SharePoint eTMF document library configuration

About this guide

Thank you for your interest in this document management setup guide. This was first built by the Nottingham Clinical Trials Unit during the COVID-19 lockdown in order to provide an alternative to document approvals from hand written signatures, and to provide a robust document management and version control system. Although SharePoint and Power Automate have the potential to provide all the functionality an eTMF needs, various practical considerations mean each implementation may need changes to this. Please feel free to share any improvements to this setup guide.

Notes about this implementation

The Library's and list in this setup include 3 managed term set fields (metadata tags) that the Power Automate approval flow references. This is because the same flow is used by the NCTU programming team on a system documentation library that tracks documents for multiple system versions for multiple projects. Therefore the 'System' and 'System Version' fields must be present when using the approval flow, do not need to be shown in the user views for this 'eTMF' implementation, leaving only the 'DocType' tag as the visible metadata tag.

This implementation is offered without any guarantees or validation. Anyone following these setup steps should validate the implementation themselves.

Brief risk assessment

Risk	Impact	Likelihood	Overall risk level	Mitigation	Comments
Document deletion/loss	High	Low	Low	O365 library version history maintains copies	
Document approval – approved in error	High	Low	Low	Document approval is managed by MS Approval Flow task configured to require all approvers to approve. Automated email notifications can be saved to verify these steps were taken	This is a globally used MS document approval task, and can be relied upon for correct function.
Document approval – not approved error	Low	Medium	Low	Email notifications report when there is a problem with the approval flow, which may be caused by using an incorrectly entered approver email address. The flow can be re-run with the correction made.	
Document approval – fraud	High	Low	Low	A member of the document approval flow group can simply set a document status to	The document approval flow also copies the document into

				approved, but this will not show approval coming from other listed approvers, and there will be no automated emails to match.	a 'DocCopies' library at the time of approval, as well as logging the actions of the approvers in the Approval Log list. This combined with the absence of automated email notifications makes defrauding the approval system virtually impossible, so long as all user account access is maintained private.

