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Guidance: Adobe Sign for Electronic Consent

Preparing and Sending Consents, Creating Consent Templates, and Tips

Contents

1. Overview – Adobe Sign for Electronic Consent 2
2. Step by Step Consent Process with Adobe Sign 4
3. Access to Adobe Sign 4
4. Sending Adobe Sign Consents / Creating a Consent Template 5
   4.1 Create an Adobe Sign Consent Template in Advance 6
   4.2 How to send an Adobe Consent / Create an Adobe Sign Consent Template with First Participant 7
   4.3 Adding Fields 9
   4.4 Signature Fields – Signature and Initials 10
   4.5 Signer Info Fields – Date and Printed Name 11
   4.6 Assigning Recipients to Fields 12
   4.7 Editing a Specific Field and Adding Conditions 13
   4.8 Other Commonly Used Fields 20
   4.9 Text Input – Date Consent Discussion Initiated 21
   4.10 Checkboxes – How to Add and Edit 22
   4.11 Radio Buttons – How to Add and Edit 23
   4.12 Review and Save Template 24
5. Using an Adobe Sign Consent Template Already Created 25
6. Other Helpful Tips for the Adobe Sign Consent Process 27
   6.1 Adobe Sign Reminders 27
   6.2 Saving an Adobe Signed Consent Form 28
   6.3 Consent Errors 28
   6.4 Difficulty with Signing Forms 29
7. References 29

1. Overview – Adobe Sign for Electronic Consent

As discussed during the joint-CTO and DFCI training in October 2020, electronic signatures must comply with the FDA's requirements in 21 CFR Part 11 to be considered the legally-binding equivalent of handwritten signatures. Due to HIPAA and Part 11 regulations, all consent forms must be signed with an authenticated signature.

DFCI has selected Adobe Sign as a system that is able to fulfill Part 11 requirements as configured in our enterprise system. Not all installations of Adobe Sign are Part 11 compliant. This means that users at other institutions, or users who set up a free Adobe account online, may not be compliant with Part 11 requirements. At DFCI, all users must have and use their enterprise DFCI account.

DF/HCC Policy CON-100 that governs the informed consent process still applies when using Adobe Sign for electronic signatures. Adobe Sign allows for the actual signature process to occur electronically. However, Adobe Sign does not change or replace the need to have a full consent discussion with the participant and to document the entire consenting process. These steps still need to occur outside of Adobe Sign, although the way you fulfill these requirements might look slightly different than a typical in-person consent process.

Additionally, keep in mind that the following must still occur outside of Adobe Sign, in alignment with the current Mass General Brigham Recruitment Policy and the IRB-approved protocol language:

- The first contact with the participant must follow the IRB-approved method(s) and should not be an email directly from Adobe Sign.
- If the first contact with the participant is expected to be an email from Adobe sign, a clear opt-out process during recruitment must be provided, as approved by the IRB.

Anyone signing the consent form electronically should either have an institutional or Partner/Mass General Brigham email address as the person obtaining consent, or should have an email address that is documented in source documentation:

- Make sure to validate the email address in the source documentation to be used for the electronic signature. 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 the source documentation accordingly.
  - 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).
- In cases where other parties need to sign consent, including Legally Authorized Representative (LARs), interpreters, or parents, Adobe Sign should not be used unless those individuals have validated email addresses documented in the subject's source documentation.
- Ensure that the potential subject and any other individual that will be signing the consent meets any necessary requirements to be able to sign a consent form electronically, including physical and cognitive ability to use an electronic signature system, before proceeding with Adobe Sign.

Note that the use of electronic signatures on consent forms constitutes a change in recruitment and informed consent processes. Such changes must be reviewed and approved by the IRB overseeing the research. For existing studies, an amendment must be submitted to the IRB describing the proposed changes to the recruitment and consent procedures; however, the consent form itself does not need to be revised. Additionally, the protocol only needs to be revised if specific consenting and recruiting language is included. 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.

Centrally confirmed DFCI language for the Adobe Sign **Message** field and **Reminder** area is available on the DF/HCC Website. Additional step-by-step Adobe Sign instructions that can be sent to participants is available on the DF/HCC Website.

Any emails to participants, additional guidance, further instructions, and further reminders that subjects will receive about the electronic signature process will need IRB approval. Include any of these documents as part of the amendment submission as they require prospective IRB review and approval. Details about how often you plan to send reminders (see Section 6.1) should be included in the updated recruitment plan you describe as part of your amendment to the IRB.

2. Step by Step Consent Process with Adobe Sign

Below is a general overview of the Consent Process with Adobe Sign.

