DocuSign:
Sending and Collecting Consent Documents with eSignatures for Human Subjects Research

Institutional Review Board and Human Subjects Office

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IOWA

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Introduction

This guidance document provides researchers with information about how to use DocuSign to collect valid electronic signatures (eSignatures) on Informed Consent Documents. DocuSign is a software program that captures electronic signatures and provides secure transfer and storage features. University of Iowa (UI) researchers across campus have access to DocuSign. The software is available for all desktop, laptop, and mobile devices. **The University of Iowa DocuSign module cannot be used for FDA (Food and Drug Administration) regulated research.**

Benefits of using DocuSign for eSignatures:

- Meets data security requirements for HIPAA (Health Insurance Portability and Accountability Act)
- Potential subjects do not need a DocuSign account
- Documents are sent via email and researchers can prohibit forwarding for confidentiality purposes
- Subjects receive a copy of the signed Informed Consent Document

Guide to using this document: The first few pages provide written instructions, and the Appendix includes screenshots for each step in the process. There are also hyperlinks in the Appendix connected to the earlier instructions.

Setting Up a DocuSign Account

The UI has a license for DocuSign. Contact ui-docusign-support@uiowa.edu to set up a DocuSign account. There are two versions of DocuSign. **It is important to request the correct version for the type of data that will be collected:**
1) for studies that contain protected health information (PHI) as defined under HIPAA (Health Insurance Portability and Accountability Act)
2) for studies that do not contain PHI as defined under HIPAA.

It is relatively quick and easy for researchers to set up a DocuSign account. Training is provided through the Purchasing Department. Once researchers set up a DocuSign account, they will need to activate it through the UI system. A UI DocuSign account is not connected to your HawkID. The Appendix provides screen shots to demonstrate how to activate a UI DocuSign account.

Create an Envelope

Currently, UI staff/departments are not charged to use DocuSign. The UI purchases “envelopes” for UI researchers to use. A DocuSign envelope is essentially an email, which will include the Informed Consent Document to capture electronic signatures. The **Appendix** provides screenshots to demonstrate how to create an envelope. This video also gives a step-by-step guide.

Add Documents, Recipients, and Template Email

For the DocuSign program to function properly, documents to be signed must be uploaded as PDFs. Converting an Informed Consent Document to a PDF does not affect the IRB approval stamp, therefore the DocuSign version of the consent document is compliant with UI policies and procedures. The DocuSIgn envenlope can also include additional reference materials that do not require a signature, such as a Consent Summary, diagrams, videos, etc.

- Add documents in the order that you want subjects to see them.
- Add anyone who needs to sign the Informed Consent Document as a recipient.
- If more than one person needs to sign the document, set the signing order.

Once the subject and/or the parent/legal guardian or Legally Authorized Representative (LAR) has signed the consent document, the person who obtains consent should receive the envelope for the final signature. The study team should ensure that processes are in place to identify the appropriate parent/guardian or LAR to route the Informed Consent Document for signature. The signature of the person who obtains consent should be the research team member who participated in the informed consent conversation and answered the subject's questions about the study.

To ensure consistency for all DocuSign emails, the research team should use the same template language when sending the Informed Consent Document and for all reminders. The default is that the reminders use the same language, so researchers do not have to make any changes. DocuSign automatically sends three reminders. The research team can contact potential subjects once by phone if there is no response after the three reminders.

Email Template

Instructions: Copy and paste the following template language into the appropriate section in DocuSign. Replace the text in brackets with study-specific information.

[**Salutation**]

Thank you for thinking about enrolling in this study. [**I am/We are**] sending this Informed Consent Document to provide information and to describe what you will be asked to do if you decide to enroll in the study. You are not required to enroll in this study. **[Insert the following statement if the study is clinical in nature.**] Your clinical medical care will not be affected by whether you decide to enroll in this study.

If you do not sign this form, you will receive three reminders from DocuSign. We will attempt to call you if we do not receive a signed Informed Consent Document after the three reminders, to make sure you received the document and to see if you are interested in participating. If you let us know you are not interested in participating, we will not contact you again.

Please do not sign this form if you:

- Have more questions about this study that this Informed Consent Document does not answer or if you don't understand something.
- If you would like to have a member of the study team go over this Informed Consent Document with you while you are reading it. (This may already be part of the consent process)
- Would like to talk with your family, friends, or medical provider before you agree to participate.
- Do not wish to participate in the study. There may be an option for you to decline in the document or you may contact the research team directly.

This video shows you how to use DocuSign, the program that allows you to sign/decline the Consent Document.

Please call or email [**me / the research team**] at [**Insert phone number and email address**]

[**Insert signature block for the research team member or the study**]

The **Appendix** provides screenshots to demonstrate how to add documents, recipients, and the template email and set subject privileges and send reminders.

Designate Where to Initial, Sign, and Date the Informed Consent Document

DocuSign has the capability to allow subjects to select and initial optional agreements, sign and date the Informed Consent Document, and decline participation. These options are denoted by specific icons on the left side of the screen. The icons need to be placed exactly on the line where the subject must initial, sign or date. The research team may choose to add the "decline" icon next to the "signature" icon. Subjects should have the option to decline, even if they verbally agreed to participate during a conversation with a member of the research team. There are multiple ways to document that the subject declined. Indicating it in DocuSign provides an audit trail. If the subject clicks the decline icon, all reminders stop, and the research team will not follow up with a phone call. The **Appendix** provides screenshots to demonstrate moving icons to designate where to Initial, Sign, and Date the Informed Consent Document.

