


STANDARD OPERATING PROCEDURE (SOP)

TITLE: SITEDOCS PORTAL MANAGEMENT



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1. PURPOSE:

The purpose of this SOP is to provide guidelines on the implementation and use of the SiteDocs Portal

2. SCOPE:

All research activities including clinical trials conducted at Epworth.

3. APPLICABILITY:

This applies to all Epworth employees, non-employed staff and Visiting Medical Officers (VMOs) and to all relevant external persons or parties engaged in the research activity at Epworth.

4. GLOSSARY OF TERMS:

Please refer to Epworth SOP Glossary of Terms (see Related Documents).

5. PROCEDURE:

5.1. SiteDocs Portal General Use Information:

Epworth uses a combination of paper and electronic documents to fulfil the Good Clinical Practice (GCP) requirements in the management of Investigator Site Files.

SiteDocs Portal, a web-based document management platform, is used to maintain general Epworth documents and store electronic investigator site files (eISFs) online. The portal can be accessed on the following web address: https://sitedocsportal.com/login_with_best_experience_on_Google_Chrome. Documents on SiteDocs Portal can be shared with clinical trial sponsor representatives.

The portal has two main modules for document storage – Core Documents and Collaboration. The Core Documents Module contains general Epworth documents and the Collaboration Module contains remote monitoring folders and the eISF for trials from July 2021 onwards.

Core Documents Module	Collaboration Module	Paper ISF
<ul style="list-style-type: none">General Epworth Documents including:<ul style="list-style-type: none">Site Personnel documentsInternal and External Vendor InformationSite Equipment RecordsEpworth SOPsAccessible to <u>all</u> portal users	<ul style="list-style-type: none">Electronic investigator site file (eISF) - e-ISFs for commercial trials that opened from July 2021Remote Monitoring Visit File - Participant source documentsPortal administrators can provide and then <u>control</u> access to internal and external users	<ul style="list-style-type: none">Original copies of wet-ink signature documentsExternal persons can review at on-site monitoring visits

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5.2. Portal Access

Permission to the Epworth Portal is granted by adding a new user. A new user should only be created by the Research Development and Governance Unit (RDGU).

5.2.1. To add a new user:

- Email the RDGU (research@epworth.org.au) providing the details of the user to be added
- The email must include:
 - Name, role, email address and contact phone number of the new user
 - What specific eISF or remote monitoring visit file the user will require access to in the collaboration module
 - The dates portal access will be required (if the user is being added for the purpose of conducting a remote monitoring visit)
 - In the case of remote monitors, the user's SiteDocs Remote Monitoring Training Certificate (if they already have one)



The following table shows the available portal roles, their permissions and groups who are commonly assigned each type.

SiteDocs Portal Roles	Modules visible	Assignees
Internal User – Portal Administrators	All modules	Management, RDGU staff, Superusers,
Internal User – Portal User	Core Documents, Collaboration*, Internal Documents, Archived Documents	Epworth Staff
External User – Monitor	Core Documents, Collaboration*	CRAs (Monitors)
External User – Non-monitor	Core Documents, Collaboration*	Sponsor Start Up Specialists, Auditors [#]

*User type can only view specific folders where permission has been shared by a Portal Administrator

[#]Regulatory Authority Access: Special access can be granted for regulatory authorities performing inspections or audits, such as EMA, TGA or FDA representatives. This access will remove the requirement of the user to accept portal terms when activating their account. A request must be made via Trial Docs help desk.

5.2.2. To provide access to the eISF:


1. Highlight eISF folder in collaboration module
2. Select  Collaboration to view current collaborators
3. Use  button in left hand corner to add collaborators
4. Tick 'Read Only Access' if applicable (If ticked, user will be unable to delete and/or upload documents)

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5.2.3. To remove or change permissions:

1. Select  Collaboration to view current collaborators
2. Highlight user and select the required option:



Note: Collaborators of a parent folder will be adopted automatically by lower tiers of folder structure.

5.3. Site Processes

The following sections describe SiteDocs Portal related activities that occur at key clinical trial milestones.

(RDGU: Research Development and Governance Unit; SC: Study Coordinator; CTA: Clinical Trials Assistant; ESS: Cancer Trials Australia Ethics Submission Specialist).