Before starting your first consent: Submit an amendment to get IRB approval of the proposed changes to recruitment / consent procedures

This only needs to be done the first time unless you change any procedures or instructions

Step 1: Download ICF

Get the current IRB-approved and posted consent form version from OncPro

Step 2: Send an unsigned ICF to the participant

Send via Patient Gateway or secure email

Step 3: Set up a discussion between participant and person obtaining consent

Use zoom, phone call, or other method
Follow CON-100 - attending physician for studies with a drug, device, or biologic

Step 4: Consent discussion takes place

Includes explaination of the study, risks, benefits, and alternative options
Gives the participant time for questions and considerations

Step 5: AFTER discussion, send consent with Adobe Sign

Designated study team member prepares and sends the consent form for Adobe Sign
Consent can be from a template created using the guidance below

Step 6: Save the signed consent

In the subject's research chart
Email a copy of the signed consent to HIS

Step 7: Document Consent Process

- Person who obtains consent documents the process per CON-100

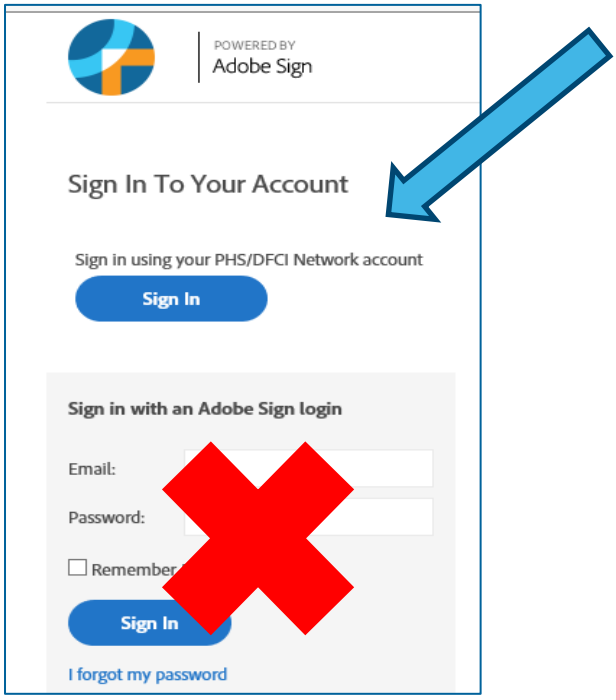
3. Access to Adobe Sign

First, ensure you have DFCI access to Adobe Sign with appropriate group access. Adobe Sign Groups establish that the required security settings for research are in place for the individuals that are a part of them. To obtain DFCI Adobe Sign access for a new user, see the DFCI IS Intranet Page for Adobe Sign. Work with your manager or contact the CTO to ensure you have the appropriate group access prior to sending a consent form for

signature. **Do not use Adobe Sign for sending consents until you have verified that you have the appropriate Group Access.**

When using Adobe Sign for research consents and other regulatory documentation, you must log in to the account linked to your individual DFCI email address linked to a group account. To ensure the correct security and protections are in place, **do not** send consent forms from an Adobe Sign account associated with a personal email address or shared mailbox.

Always access Adobe Sign using the specific DFCI Adobe Sign URL. Once you've navigated to the DFCI URL, click the PHS/DFCI Network Account **Sign in** button to log in using your DFCI username and password.



4. Sending Adobe Sign Consents / Creating a Consent Template

*Ensure you have IRB approval for obtaining consent electronically with Adobe Sign **before** you begin the process of sending Adobe Sign consents and creating Adobe Sign consent templates. See Section 1 of this guidance document for more information about IRB approval.*

There are 2 ways of creating an Adobe Sign consent template:

- Add a template to your Adobe Sign template library in advance for use later (see Section 4.1); or
- Create an Adobe Sign consent template the very first time you send a consent form to a participant to sign in Adobe Sign (see Section 4.2)

Either method is fine, but it is considered best practice to set up a consent template in advance, as it takes some time getting accustomed to Adobe Sign nuances.

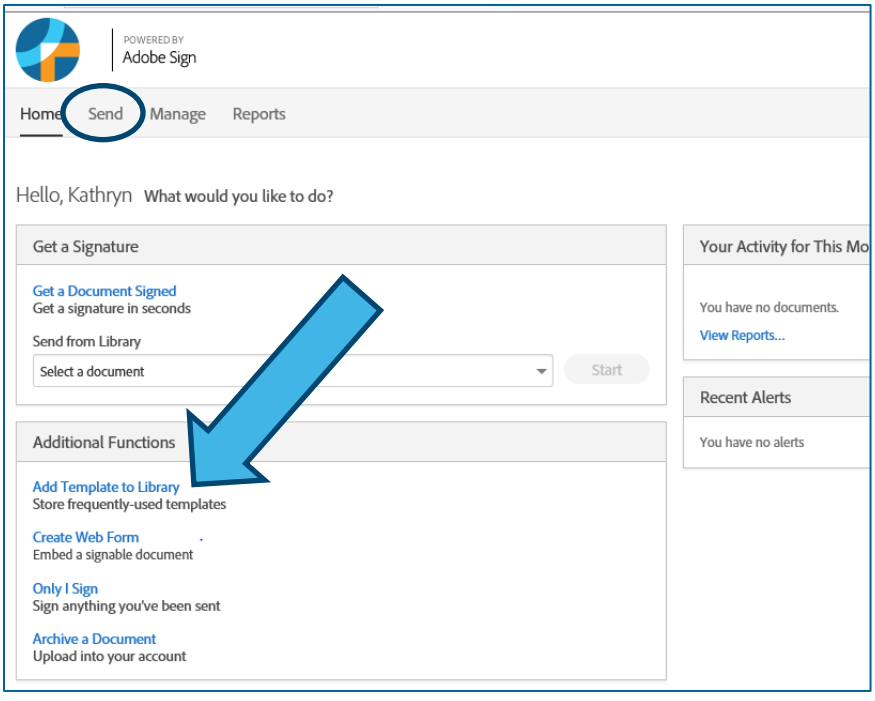
Instructions for both methods of creating an Adobe Sign consent template are provided below. Always start by downloading the current IRB-approved consent form version from OncPro. The best practice is to download and include any supplementary consent documents such as Institutional Conflict of Interest (ICOI), reimbursement forms or other forms. Note that only supplementary documents posted to OncPro that have been reviewed and approved by the IRB should be included with the consent form.

