

Section Clinical Research Center

Date Created: September 18, 2020

Title: Redacting Source Documents

Date Reviewed/Modified:

SOP Number: SOP-69

Version Number: 2

PURPOSE:

The purpose of this SOP is to provide a uniform procedure used to redact personally identifiable information (PII) from a document that is being shared with an outside sponsor.

SCOPE:

The procedure applies to all employees of the Clinical Research Center.

DEFINITIONS:

- Redaction is the process used to permanently delete or obscure sensitive information
- Personally Identifiable Information (PII) - includes the following identifiers:
The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:
 1. Names
 2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:
 - a. The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
 - b. The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000
 3. All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
 4. Telephone numbers
 5. Fax numbers
 6. Email addresses
 7. Social security numbers
 8. Medical record numbers

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9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) addresses
16. Biometric identifiers, including finger and voice prints
17. Full-face photographs and any comparable images
18. Any other unique identifying number, characteristic or code, except for as detailed below:

a. *Implementation specifications*: re-identification. A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:

i. *Derivation*. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and

- HIPPA: Health Insurance Portability and Accountability Act of 1996 – See link below to the document

PROCEDURES:

All personally identifiable information (PII) will be redacted prior to transmission and transfer of subject research data to outside entities unless contracted otherwise and the study participant is made aware in the consent that their PII will be shared. Acceptable redaction methods may include, but are not limited to: **Electronic method, Adobe Acrobat-DC, refer to Attachment A.**

PII is kept confidential within the research facility. The research facility does not send PII to outside institutions in accordance with HIPPA.

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Sources:

- 1) E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry
- 2) Health Insurance Portability and Accountability Act of 1996 (HIPAA)
<https://www.hhs.gov/hipaa/index.html>
- 3) Heinrich, Richard. (2016, November 10). How to correctly redact a PDF using Adobe Acrobat. Retrieved from <https://www.onelegal.com/blog/how-to-correctly-redact-a-pdf/>

Staff Accountability:

Developed By: Nurse Manager, Clinical Research Center

Associate Vice Chancellor for Clinical Research, Clinical Research Center

Reviewed By: Director of Clinical Research Operations, Clinical Research Center

Department Approval

Signed



Director of Clinical Research Operations

Signed

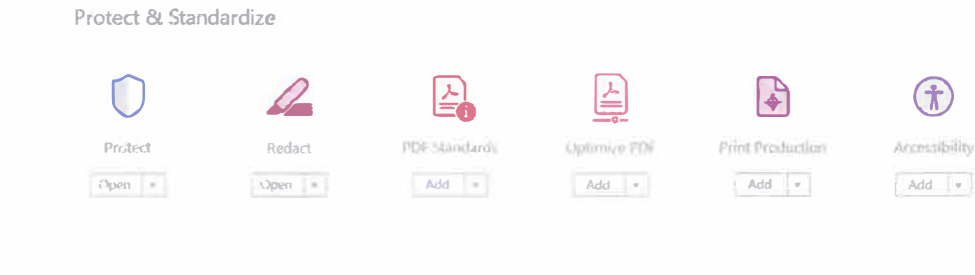


Medical Director for Clinical Research Center

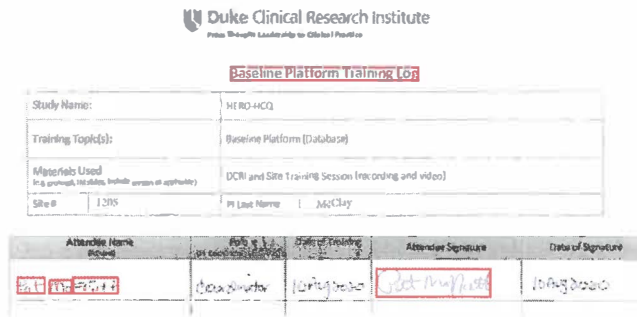
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How to redact in Adobe Acrobat DC

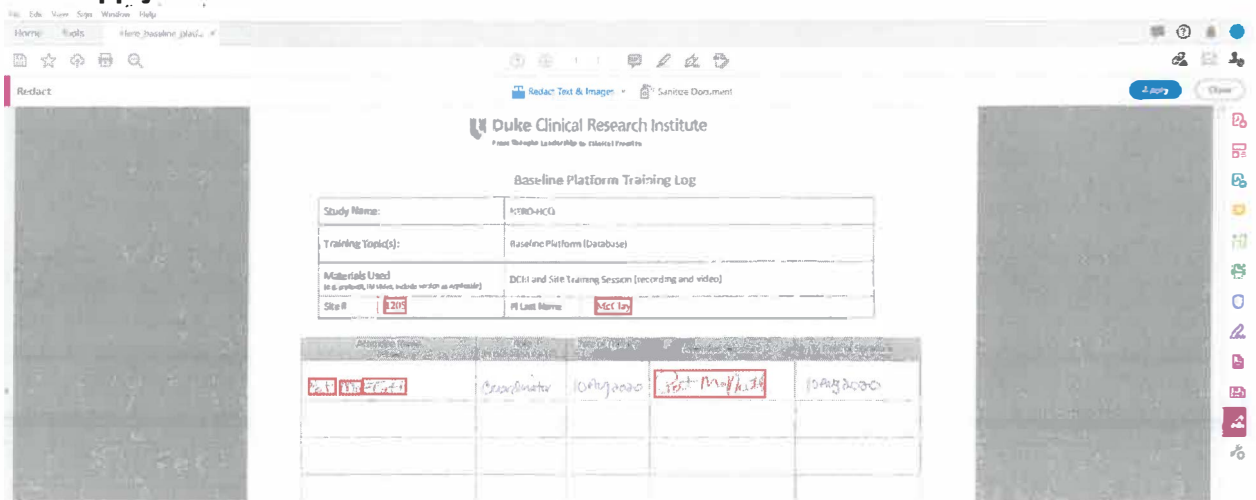
1. Open the document you want to redact with Adobe Acrobat DC.
2. Go to the **Tools** menu, then select **Redact**.



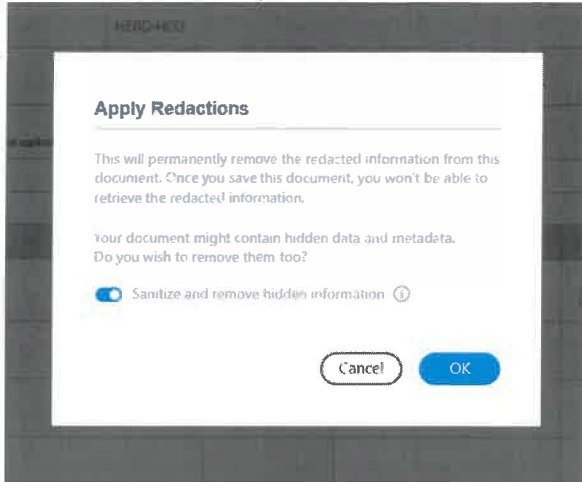
3. Select the text that you want to redact. Once selected, Acrobat DC will highlight your selections in red.



4. Click **Apply** to redact.



5. This is a permanent redaction, and so Acrobat pops up a **warning** box letting you know. Ensure the “Sanitize and remove hidden information” is **ON** – this is to ensure all the hidden information (otherwise known as metadata) is also removed.



6. Then the document can be saved to include the addition of `_Redacted`.