Trial Start-Up

Actions	Completed by
Study Folder is created in the Collaboration Module	RDGU/SC/CTA
Essential documents collected during start-up are uploaded into relevant folders in the eISF (e.g. Financial Disclosure Forms, CTRA, Insurance Certificates, Protocol Signature Pages, IB Signature Pages)	SC/CTA
Department agreements uploaded into the relevant folders in the eISF	ESS/SC/CTA
Study monitor is added as a portal user and granted access to eISF and core documents module	RDGU
Initial HREC/RGO Submission and approved documents are uploaded into relevant folders in the eISF	ESS/SC/CTA
Hardcopy ISF Folder is prepared to contain wet-ink documents	SC/CTA

Post-Approval Submissions (e.g. amendments)

Actions	Completed by
New folder is created for the submission	ESS/SC/CTA
Submission documents are moved to the amendment folder in the eISF	ESS/SC/CTA
Approved documents are moved to appropriate folder/s in the eISF	ESS/SC/CTA

Annual Reports

Actions	Completed by
Report is uploaded	SC/CTA
Acknowledgement email is converted to PDF and uploaded	SC/CTA

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Trial Close Out & Archival

Actions	Completed by
Import Core Documents to eISF using 'Import Core Documents' tool	SC/CTA
Scan copies of delegation and training logs to eISF	SC/CTA
Check all documents have been filed in the eISF	SC/CTA
Download complete document listing and print for archival records	SC/CTA
Download complete set of documents and save to disc to archive with hardcopy documents	SC/CTA
Lock the eISF using the 'Lock' tool	SC/CTA
Move eISF to Archive Module when there are no outstanding documents	RDGU/SC/CTA

Abandoned Trials

Timepoint of Abandonment	Action Required	Completed by
Prior to activation	Delete eISF Folder	SC/CTA
Post activation	Follow steps in 5.4.4	SC/CTA

Remote Monitoring Visits

Actions	Completed by
Remote Monitoring Study Folder is created in the Collaboration Module (including trial participant folders)	RDGU/SC/CTA
Participant source documents uploaded into relevant folders	SC/CTA
Study monitor is added as a portal user and granted access to the Remote Monitoring Study Folder	RDGU
Once visit is complete, study monitor's access the Remote Monitoring Study Folder is revoked	RDGU

5.4. Staff Training Within the Portal

Email notifications can be enabled to enhance study team oversight by alerting specified users as documents are uploaded into a folder.

Examples of email notifications that may be applied:

Document	Personnel to be alerted of new document
Current HREC Approved PICFs	Primary Coordinator, Investigators
Project Newsletter	Principal Investigator, Primary Coordinator

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Workflows gives the option to create a training action item for users through the SiteDocs portal and can be set to be countersigned if/where required. These workflows can be utilised for either internal department training or study specific protocol training and fall into two categories, Primary or Secondary Workflows.

- **A Primary Workflow** is applied to a specific document. Once a document is uploaded, the workflow can be created that will apply only to that document.
- **A Secondary Workflow** is applied to a folder and will trigger training for every document placed in the folder.

Examples of workflows that may be applied:

Document	Workflow	Workflow Type	Counter Signature	Collaborators
Current Approved IB	Secondary Workflow	Submit and Received	N/A	Principal Investigator, Primary coordinator, Pharmacy lead
Current Approved Protocol	Primary Workflow	Read and Understood	Principal Investigator	All delegated staff
Monitoring Visit Reports/Letters	Secondary Workflow	Submit and Received	N/A	Principal investigator, Primary coordinator, Pharmacy Lead

6. REFERENCES:

7. RELATED DOCUMENTS:

7.1 Related Documents

- Resources Available for Internal Site Users
 - SiteDocs Portal Internal User Guide
- Resources Available for External Users
 - SiteDocs Portal External User Guide
-

7.2 Related SOPs

- SOP-Glossary-of-Terms
- SOP-TM-02 ISF and Essential Documents
- SOP-TM-09 Remote and On-Site Monitoring
- SOP-TM-13 Trial Archiving

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- SOP-TM-15 Working with Cancer Trials Australia

8. VERSION CONTROL

Document History	
Version	Summary of Changes
1.0	N/A First issue

9. APPENDIX

Appendix 1: Document Upload and Naming

Documents should be uploaded in PDF format where possible. To upload a document:

- Open the folder where the document will be located. At the top right, click upload to open the following window:

A screenshot of a web-based document upload interface. On the left, there is a grey box with the text "Drop files here or browse files by clicking below button" and a "Choose Files" button. To the right, the text "Document queue to be uploaded" is displayed above "Queue length: 0". Below this is a table with columns for "Name", "Size", "Progress", "Status", and "Actions". Underneath the table is a "Queue progress:" indicator. At the bottom, there are three buttons: "Upload all" (blue), "Cancel all" (yellow), and "Remove all" (red).