Make sure you rename the consent form (and supplementary documents) you download from OncPro with the protocol number, type of document (consent), and date posted for use. An example of this format is *XX-XXX Consent Form Posted for Use 01OCT2020*.

Keep in mind that study teams are responsible for ensuring templates are revised or deleted when a new version of the consent form is IRB approved and posted to OncPro.

4.1 Create an Adobe Sign Consent Template in Advance

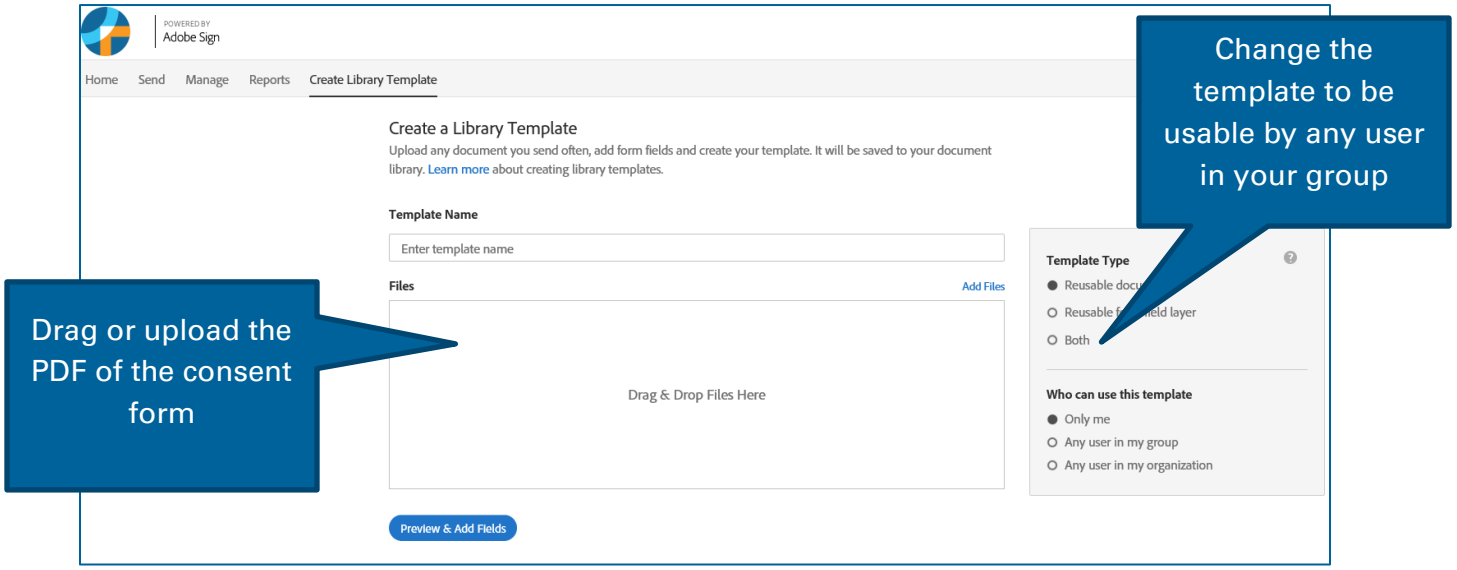
If you wish to create a consent form template in advance, go to the Adobe Sign **Home** Page and click **Add Template to Library**.



On the next screen you can list a template name, add the consent form, and change the parameters of the template

The next step is to drag and drop or click **Add Files** to upload the PDF of the consent form and any supplementary forms you downloaded from OncPro.