Send and Receive Documents

When the research team sends an Informed Consent Document for a subject to sign, the email contains the official DocuSign logo, a link to the document, and the customized email from the research team. Once the subject opens and reviews the document, DocuSign sends an automatic email to the research team. After the subject signs the Informed Consent Document, the research team and the subject receive an email that the process is complete with the signed document attached. The **Appendix** provides screenshots of What the Subject Sees. There is a link to the DocuSign video in the template email to demonstrate the signing process.

Data Security and Audit Trail

DocuSign provides secure storage of all documents sent and received through the program. The system also creates a Certificate of Completion with an audit trail of the Informed Consent Document, which includes the location of the persons who signed the document (i.e., subject, parent/guardian or LAR, and research team member who obtained consent). The **Appendix** provides screenshots of how to access the Certificate of Completion.

Describe eConsent in the HawkIRB Application

HawkIRB Section	eConsent Information
VII.D.8	Answer "yes" if the consent process will be conducted through a video meeting over Zoom/Skype for Business.
VII.D.9	Describe that the consent process is conducted through a video meeting over the internet, at a location of convenience for the subject.
VII.D.10	Answer "yes" if the consent process will be conducted through an audio only call over the phone or by Zoom/Skype for Business.
VII.D.29	Describe the eConsent process and documentation procedures for adult subjects, in detail. • Include DocuSign as the tool that will capture the electronic signature • Describe which DocuSign icons will be added to the consent document (i.e., radio buttons for optional agreements, the option to decline consent, etc.)

HawkIRB Section	eConsent Information
VII.D.30	Describe the eConsent process and documentation procedures for minor subjects, in detail. • Include DocuSign as the tool that will capture the electronic signature • Describe which DocuSign icons will be added to the consent document (i.e., radio buttons for optional agreements, the option to decline consent, etc.)
X.4	List the electronic systems used in the eConsent process and for documentation of consent. Describe the confidentiality protections/data security methods. • Explain where the signed Informed Consent Document is downloaded and saved in research files so there is a copy to meet UI record retention requirements. • Explain that the Certificate of Completion shows the audit trail of the consent document and the location of where all signatories signed the consent document. • The Certificate of Completion contains identifiable information. Describe where and how it will be stored. If Zoom will be used to meet with or record subjects, be sure to describe the IT security requirements as outlined in the Data Security Guidance and Secure Zoom Meetings and Recordings for Restricted Data.
Miscellaneous Attachments	Attach a document that contains the template email, which will be sent with the Informed Consent Document through DocuSign.
Informed Consent Document	**Insert the following template language into the Informed Consent Document before the Person Who Obtained Consent signature line:** **Check the method by which consent is being obtained:** ☐ Consent is being obtained electronically without a discussion between a research team member and the subject. (Research team member does not sign this document) ☐ Consent is being obtained electronically after a discussion between a research team member and the subject (in person or virtually). [End of template language] **Instructions:** • The research team member will check the box in this section of the document for the method of consent used for each subject. • The research team member signs the document after the subject signs it. • Since the subject may sign outside of work hours, the dates the subject and research team member signs may not be the same. The dates should be before the start of research procedures. ○ If the dates are not the same, the research team may note this discrepancy as a separate “Note to File” in the research files or as an optional note on the Informed Consent Document under the signature line for the Person Who Obtained Consent.

