Glasgow Clinical Trials Unit Guideline

Guideline number	**57.005C**	Version	**1.0**
Title	**Redaction Process**		

There may be instances where documents containing personal identifiable information has to be transferred to external party for end point, safety or monitoring purposes. The requirements and process must be discussed with Sponsors/CROs including GCRF Senior Management and QA Lead during site selection or initiation.

Procedure

1. Once redaction has been agreed and approved, Lead Study Nurse must discuss time points with Principal Investigator and Project Assistant.
2. Documents to be redacted must be saved in study folder, clearly labelled for redaction.
3. Lead Study Nurse to notify Project Assistant when documents for redaction available.
4. Project Assistant to use PC 2 in administrative area.
5. Open Adobe PRO.
6. Click **Open**, **Edit PDF** and select the document for redaction.
7. Select area to be redacted, click **Delete**.
8. Redact all personal identifiers from the document – name, address, DOB, CHI.
9. Create **Redacted documents** folder. Click **Save As**, keeping the file name as original by Lead Study Nurse.
10. Scanned documents must be redacted differently:
    a. Open the document in Adobe PRO.
    b. Click **Save As** and select **JPEG (*.jpg, *jpeg, *jpe)**
    c. This will create a JPEG of each individual page of the document.
    d. The JPEGs need to be redacted using **Microsoft Paint**. Open each page and select the square box draw tool, select solid colour from the dropdown menu and select colour 1 and colour 2 as black. This will draw a solid black box that can be used to redact patient-identifiable information.
    e. Once all information has been redacted, open Adobe PRO and select **Create** and then **Combine files into a single PDF**.
    f. The document can now be saved in the **redacted documents** folder following the process above.
11. Once all document redacted, email to confirm documents are available for review by Lead Study Nurse.
12. Lead Study Nurse to review redacted documents ensuring all personal identifiers removed.
13. Click **Print Screen** of the folder contents, copy to Word and **Print**.
14. Confirm on either printed version of folder contents: All document listed above folder are confirmed as redacted and can be transferred to external party.
15. Print name, sign and date.
16. File in Investigator Site File.
17. Follow the process agreed at SIV to transfer redacted data.

Guideline signatories

Prepared by Signature	Eilidh Wright Date
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Document history

Version	Date	Description
1.0	03/08/2023	First release