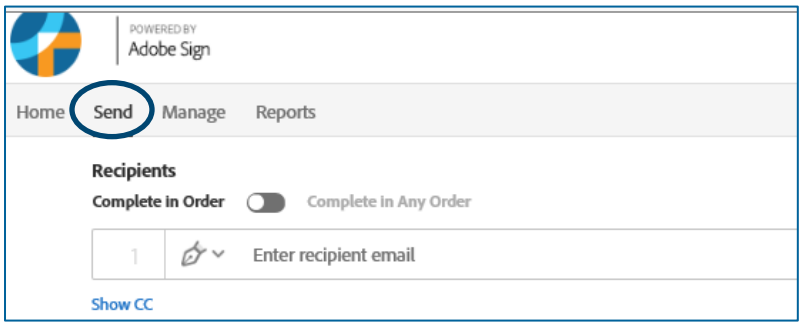
Under **Template Type**, keep the selection of **Reusable document**. It is recommended to make the template available for any user in your group to access, so under **Who can use this template**, change the option to **any user in my group**.



Click **Preview & Add Fields** to continue the process of creating a consent template. Skip to Section 4.3 to continue the process of creating the consent template.

Note that only the template-owner / original creator of a template can edit the template. This means if someone who created the template leaves your group, you or your group's manager will need to contact DFCI IS to have that account removed and templates removed.

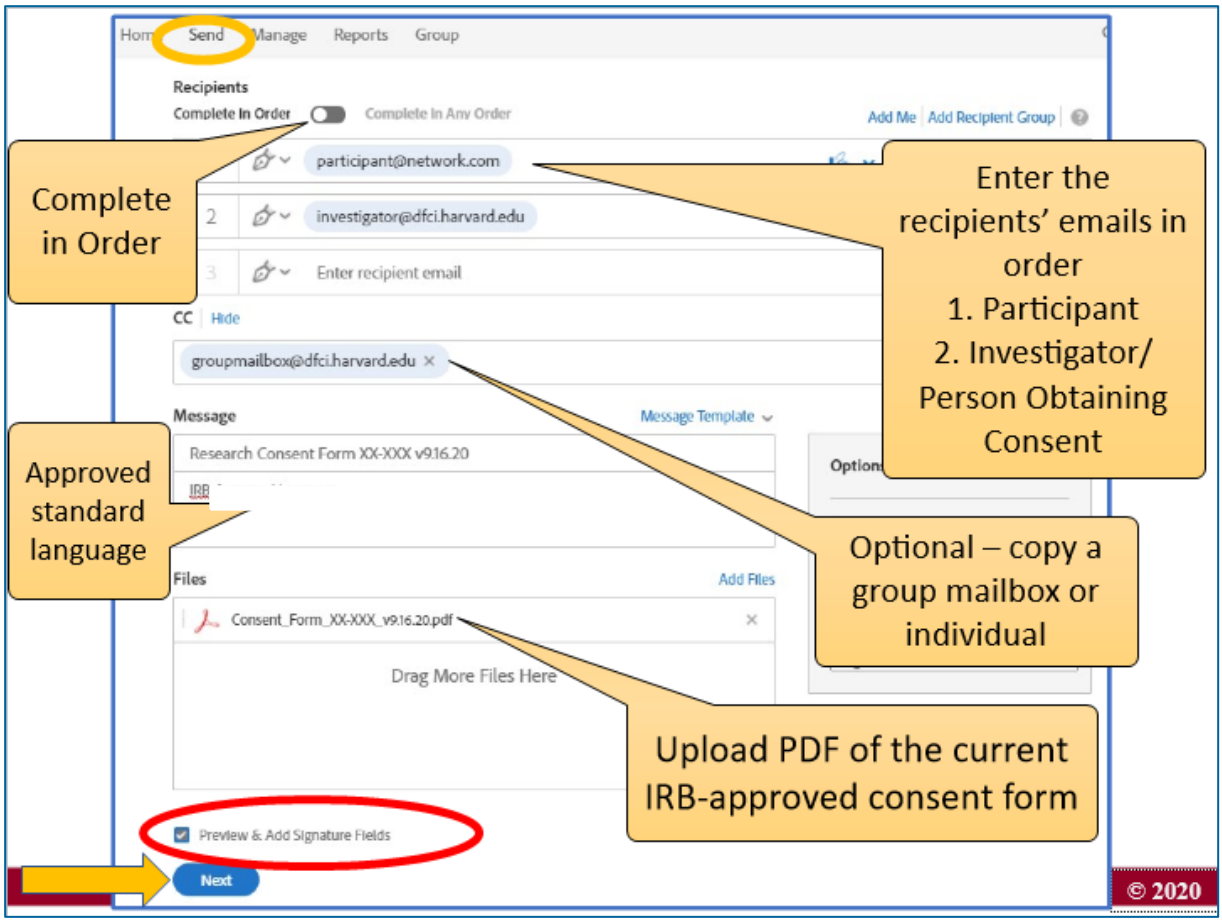
4.2 How to send an Adobe Consent / Create an Adobe Sign Consent Template with First Participant



Another method of creating an Adobe Sign consent template is by using the consent form you will send the very first time you send a consent form to a participant to sign in Adobe Sign.

The instructions below can also be used to create a one-off consent form to send to a participant. Section 4.12 contains information about how to save the consent you are sending to the participant as a template you can use with other participants.

Typically, when you first log in to Adobe Sign you will be brought to the **Send** page, or you'll be able to select **Send** from the banner at the top of the page.



