Clinical Trials Office
Dana-Farber Cancer Institute
450 Brookline Ave
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Guidance: Adobe Sign FAQs

Frequently Asked Questions and Answers for Study Teams Using Adobe Sign

This resource document is specific to DFCI and includes institutional policies and system configuration that may not be applicable for non-DFCI staff.

Contents

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1 Questions related to Adobe Sign for Consent

1.1 What's the difference between remote consent and using Adobe Sign for consent?

There are two components to the consent process as described in in DF/HCC Policy CON-100. First is the consent discussion held between the person obtaining consent and the potential participant, second is how the signatures are obtained on the consent. The discussion can take place in-person or remotely. The signatures can be obtained in person-or electronically via Adobe Sign.

- Remote consent is referring to how a potential research subject is approached and how the informed consent discussion takes place. For example, a remote consent process could involve telephone calls, Zoom, or other telehealth visits depending on what the IRB approved for a particular study.
- Adobe Sign for consent is a method of obtaining consent signatures. The Adobe Sign consent process does not replace the need to have a consent discussion between the person obtaining consent and the potential participant. For protocols where electronic consent is approved, the consent form can be sent for electronic signature following either a remote or in person consent conversation. See the DFCI CTO Guidance - Adobe Sign for Electronic Consent for more information.

These methods can be used together or apart. For example, you could have: 1) a traditional in-person discussion and in-person paper signing; or 2) a remote discussion with in-person paper signing; or 3) an in-person discussion with Adobe sign signing; or 4) a remote discussion with Adobe Sign signing.

1.2 What steps are needed before I can start using Adobe Sign for consent?

For externally-sponsored studies, first notify the study sponsor that you will be using eConsent and get their acknowledgement.

For investigator-sponsored studies, confirm if the sponsor-investigator approves of using Adobe sign for consent. Next, review your protocol to see if specific consenting and recruiting language is included in the protocol document. If so, update the protocol to specify your plan of using electronic signatures. Note: references to the DF/HCC Policy CON-100 in investigator-sponsored studies do not need to be updated as the policy hasn't changed with this process.

Next (for all studies), submit an amendment to the IRB. In the amendment form, or updated NPA, include language about:

- Updated consent plan
- Sample emails you plan to send to participants
  - Note: the centrally confirmed language is meant for the Adobe Sign message and reminder fields, not necessarily a secure email or patient gateway message to them
- Additional guidance or further instructions provided to participants beyond the centrally confirmed Adobe sign message/reminder fields and centrally confirmed step-by-step instructions for participants
- How often you plan to send Adobe Sign reminders to potential participants
- An opt-out process during recruitment must be provided if the first contact with the participant is expected to be an email from Adobe Sign

Once the amendment has been approved and activated, you can start using the Adobe Sign for consent process. Ensure you have the correct Adobe Sign group access before starting and sending a consent form in Adobe Sign. See Question 2.4 below and the DFCI CTO Guidance - Adobe Sign for Electronic Consent for more information.

1.3 Can Adobe Sign be used for any research trial consent?

Yes, Adobe Sign can be used for any research trial where documentation of informed consent is required.

1.4 Should I set-up a Zoom call with a patient signing a consent?

Provide the participant with the centrally confirmed step-by-step instructions for participants. If participants have additional questions, consider setting up a secure Zoom meeting or phone call to answer any of their questions.

1.5 What email address should I use for the patient? What if the Email Address I have is incorrect?

In order to verify the identity of the potential subject signing the consent form, electronic signatures must be obtained from an email address linked to source documentation. The email address used for the subject MUST be the one listed in the subject's source documentation.

If the email address listed in Epic is incorrect, you can request that it be corrected by either emailing the DFCI Access Management mailbox or directing the potential subject to call the Pre-Registration team.

If the email address listed in other source documentation is incorrect, contact the potential subject to obtain the correct email address and update it accordingly in the source documentation.

For assent, the email address belonging to the parent that is providing consent is the only one that needs to be linked to the source documentation. The parent may provide the minor's email that will be used to obtain assent (if you obtain the email from the parent that is sufficient).

2 General Questions about Adobe Sign, Groups

2.1 Who can access/log-in to DFCI Adobe Sign to send research documents?

Only users with a DFCI-email address (@dfci.harvard.edu) can access and log-in to DFCI Adobe Sign to send research documents. Users with BWH or other institutional email addresses may not access the DFCI Adobe Sign to set-up and send a research document. Once a document has been set-up by a DFCI user in DFCI Adobe Sign, a user outside of DFCI may sign the document. See Question 2.2 below for more information.

2.2 Who can sign DFCI research documents sent via DFCI Adobe Sign? Only users with a DFCI email address? What about BWH or Partners emails?

Anyone signing research documents in Adobe Sign should either have an institutional or Partners/Mass General Brigham email address or should have an email address that is documented in the potential subject's source documentation (for signing research consents).

The process of signing documents is easier for signers with a DFCI email address but is still possible for other emails. See DFCI IS Intranet Page for Adobe Sign for more information about how signers with other email addresses can sign documents in Adobe Sign. See the DFCI CTO's Adobe Sign SharePoint Resources for details about additional documentation required of users outside of the Partners/Mass General Brigham system.

2.3 Can I send a research document to many signers using Mega Sign?

Unfortunately, Mega Sign is not compliant with 21 CFR Part 11, so you cannot use it to obtain signatures for research documents.

2.4 I'm not sure if I'm in an Adobe Sign group. How do I check?

Remember that being in an Adobe Sign Group is required to have the correct security needed for research documents. To check if you're in an Adobe sign group, ask your research manager or reach out to the DFCI CTO.

2.5 How do I create a new Adobe Sign group?

Reach out to the DFCI CTO to create a new Adobe Sign group.

2.6 Can I be in more than one Adobe Sign group?

No, you may only be placed in one Adobe Sign group. However, if your disease group has more than one Adobe Sign group (e.g., one for CRCs, one for Regulatory), you can place a ticket with IS to easily switch from one group to another if you need to manage or see documents from the other Adobe Sign group.

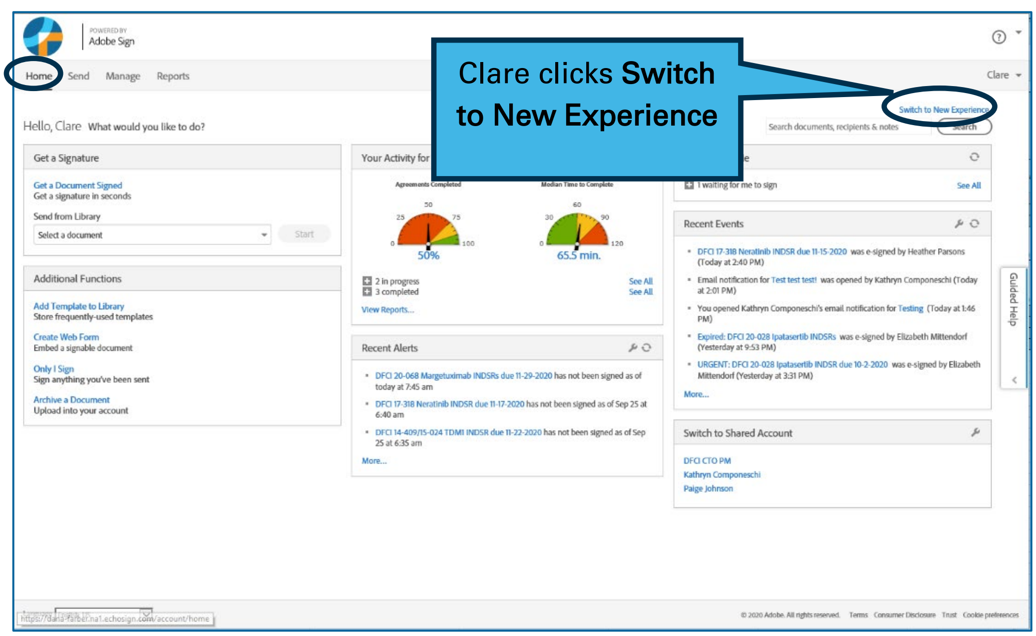
2.7 How do I view documents sent by others within my Adobe Sign group?