1. Create MS Teams Trial site using the 'Staff' template. Give it a name, and make sure only team owners can add team members. Note if you want to find out what templates other TEAMS sites use: switch TEAMS to grid view, one can filter for team type. https://techcommunity.microsoft.com/t5/microsoft-teams/how-can-i-find-out-what-type-a-team-is/m-p/1280064
2. Open Teams site in SharePoint – click the star so you are 'Following' the site.
3. Edit 'Quick Links' on the home page
    a. Add a link with Title 'People and Groups' to (change as appropriate) https://**<institution-name>.**sharepoint.com/sites/***<site-name*>**/_layouts/15/groups.aspx - one can copy the bulk of this URL from the current browser page.
4. From 'Home', Site Settings (cog in very top right) – Site permissions – Advanced permissions settings
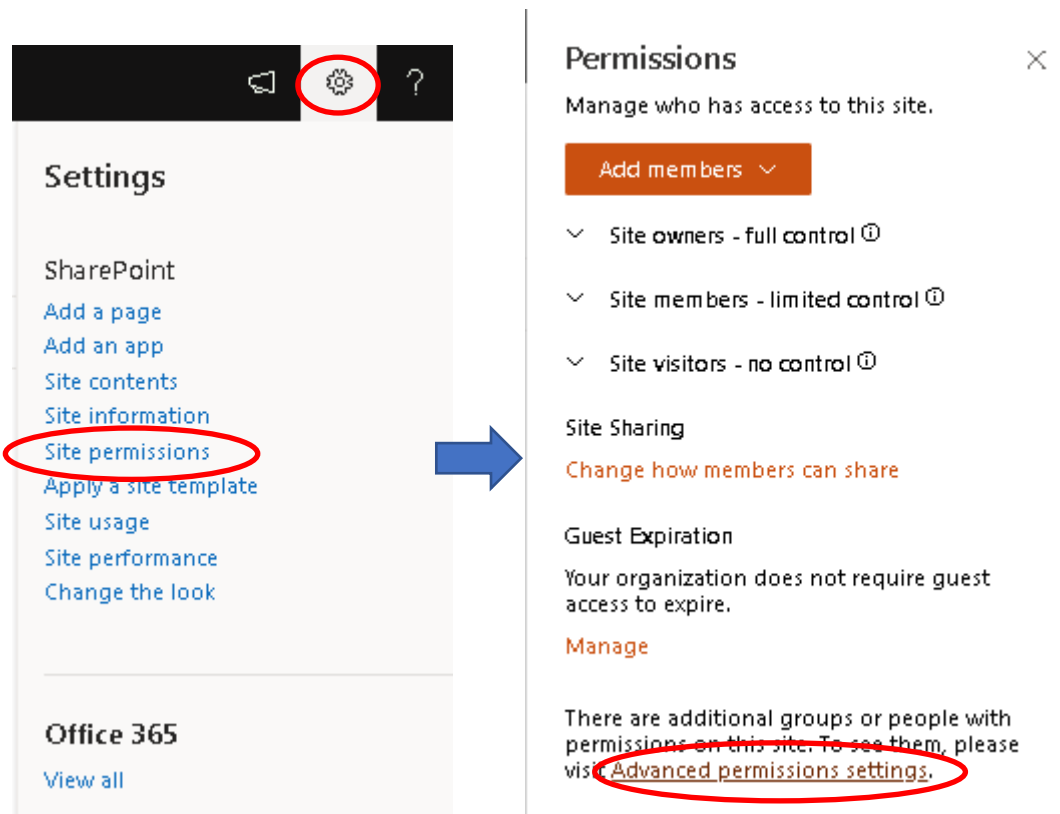
5. Permissions tab – Grant menu – Create Group. No need to add specific permissions or members yet. Create the following groups/permissions/members:
    a. <Trial-name> eTMF Admin
    b. <Trial-name> eTMF Approver
    c. <Trial-name> eTMF Reader
    d. <Trial-name> eTMF Editor
    e. <Trial-name> eTMF Term Store (users in this group will control metadata tags)
6. Select 'site contents' page in left hand menu, then Site settings – Manage Site Features
    a. Following Content = Active
    b. Metadata Navigation and Filtering = Active
    c. SharePoint Recommendations = Active
    d. Site Notebook = Active
    e. Site pages = Active
    f. Team Collaboration Lists = Active
    g. Workflow Task Content Type = Active
7. Site Settings – Site Collection Features
    a. Limited-access user permission lockdown mode = Active
    b. Reporting = Active
    c. SharePoint Server Publishing Infrastructure = Active
    d. Three-state workflow = Active
8. Site Settings – Navigation – Navigation Settings
    a. Global Navigation = Structural Navigation
    b. Current Navigation = Managed Navigation
    c. Structural Navigation: Sorting = Sort Manually
    d. Make "Show Ribbon" and "Hide Ribbon" commands available.

9. Site Settings – Term Store Management –Site level term groups – Site Collection – <institution link> –click on ellipsis (…) and choose "Add Term Set"
    a. Term Set Name = eTMF tags
    b. Term set ellipsis – Add Term. Suggest use terms from the TMF Reference Model, available here: https://tmfrefmodel.com/ . Recommend to prefix all terms with 't' and leave out spaces so tTermsLookLikeThis. The prefix ensures searching on terms won't pull back results from document contents, as the tags will be unique. In addition, when adding a term/tag to a document, typing in the initial t will bring up the entire list. One or more Synonyms/aliases may also be added to terms to help in searching for them – typing the alias will bring up the term wanted.
        i. tTMFPlan – alias "Trial Master File Plan" (remember to click save after adding synonyms)
        ii. tTrialManagementPlan
        iii. tQualityPlan
        iv. tSOPList – alias "Standard Operating Procedure"
        v. tSOPManual
        vi. tRecruitmentPlan
        vii. …etc
10. From Home, add new document library named **eTMF**
11. eTMF Document Library Settings – more library settings
    a. List Name, description and navigation
        i. Enter library name and description. (eTMF, ….)
    b. Library Settings – more library settings – Versioning Settings
        i. Require content approval for submitted items = Yes
        ii. Create a version each time = Create major and minor (draft) versions
        iii. Keep following number of major versions = 5000
        iv. Keep drafts for the following number of major versions = 5000
        v. Who should see draft items = Any user who can read items.
    c. Columns
        i. Title – Single line of text. Created by default – Keep.
        ii. Description – Multiple lines of text. Created by default – keep.
        iii. Created/Modified – Date and Time. Created by default – keep.
        iv. Created by/modified by/checked out to – Person or Group. Created by default – keep.
        v. Create Column
            1. Column name = DocType
            2. Type = Managed Metadata
            3. Require that this column contains information = No
            4. Enforce unique values = No
            5. Check Add to default view
            6. Check Allow multiple values
            7. Display value = Display term label in the field
            8. Use a managed term set = eTMF tags
        ii. Create Column
            1. Column name = System (this column is reference by the approval flow, but is not needed in an eTMF implementation, so can be hidden)