A screen shot of the full **Send** page is included on the next page.

The first section is **Recipients**. Always make sure the **Complete In Order** toggle is set when you are sending a consent document so that the potential participant is required to sign before the investigator or person obtaining consent.

In the **Recipients** section, enter the participant's email address in the first box, then add a second recipient field for the email address of the investigator or person obtaining consent. Always make sure to double-check that you are entering the correct participant contact information in the recipients section. A carbon copy or **CC** field is located directly below the initial recipient email boxes. You use the **CC** field to send a copy of the signed consent to a study team mailbox or other research team member.

The next section is a **Message** field that allows you to enter custom language to appear in the email notifications sent to both signers (the participant and the Investigator or person obtaining consent). Note that any language entered in the **Message** field is a communication to the research subject. Centrally confirmed DFCI language for the **Message** field is available on the DF/HCC website. Any changes to this language must be

reviewed and approved by the IRB of record for each protocol separately. Additional instructional language for participants with step-by-step Adobe Sign instructions has also been centrally confirmed by DFCI and can be sent to the subject. These instructions are also listed on the DF/HCC Website.

See Section 1 for more information about IRB approvals needed for the Adobe Sign consent process.

The next step is to drag and drop or click **Add Files** to upload the PDF of the consent form and any supplementary forms you downloaded from OncPro.

It is extremely important that you always check the **Preview & Add signature Fields** box so that you can place the appropriate signature and date fields on the document for each signer. This step must be done whether you are creating a template or just sending a consent to a participant. If this box is not checked, the consent form will not be signed correctly, and you will need to start over.

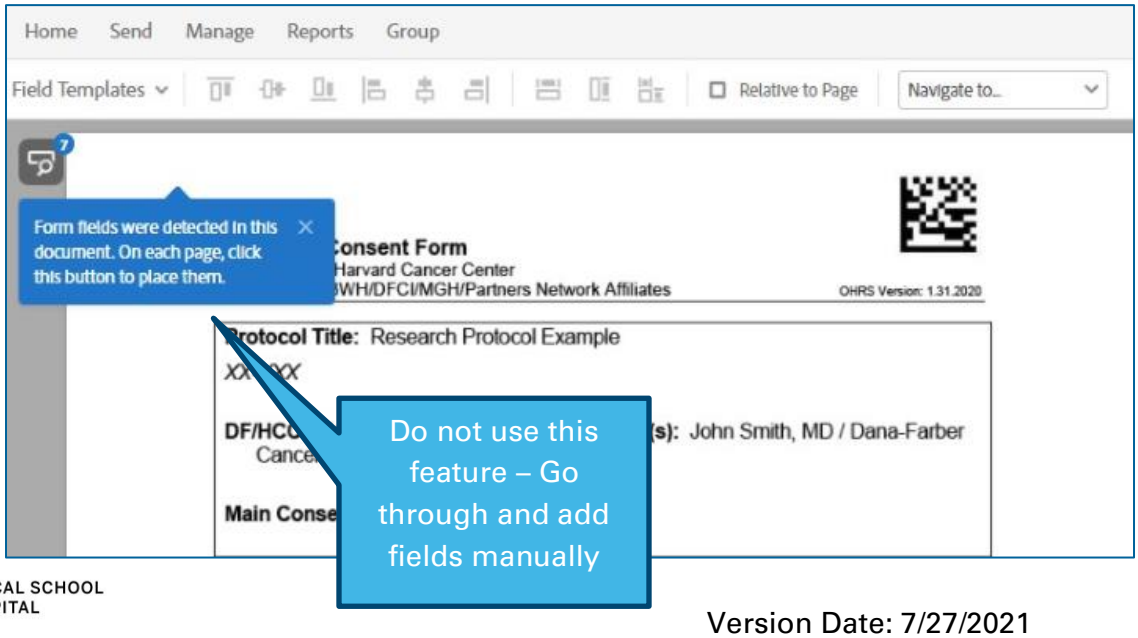
Once all these steps are complete, click **Next** on the bottom of the page.

4.3 Adding Fields

The **Preview and & Add Signature Fields** page in Adobe Sign will generate a preview of the consent form on which you can add signature boxes and other fields.

The first time you create a template from scratch or send a consent form, you will need to add the fields to the form manually. **Keep in mind that you need to ensure any templates you create are revised or deleted when a new version of the consent form is IRB approved and posted to OncPro.**

A bubble may appear on the screen indicating Adobe Sign has "detected fields in the document." We advise that you don't use this auto-fill feature as Adobe Sign



