UCL

Standard Operating Procedure for the Use of an eSignature system

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Revision Chronology:

SOP ID Number:	Effective Date:	Reason for Change:	Author:
JRO/SPON/S32/01	18/03/19	New SOP	Helen Cadiou, Keith Boland
JRO/SPON/S32/01	11/12/22	UCL purchased the license for DocuSign	Joanna Saville

ACRONYMS:	
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
JRO	Joint Research Office
QA	Quality Assurance
SOP	Standard Operating Procedure
UCL	University College London

Standard Operating Procedure for the Use of an eSignature system

1. PURPOSE

This Standard Operating Procedure (SOP) has been written to describe the procedure for the use of an eSignature system.

Please check that this document is the latest version, by looking up: https://www.ucl.ac.uk/joint-research-office/sops-and-templates/sops-ucl-and-uclh-sponsored-ctimps

2. JOINT UCLH/UCL RESEARCH OFFICE POLICY

All SOPs produced from the JRO must be used in conjunction with local NHS Trust and UCL policies and procedures.

The JRO acts as the representative of the Sponsor and will be the official name used on all SOPs.

3. BACKGROUND

All SOPs are written in accordance with applicable GCP requirements as outlined in Directives 2001/20/EC and 2005/28/EC (in the UK, these Directives were transposed into UK law by SI 2004/1031, SI 2006/1928) and subsequent amendments. Where applicable it incorporates elements of ICH GCP tripartite guidelines (E6)". In addition, as UCL sponsors trials with EU and Northern Ireland sites, the SOPs are written to be compliant with EU Clinical Trials Regulation No. 536/ 2014,

As UCL has purchased DocuSign as an eSignature provider, JRO has transitioned to using mainly DocuSign, however other organisations would have purchased other providers and these can also be used when receiving these documents for signature.

4. SCOPE OF THIS SOP

This SOP relates to the use of eSignature for documents pertaining to trials sponsored by UCL and managed by the JRO. UCL has purchased a license via DocuSign. DocuSign will be used as an eSignature model system in this SOP, however other organisations would have purchased other eSystems such as Adobe, which can also be utilised.

5. RESPONSIBLE PERSONNEL

Any staff involved in the management of UCL sponsored CTIMPs managed by the JRO.

6. PROCEDURE

6.1 HOW TO OBTAIN A DOCUSIGN ACCOUNT

Upon becoming aware of a JRO starter, the Head of QA will create a DocuSign account. An email from DocuSign should be received by the starter. The JRO Pharmacovigilance Manager is also a DocuSign Administrator and can create an account.

Please read: **DocuSign System Setup, DocuSign GXP Data Integrity Compliance Risk Assessment.**

AS A MINIMUM WHAT MUST BE INCLUDED ON AN ELECTRONIC SIGNATURE:

- Name
- Job Title
- Signature
- Date of signature
- Meaning of (**where applicable,** Author/Reviewer/Approver)

If the document does not have pre-existing spaces for the name, date, and Job Title, these can be added in DocuSign.
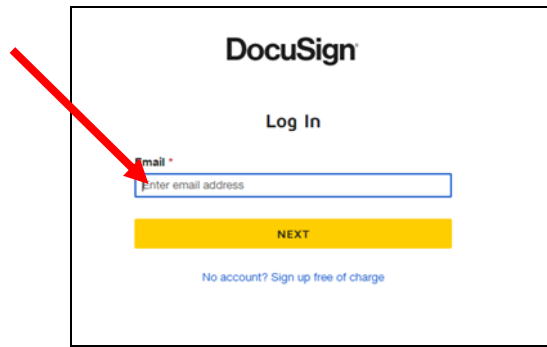

6.2 CREATING AN ACCOUNT AND LOGGING IN

After you have received the DocuSign email from the DocuSign Administrator:

6.2.1 HOW TO LOG IN

Once you have created your account, log in to your DocuSign account by going to https://account.docusign.com/
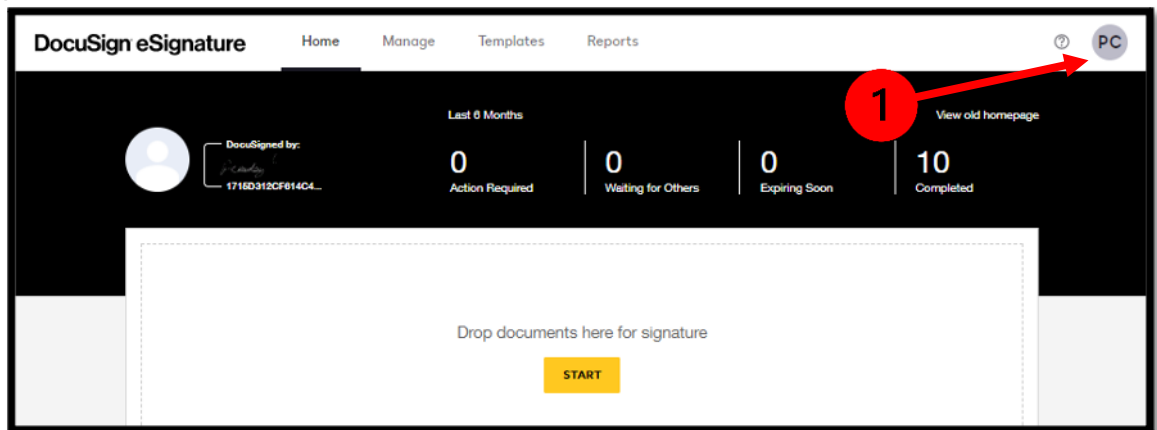
1. Enter your user name (UCL email address)
2. Press next

3. This will take you to the UCL Single Sign-on page
4. Enter UCL username and password and click **Login.**

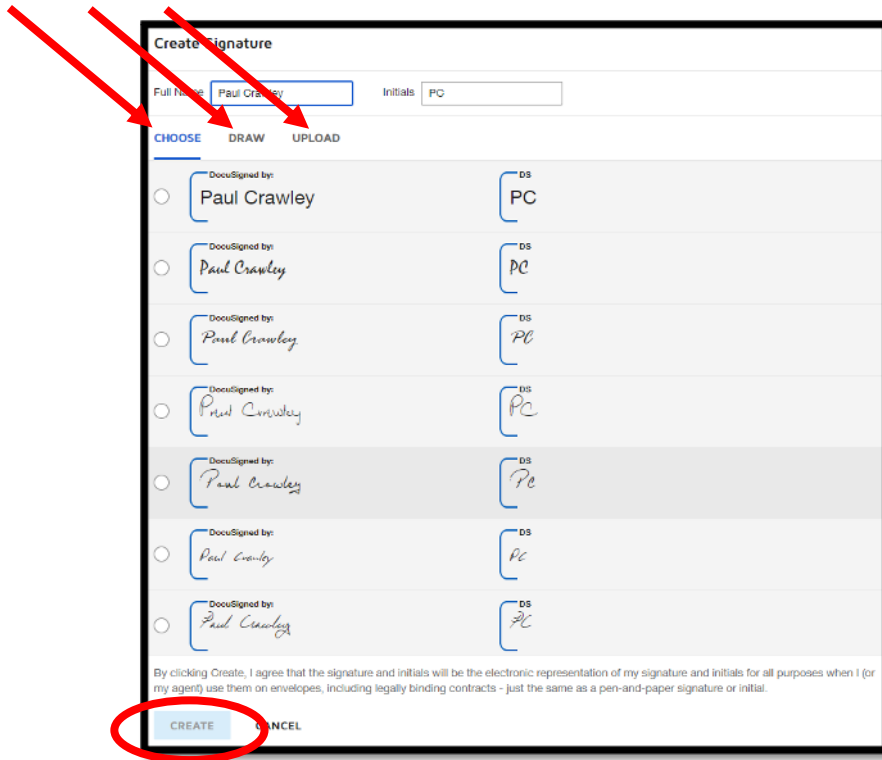### 6.2.2 HOW TO SET UP YOUR SIGNATURE

1. When logged in, click on your initials in the top right screen: and then click "manage profile"

2. Click on "Signatures"
3. To create a new signature, click on "+Add New" or "Actions" then "Edit" to modify an existing signature


4. You have a choice to select one of the auto-generated signatures, draw a new signature using the mouse, or upload a picture file (jpeg, gif, png or bmp no larger than 200kB).
   Click on "Create" to confirm your selection.