Adobe Sign users can create and share templates within their Adobe Sign group directly. Users within each Adobe Sign group can access documents out for signature, send reminders for documents out for signature, and access signed documents from other users within their Adobe Sign group by requesting permission to view everyone's pages. Permissions are requested for each individual user's accounts. Note that the user you are requesting from must still be at DFCI (i.e. haven't left their position) to grant permission to another user to access their account.

The process to obtain access to another user's page within your group requires several steps outlined below. In the screenshot examples below, Clare is a Regulatory Coordinator who will be requesting and obtaining access to view documents from various users in her Adobe Sign Group.

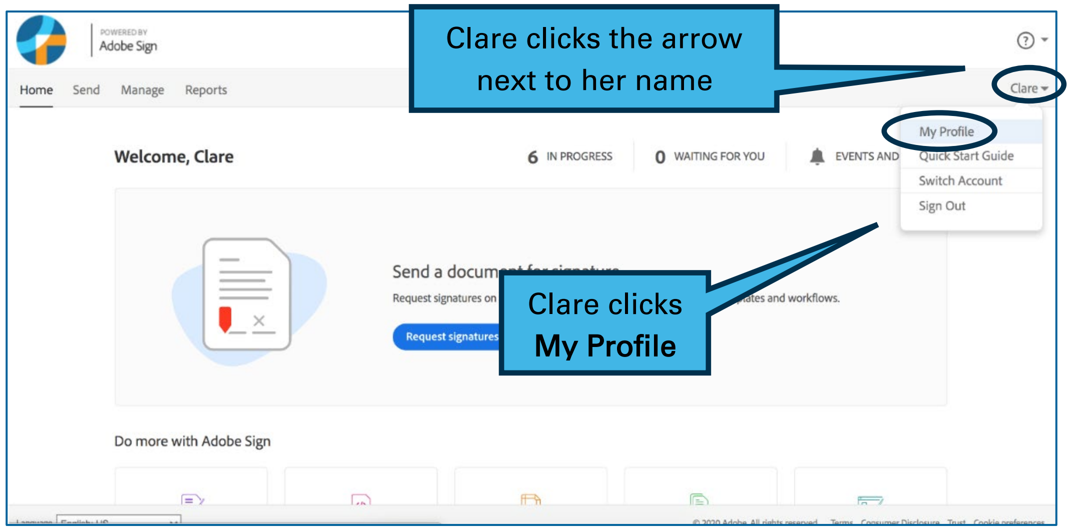
2.7.1 Start by Requesting Access to View Another's Account within your Adobe Sign Group

Start by logging in to your DFCI Adobe Sign page. Go to the **Home** page. Your screen may look like the screenshot to the right. In the top right part of this screen, click **Switch to New Experience**.

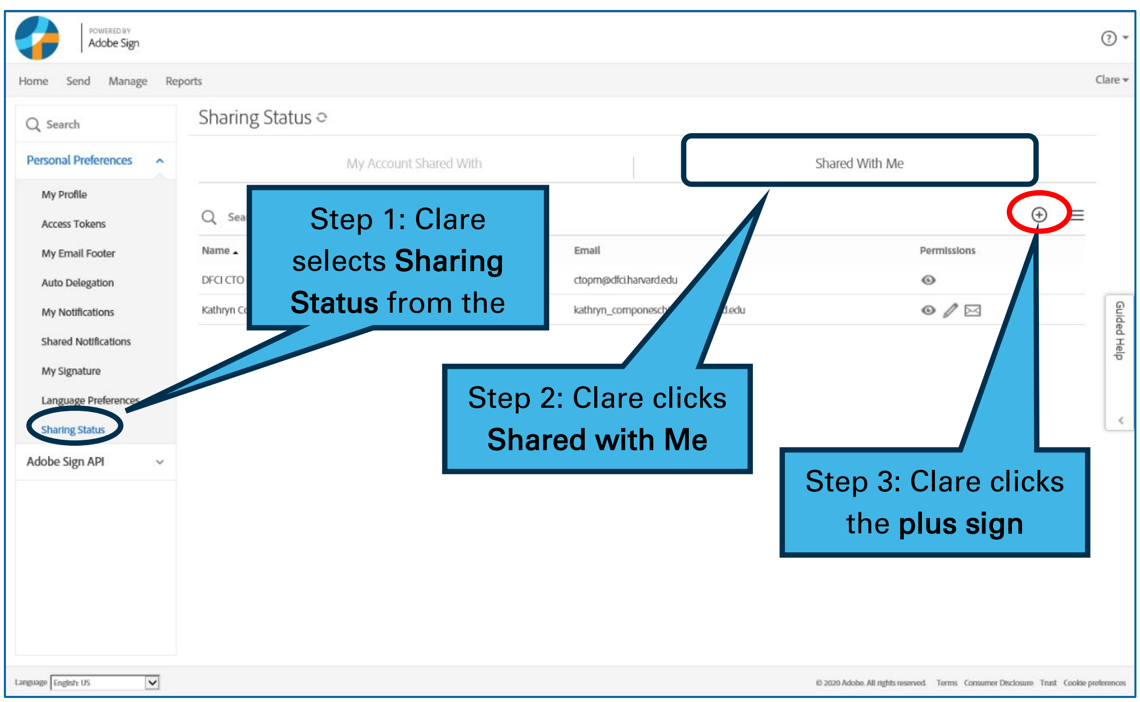


The page will reload and look like the screenshot below. If your page starts off looking like the screenshot below, start from the steps listed below.

