



**Center for Clinical and
Translational Research
Administrative**



Section: **Clinical Research Center**

Date Created: **September 18, 2019**

Title: **Redacting Source Documents**

Version Date: **January 1, 2023**

SOP Number: **SM40**

PURPOSE:

The purpose of this SOP is to provide a uniform procedure used to redact personal 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.

Procedures:

- Redaction is the process used to permanently delete or obscure sensitive information
- HIPPA Identifiers - includes the following identifiers of the individual or of relatives, employers, or household members of the individual, and should be 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
 9. Health plan beneficiary numbers
 10. Account numbers



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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 HIPPA Identifiers 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.

Sources:



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- 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/>
- 4) **HPRR Policy 3.4 Use of Protected Health Information in Research**

Department Approval

Signed *Serena Gaines*
Research Nurse Manager

Signed: 2/21/2023

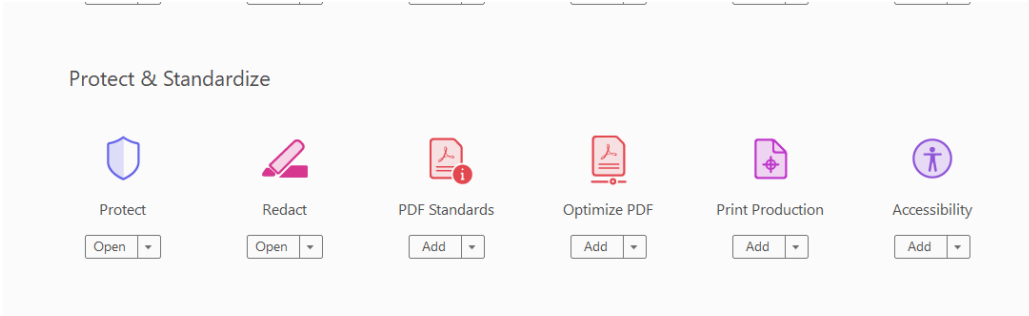
Signed 
Assistant Vice Chancellor for Clinical Research

Signed: 4/3/2023

SM40 Redacting Source Documents

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.

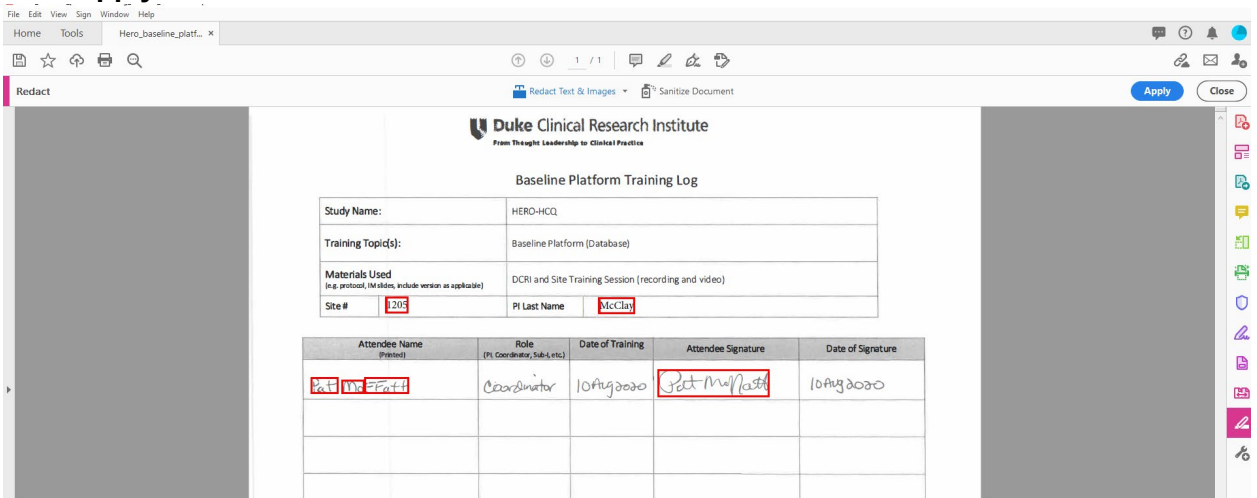
Duke Clinical Research Institute
From Thought Leadership to Clinical Practice

Baseline Platform Training Log

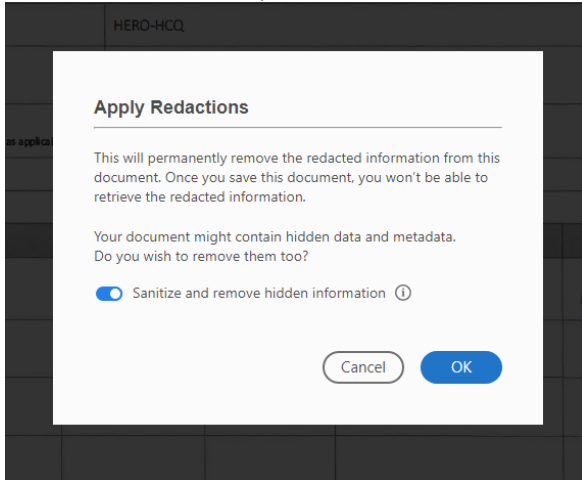
Study Name:	HERO-HCQ
Training Topic(s):	Baseline Platform (Database)
Materials Used <small>(e.g. protocol, IM slides, include version as applicable)</small>	DCRI and Site Training Session (recording and video)
Site #	1205
PI Last Name	McClay

Attendee Name <small>(Printed)</small>	Role <small>(PI, Coordinator, Sub-I, etc.)</small>	Date of Training	Attendee Signature	Date of Signature
Pat McFerrin	Coordinator	10 Aug 2020	Pat McFerrin	10 Aug 2020

4. Click **Apply** to redact.



- 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.



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