C:\ProgramData\activePDF\Temp\DocConverter\API\Input\$9a2bd3d37f75$323B20CA94A84E658407C00076754B44.
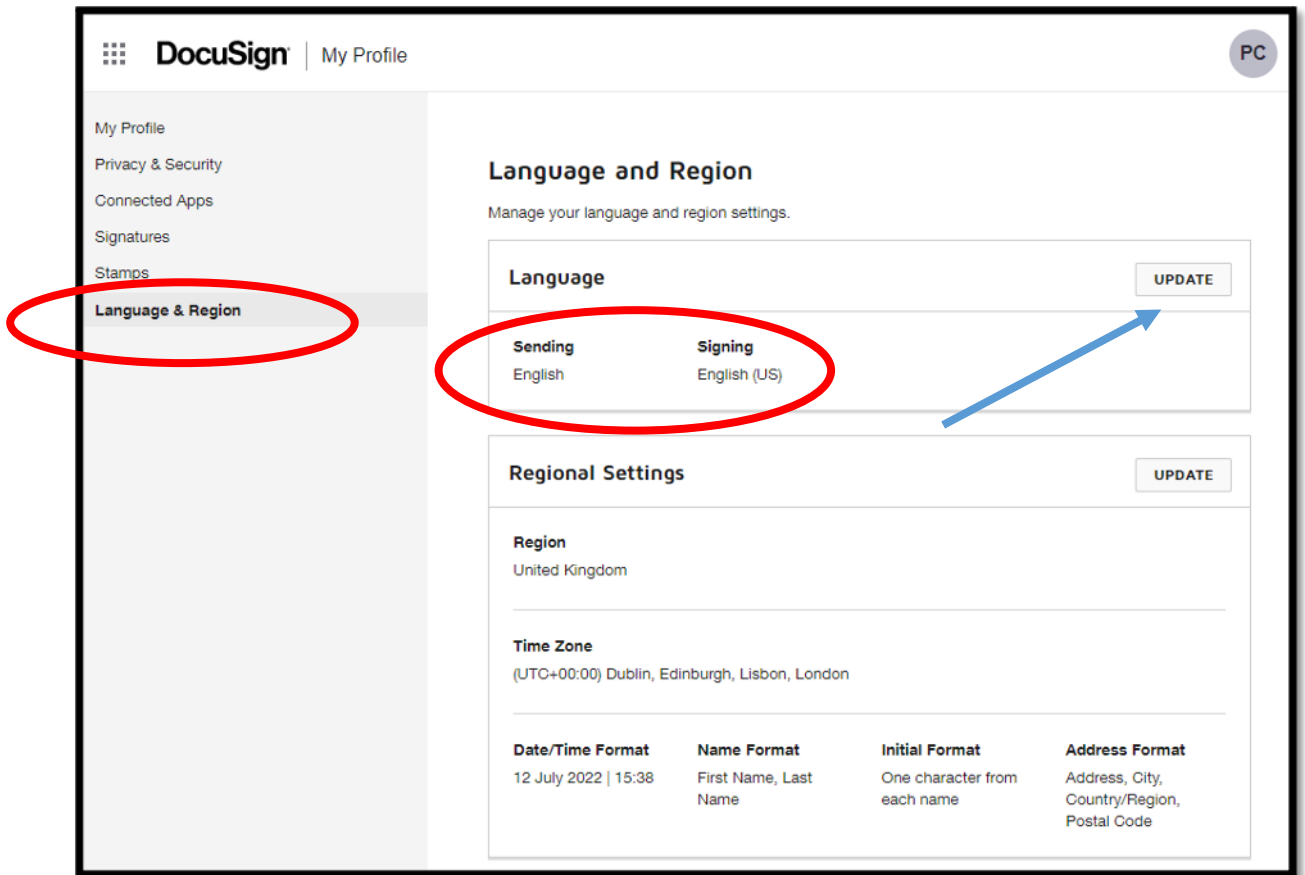doc   Page 6 of 15