2. Type = Managed Metadata
3. Enforce unique values = No
4. **Uncheck** Add to default view
5. Check Allow multiple values
6. Display value = Display term label in the field
7. Use a managed term set = eTMF tags

iii. Create Column
1. Column name = System Version (this column is reference by the approval flow, but is not needed in an eTMF implementation, so can be hidden)
2. Type = Single line of text
3. Require that this column contains information = No
4. Enforce unique values = No
5. Uncheck add to default view

vi. Under Views, click on "All Documents". Make sure the following are selected and ordered as you want. Suggest:
1. Type (icon)
2. Name
3. Version
4. Checked Out To
5. Approval Status
6. DocType
7. Modified (Settings – Edit Column – Display Format = Standard)
8. Modified By
9. Comments (use link 'Add from existing site columns' to add this)

vi. Require documents to be checked out before they can be edited = Yes

d. Library Settings – more library settings – Advanced Settings
i. Allow management of content types = No
ii. Template URL: leave as default.
iii. Opening Documents in the Browser = Use the server default
iv. Custom Send To Destination: leave blank
v. Folders: Make "New Folder" command available = No (note leave as Yes to first create folder structure to use, then change to No to preserve the structure, or use file import in library to import a folder structure)
vi. Search: Allow items to appear = Yes
vii. Index Non-Default Views = No
viii. Offline Client Availability = Yes
ix. Site Assets Library = No
x. Quick property editing = Yes
xi. Dialogs: Launch forms in a dialog = No
xii. Automatic Index Management = Yes
xiii. List experience = Default experience for the site.

e. Validation Settings – leave blank
f. Column default value settings – leave blank
g. Change Default Column Values – leave blank
h. Rating Settings = No
i. Audience Targeting Settings – all unchecked.

      j. Metadata Navigation Settings
           i. Add to Selected Hierarchy Fields: Folders, DocType
           ii. Leave Select Key Filter Fields blank
           iii. Automatically manage column indices on this list
      k. Per Location View Settings – default
      l. Form Settings – Use the default SharePoint form
      a. Open **eTMF** library – Settings (cog in top right) – Library settings – More Library Settings – Permissions for this document library – Permissions tab.   Note, when adding a new group to a list or library, click the 'Show Options' link to turn off the automatic email and change the permission level.
           i. Stop Inheriting Permissions
           ii. Grant Permissions – add the groups created previously created. Note you may need to refresh the page after adding a group to see it.
               10. Trial-name> eTMF Admin
                    a. Permission level = Full Control
               11. <Trial-name> eTMF Approvers
                    b. Permissions level = Edit, Approve (after adding group, select it, then use 'Edit User Permissions' menu to add 2nd permission. Note that approval flow runs under the account of person who initiates the flow. Approvers will need to write to the Doc Copies library, but everyone else should be read only. The members of the Approvers group may start the approval flow – but the users who actually approve the documents can be anyone with read access.
               12. <Trial-name> eTMF Reader
                    c. Permissions level = Read
               13. <Trial-name> eTMF Editor
                    d. Permission level = Edit
      m. Remove other inherited groups so eTMF access limited to those above, not just by MS Teams membership, as there may be outside collaborators added to this who should not have access to the eTMF