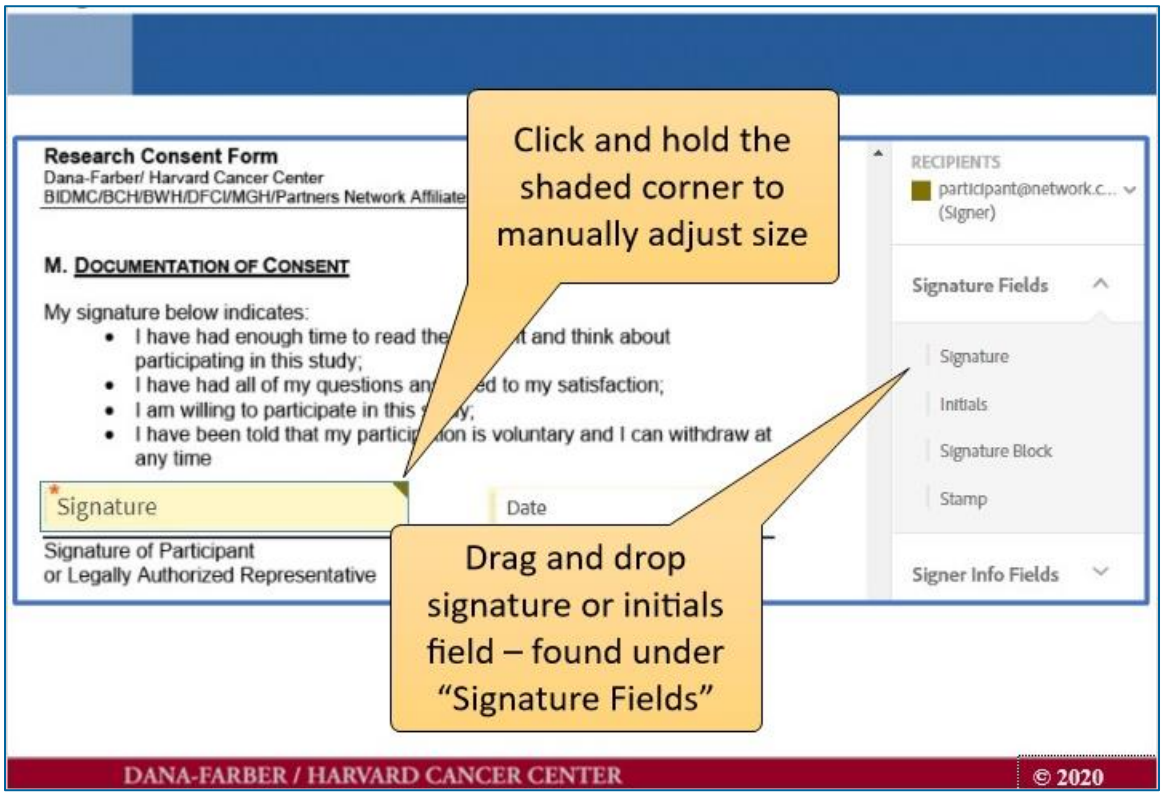
tends to place unnecessary fields in the consent document. Instead, you should scroll through and add fields manually wherever they are needed for each consent.

You may need to add fields throughout the consent in addition to the signature and date fields at the consent forms. Examples of these fields include fields for participant name and MRN, participant initials, Yes/No fields for optional studies, etc. We'll review how to add each of these fields in the next few sections of this guidance document.

4.4 Signature Fields – Signature and Initials

The most common fields used on a consent form are located under **Signature Fields** on the **Preview & Add Signature Fields** page.

The right side of the screen displays several drop-down categories of fields to the right of the document. The "**Signature Fields**" drop down includes the **Signature** and **Initials**, two boxes which will typically be used on research consent forms. We recommend not using the Signature Block or Stamp as they do not fit the DF/HCC consent template.



