

HOW TO ACCESS AND MAINTAIN THE eISF

The CRASH-19 electronic Investigator Site File (eISF) is the record of the trial at your hospital. The eISF will be hosted on a Google Drive, accessible via the trial tablet provided, and consists of two folders each with multiple sub-folders:

1. Investigator's Site File 1 (eISF 1):

- contains, core trial documents e.g. the trial protocol, national ethics and regulatory approvals, blank copies of logs and forms
- Sites have **view only access** to eISF 1, meaning they can view and download the documents within the folders but do not have permissions to upload, edit or delete documents

2. Investigator's Site File 2 (eISF 2):



- contains site specific documents e.g. the Participating Site Agreement, completed logs and forms
- Sites have **edit access** to eISF 2, meaning trial team members will have full permissions to view and edit the documents within the folders and will be able to upload new documents to these folders

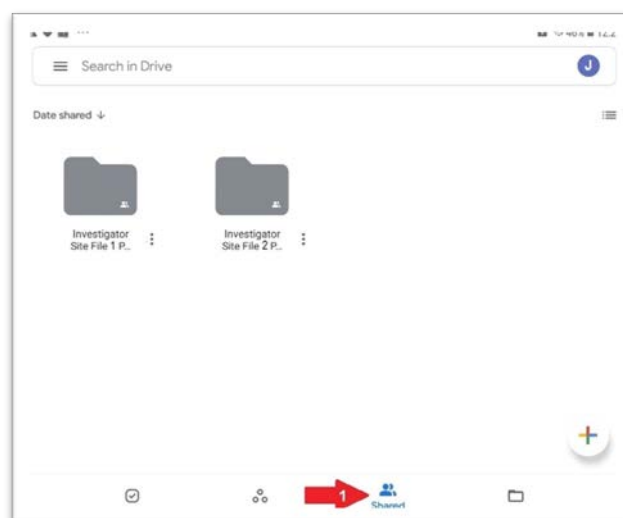
Please familiarise yourself with the contents of both eISF folders.

ACCESSING THE GOOGLE DRIVE AND eISF

Via the trial tablet:

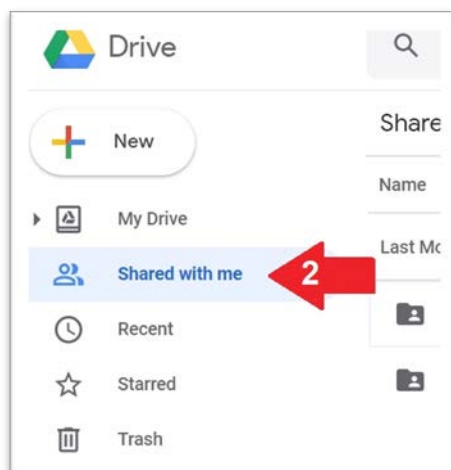
The trial tablet has been set-up with your site-specific Google details giving you access to your site's Google Drive and eISF. To view the eISF:

- On the trial tablet, tap on the google drive icon  
- Your site Google Drive will open
- Tap on the 'shared' icon (1) to view the eISF 1 and eISF 2 folders



Via a PC

- Enter <https://drive.google.com> into your browser
- Sign in using the Google details provided to you by the NCC / LSHTM-CTU
- In the Google Drive, click 'Shared with me' (2) to view the eISF 1 and eISF 2 folders



Because confidential data will be stored in both eISF folders, please do not login to the Google Drive on personal devices e.g. your smartphone, as confidential trial documents could be unintentionally stored on your device.

