Veeva Site Vault Working Instructions

Description:	Work instructions for granting/revoking access requests for staff and sponsor/auditor, setting up vendors, and adding vendor documentation in Veeva Site Vault
Site Name:	South Western Sydney Local Health District
Department:	All departments across the district

When does this working instruction apply?	For all staff who use Veeva Vault Process relating to: Access requests for staff and monitors Vendor/partner organisation documents upload
Author:	Name: Belinda Kleut Signature: On file Date: 06 October 2023
Approval:	Name: Jenny Seymour Signature: On file Date: 06 October 2023

1.0 Purpose

To briefly describe the purpose of the Veeva Site Vault (VV) work instruction for granting and removing user access for staff and monitors, and for setting up vendors and adding vendor documentation.

2.0 Scope

This work instruction (WI) applies to all staff using Veeva Site Vault and is to inform how Veeva Site Vault is utilised across SWSLHD and Ingham Institute. For training, please go to the 'Help' section of the website.

Veeva SiteVault Free is a free eRegulatory solution built specifically for clinical research sites. Veeva SiteVault allows sites to more effectively manage regulatory documents and trial processes to speed up study activation and improve investigator site file management. Now all sites can have access to a modern cloud solution to streamline trial activities and accelerate clinical research.

Veeva SiteVault reduces the administrative burden of managing regulatory documents and processes with capabilities such as electronic signatures, remote monitoring, certified copy workflows, and reporting. Veeva SiteVault can be used for all trials regardless of what technology sponsors are using, as well as the site file for investigator-initiated trials. Both editions, SiteVault Free and SiteVault Enterprise, support compliance with 21 CFR Part 11.

Veeva Site Vault offers the following features;

- eISF management
- Remote monitoring capabilities
- eDelegation log
- eConsent
- eSource capabilities
- document certification
- electronic archiving

3.0 Rationale

There is currently no document type for vendor documents in Veeva Site Vault and due to our district's unique structure in (VV) of having multiple departments under multiple sites across SWSLHD, the Clinical Trials Support Unit (CTSU) centrally manages Vendor/Partner Organisations in (VV). Our aim is for CTSU to streamline document uploading by uploading all required documentation for each vendor. This will prevent duplication of both vendors

and vendor documentation. The CTSU also centrally manages access requests for staff and monitors to be in line with our identification policy therefore this (WI) is being implemented.

4.0 Roles and Responsibility

The following roles perform tasks described within this WI:

Role	Sections
CTSU	Set up new vendors
CTSU	Upload vendor documents
CTC	Share vendor documents with CTSU for uploading
CTSU	Grant sponsor/auditor user access
CTSU	Grant staff user access to relevent department
CTC	Grant staff user access to study
CTC	Complete pending tasks and notify CTSU when leaving organisation or when the sponsor/auditor visit, or when study involvement ends
CTSU	Revoke staff or sponsor/auditor access

5.0 Procedures

5.1. SWSLHD & Ingham Institute Veeva Site Vault Structure

Veeva has been implemented at an Organisational level under SWSLHD. Each individual department has been setup as its own site to ensure confidentiality across SWSLHD & Ingham Institute. To set up a new department, the CTSU mailbox should be contacted to request setup. This takes 24 hours as a new organisation is created by Veeva. The CTSU administrator will complete the relevant requests for this to occur.

Each study will be set up in the department by the department administrator who has been assigned by the CTSU administrator.

5.2. Access Requests for internal staff and external monitors

CTSU centrally manages internal staff and external sponsor/auditor access requests in (VV). All new staff including CTC and Principal Investigators across SWSLHD and Ingham Institute are added to (VV) when CTSU has been notified that the staff member has commenced and identification checks including National Police Check have been completed. The appropriate (VV) delegation responsibilities are added to the staff depending on their study roles. For

external sponsor/auditor, a National Police Check must be sighted before CTSU granting access. We cannot grant (VV) access to external sponsor/auditor who reside overseas as there is no jurisdiction over NSW Health policy and the Privacy Act of 1988. When CTCs request external sponsor/auditor access, CTSU requires the NPC, research group, study name and timeframe the sponsor/auditor will be monitoring the study. If a timeframe is not provided to CTSU, an end date of 12 months will be selected so that sponsor/auditor access will automatically be revoked.