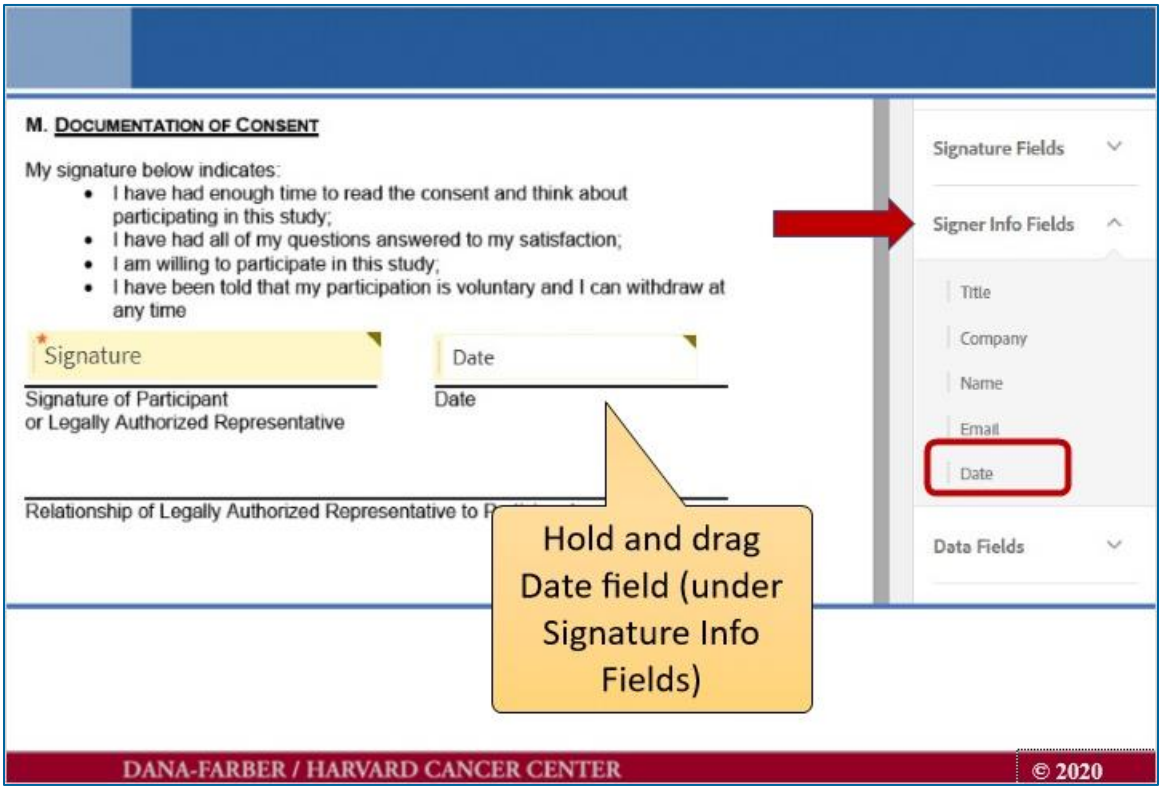
To apply a **Signature** or **Initials** field, click and drag the field to the desired location in the document. Typically, it will automatically adjust size to fit the signature line, however you can manually adjust the size as well by clicking and holding the shaded corner of the box.

4.5 Signer Info Fields – Date and Printed Name

Other common fields used on a research consent form are the **Date** and **Name** fields located under **Signature Info Fields** on the **Preview & Add Signature Fields** page.

Signer Info Fields, found in the drop down directly under **Signature Fields**, allow you to add fields such as **Date** or **Name** that are linked to the **Signature** field and will automatically fill in when the recipient completes the **Signature** field. This means when the signer is completing their section of the form, they are not able to edit the field, the date will automatically appear as the current date they are signing the form and their typed name will appear using the name used for their signature.

To apply the **Date** or **Name** fields, click and drag it to the desired location in the document. Again, Adobe Sign will usually automatically adjust the size to fit the date line, however you can manually adjust the size as well by clicking and holding the shaded corner of the box.



Note: Do not use the **Date** field if a signer needs to manually enter a date in a document. We will show you how to create a manual entry date field in Section 4.9 of this guidance document.