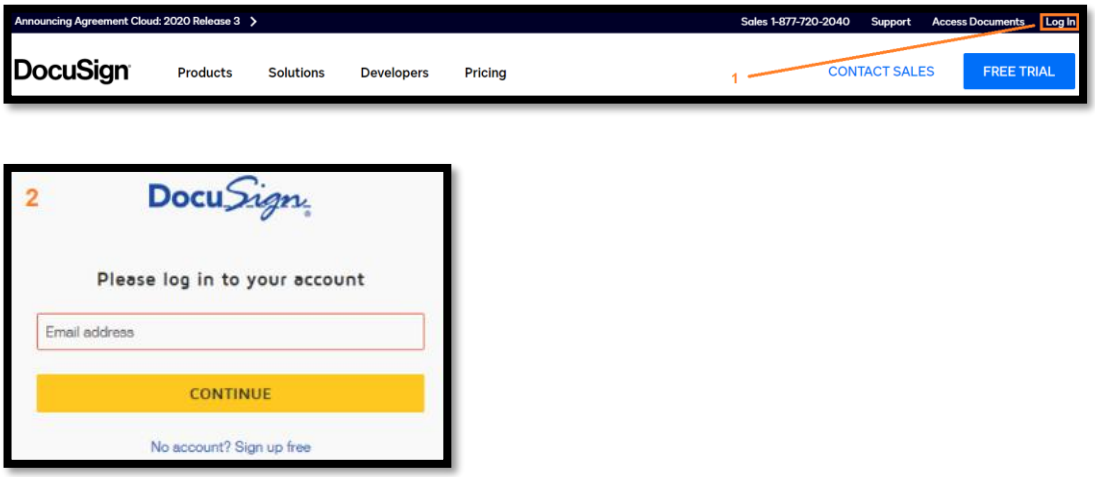
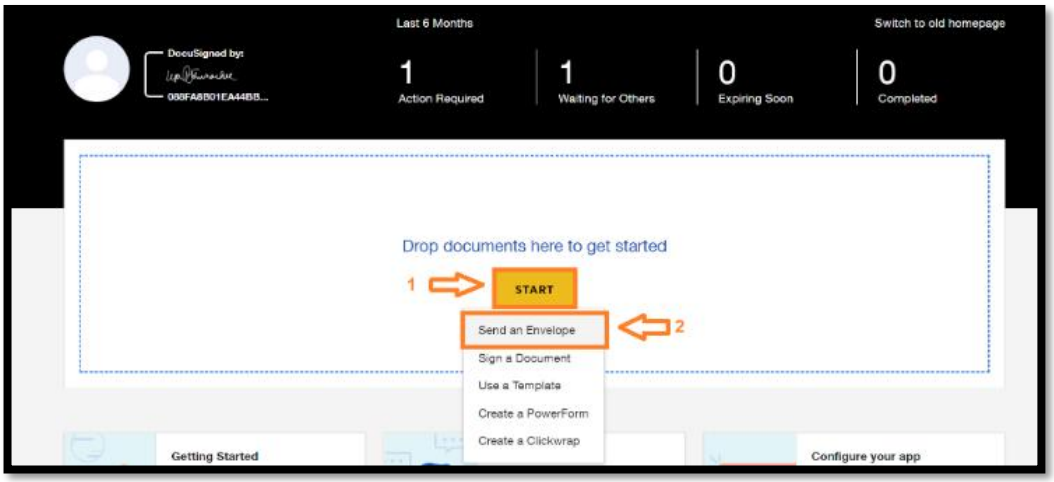
Appendix

UI researchers may activate a DocuSign account under the UI license.
The following screenshots guide researchers through the process of creating a document for eSignatures, sending and receiving the document, and maintaining an audit trail of the document.

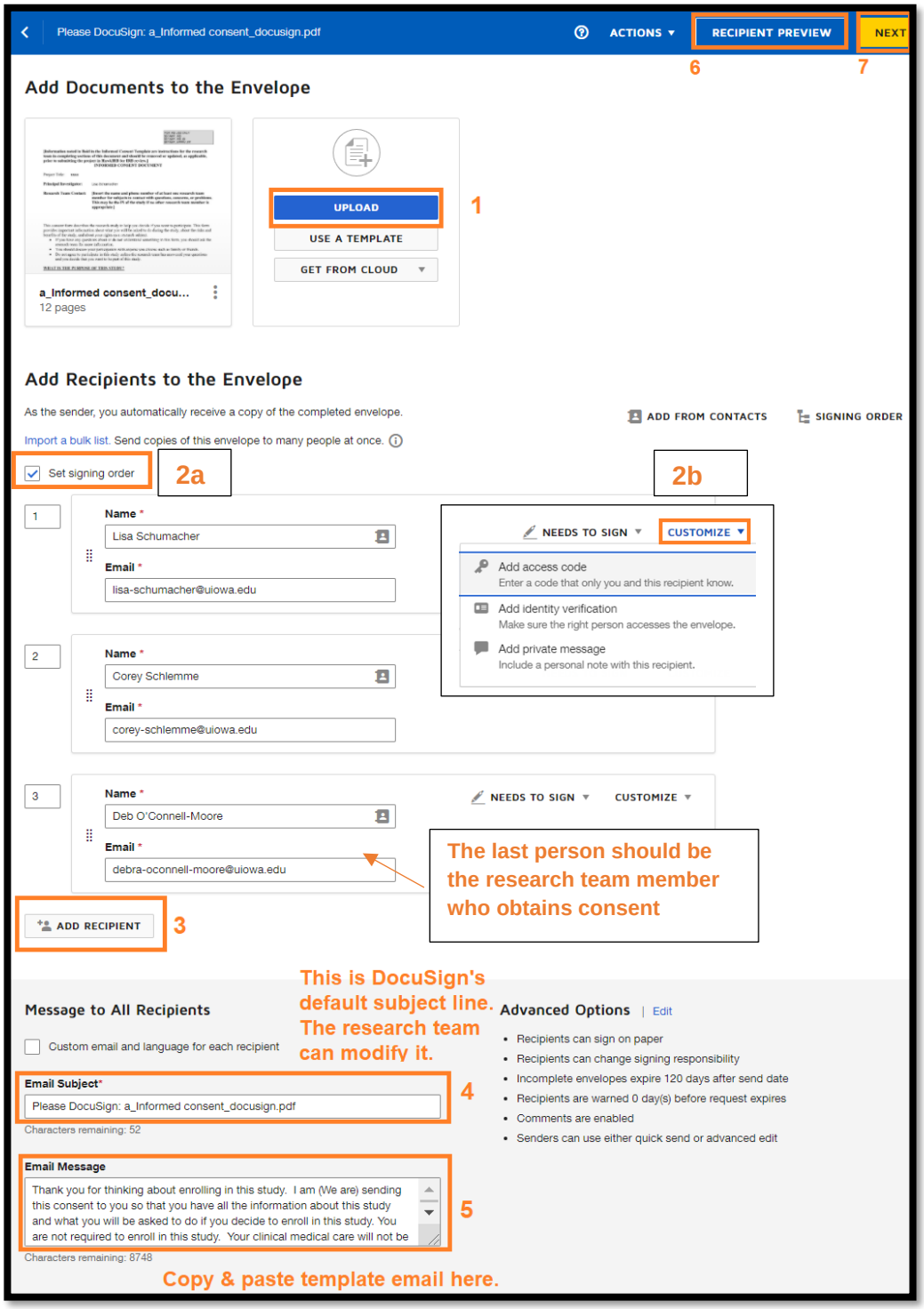
Acronym Reminder:

- **ICD** = Informed Consent Document
- **LAR** = Legally Authorized Representative
- **PWOC** = Person Who Obtained Consent

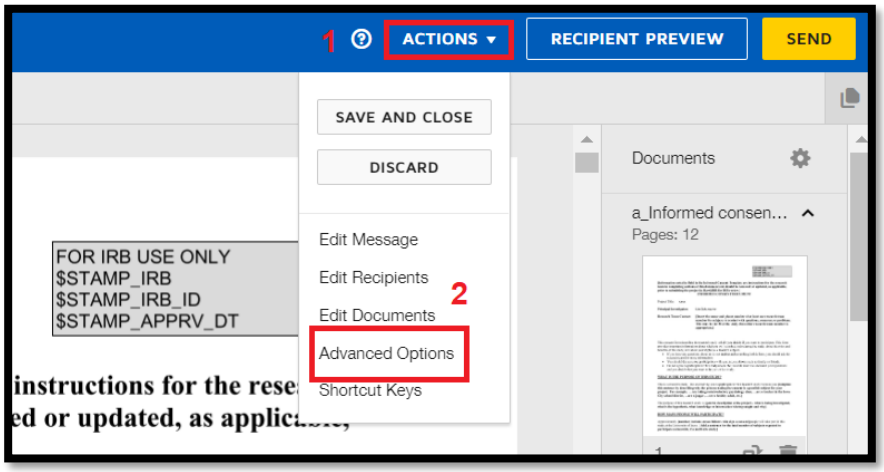
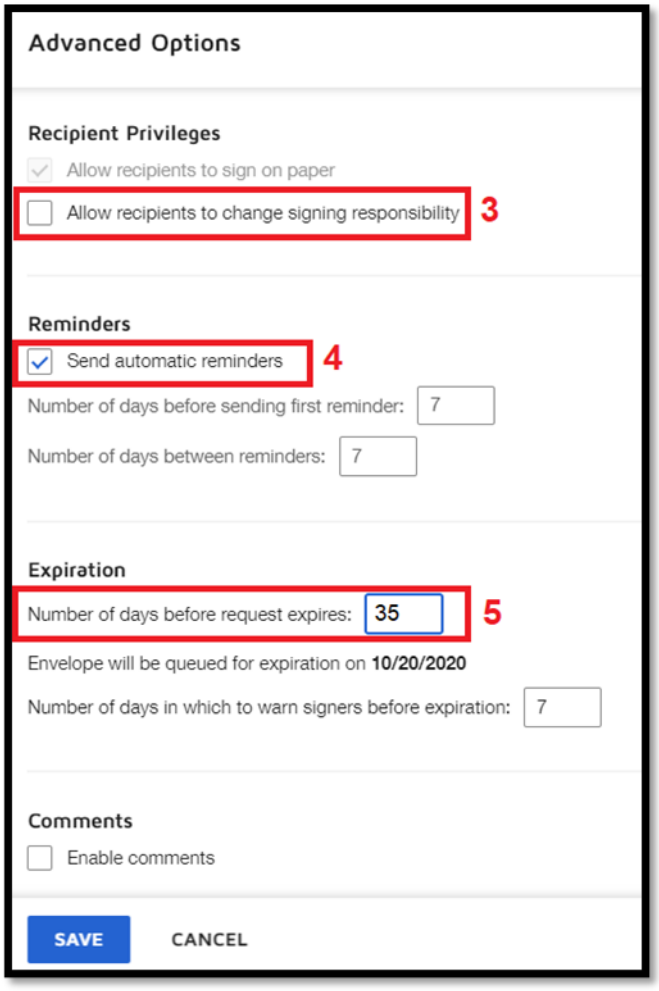
Activate DocuSign and Create an Envelope

Instructions	Screenshots
Activate UI account 1. Go to Docusign.com 2. Log in or create a DocuSign account.	
Create an Envelope 1. Click the Start button and the dropdown menu will appear 2. Choose "Send an Envelope"	

Add Documents, Recipients, and Template Email

Instructions	Screenshots
1. Upload the Informed Consent Document 2. a. Check “Set signing order” if multiple people need to sign the document, such as the LAR and the research team member who obtained consent. b. Use the dropdown menu to add access/verification code 3. Be sure to add the recipients in the order they need to sign, the subject/LAR should sign prior to the research team member who obtained consent. 4. Decide if you want to use the DocuSign default subject title or if you want to choose your own. 5. Copy and paste the template email. 6. Review the email before moving to the next section. 7. Click “Next” to designate where subjects select and initial optional agreements and add their eSignature	

Setting Privileges, Reminders, and Expiration Date

Instructions	Screenshots
1. Dropdown menu to access Advanced Options. 2. Advanced Options allows access to setting privileges, reminders, and expiration dates.	
3. Uncheck this box. This prohibits the recipient from forwarding the email or allowing someone else can sign. 4. Check this to set up automatic reminders. The original email automatically gets sent with each reminder. 5. Set the expiration for 35 days to assure subjects will not receive any notices after the last follow-up call, which occurs after the third reminder.	

