

These instructions apply only to **Initial Study Action** and **Continuing Review (CR)** submissions for review. To include the following: initial PI/SC Applications, initial LSI Applications, initial CR Applications, initial Amendments, initial Audit Reports, and initial Pre-Reviews. Instructions for uploading initial submissions can be found below. **Please do not upload any documents until the submission is complete and ready for review, this is not a “holding” location for study documents.** Once the documents have been uploaded to the “Initial Submission” folder and the submission is complete please notify the VA Central IRB by e-mail at [VACentralIRB@va.gov](mailto:VACentralIRB@va.gov). This will aid the VA Central IRB staff in ensuring that all initial study actions are entered into our CATS tracking system in a timely manner.

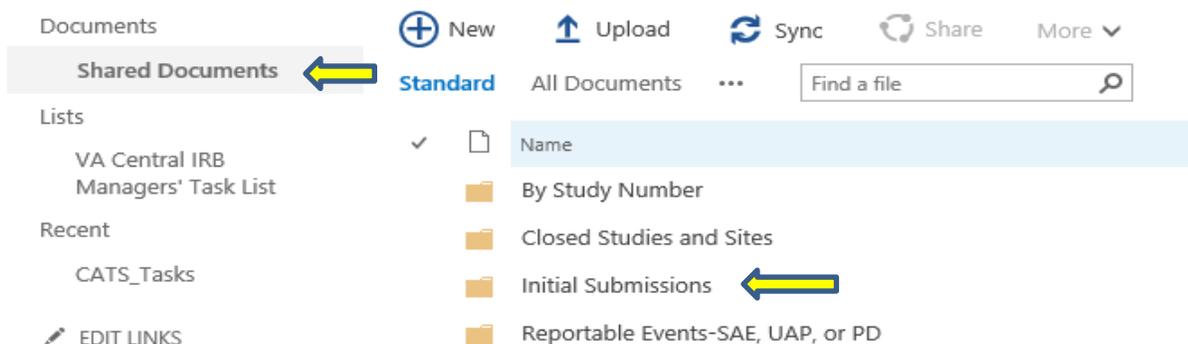
Responses to Reviewer comments and any administrative updates should be uploaded into the “Responses and Updates” folder which is in the study folder under “By Study Number”. This does not apply for Continuing Review documents.

Ensure the file name includes the form number or type of document and date, **with a limit of 15 characters** (e.g., Protocol 010114 or Form 103 010114). **This is extremely important as long titles will inhibit processing and slow down the review.**

Serious Adverse Events (SAE), Unanticipated Problems (UAP), and Protocol Deviation (PD) reports should be submitted to the “Reportable Events- SAE, UAP, or PD” folder.

Step-by-step instructions for submission:

1. To access the VA Central IRB SharePoint site, click on the following link:  
<https://dvagov.sharepoint.com/sites/VACOVHAORPPE/vacirb/Shared%20Documents/Forms/Standard1.aspx>
2. Click on “Shared Documents” and then double click the “Initial Submissions” folder



3. Click “New Folder” under the “Files” or click the “New” button, then “New Folder” to create a folder for the submission (Fig. 1). Enter the name of the folder according to the action being submitted. Please be very specific when naming the folder and reference the **VA Central IRB Study #** and the **action**. For an initial Pre-Review submission, please name the folder “Pre-Review” and include the **funding source** and **PI’s last name** (Fig. 2). Click “Save”.

Fig. 1

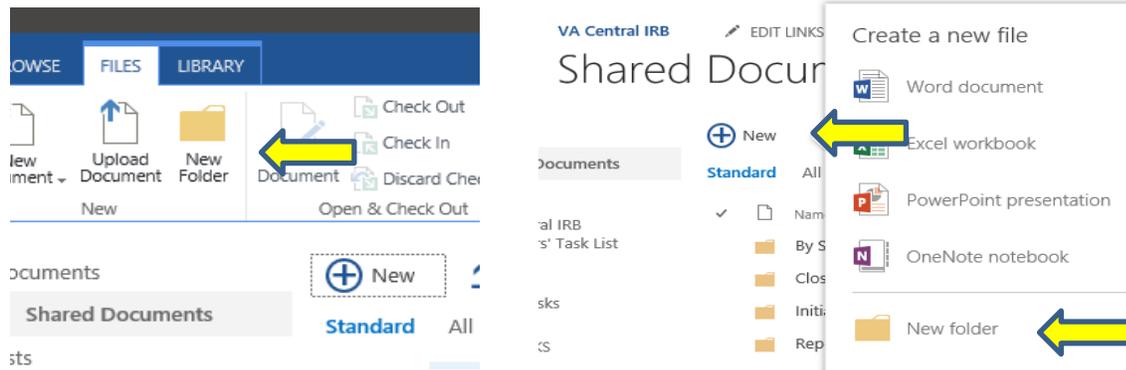
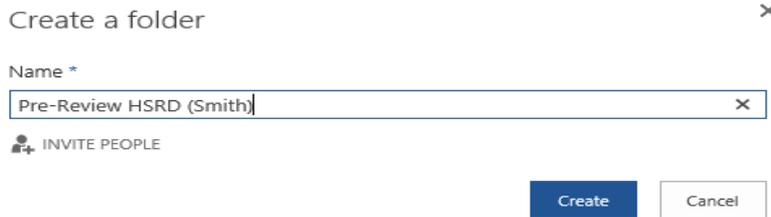