12. Create new document library Name = **Doc Copies** ,
      a. description = Copies of all documents made at time of approval
      b. Open **Doc Copies** library – Settings (cog in top right) – Library settings – More Library Settings – Permissions for this document library – Permissions tab.
           iii. Stop Inheriting Permissions
           iv. Grant Permissions – add the groups created previously created. Note you may need to refresh the page after adding a group to see it.
               14. Trial-name> eTMF Admin
                    e. Permission level = Full Control
               15. <Trial-name> eTMF Approvers
                    f. Permissions level = Edit, Approve (after adding group, select it, then use 'Edit User Permissions' menu to add 2nd permission.
               16. <Trial-name> eTMF Reader
                    g. Permissions level = Read
               17. <Trial-name> eTMF Editor

> h. Permission level = **Edit**
>> v. Remove other inherited groups so eTMF access limited to those above, not just by MS Teams membership, as there may be outside collaborators added to this who should not have access to the eTMF

13. Doc Copies – Library settings – Versioning settings
    a. Require content approval for submitted items = No
    b. Create a version each time (1, 2, 3…)
    c. Keep following = 500
    d. Require document to be checked out before they can be edited = No
14. Doc Copies – Library settings – Advanced settings
    a. Make "New Folder" command available = No
15. Doc Copies – Create Columns
    a. Document Version = Single line of text
    b. DocType = Single line of text (note that we don't use managed metadata here – the document tags text will be copied here instead when document is approved)
    c. System = Single line of text – but don't include in default view as unused in eTMF
    d. System Version = Single line of text – but don't include in default view as unused in eTMF
    e. Approval date = Date and Time
    f. Approvers = Single line of text (note 256 char limit)
    g. Comments = Multiple lines of text (added from existing site columns)
    h. Folder = Single line of text
16. Create new list called name = **Approval Log**
    a. Add columns:
        i. Document version = single line of text
        ii. DocType = single line of text
        iii. System = single line of text – but don't include in default view
        iv. System Version = single line of text – but don't include in default view
        v. Approvers = single line of text
        vi. Comments = multiple lines of text
        vii. Folder = single line of text
        viii. Approval Status = single line of text
        ix. Approval Date = date and time (include time, friendly format = No)
17. Approval Log – List Settings – Permissions for this list – Permissions tab. First, stop inheriting permission.
    a. <Trial-name> eTMF Admin = Full Control
    b. <Trial-name> eTMF Editor = Read
    c. <Trial-name> eTMF Reader = Read
    d. <Trial-name> eTMF Approver = Edit
18. Approval Log – List Settings – Versioning Settings
    a. Require content approval for submitted items = No
    b. Create a version each time you edit an item in this list = No
19. Approval Log – List Settings – Advanced Settings
    a. Allow management of content types = No
    b. Read access = read all items
    c. Create and Edit access – create and edit all items
    d. Attachments to list items = Disabled

e. Make "New Folder" command available = No
f. Allow items from this list to appear in search results = Yes
g. Allow non-default view from this list to appear in search results = No

20. Form label for version number
    a. Open eTMF library settings – more library settings – Information Policy Management Settings, and click on Document
        vi. Check 'Enable Labels'
        vii. Label format = {Version}-{Approval Status}
        viii. Also try label format = {_UIVersionString}-{Approval Status} if previous one doesn't work.