6.2.3 HOW TO CHANGE TIME ZONE AND CONFIRM DATE FORMAT

1. When logged in, click on your initials in the top right of your screen: and then click "manage profile"
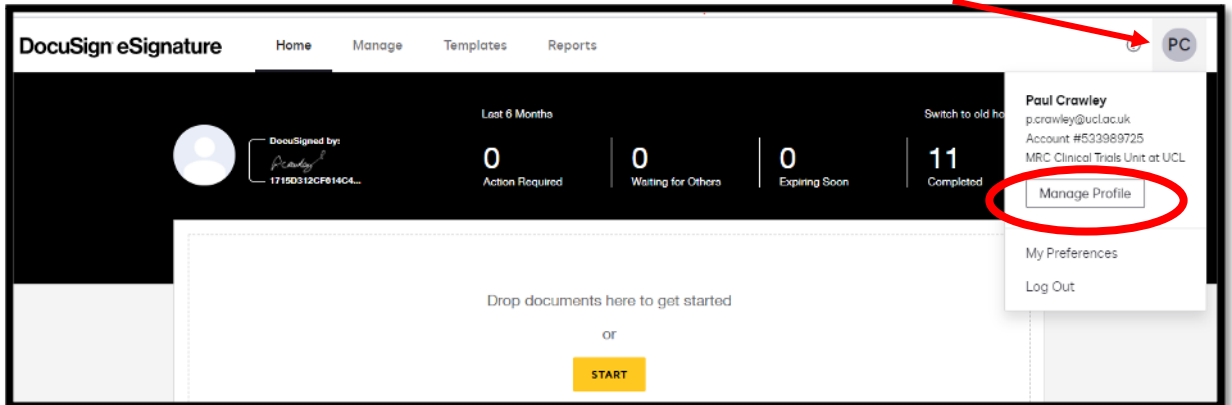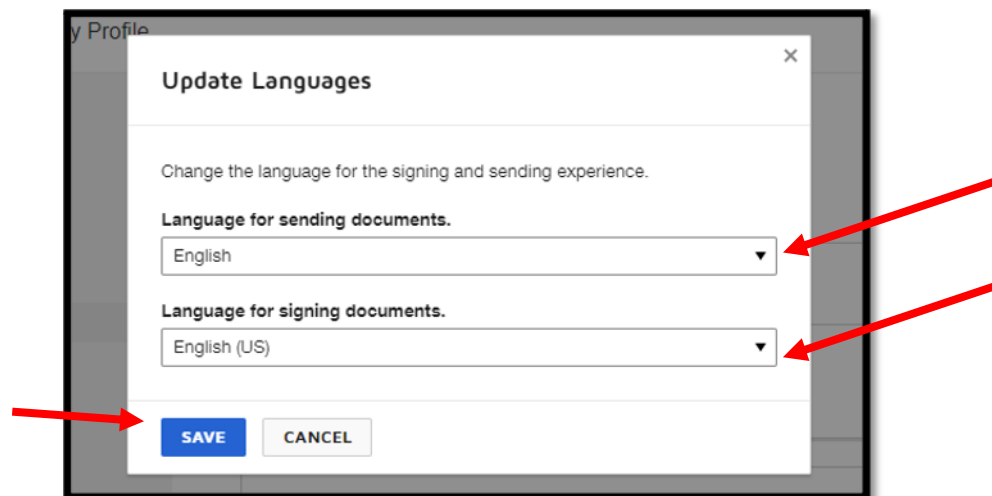
2. Go to language and region and check that the language is set to English
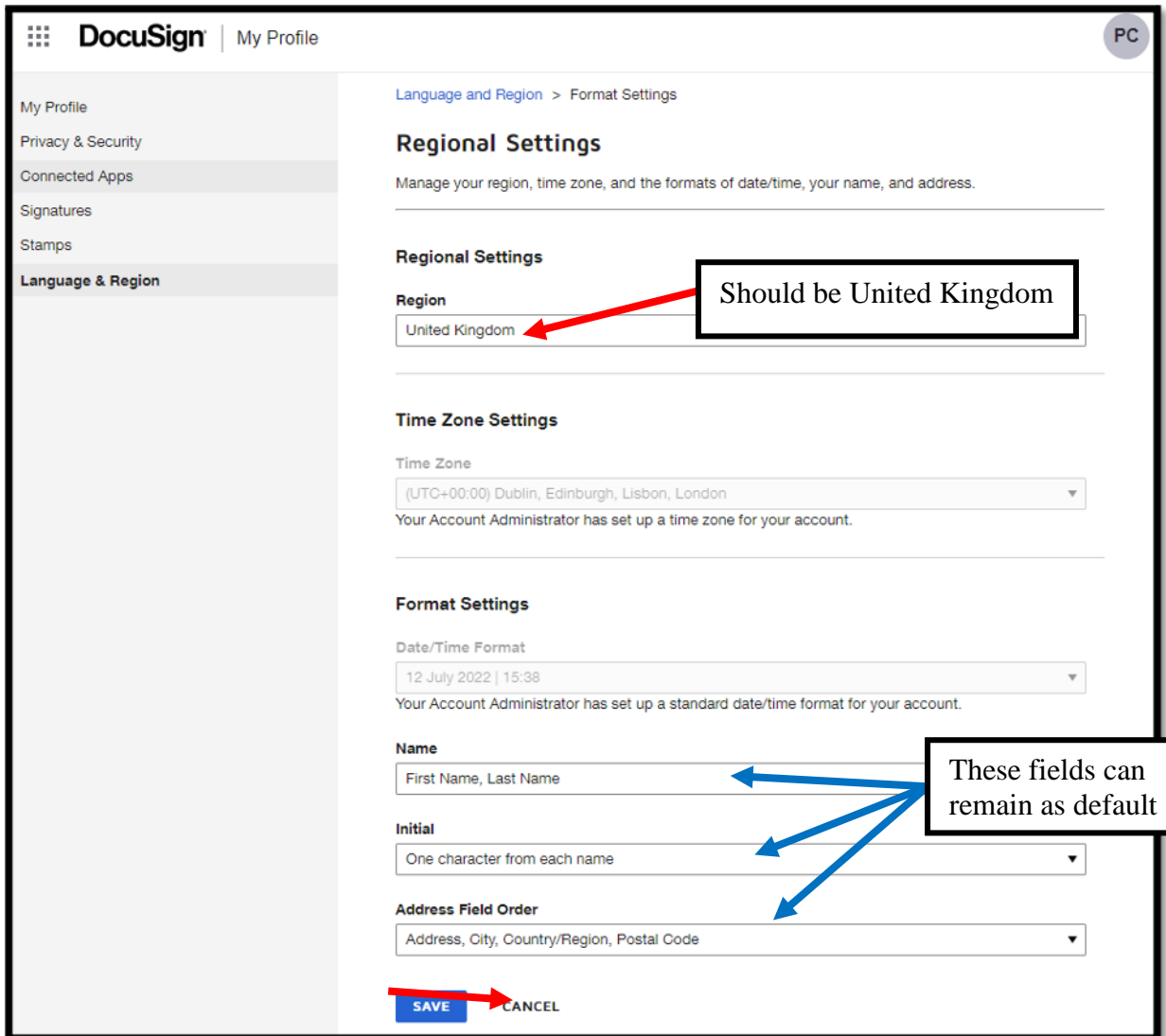