- Select 'Choose Files' or drag and drop files into the grey box under 'Select Files' heading. This provides the option of uploading either single documents or multiple documents at once.
- Once the document(s) name has appeared click upload all.
- Complete document details and click 'Update'
- Following uploading the certification window will appear giving the option to certify the digital version is an accurate and complete representation of the hard copy document. User will be required to enter email and password or to click 'Update without Certification'.

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The following indexing window will appear to help the user name the document correctly:

A screenshot of a web-based document indexing window. The breadcrumb trail at the top reads: "Collaboration Documents > Projects - Gynaecology > 17/213 BEACON George Au-Yeung > 1.0 Contacts > GYNAECOLOGY_17/213_pcctu-contacts_Template_Generic_doc_Sept_2016_2018-07-02". The main title of the window is "GYNAECOLOGY_17/213_pcctu-contacts_Template_Generic_doc_Sept_2016_2018-07-02". The form contains several fields: "Name" (pre-filled with the full path), "Description" (pre-filled with "Template_Generic_doc_Sept_2016"), "Document date" (pre-filled with "2018-07-02"), "Renewal date" (pre-filled with "2018-07-02" and a checked checkbox for "Renewal date not applicable"), and "Document date type" (pre-filled with "DOD"). At the bottom left, there are "Update" and "Cancel" buttons.

- **Name** will automatically populate by folder location, 'Description', 'Date' and 'Document Date Type' and therefore is not required to be altered.
- **Description** should be simple and consistent; keeping in mind the folder name will automatically be part of the document title. For example, a new version of a document could be named 'Version 2'.
- **Document date:** Select date and apply corresponding date type
- **Renewal date:** Apply renewal date if applicable, this will prompt reminders to update the document.
- **Document Date Type:**
 - DOS – Date of Signature for scanned wet-ink documents*
 - DOD – Date of Document for native electronic documents*
 - NTF – Note to File*

When uploading multiple documents at once, documents are individually named and dated within the same indexing window.

Document Certification

- Upon uploading a document, the option of certifying a document will be provided. A document should be certified when replacing the original document. Certifying a document will require the user to re-enter their SDP credentials to confirm this action.
- Only wet ink documents which have been scanned and uploaded onto SiteDocs Portal require certification. Native electronic documents do not require certification.


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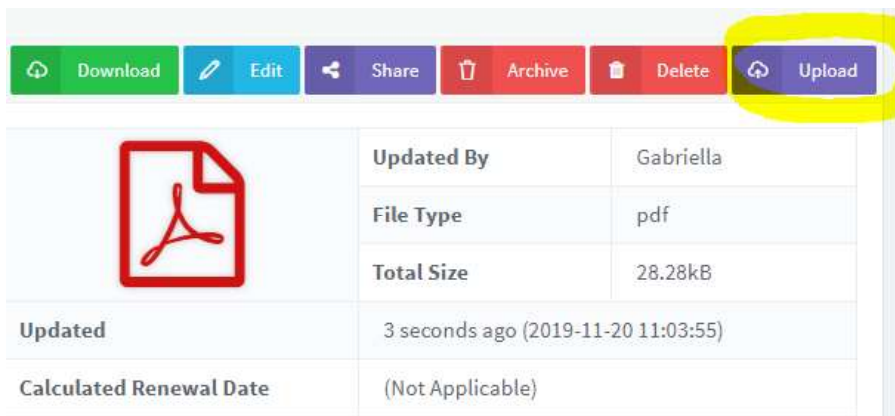
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Appendix 2: Updating & Superseding Documents (Document Stacking)

Stacking allows only the most current version of a document to be viewed with superseded versions downloadable within the metadata of the document.

1. Open document to be superseded
2. Select  Upload within the document



The screenshot shows a document management interface. At the top, there is a toolbar with buttons for Download, Edit, Share, Archive, Delete, and Upload. The 'Upload' button is highlighted with a yellow circle. Below the toolbar, there is a document icon (a red square with a white document symbol) and a table of metadata.