Designate Where to Initial, Sign and Date the Informed Consent Document

Instructions for Screenshot on the following page

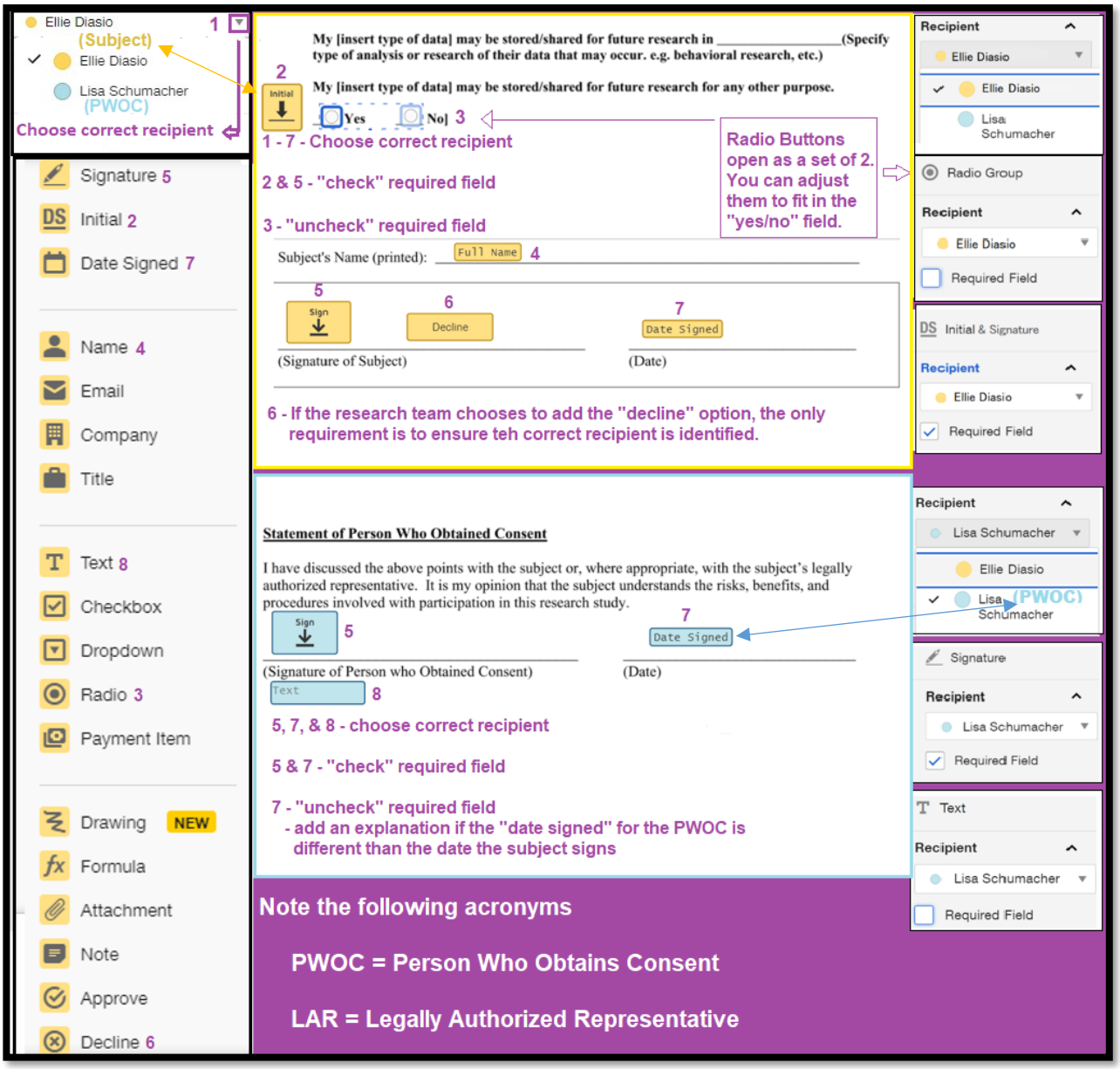
Instructions:

- **Use the icons** on the left side of the screen to configure the Informed Consent Document.
  - Drag the icons to the exact location where the information is required.
  - These icons can be moved with a mouse or trackpad.