The new screen will look slightly different. In the top right part of the screen, select the **drop-down arrow** next to your name. Select **My Profile.**

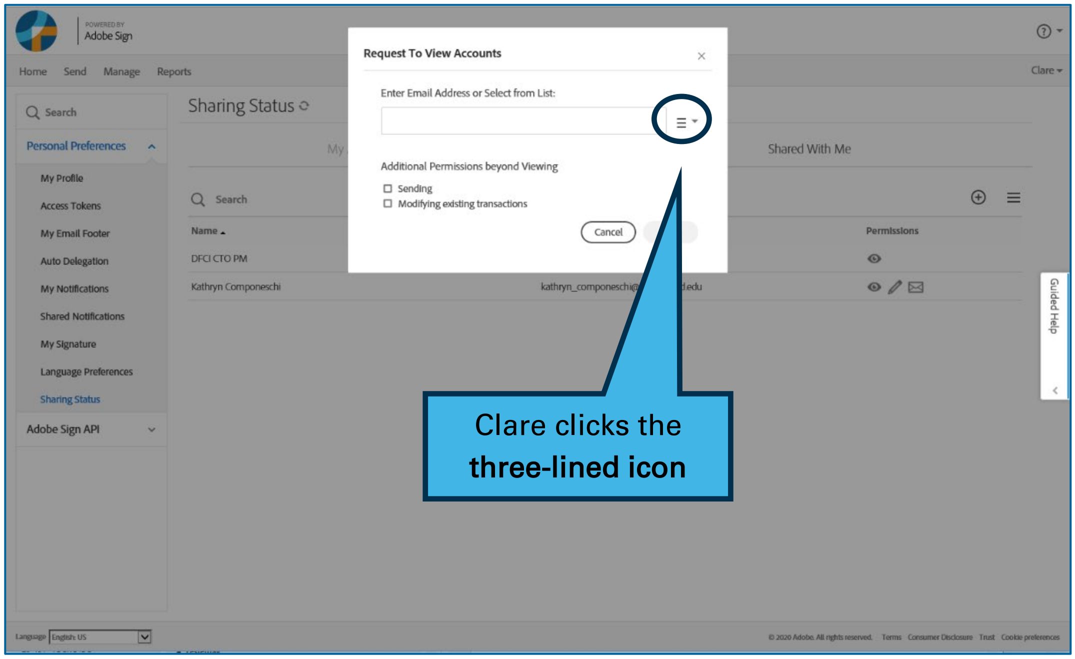


A new page will display showing a left panel of options called **Personal Preferences.** In this column of options, select **Sharing Status** from the menu. Next select **Shared with Me** to see users you may already have access to. If this is your first time requesting access from others in your group, you may see nothing on this screen or you may see the previous group email box you used before May 2020.

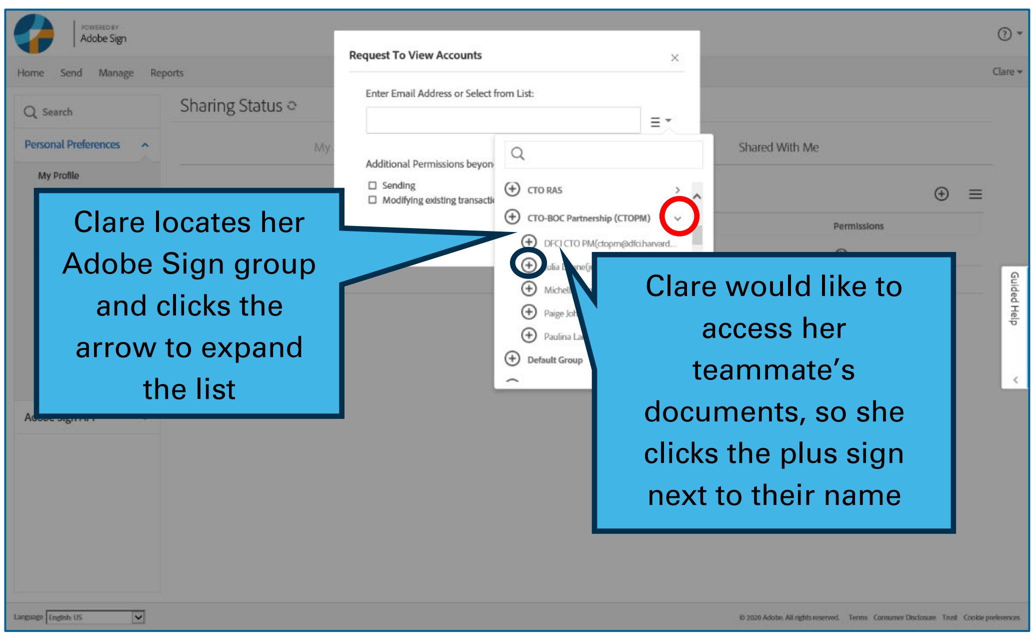


Next, under the **Shared with Me** area, click the plus sign.

A new window titled **Request to View Accounts** will open. Click on the three lined icon circled here to see different DFCI Adobe Sign groups.



Scan through the list of group options to get to your assigned Adobe Sign group. You can either click the plus sign next to the group name to add the entire group and request the same permissions from everyone or you can click the drop down arrow (red circle on the screenshot) next to your Adobe Sign group to expand the list.



Next locate the name of the person's account you would like to access. Click the plus sign next to their name (blue circle on the screenshot).

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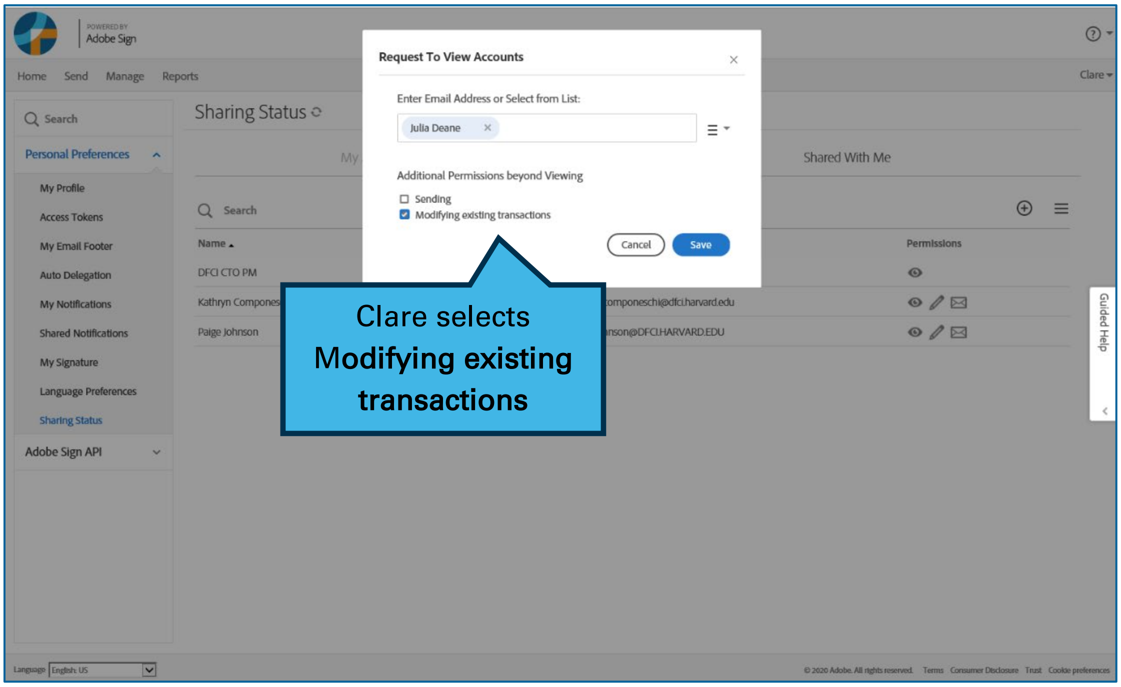
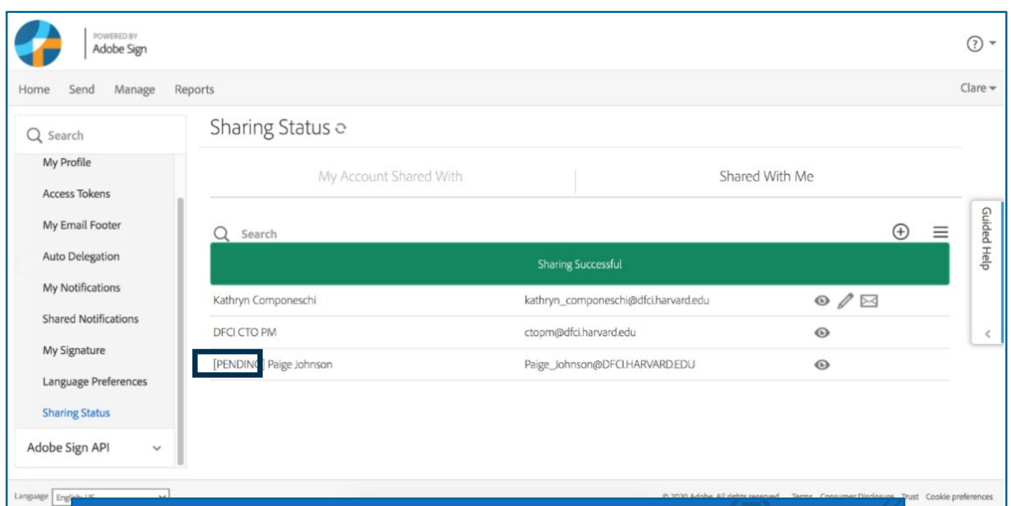
The person's name will now appear in the list on your screen. At this point you can add more names of staff from your Adobe Sign list by clicking back on the three lined icon. You can also add every member of an Adobe Sign group by selecting the plus sign next to the group's name on the previous screen.