Updated By	Gabriella
File Type	pdf
Total Size	28.28kB
Updated	3 seconds ago (2019-11-20 11:03:55)
Calculated Renewal Date	(Not Applicable)

3. Upload new version of document
4. The document naming window will show information of previous document. Update this information as required (e.g. version number).
5. Once complete, previous versions will appear at the bottom of the page.



Please click "Unlock Prior Versions" to download versions 

Id	Version code	Description	Document Date	Last Modified	Size	Storage Class
29037	Kgm.UAglYMXEHMv1wjJDqKmoZHE6u4cC	Test 2	2019-11-21	2019-11-20 00:06:36	28.28kB	STANDARD
29036	eJFmx0v2yQaHFSEyFnhiT120PHnErhWp	Test	2019-11-20	2019-11-20 00:03:43	28.28kB	STANDARD

6. Previous versions can be downloaded by selecting 



Appendix 3: Managing Email Notifications and Workflows

10. Setting up email notifications

Email notifications can be applied to specific folders and will trigger a notification to selected users when a document is uploaded into the folder. Email notifications can be updated at any time by altering the users to be alerted. Only portal Administrators have permissions to set email notifications. To set an email notification follow the below steps:

- Open settings
- Navigate Collaboration Structure to find folder requiring email notification
- Highlight folder and select 'edit'
- Ensure Email Collaborators is enabled

Email Collaborators



Email notifications when a new document is added to this folder.

- List users requiring notification under 'users to be alerted'.

11. Creating Document Workflows

Primary Workflow:

A primary workflow is applied to a specific document. Once a document is uploaded, the workflow can be created that will apply only to that document. A pending action item will be created for users to complete. Follow the below steps to set a primary workflow:

- Check that all staff requiring workflow are collaborated to the eISF
- Open the document in the collaboration module
- Within the document select 'Workflows'
- Apply the following settings and click update:
 - Workflow Type: as per requirement
 - Counter Signature: as per requirement
 - Collaborators: Select 'Specific users only' and specify in corresponding box
 - Due Date: should be set at 'Week' and due by '1'.
 - Reminder: should be set at 'Weekly' and reminder every '1'.

Secondary Workflow:

A secondary workflow is applied to a folder and will trigger training for every document placed in the folder. Follow the below steps to set a secondary workflow:

- Check that all staff requiring workflow are collaborated to the eISF

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- Open settings
- Navigate Collaboration Structure to find folder that requires workflow
- Highlight folder and select 'edit'
- Ensure that Secondary Workflow is enabled



- Return to the collaboration module and find folder
- Highlight folder and select 'Secondary Workflow'
- Apply the following settings and click update:
 - Workflow Type: as per requirement
 - Counter Signature: as per requirement
 - Collaborators: Select 'Specific users only' and specify users in corresponding box
 - Due Date: should be set at 'Week' and due by '1'.
 - Reminder: should be set at 'Weekly' and reminder every '1'.
 - Elect either all future documents or all current documents

Users receiving the primary or secondary workflow can be added or removed at any time by updating specified users within the 'workflow' settings.

12. Completing Document Workflows

Workflows pending completion appear on the Home Page in the action dashboard under pending actions.




To complete the workflow:

- Select Workflows on the Home Page

- Click on the document title. This will open a new tab where the document can be downloaded and training can be completed if required.

Note: the audit trail of SiteDocs Portal records when you view and download a document

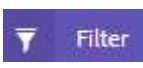
- Return to workflow tab
- Highlight completed workflow item
- Select 
- Enter SiteDocs Portal credentials
- Click 'Read and Understood' to Confirm

The same steps apply for a 'submit and received' workflow.

13. Workflow Tracking

There are multiple functions on the SiteDocs Portal that allow tracking of complete and incomplete workflow items.


Method 1:

- From the home page, under the 'Action Dashboard' click 'History'
- Select the 'Workflow' tab
- Select  to enter search parameters. Information can be filtered by user, date or document

Method 2:

- Under the collaboration module, open the document with active workflows
- Workflows are listed as 'Workflow Stats' (primary workflow) or 'Secondary Workflow Stats' (Secondary Workflow)

Method 3:

- Under the collaboration module, open the document
- Select  for a report on current workflow data and workflow data of stacked documents

Method 4:

- From the home page, under the 'Action Dashboard' click 'Reports'.
- This will generate an excel report on current pending action items/work flows.