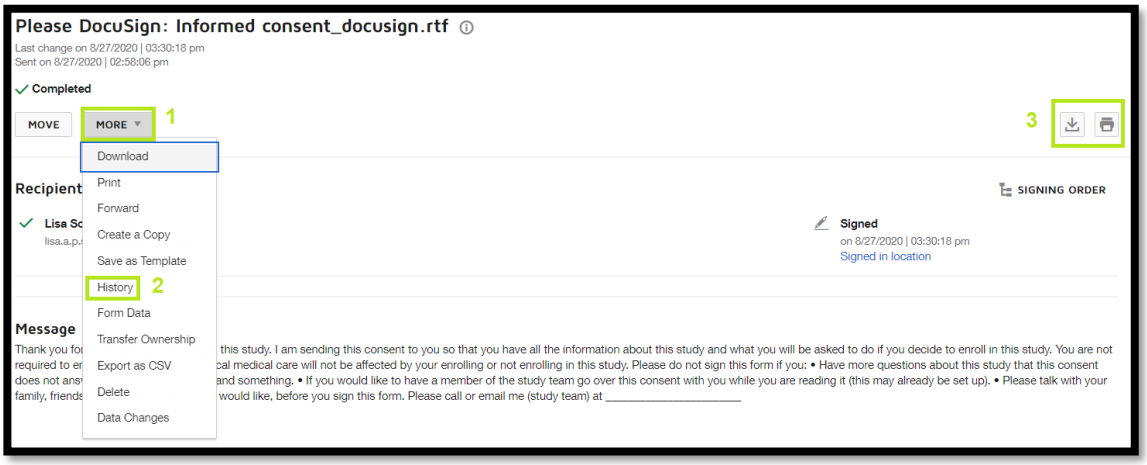
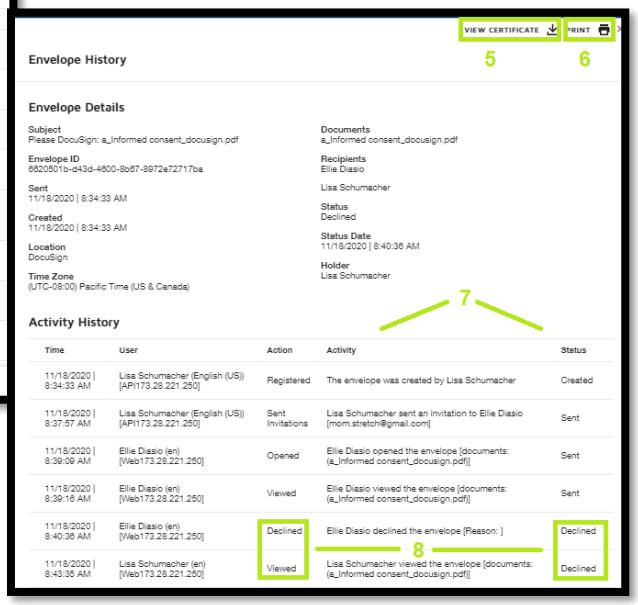
- **Optional agreements:**
  - Radio buttons designate subject preference for optional study activities.
    - The research team will only add radio buttons if the study includes optional activities.
    - The subject must select an optional agreement and add their initials.
    - DocuSign will not allow the document to be "Finished" until the subject selects a response to an optional agreement and adds their initials. This ensures subject response to all optional agreements.

  - Set up optional agreements in DocuSign:
    - Click the "Radio" icon on the left and drag it to the "Yes" option. This will bring two stacked radio buttons.
    - Drag the lower radio button to the "No" option
    - Click the "+" to add more radio buttons, as needed (i.e., "Not Applicable")
    - Click the "Initial" icon on the left and drag it to the left margin next to the optional agreement
    - Repeat for each optional agreement in the Informed Consent Document

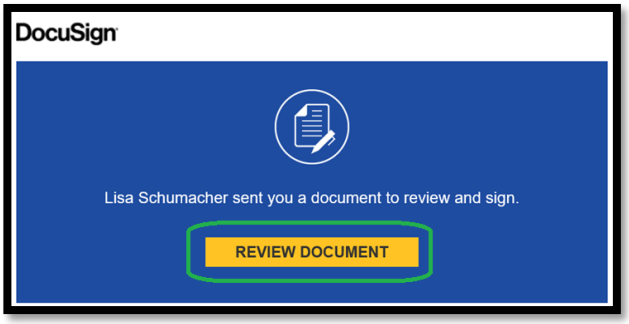
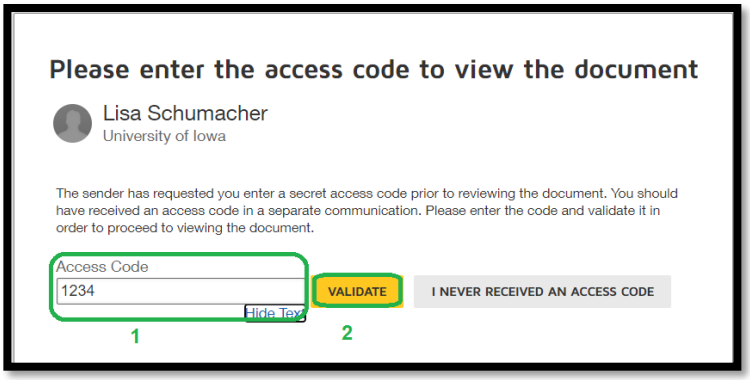
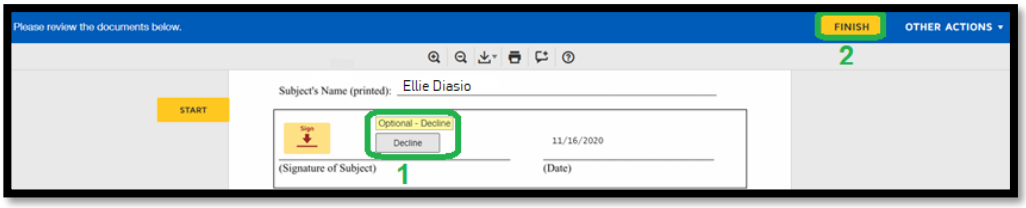
- **The recipients drop down menu** is in the upper left corner of the page. It shows everyone listed under "Add Recipients to the Envelope" in the first part of the DocuSign set up process.
  - Use this menu to assign the order of signature for the subject and anyone else (i.e., LAR, or Person Who Obtained Consent).
  - When you select a name, the icons will change color.
  - Drag the appropriate icon (Signature, Date Signed) on the left side of the screen to the section of the Informed Consent Document that each person will complete.