3. If it needs to be changed, click "Update" in the above screenshot shown with the blue arrow

4. Select English (UK) in the drop-down menu (red arrow) and ensure you click save

5. Repeat the above process for Region Settings (use the options shown below)

## 6.3 HOW TO PREPARE A DOCUMENT FOR SIGNATURE IN DOCUSIGN

1. Design the signature area of your document to allow enough space for the signature. See below in point 8 for screen shots of the how large the signatures will be but allow at least 2 lines of size 11 font for each signature (or 3 lines if for a CFR licenced document).

2. From your DocuSign Account, click **NEW**, then click **Send an Envelope**.

3. You can drag a document from your computer in to the **Add Documents** box. Alternatively, click **UPLOAD A FILE** to upload a document from your computer, or click **GET FROM CLOUD** to upload a document from an online location. Locate the document you want to upload and click Open.
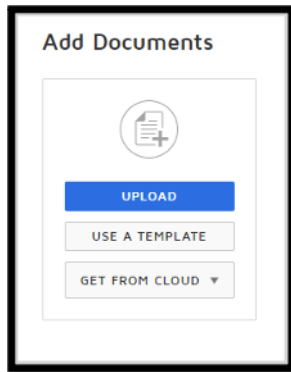
Notes:
- You can upload documents in most common formats, including Word and PDF.
- Make sure you have left enough space for the signatures.
- If a watermark is required, add this before uploading to DocuSign because amending a document after signatures have been obtained invalidates the signatures.

