Electronic Signature

SOP Reference: RGIT_SOP_043	
Version Number: 2.0	
Effective Date: 19 Oct 2020	Review by: 19 Oct 2023
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Version	Date	Reason for Change
Version 1.0	21 April 2020	1st Edition
Version 2.0	19 Oct 2020	Scheduled Review Administrative changes to SOP. JRCO name change to RGIT.

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1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure of using Electronic signatures (E-signature) in documents.

2. INTRODUCTION

There are several documents which are created for the set-up and management of research studies that will require a signature. The process of gaining a signature certifies that the document adds value and can be used to approve, review and validate certain events or actions that may occur throughout the duration of the research. The existing process of signing documents as 'wet ink' will be a process that will still be utilised but for a certain number of documents. The following documents listed below can be considered as mandatory wet-ink signed documents, but may also be considered by a case by case basis:

- Protocols and Amendments
- Consent forms
- Completed Case report forms
- CRF correction signature sheet/ signature logs

Electronic signatures can be accepted for agreements and contracts but there may be some cases where a wet ink signature may also be required if the sponsor deems it necessary. However, if in doubt, double check with the college/trust contracts team on a case by case basis.

The process of e-signatures can be completed using either Acrobat or Adobe reader which is described in section 4. The PDF e-signature process is able to capture the date, time and signee of the document; producing an audit trail of signatures.

2.1. European Medicines Agency (EMA) Introduction of digital signatures

The EMA decided to introduce the use of digital signatures in September 2013 for outgoing documents that require a legally binding signature. The EMA have put in place a strategy to increase electronic documents between the pharmaceutical industry and the Regulatory bodies. The EMA have creating a service to test PDF electronic documents and the criteria for exchanging signed electronic documents which can be found on their website: e submission EMA Europa (cited 18 June 2020)

2.2. Medicines & Healthcare products Regulatory Agency (MHRA)

The MHRA have also produced guidelines to assist with the use of electronic signatures in March 2018. The appropriate validation of the signature will need to be demonstrated to ensure control over the signed records can be maintained; this means the metadata associated with the electronic signature must be maintained within the associated signed document.

The use of an inserted image in place of a signature to indicate the document has been signed electronically will not be an adequate form of the signature process. Therefore, it is essential that the metadata is retained within the document for the electronic signature to be valid.

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The MHRA have included within the 2004 Regulations that the acceptance of electronic signatures for consent can also be valid but will depend on the type of electronic signature that will be required. Further information can be found in the Joint Statement on Seeking consent by Electronic Methods guidance by the HRA and MHRA – Version 1.2: September 2018.

3. RESPONSIBILITIES

This SOP is to be followed by any staff involved in the management of RGIT sponsored CTIMPs and non-CTIMPS studies. Alongside any staff working within the RGIT unit.

4. PROCEDURE

4.1. Creating the digital Signature

Please see the screenshots below which demonstrate the following instructions:

1. Open the created PDF file and navigate to the "Tools" tab on the top left side.
2. Click on the "Certificates" icon

3. Click on "Digitally Sign" option

4. Highlight the area where you would like to place the signature

- *How to configure your new digital ID?*
  i. Click "Configure digital ID"
  ii. Select the "Create a new digital ID" option

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iii.   Select the "Save to Windows Certificate store" as the destination
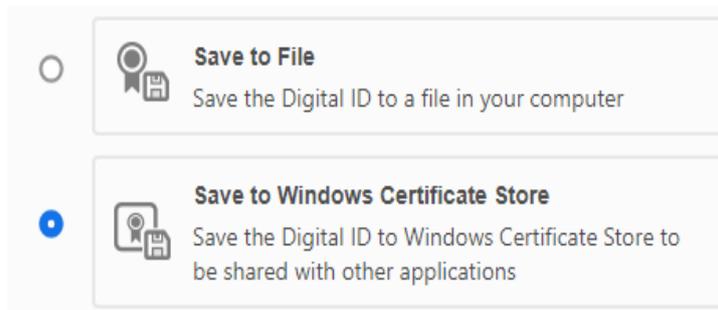
iv.   Enter the required information and ensure the Country/Region has been correctly selected
v.   Click save

5. Now the Digital ID has been created you can choose an ID for signature
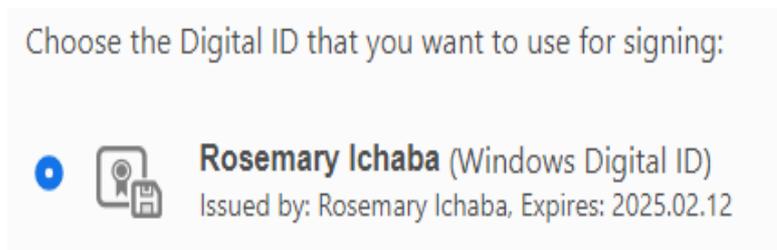
6. Once an ID has been selected click "Continue"
7. A preview of the signature will appear, click "Sign"

8. The signed document can then be saved in the desired location with the metadata displayed.

4.2. Applying the E-signature to a Document

4.2.2. Applying a signature to a Word document

1. Open the desired word document, click file and then "save as".
2. Change the file format from word document to "PDF".
3. Ensure the name of the document is correct and click save.
4. Navigate to the location of the saved PDF and open the document.
5. Click "Tools" on the top left tab and then click "Certificates".
6. Click "Digitally Sign" and highlight the area where you would like the signature placed.
7. As you have created a digital ID, following the steps in Section 4.1. "Creating the digital Signature", you should be able to choose your digital ID signature and click continue.
8. Confirm that the signature name and date/time stamp (metadata) is correct and click Sign.
9. You may be required to rename the signed document to ensure the document with the signature has been saved.
10. Your signature should now be applied in the document and saved.

4.2.3. Applying a signature to a Scanned document

1. Locate the scanned document and ensure that the document has been saved as a PDF Formatted document.
2. If the document is not saved as a PDF, right click the document and click "open with". Within the list of options, navigate to Adobe and proceed to open the document using the Adobe Application.
3. Save a copy of the document as a PDF.

4. Once the document has been saved correctly, you can now follow steps 5-10 within section *4.2.2. Applying a signature to a word document.*

5. REFERENCES

European Medicines Agency (EMA) Introduction of digital signatures

Medicines & Healthcare products Regulatory Agency (MHRA) 'GXP' Data Integrity Guidance and Definitions – Revision 1: March 2018 (cited date: 23 Sep 2020)

Joint Statement on Seeking Consent by Electronic Methods v1.2 September 2018 (cited date; 23 Sep 2020)

6. APPENDICES