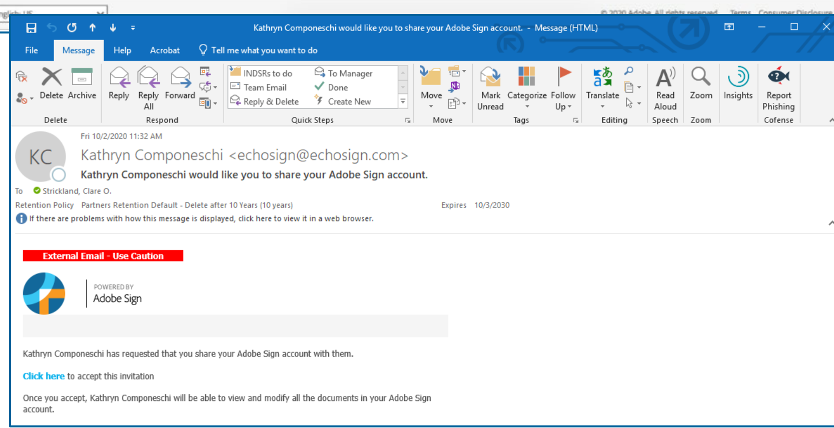


Next, click to check off **Modifying existing transactions.** This level of permissions for viewing and modifying will allow you to see other user's documents. We strongly advise that you <u>do not select **Sending**</u>, as this will mean you can send documents as if you are the user(s) you selected. You should always send documents from your own account, so <u>do not select **Sending**</u>. Once you click **Modifying existing transactions**, click **Save.**

After you click **Save**, a quick green banner will pop up saying **Sharing Successful** to notify you that a request was sent to the users you requested. This screen also displays requests that haven't been fulfilled yet as PENDING.

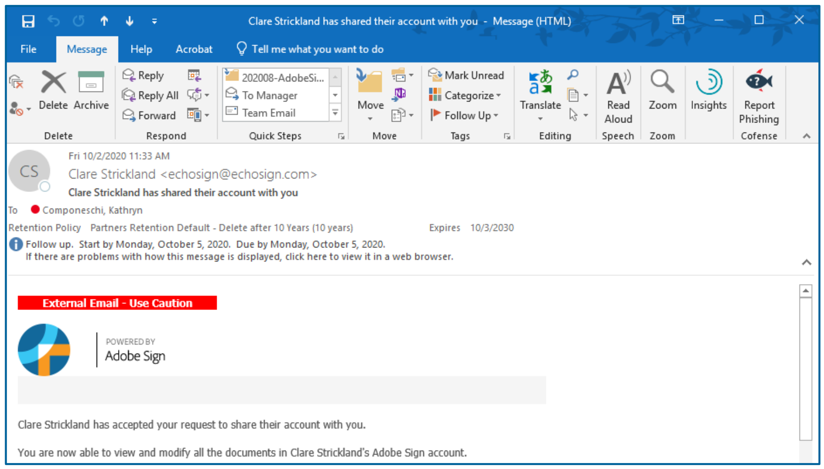


The requested user then receives an email asking them



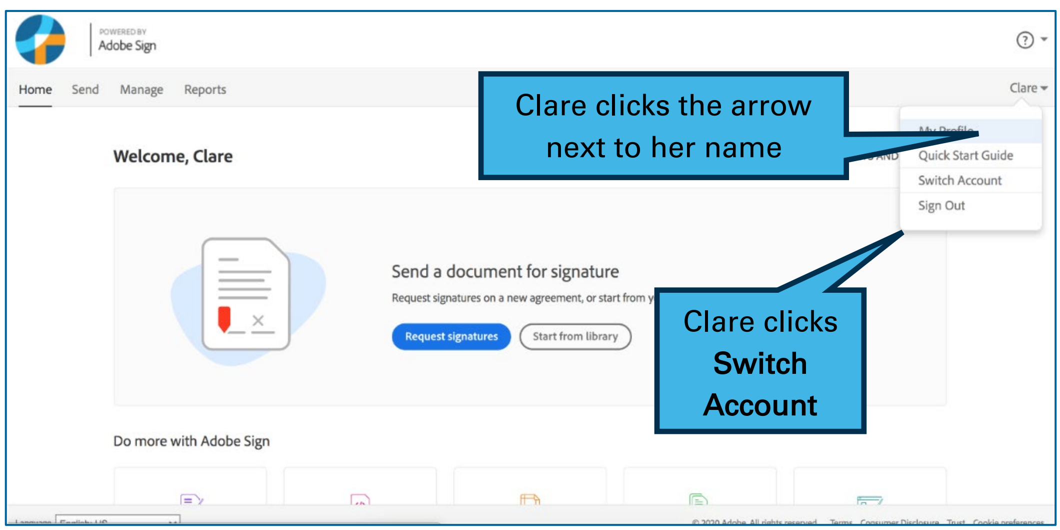
to accept the invitation. The requested user selects **Click here** to accept the invitation.

After they accept the invitation, you as the requestor will receive an email notifying you that the user has accepted your request, meaning they have successfully shared their account with you. You are now able to view their account, see documents sent by their account, and modify documents in their account.