NAVIGATING AND MAINTAINING YOUR SITE FILES

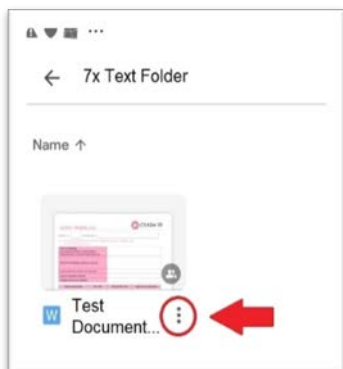
Navigating

- An index is available in each eISF which lists the folders and sub-folders included
- Use the indexes to locate documents you need or to identify where completed forms / logs should be saved

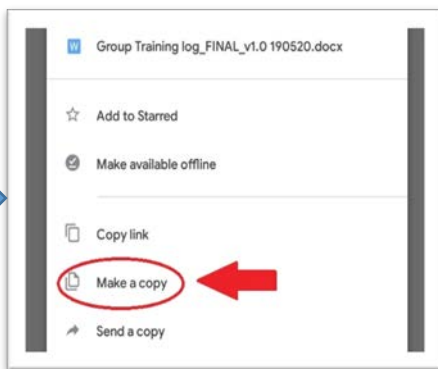
Viewing and copying documents across folders (on the trial tablet)

- Tapping on any of the documents in the Google Drive will open it to view
- Blank copies of trial forms and logs are available in eISF 1, folder 7. To edit these documents, they must first be copied into their corresponding folder in eISF 2; to do this:
 1. Tap on the three dots next to the document you want to copy
 2. Select the option "make a copy"
 3. Select "Shared with me" when asked to choose a location
 4. Tap the back arrow ← in the left-hand corner of the screen until the two eISF are visible.
 5. In the new pop up window, navigate to the correct eISF2 folder (check the index for guidance on where documents should be saved)
 6. Click "select" when you reach the desired folder

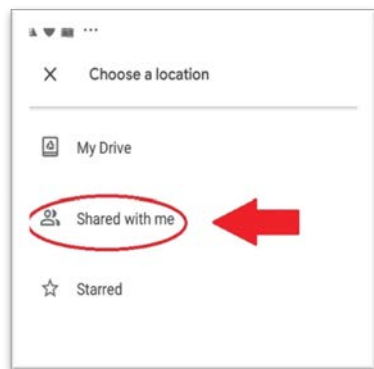
1 – Tap on the three dots



2 – Select “Make a copy”



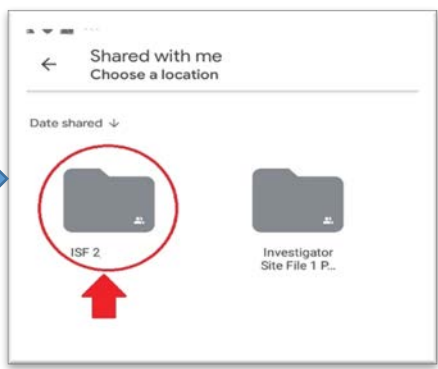
3 – Select “Shared with me”



4 – Go to the initial page



5 – Navigate to the selected folder



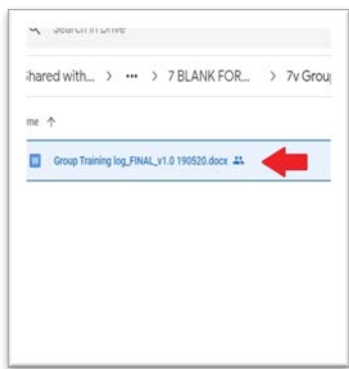
6 – Find the correct folder for the document according to the index and click on “Select”



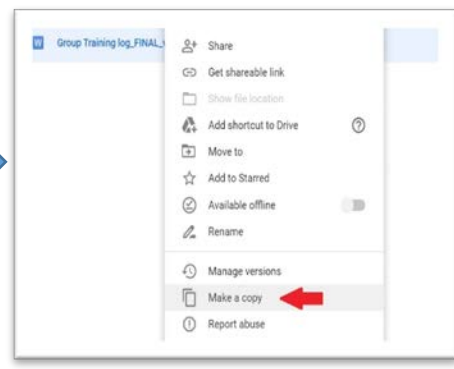
Copying documents across folders (on a computer)