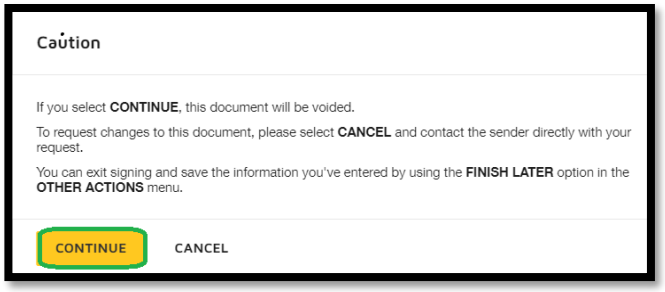
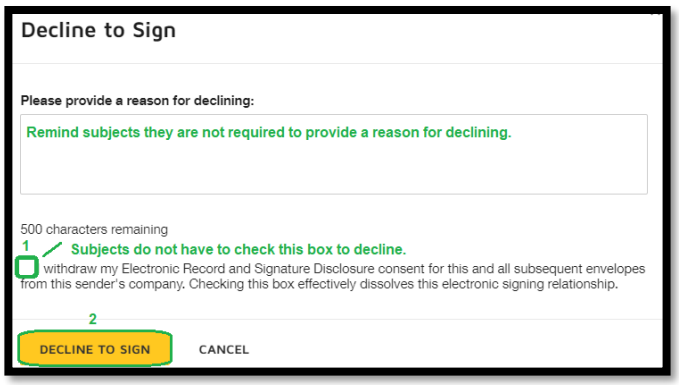
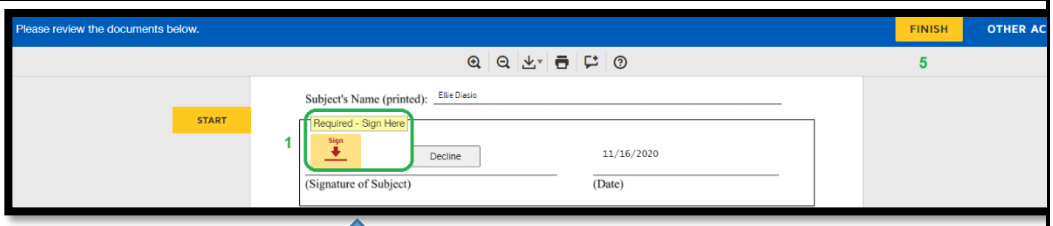
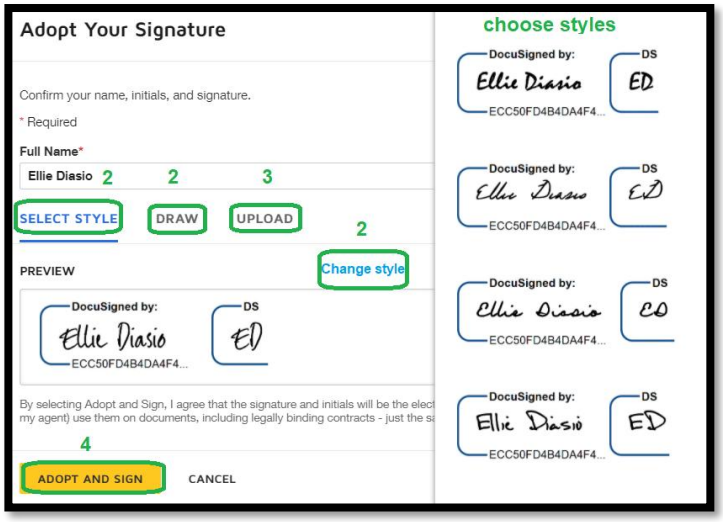

Ellie Diasio 1
(Subject)
Ellie Diasio
Lisa Schumacher
(PWOC)
Choose correct recipient
Signature 5
Initial 2
Date Signed 7
Name 4
Email
Company
Title
Text 8
Checkbox
Dropdown
Radio 3
Payment Item
Drawing NEW
Formula
Attachment
Note
Approve
Decline 6
My [insert type of data] may be stored/shared for future research in _____(Specify type of analysis or research of their data that may occur. e.g. behavioral research, etc.)
My [insert type of data] may be stored/shared for future research for any other purpose.
2
Initial
Yes
No] 3
1 - 7 - Choose correct recipient
2 & 5 - "check" required field
3 - "uncheck" required field
Radio Buttons open as a set of 2. You can adjust them to fit in the "yes/no" field.
Subject's Name (printed): Full Name 4
5
Sign
6
Decline
7
Date Signed
(Signature of Subject)
(Date)
6 - If the research team chooses to add the "decline" option, the only requirement is to ensure teh correct recipient is identified.
Statement of Person Who Obtained Consent
I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.
Sign 5
7
Date Signed
(Signature of Person who Obtained Consent)
(Date)
Text 8
5, 7, & 8 - choose correct recipient
5 & 7 - "check" required field
7 - "uncheck" required field
- add an explanation if the "date signed" for the PWOC is different than the date the subject signs
Note the following acronyms
PWOC = Person Who Obtains Consent
LAR = Legally Authorized Representative
Recipient
Ellie Diasio
Lisa Schumacher
Radio Group
Required Field
Initial & Signature
Signature
Text
(PWOC)