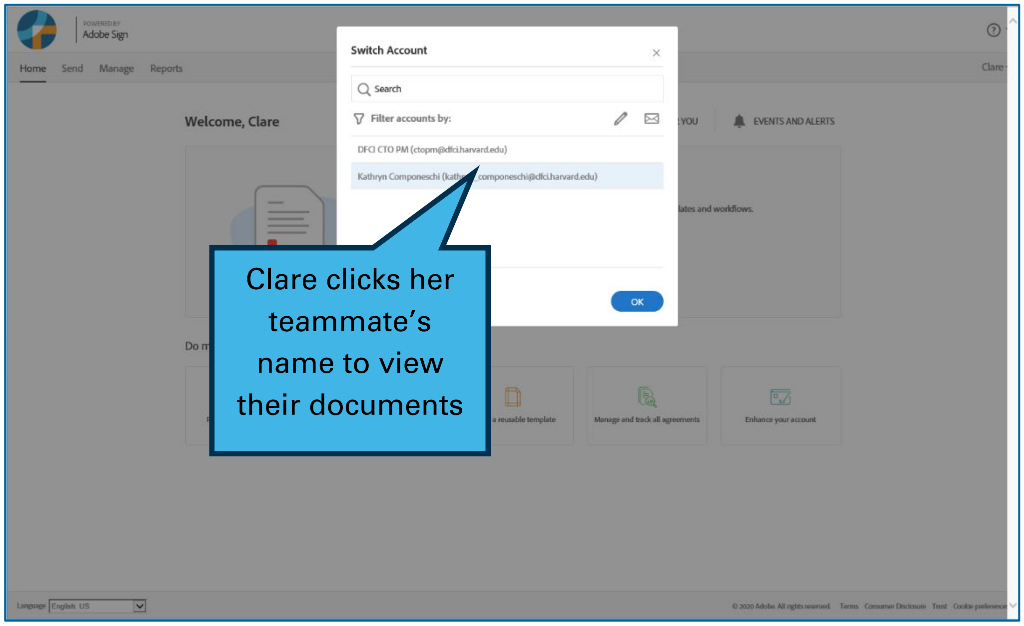


2.7.2 Once Request is Approved, Accessing and Viewing Another User's Documents

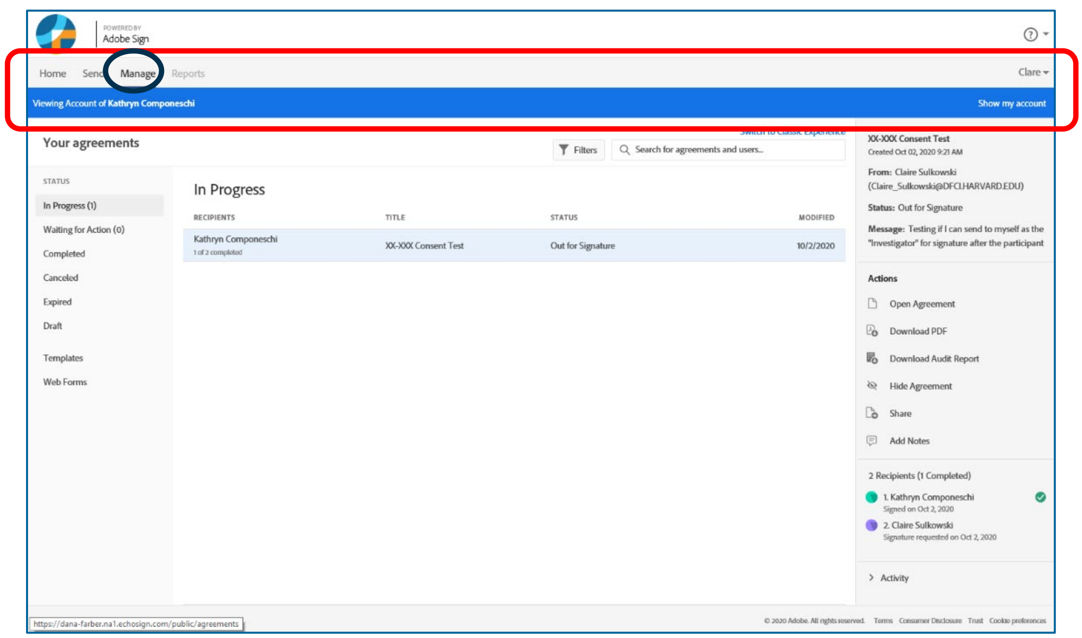
Once the request has been approved as part of the steps above, go back to your Adobe Sign **Home** page. In the top right corner of the page, locate your name and click the dropdown arrow next to your name. Select **Switch account** from the dropdown list.



A new **Switch Account** window will appear on the screen showing you the name or names of accounts you've gotten permission to view. Select the name of the person whose account or documents you are trying to access, then click Ok.



A new screen will open showing you the account you selected. You'll notice a banner at the top of the page indicating that you are viewing the account of the person you clicked on in the previous page. The screen brings you to that user's **Manage** page.

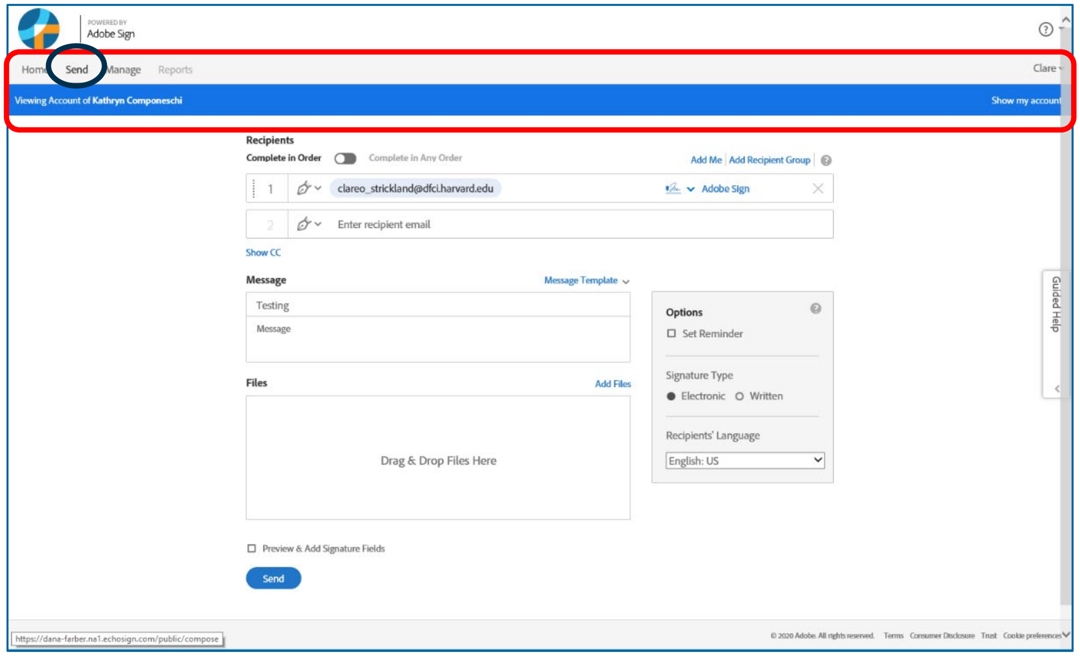


Depending on the level of permissions you requested or that have been granted to you, you can view that user's documents (past and current documents out for signature), hide agreements, and set reminders for their documents awaiting signature, etc.