1. Right-click on the document you want to copy across
2. Select “Make a copy”
3. This will automatically make a copy of the selected document in the same folder
4. Right-click on the copied document and select “Move to”
5. Navigate to the correct folder in the appearing pop-up window
6. Once the selected folder is reached, click on the “Move Here” button at the bottom of the pop-up window. The document is now saved on the selected folder

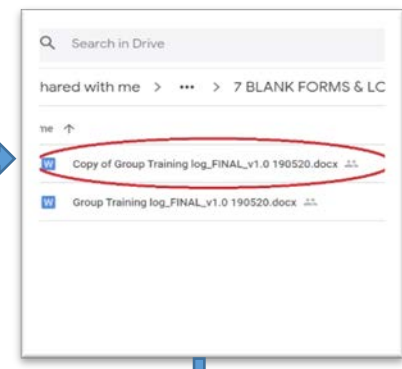
1 – Right-click on the document to be copied



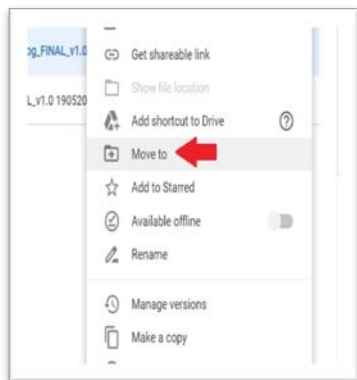
2 – Select “Make a copy” from the pop-up menu



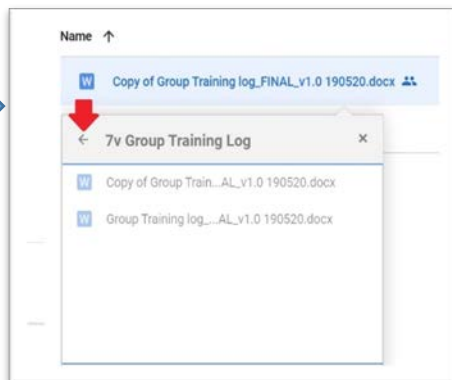
3 – the file will be copied in the same folder



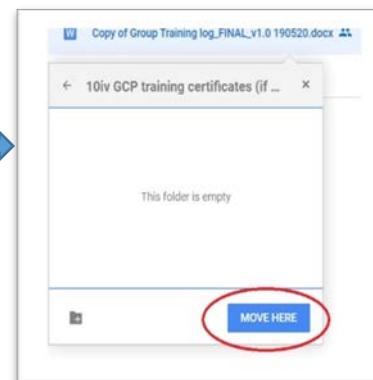
4 – Right-click on copied document and select “Move to”



5 – Navigate back in the structure towards the chosen folder

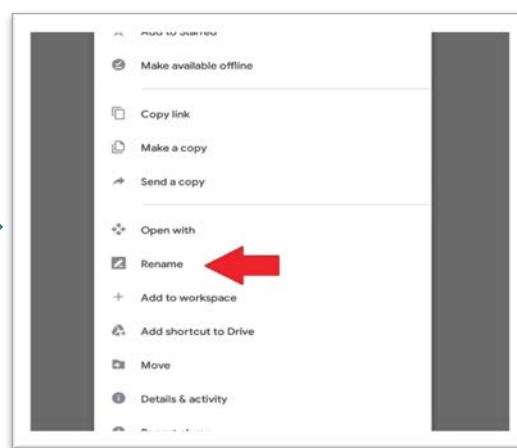
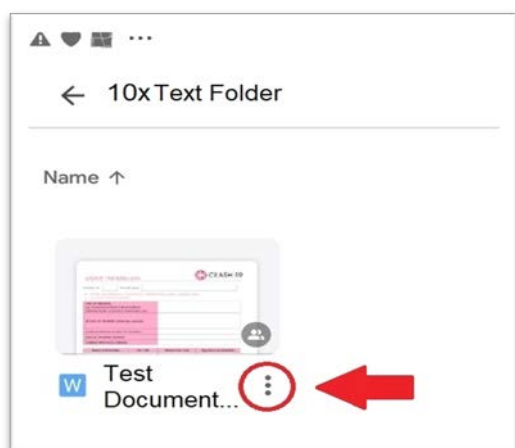