4. In the **RECIPIENTS** field, enter the recipient's name and email address. Click **ADD RECIPIENT** and add additional name/emails until all recipients have been added.
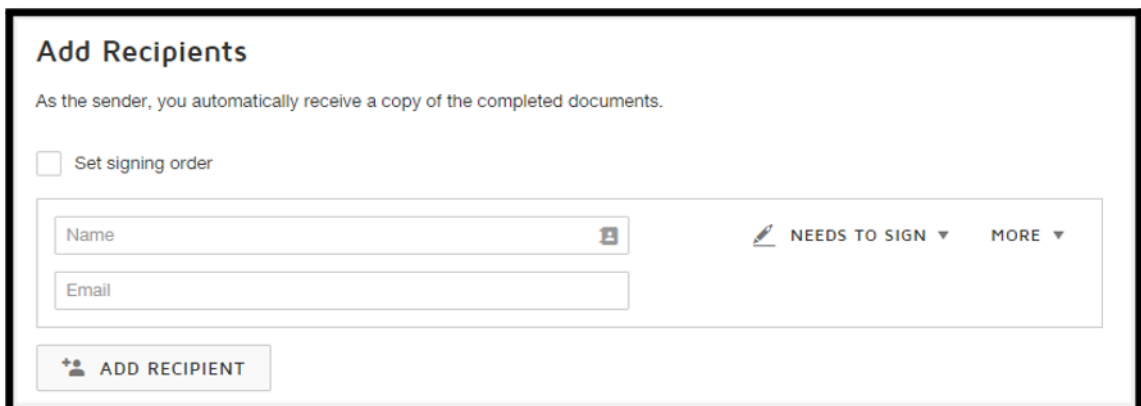
Notes:

- Work email addresses should be used as far as possible.

5. When finished, click NEXT.

6. Next, you will add signing fields. The Fields Palette and your document appear. The recipient's name is displayed in the Recipients List, and each recipient is represented by a different colour.

   To assign a signature or other field for the recipient, click and drag a field from the Fields palette and place it on the document. You will need to do this for each recipient by choosing them from the drop-down list before dragging the field from the Fields Palette.
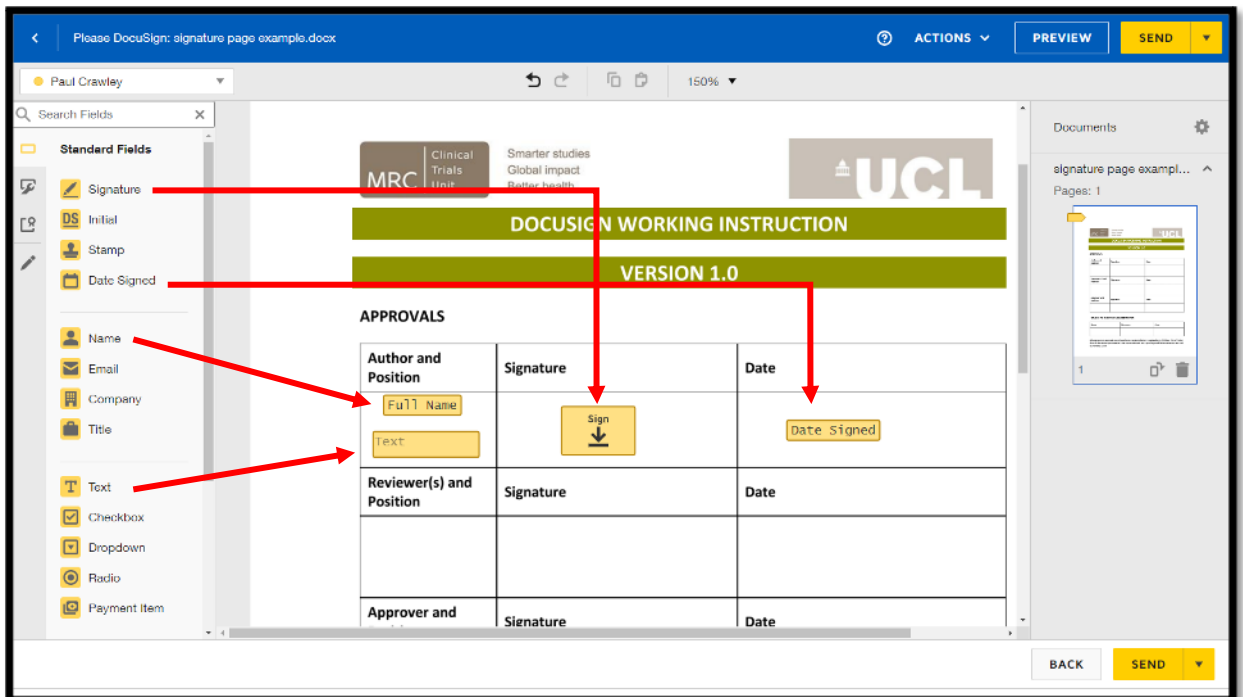
Below are screenshots of a document showing how much space these fields take before and after signing, for both standard licence (compliant with MHRA's GXP data integrity guideline) documents and FDA 21 CFR Part 11 licence documents. If there is not enough vertical space in your document, signatures may need to be horizontally staggered to avoid overlap. FDA 21 CFR Part 11 licence signatures especially should be aligned to the top of the signature box to allow enough space.