If you accidentally requested **Sending** permission in one of the previous steps, you would be able to send documents from the selected user's account as if you were them sending the document. This should be avoided. If you accidentally selected this option and go to the **Send** page, it will appear as if the document is being sent from that user, not you.

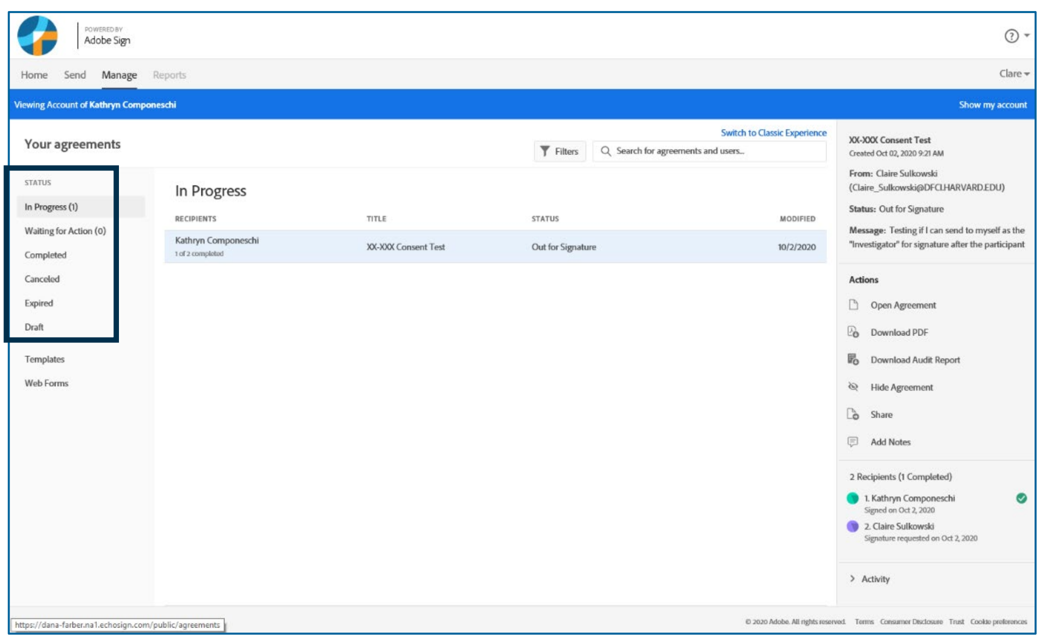
On the screenshot to the right, Clare is looking at Kathryn's account – she can tell this based on the blue banner at the top of the page.

Again, sending documents from another account should be avoided as you should only send documents from your own account.



If you send something from another user's account, that user will receive an email confirmation saying their agreement has been sent for signature (as if they had been the one to send it from their own account).

When viewing someone else's account, you can navigate the documents the same way you would your own documents using the **Manage** tab. You can view document **In Progress** to see what they've sent out for others to sign, **Waiting for Action** to see what they still need to sign,

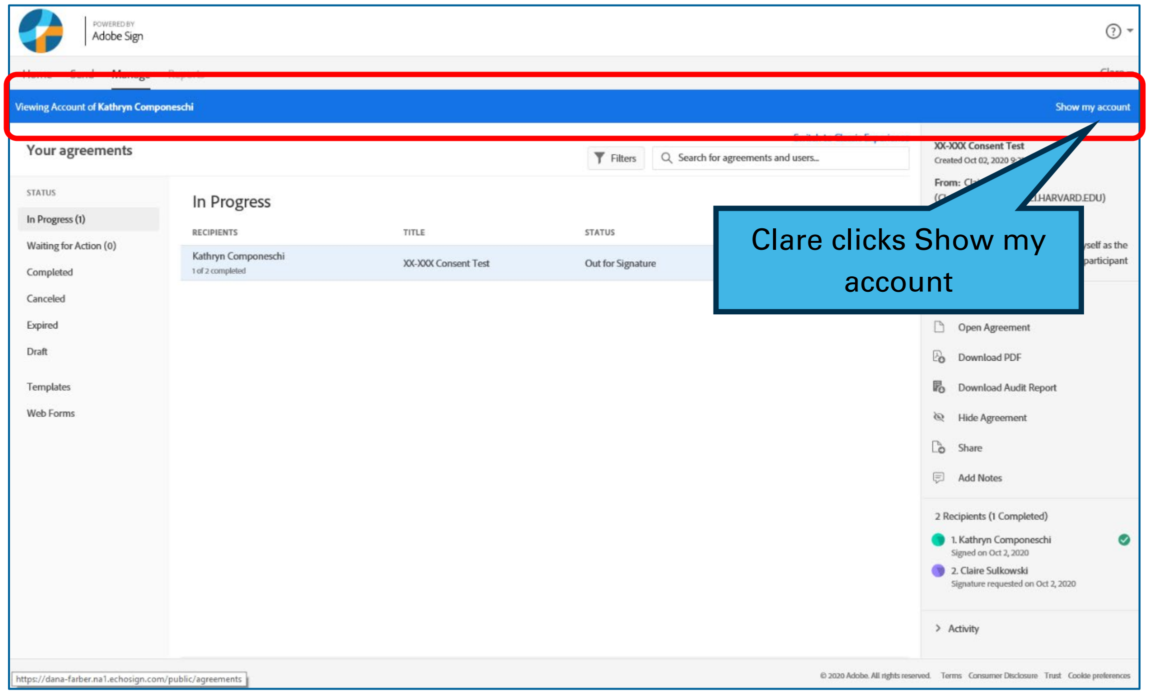


Completed to see both documents they've sent for signature that have been signed and any documents they have signed in the past, as well as **Canceled**, **Expired**, and **Draft** to see those specific documents, as well. The ONLY way to know that you are looking at a differ user's page is the blue banner saying **Viewing Account of [Other Person's Name].**

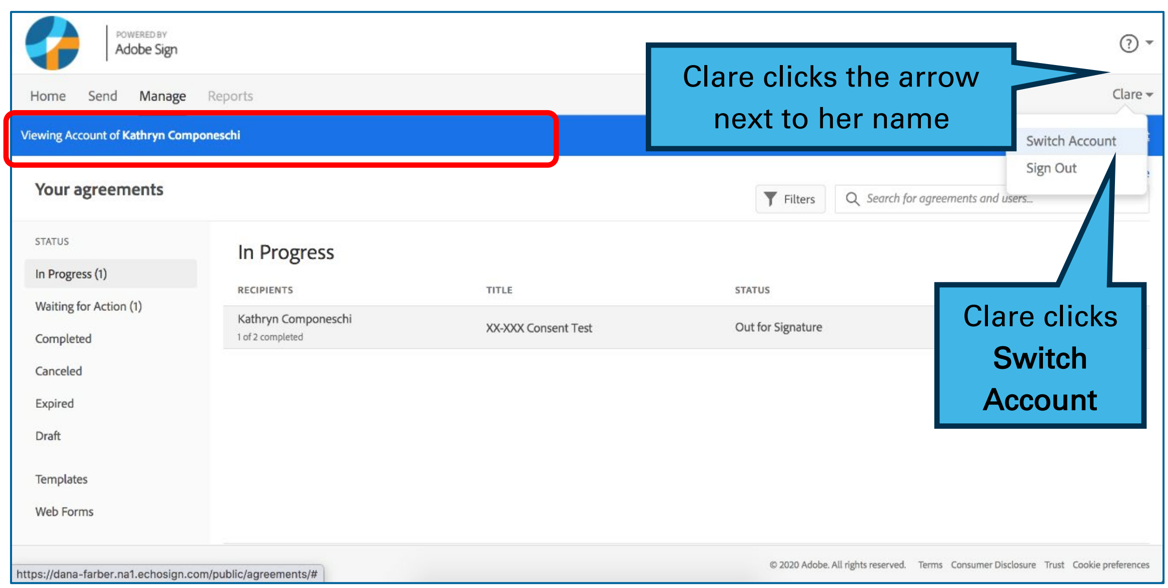
2.7.3 How to Go Back to your Account after Viewing Another User's Account

There are two methods to get back to your own account to send documents.