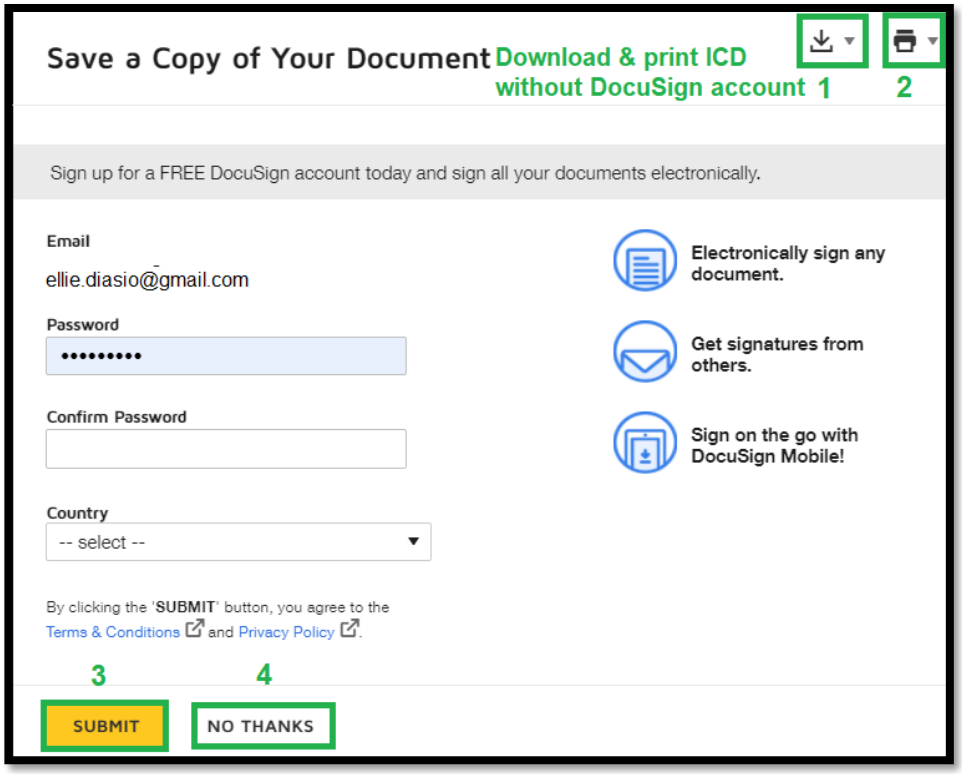
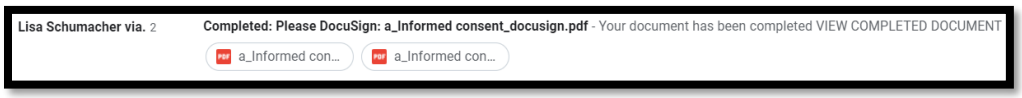
Certificate of Completion

Instructions	Screenshots
1. Dropdown menu to access Certificate of Completion 2. Link to Certificate of Completion 3. Links to download or print the signed Informed Consent Document	
4. Link to location where the document was signed 5. Download Certificate of Completion 6. Print Certificate of Completion 7. History of all document activities and the status of each activity. 8. How the Certificate of Completion documents the subject declined	 

What the Subject Sees

Instructions	Screenshots
Subject line in subject's email inbox	
This is the prompt subjects see when they open their email. Click on "Review Document" to go to next step.	
1. If the research team sets up an Access Code, subjects will get a prompt to enter the access code. 2. Click "validate" before they can view the Informed Consent Document.	
1.Subjects must agree to electronic signature disclosures. 2. Click "continue" to view Informed Consent Document.	
1. Subjects may decline. 2. Click "Finish" to complete the process after declining.	

Instructions	Screenshots
This is the “safety” screen when subjects choose to decline. They must click “Continue” to complete the process.	
1. This checkbox does not need to be checked before subjects can complete the process to decline. 2. This completes the process of declining.	
1. This is the first step in creating an electronic signature. 2. There are multiple signature styles subjects can choose, or they can draw their own signature. 3. Subjects must upload their signature. 4. Click “Adopt and Sign.” 5. Click “Finish” to complete the process.	 

Instructions	Screenshots
If subjects do not have a DocuSign account, this is the prompt they see once they sign. Subjects are not required to have a DocuSign account. 1. Subjects can download a copy of the signed Informed Consent Document. 2. Subjects can print the signed Informed Consent Document. 3. Click “Submit” to sign up for DocuSign account. 4. Click “No Thanks” to continue without a DocuSign account.	
This is the notice subjects see once they sign, and while they wait for the Person Who Obtained Consent to sign.	
Subject line in subject’s email inbox when all signatures have been captured.	
Link to view completed document