21. Importing eTMF Approval Flow
    a. First, find the IDs for the 2 libraries and lists, and note them down. If you go to the list or library settings – more settings, this ID is in the URL bar between %7B and %7D and should look something like this:

https://unioflife.sharepoint.com/sites/MyGreatTeam/_layouts/15/listedit.aspx?List=%7B7024ce7f-4535-430c-99be-343c1f4fffe4%7D

make a note for eTMF, Doc Copies and Approval Logs

    b. Download eTMFApprovalFlow_20221003130140.json
    c. Open the zip archive and edit Microsoft.Flow\flows\8e95a91d-ceb3-42ee-b87f-41830cc57cd4\definition.json
        i. Replace all occurrences of SITE_NAME with your SharePoint site name, as in https://**universityoflife**.sharepoint.com/sites/....
        ii. Replace all occurrences of TEAM_NAME with your SharePoint team name, as in https://universityoflife.sharepoint.com/sites/**MyGreatTeam**
        iii. Replace all occurrences of eTMF_GUID with the ID for your eTMF library.
        iv. Replace all occurrences of ApprovalLog_GUID with the ID from your Approval Log list
        v. Replace all occurrences of DocCopies_GUID with the ID from your Doc Copies library
        vi. Save the changed file into the archive.
    d. Open Power Automate – My Flows – Cloud Flows – Import Package
    e. Upload the edited archive file.
    f. On Package Content, change IMPORT SETUP from 'Update' to 'Create as new' and save.
    g. On each of the related resources, click the action spanner icon, then select the listed resource type so that a tick appears on the right and side and click Save.
    h. Click Import
    i. Go back to My flows, and click on the sharing icon of the newly imported and share with users who should be able to initiate the approval flow. (This list can always be amended later)
    j. Click on the pencil icon to edit the flow in the 'Shared with me' view.
    k. For each task step that references a SharePoint site and library or list, update to new library or list. Note if any custom fields have spelling variations, their names will need updating.
    l. Refresh the list of your cloud flows, you should see 'eTMF – Approval Flow' in the list
    m. Rename it if you want to

n. Open it in the flow editor and replace all the library and list names that are showing as long alphanumeric GUIDS with the appropriate library name. It should be fairly clear from the context, so long as the site address is correct. Most libraries will refer to the main 'eTMF' library, except when it is making a copy into 'Doc Copies'. The references to the approval log is to a SharePoint List, so choose the one created for this.

- Click anywhere on title bar to expand the task
- Click the X on the 'Library Name' this will then turn into a drop list to allow you to select the correct library.

o. Check for errors – these will need to be resolved. They will most likely be down to names of libraries, lists and columns you have created. Sometimes tasks seem to create new 'duplicate' fields, in which case if one copies the contents into the correct field, and remove it from the incorrect duplicate, it will then be OK.

p. Click on the ellipsis again, and choose 'Turn on'

q. Click on the Approval Flow link and add all the users to the 'Owners' from 'eTMF Admin' and 'Run only users' that you also want to list in the group 'eTMF Approvers' (Sorry – Power automate only seems to recognise groups in organisations domain, not ones created for this site.   It may be better to have those groups Reader/Editor/Admin/Approver created at the organisational level first)

  r. Select flow zip file to import and click upload

22. Including version number and date automatically in an eTMF Word document
  a. Create word document in the eTMF
  b. Check it out, and open 'In App' (note browser version of Word doesn't have required features for this bit)
  c. Insert cursor where you want version number, status (Draft/Approved) and date to go. Suggest put a couple of spaces in before next step, as this helps for clicking outside of the label that is inserted in the next step.
  d. On Word – Insert ribbon – Quick Parts – Document Property – Label. This will insert the version number and status, e.g. 1.0 Approved.
  e. Move cursor past the spaces entered, then Insert ribbon – Quick Parts – Field – SaveDate and choose the date format you want. When the document is approved, this will be the approval date. When in draft, this will be the date last saved.

23. Running an approval flow
  a. Click on the ellipsis of a document, and choose Automate – eTMF – Approval Flow (or whatever name you have given it)
  b. First time you run it, it will ask for authentication for services used, OK this.
  c. There is a pdf guide for an older version which I haven't had time to update yet, but operation is basically the same, except this is only using one 'DocType' tag column, the approval flow is a bit more forgiving, and one can start approval flows on draft documents as it will move them into Pending status for you. The Approvers emails you choose are entered into a single box, and you will need to always use the 'Ignore warnings' option
  d. If something goes wrong, you can view run history of approval flows and see at what step the problem occurred, in order to fix it.