpenClinica to collect and manage data should include the following CTSA acknowledgement:

The project described was supported by Award Number UL1TR001070 from the National Center For Research Resources. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Center For Research Resources or the National Institutes of Health.

11. The user understands that any violations of this agreement could result in the termination of OpenClinica privileges.

[1] http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102
[2] http://dhhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html