Who	Step	When
CTC	Notify CTSU of new staff members to be added to Veeva	As required
CTC	Notify CTSU of external sponsor/auditor to be added to Veeva with NPC and details mentioned above	As required
CTSU	Grants (VV) access to staff department or external sponsor/auditor	As requested
CTC	Once CTSU has added the staff member to study, the CTC/Administrator of the department can add the staff member to the appropriate study role in 'study team assignments'	As required

5.3. Vendors and vendor documentation

CTSU centrally create vendors/partner organisations in (VV) and we ask that research groups do not create new vendors to avoid duplication of vendors and documents. There is currently no document type for vendor documents in Veeva Site Vault therefore as a workaround, we add vendor documentation as; Lab Certifications and/or Lab Normal Ranges document types. These document types will allow the documents to be viewed at an organisation level and not just at the site level. A description of the document is added to correctly identify the document type as Lab Certificate and/or Lab Normal Ranges will most likely not be the correct name of the document. Vendor documents have been added to a study called: Vendor Set up which resides in the Ingham Institute site. Staff can add the Vendor Set up to their sites so that the attached Vendor Documents populate into studies selected. Another alternative is to add the vendor directly to the study in the Partner Organisation tab on the study page. Documents will not populate in the study documents unless the Partner Organisation lifecycle status is changed from Proposed to Active.

CTCs are to share documentation such as lab ranges, fridge/freezer logs, calibration reports etc. with the CTSU for uploading. CTSU may work with research groups to request documents for uploading. Please note that some reports/ranges are required to be uploaded at monthly frequencies so this should be considered as required.

Who	Step	When
CTSU	Set up vendor	As required
CTC	Send CTSU documents for uploading	As required depending on document frequency
CTSU	Upload vendor documents	As required
CTC	Attach vendor set up to studies	As required

Due to vendor duplication in (VV), it is vital that the correct vendor/partner organisations that have been centrally managed by CTSU are added to studies. If CTCs required additional documents to be uploaded under a vendor, please contact CTSU.

Please refer to the below list using the correct spelling when adding vendors to studies:

Vendor Name
#NSW Health Pathology – Liverpool Hospital Final#
NSW Health Pathology - Campbelltown Hospital Final
NSW Health Pathology - Fairfield Hospital Final
NSW Health Pathology - Bowral Hospital Final
NSW Health Pathology - Bankstown Hospital Final
Douglass Hanly Moir - Final
Liverpool Cancer Therapy Centre Pharmacy - Final
Liverpool Hospital Pharmacy - Final
Campbelltown Hospital Pharmacy - Final
Spectrum Medical Imaging - Liverpool Final
Spectrum Medical Imaging - Bankstown Final
South West Radiology - Campbelltown Final
Ingham Institute Level 4 PC2 Lab - Final
Phase I Unit - Liverpool Hospital Final

5.4. Revoking Staff and Sponsor/Auditor access from Veeva Site Vault

All staff and external sponsor/auditor access must be revoked if staff have left the organisation and/or the sponsor has finished monitoring the trial. For staff access, it is the responsibility of the staff member to complete all pending delegation tasks and remove themselves from studies in (VV) before leaving the organisation. If staff know they are leaving, the best practice is to complete pending tasks as soon as possible. The manager of the leaving staff member should review (VV) with the staff member before offboarding. For external sponsor/auditor, the CTC should notify CTSU when the sponsor is no longer monitoring or if an end date is known.

Who	Step	When
CTC or PI	Complete all pending delegation	Ahead of leaving the organisations
CTC	Notify CTSU when external sponsor/auditor has finished monitoring or with an end date	As soon as aware that external monitor will finish monitoring
CTSU	Remove staff member or external sponsor/auditor when notified	As advised

6.   References and Supporting Documentation

Document Number	Title

7.   Amendment History

Version	Date	Amended by	Details of Amendment
1.0	28 September 2023	Belinda Kleut	Document established in line with work instructions for adding/removing users and Vendor/ Vendor Document requirements for Veeva Site Vault

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