6 – Once on the selected folder, Click on “Move here”



Re-naming documents

- All documents saved in eISF 2 must be uniquely named so that they are identifiable
- To edit the name of a file, tap on the three dots next and select “Rename” from the pop-up menu. Type the new name and save.
- Documents should be named in a standard format as follows:
 - [name of form]_[Initials of trial team member / patient randomisation number]_[Date form created]
 - For example:
 - A breach form for participant with randomisation number ‘12-34’ on 2nd January 2021, would be named: “Breach form_1234_02012021”
 - NOTE: DO NOT USE participant identifiers to name the documents



Editing Documents

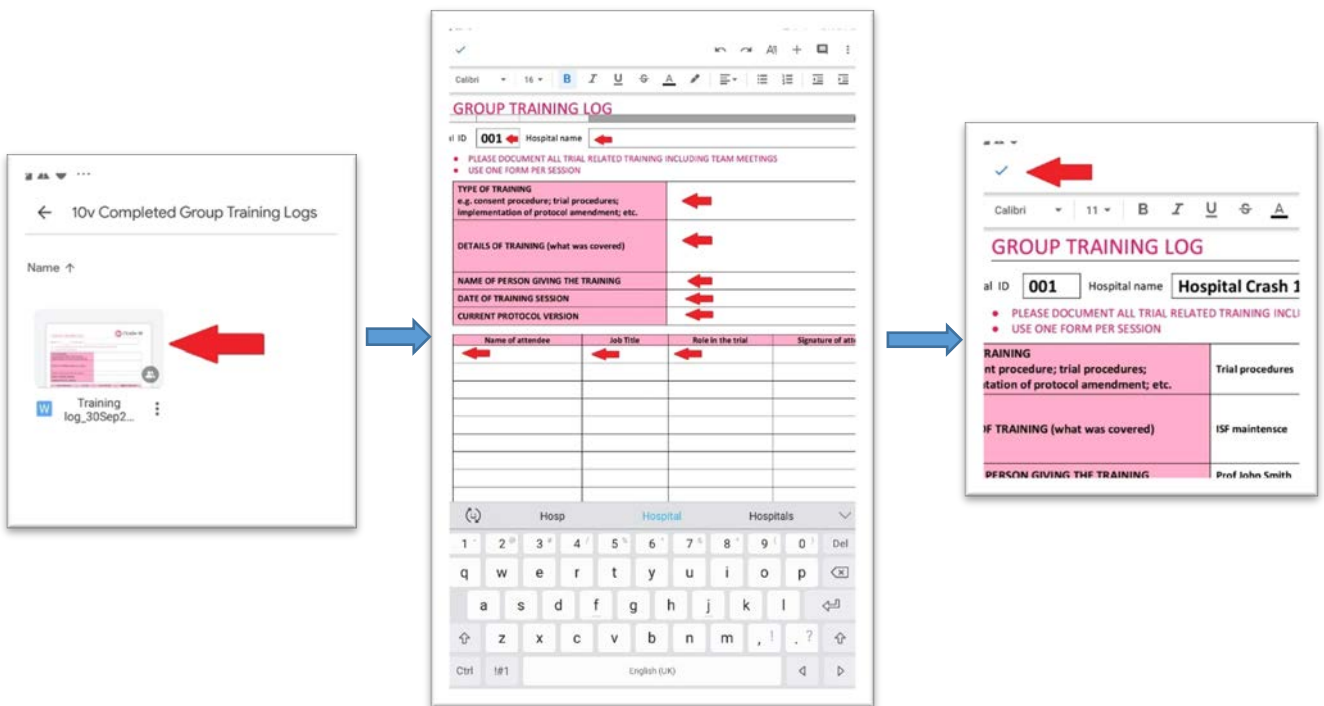
Editing the blank logs and forms in eISF1 is possible only once a copy of the document has been moved to eISF 2. To edit a document:

