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Information and guidance for primary care sites on how to file amendment documents.

If the sponsor has not specified what to do with the amendment <u>documents</u> please follow this guidance as required:

- Save copies of the attached new document versions in the correct section of the study's e-ISF
- Move previous document versions into superseded folders
- Destroy un-used paper copies of superseded paperwork
- Where required, prepare copies of new versions, eg PIS, consent, source data collection forms
- Update your version control document in the e-ISF and paper site file, use file notes as appropriate.
- Disseminate new versions to the study team within your practice as appropriate
- Update local training log, if required.
- Update Delegation log, if required.

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Extracted from the: Template - SPC Amendment email to notify the practices

Created by Linda Mulunda, May 2023