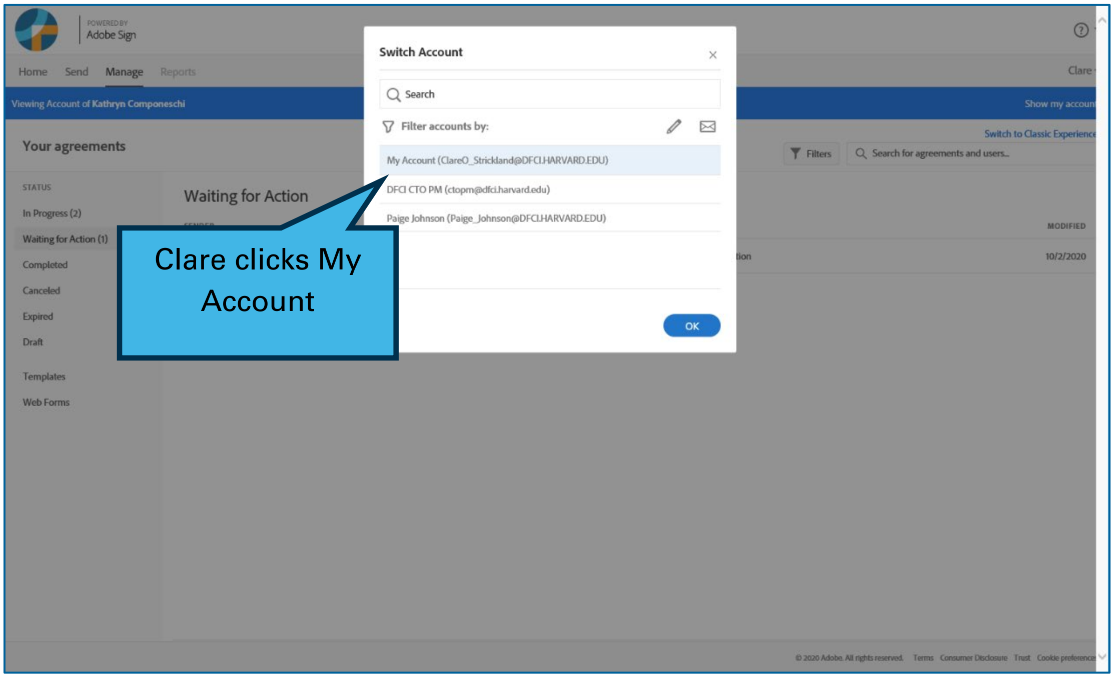
Option 1: On the banner at the top of the screen, select **Show my account** located on the far right.



Option 2: Locate your name in the top right corner of the page and click the dropdown arrow next to your name. Select **Switch Account** from the dropdown list.

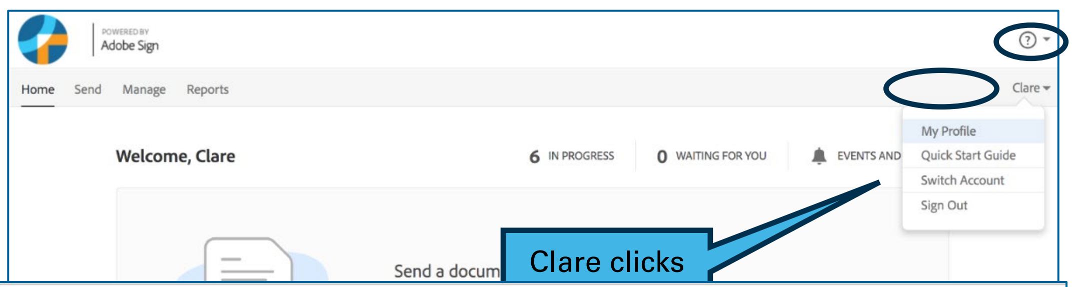


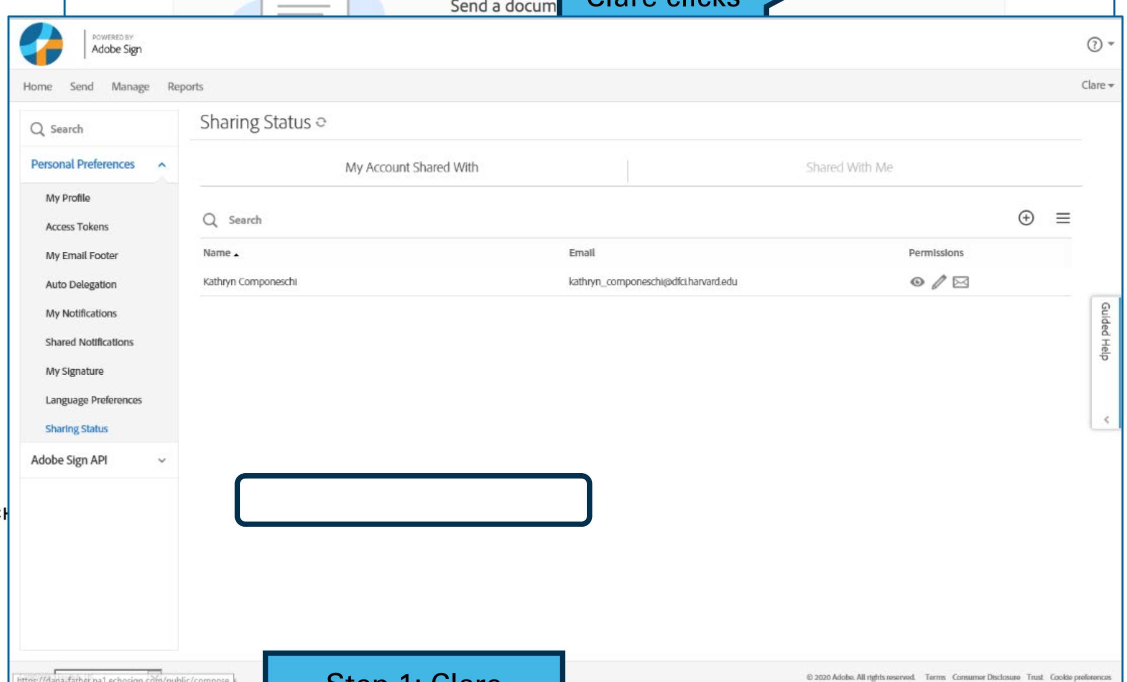
A new **Switch Account** window will appear on the screen showing you the name or names of accounts you've gotten permission to view in addition to your own. Select My Account then click Ok.