1. Tap on the document to open it. It will automatically open in the Google Docs app which has been installed on the trial tablet
2. To enter text, double tap on any of the fields in the document. The tablet keyboard will pop-up automatically. *If a signature is required, you can either insert an electronic signature as an image or save the document as a PDF and e-sign using the Adobe Acrobat app (further guidance below)*
3. Click on ✓ once you have filled all the necessary fields close the document. Remember to name your document appropriately.

1 – Tap on the document to open it

2 – Double tap on the editable fields and complete them

3 – Click on ✓ to finish

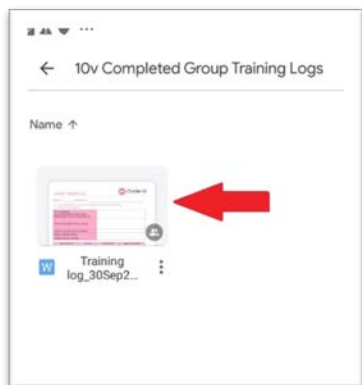


Converting documents into PDF

For compatibility reason, and to ensure no forms are over saved with new data, **all completed forms and logs should be converted into PDF documents**. To do this:

1. Open the word document. It will automatically open with Google Docs
2. Tap on the three dots on top right-hand corner and choose "Share & export" from the menu. Then select "Save as"
3. Select the option "PDF Document (.pdf)". The file will automatically be saved in the "My Drive" area.
4. From the "My Drive" area, tap on the three dots next to the PDF
5. Select "Move to" and navigate to the correct eISF 2 folder
6. Once the selected folder is reached, tap the "Move Here" button at the bottom of the pop-up window. The document is now saved in the selected folder

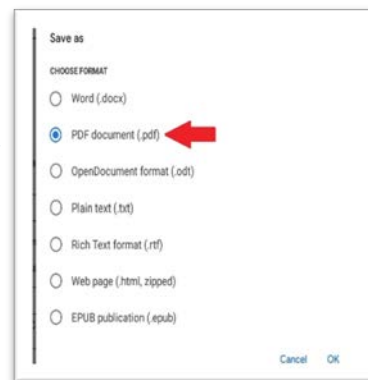
1 – tap on the document to open it with Google Docs



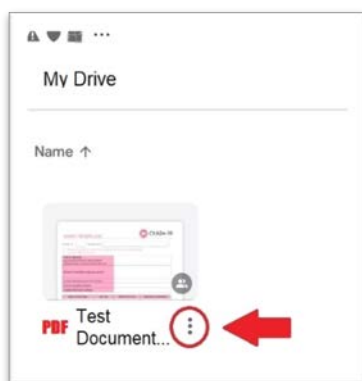
2 – Click on the three dots, choose “Share & export” and select “Save as”



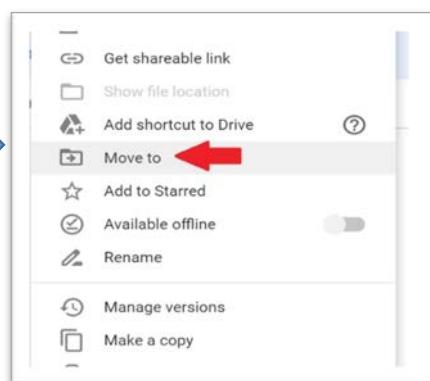
3 – Save as “PDF Document (.pdf)”