Fig. 2



4. New CR submissions should be uploaded into the “0 CONTINUING REVIEW SUBMISSIONS” folder (Fig. 3). Please create a folder for the submission named with the VA Central IRB study number and CR information (Fig. 4). Please create sub-folders for each local site to keep the documents organized by PI/SC and LSI.

Note: Revised documents for Continuing Review should be uploaded into the same folders created in the “0 Continuing Review Submissions” folder (we do NOT want any revised documents in the “Response and Update” folder.)

Fig. 3

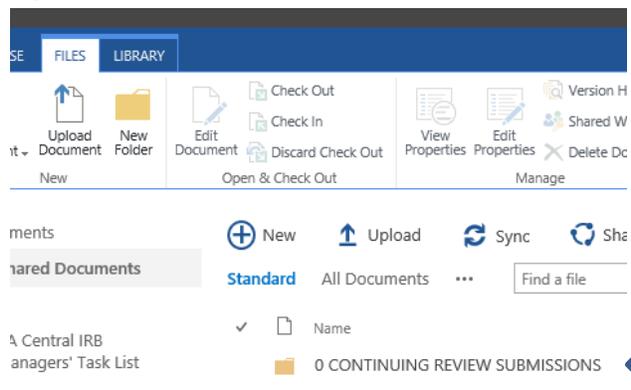
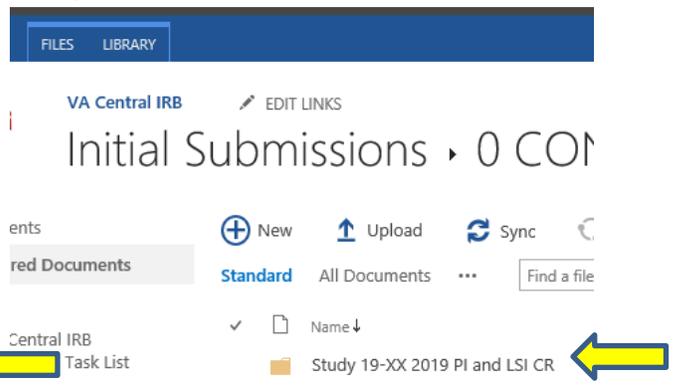
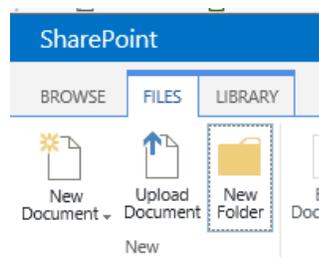


Fig. 4



5. To upload documents, click on the “Upload Document/Documents” dropdown box (found under the “Files” tab) then browse for the file/files on the desktop and click “OK”. Or use the “Drag files here to upload” feature.



6. Once the submission is **complete**, please notify the VA Central IRB via e-mail at [VACentralIRB@va.gov](mailto:VACentralIRB@va.gov).
7. Once the submission is uploaded to SharePoint, the VA Central IRB staff will be notified via an automated alert from the SharePoint website. An acknowledgement of receipt will be sent to the Study Team via e-mail.
8. Any follow-up submissions or responses should be uploaded to the “Responses and Updates” folder in the specific study folder accessed via the “By Study Number” folder. This does not apply for CR submissions.

Please contact the VA Central IRB staff at 1-877-254-3130 or [VACentralIRB@va.gov](mailto:VACentralIRB@va.gov) with any questions or concerns regarding the Initial Submission process.