2.7.4 Edit Permissions Granted to Others within your Adobe Sign Group

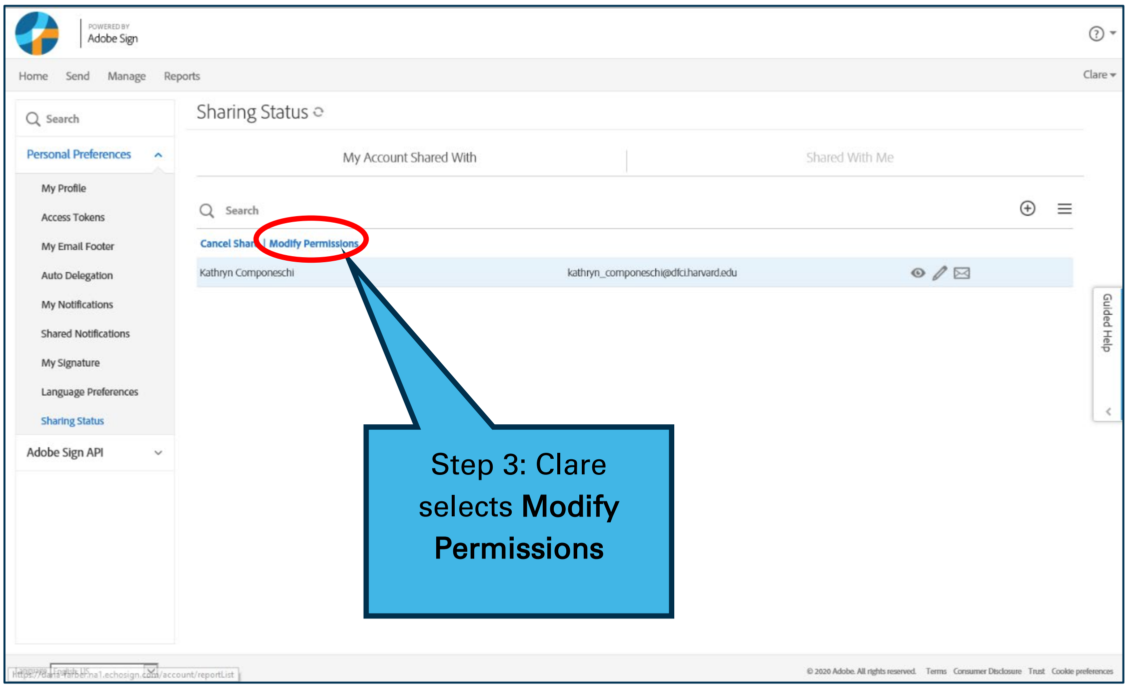
You may edit the permissions another user has on your page anytime, not just when you first request their access. In the top right part of the screen, select the **drop-down arrow** next to your name. Select **My Profile.**



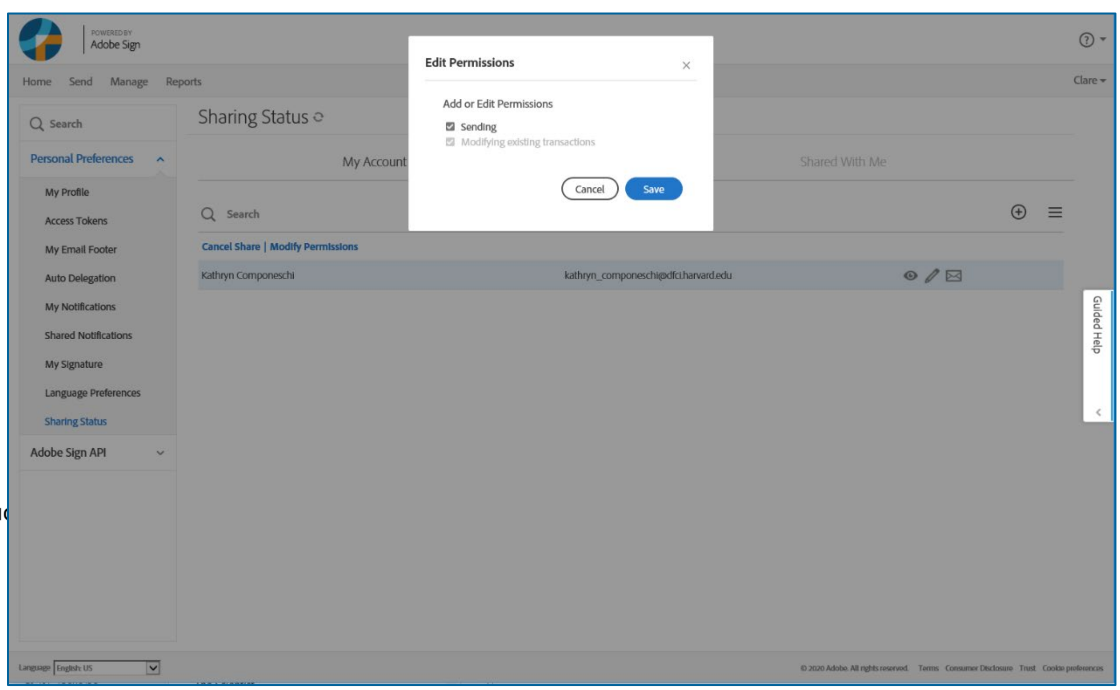


The next page will display a left panel of options called **Personal Preferences**. In this column of options, select **Sharing Status** from the menu. Next select **My Account Shared with** to see users you have already granted access to.

Select the user whose permissions you are trying to edit by clicking on their name. Then select **Modify Permissions.** This screen is also where you can stop sharing your account with users at any time by selecting **Cancel Share.**



By clicking **Modify Permissions**, a new window will appear allowing you to add or edit permissions. As stated earlier, we strongly advise that you <u>do not select **Sending**</u>, as this will mean



users can send documents as if they are you.

2.8 How can I update a document that has already been signed in Adobe Sign (e.g. Delegation End Date)?

A completed and signed Adobe Sign document can only be edited in Adobe Sign. The signed document is secure, certified, and an audit trail is required of all changes. Therefore, any errors on a signed Adobe Sign document must be corrected in Adobe Sign. Do not edit or "break" the original secure PDF.

If you need to update a document that was previously signed in Adobe Sign such as a Delegation of Authority Log end date, you have two options (Following RCO-OP-1 for who can edit or add information):

1. Wet-ink: print the PI-signed version and update the document when staff goes on site at DFCI.
2. Adobe Sign: the PI signed version is secure and can be edited in Adobe Sign only. Use a text box in Adobe Sign to identify the document as an edited version, identify who is making the edits and when the edits were made, and clarify that the PI will not sign, if applicable. If the change is specific to individuals, the names of the individuals should be included in the note rather than the page numbers.

Note: if you are correcting the role or start date, the PI must initial and date the change. For changes to the role or name please refer to RCO-OP-1 for the process.

Be sure to save all signed and/or updated delegation log versions in your regulatory files.

If wet ink edits were made and future updates are made with Adobe Sign:

- The wet ink copy must be saved as is and available for auditors or monitors
- Any updates in Adobe Sign to a document with wet ink updates must include the Certified Copy language (from the CTO template) in a text box, in addition to the information about the change.