



Standard Operating Procedure:

OpenSpecimen User Accounts

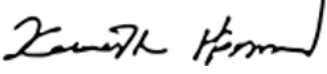

SOP Number:	205
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Department/System:	Digital Solutions– Data Management /OpenSpecimen

DOCUMENT HISTORY

Version Number:	Summary of Changes Made:	Effective Date
1	New Document	February 16, 2021
2	<ul style="list-style-type: none"> Adjusted language to PI/PA responsibilities to reflect that PI/PA requests user roles/permissions and DM Team fulfills request on OpenSpecimen Added language to reflect PHSA/VCH/PHC federation Removed references to enabling CWL accounts as this procedure has ceased Split procedures into requests for Adding Terminating and Unlocking user accounts Branding 	December 18, 2023
3	<ul style="list-style-type: none"> Removed references to User Account Request instructions on the UBC FoM MedNet Data Management space which no longer exists 	February 28, 2024
4	<ul style="list-style-type: none"> Updated definitions 	June 19, 2024



APPROVALS

Approver Name	Approver Signature	Date
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1. PURPOSE

- 1.1. To define the procedure used for on-boarding and off-boarding OpenSpecimen User Accounts through the UBC Faculty of Medicine (FoM) Research Data Management (DM) Team.

2. SCOPE

- 2.1. This procedure applies to all FoM Research DM Team members, Principal Investigators (PI)/Project Leads and Project Administrators (PA) involved in the request and creation of OpenSpecimen user accounts on the production instance of OpenSpecimen.

3. RESPONSIBILITIES

- 3.1. Users are responsible for having an active UBC Campus Wide Login (CWL) or Provincial Health Services (PHSA)/Vancouver Coastal Health (VCH)/Providence Health Care (PHC) account.
 - 3.1.1. Users must have the ability to complete a multi-factor authentication challenge.
- 3.2. Principal Investigator (PI) and/or Project Administrator (PA) is responsible for contacting the FoM DM Team and providing the Collection Protocol (CP) level access details (CWL, role, CP) for each user. The PI/PA is also responsible for contacting the FoM DM Team and requesting User access termination when needed.
- 3.3. OpenSpecimen user accounts automatically lock after 180 days of inactivity.



3.3.1. Users are responsible for contacting the FoM DM Team to request their account be unlocked. The DM Team requires PI permission to unlock user accounts. Access requests will be responded to within 1-2 business days.

3.4. The FoM DM Team is responsible for adding/removing requested authorized User Accounts as outlined by the PI/PA. Access requests will be responded to within 1-2 business days.

4. RELATED SOPS/DOCUMENTS

4.1. FoM OpenSpecimen User Roles and Privileges

5. DEFINITIONS

5.1. **Principal Investigator (PI)/Project Lead:** Primary individual in charge of and responsible for the proper conduct of a research project/Collection Protocol and/or sponsor for non-research projects/CPs.

5.2. **Project Administrator (PA):** Person responsible for the development of OpenSpecimen CP design, forms, containers, specimen requirements and overall management of the CP data.

5.3. **Research/Project Team:** Research/project assistants, nurses, data entry and other personnel involved with and granted access to the OpenSpecimen CP. The Team members report to the PI/Project Lead but are generally directly supervised by the PA.

5.4. **FoM Data Management (DM) Team:** Manager, Research Data Services, Team Lead, Scientific Analyst and other FoM DM individuals responsible for managing CPs in OpenSpecimen and providing support to Research/Project Teams in conducting their CP.

5.5. **OpenSpecimen Collection Protocol:** Defines the details of a standardized protocol used for the collection of biospecimens. This includes any information on the approved CP such as the title of the study, institution, name of the investigator, ethics approval number, consent forms, standard operating procedures (SOPs), participant registration, specimens to be collected and processed, etc.

5.6. **User accounts:** Provincial Health Services Authority/Vancouver Coastal Health/Providence Health Care (PHSA/VCH/PHC) and/or Campus Wide Login (CWL) accounts that have multifactor authentication and provide access to online systems, like FoM OpenSpecimen.

6. PROCEDURE

6.1. Request to Add User Accounts



- 6.1.1. PI and/or PA contacts the FoM DM Team outlining access details for each user, including the user's CWL or PHSA/VCH/PHC login ID, first and last name, email address, and CP-specific permissions including site(s) and role(s).
- 6.1.2. FoM DM Team adds user(s) and assigns role(s) to user(s) accounts within 1-2 business days.
- 6.2. Training
 - 6.2.1. FoM DM Team provides any ongoing PI and/or PA support or training as requested and as necessary.
 - 6.2.1.1. Initial training on user accounts occurs during the Project Initiation step.
- 6.3. Request to Remove User Accounts
 - 6.3.1. PI and/or PA contacts the FoM DM Team to remove access for user(s) by providing the name(s) of the user account and specific CP-level permissions to terminate.
 - 6.3.2. FoM DM Team removes access to CP-level permissions as requested within 1-2 business days.
- 6.4. Request to Unlock User Accounts
 - 6.4.1. User contacts the FoM DM Team to unlock user account. DM Team receives PI approval and unlocks user account within 1-2 business days.

7. REFERENCE(S)

OpenSpecimen User Roles and Privileges:

<https://openspecimen.atlassian.net/wiki/spaces/CAT/pages/7700590/Roles+and+Privileges>