Standard licence document compliant with MHRA's GXP data integrity guideline

1 line, size 11 font

Name	Signature	Date
Full Name	⤓	Date Signed
Full Name	⤓	Date Signed

2 lines, size 11 font

Name	Signature	Date
Full Name	⤓	Date Signed
Full Name	⤓	Date Signed

3 lines, size 11 font

Name	Signature	Date
Full Name	⤓	Date Signed
Full Name	⤓	Date Signed

1 line, size 11 font

Name	Signature	Date
Paul Crawley		13-Jul-2022
Paul Crawley		13-Jul-2022

2 lines, size 11 font

Name	Signature	Date
Paul Crawley		13-Jul-2022
Paul Crawley		13-Jul-2022

3 lines, size 11 font

Name	Signature	Date
Paul Crawley		13-Jul-2022
Paul Crawley		13-Jul-2022

7. REFERENCES NA

8. APPENDICES

8.1 DocuSign System Setup: Guideline to create a DocuSign account which is compliant with the MHRA GXP Data Integrity guidelines.

8.2 DocuSign GXP Data Integrity Compliance Risk Assessment: Risk assessment for the implementation of DocuSign.
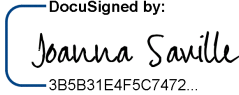
9. TEMPLATES/LOGS ASSOCITATED TO THIS SOP NA

10. SOP DISSEMINATION AND TRAINING

SOPs will be distributed to the concerned staff. Staff concerned by the SOP will sign the SOP training log (12. SOP TRAINING LOG) which is part of each SOP.

In some instances, the SOP or the changes to the SOP will be basic. The training will constitute of the person reading the SOP and being provided with the opportunity to ask specific questions to the author of the SOP.

11. SIGNATURE PAGE

Author and Job Title:	Joanna Saville, Compliance Oversight Advisor
Signature:	DocuSigned by: *Joanna Saville* 3B5B31E4F5C7472...
Date:	11/11/22

Authorised by: Name and Job Title	Helen, Cadiou, Head of QA
Signature:	DocuSigned by: Helen Cadiou 9FE319AE9B744D5...
Date:	11/11/22

12. SOP TRAINING LOG

	Name of Staff (Capital letters)	**Job Title:** **Department:**	**Training Date**	I confirm that I understand & agree to work to this SOP **SIGNATURE**	**Name of Trainer** (if training required)	**Signature**	**Date**
1							
2							
3							
4							
5							
6							
7							

	Name of Staff (Capital letters)	Job Title: Department:	Training Date	I confirm that I understand & agree to work to this SOP SIGNATURE	Name of Trainer (if training required)	Signature	Date
8							
9							
10							
11							
12							
13							
14							

	Name of Staff (Capital letters)	Job Title: Department:	Training Date	I confirm that I understand & agree to work to this SOP SIGNATURE	Name of Trainer (if training required)	Signature	Date
15							
16							
17							
18							
19							
20							

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