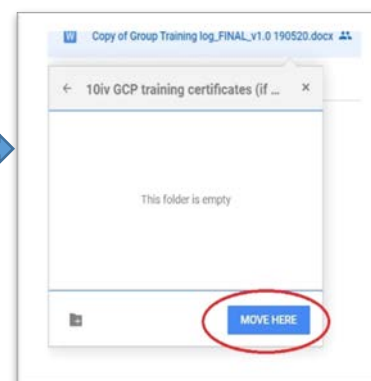
4 – Tap on the three little dots next to the PDF file



5 – Choose “Move to” and navigate through the ISF to the selected folder



6 – Save as “Move here”

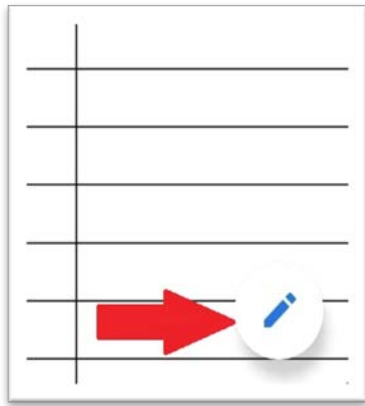


Adding signature to a PDF document

To add signature to a PDF document, use Adobe Acrobat app which has been pre-installed on the tablet. To do this:

1. Tap on the PDF document that needs signing to open it
2. Tap on the blue pencil in the right-hand corner of the screen and when prompted, select ‘Adobe Acrobat’. The document will open in Adobe Acrobat. Next, tap on the option ‘Fill & Sign’,
3. Tap on the fountain pen icon from the top bar and choose the option “Create a signature”
4. Draw your signature inside the Pop-up window and tap “Done” to save it
5. Tap anywhere in the page where you want the signature appear, then adjust its position and resize it by sliding the blue arrow in the right-hand side of the signature.
6. Click on ✓ to save it (it may take up to 30 seconds to save)

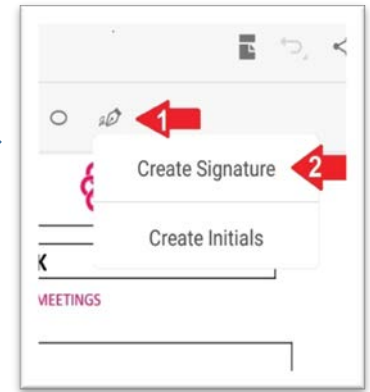
1 – Open the document and tap on the blue pencil



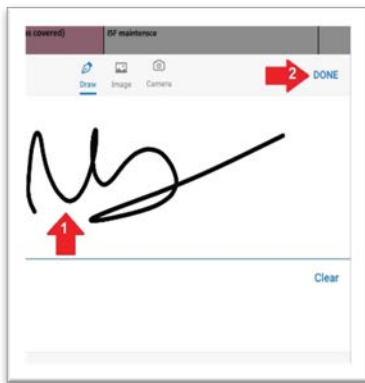
2 – Choose Adobe Acrobat and select “Fill & Sign”



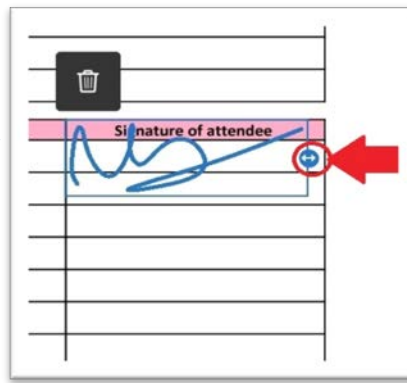
3 – Tap on the fountain pen on the top and select “Create Signature”



4 – Draw your signature and click “Done”



5 – Tap on the document to insert the signature and adjust size and position



6 – Click on ✓ to save the signed document



Uploading documents that you have printed and manually completed:

- Using the tablet, open the eISF 2 folder where the document should be saved:
 - Tap on the '+' sign at the bottom right-hand corner of the screen (1).
 - Select 'Scan' (2) from the pop-up menu; this will automatically launch the tablet's camera. Simply take a picture of the completed document and click on "Save" when you finish. The document will be saved in the selected folder.