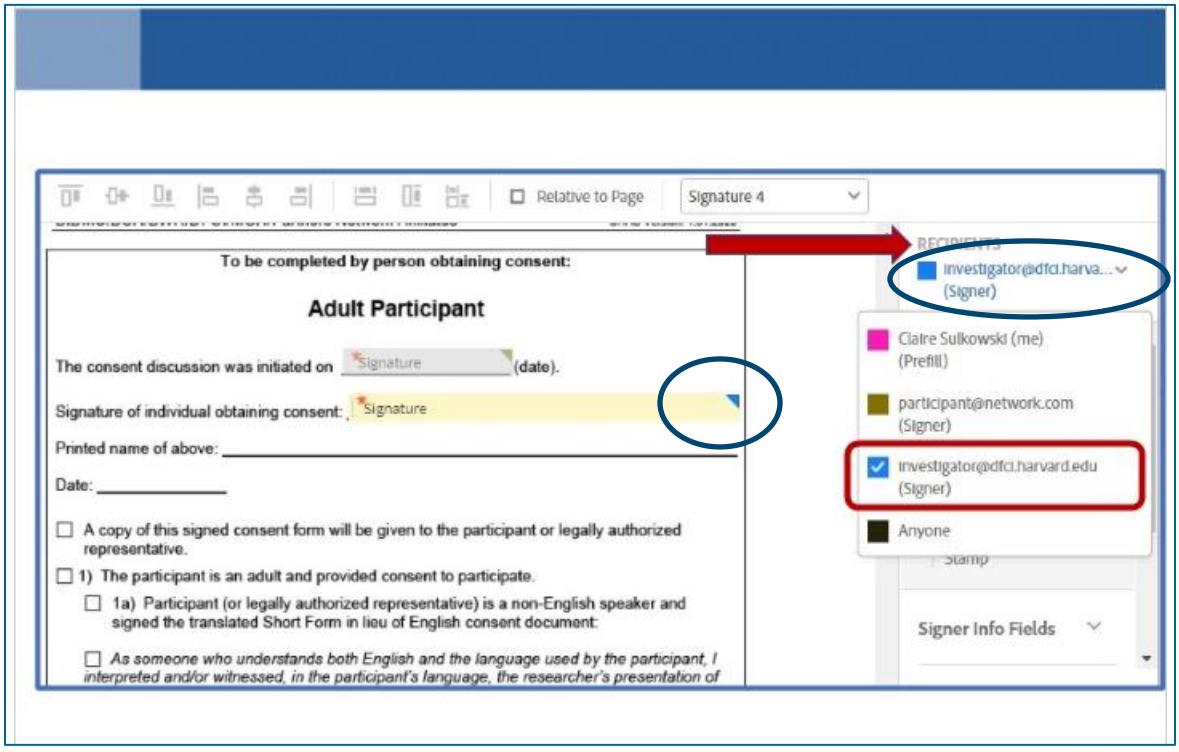
4.6 Assigning Recipients to Fields

When adding fields to the consent, you need to specify which fields will be prefilled by you or by others on the study team before the consent is sent, which fields will be completed by the participant, and which fields are to be completed by the person obtaining informed consent. It is critical that this is done correctly when creating a template or sending a consent to a participant.

Note that for any field you add in Adobe Sign the default person assigned to complete the field will be the participant, since they are the first recipient you added on the Send page (as mentioned in Section 4.2).

You can click into the **Recipients** list on the **Preview & Add Signature Fields** page to change the signer that you are adding fields for or change the specific field assigned to the recipient. You can also change the recipient assigned to a field, by double-clicking the field or right-clicking to edit and selecting the appropriate individual in the **Assigned To** drop down box (see an example on the next page).

Typically, you will want to add all fields you will need to prefill first, then add fields for the participant, finally add fields for the person obtaining informed consent.



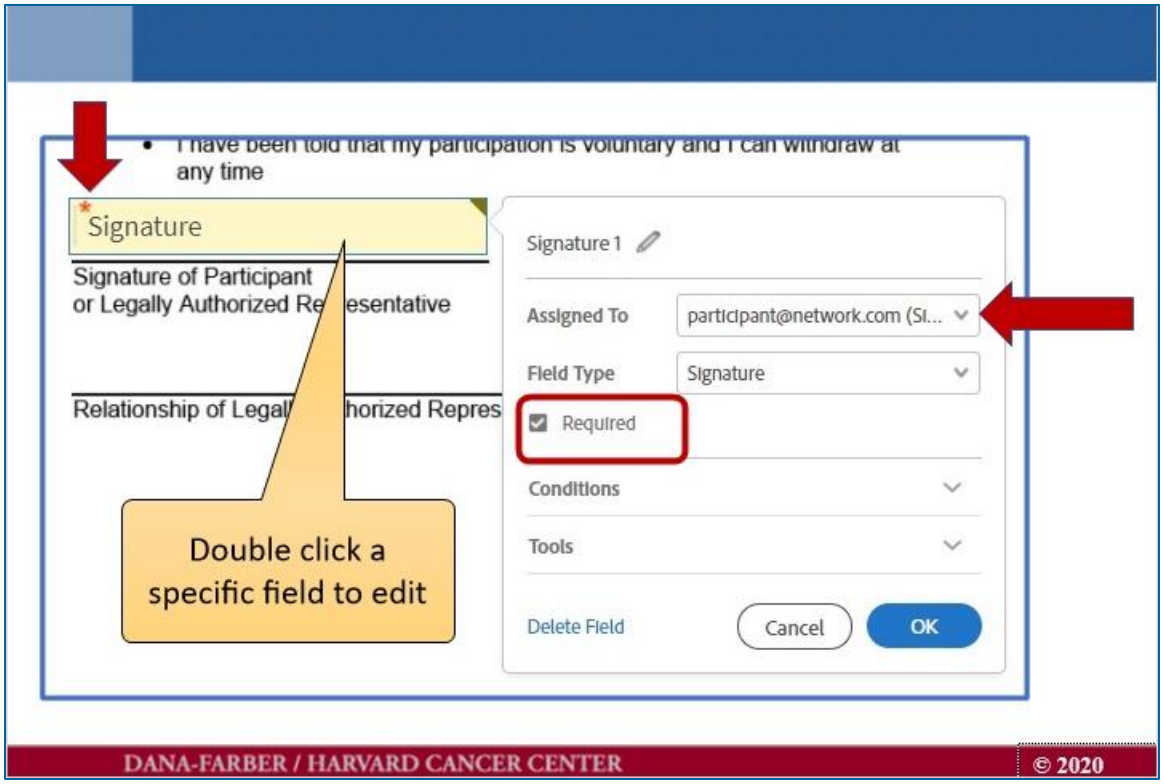
Notice the top right corner of the screenshot above shows the **Recipients** list and highlights the current **Signer** in the recipients in blue. Also notice on the consent form

itself the **Signature** field we added has a blue flag in the top right corner indicating it is assigned to the Investigator.

4.7 Editing a Specific Field and Adding Conditions

You can make changes to any field after it's placed on the document by double-clicking on or right-clicking to edit the field. Edits to the field include changing who is assigned to the specific field, marking it as required, or other applicable changes based on the type of field added.

As described earlier, you can change the recipient assigned to a field, by selecting the appropriate individual in the **Assigned To** drop down box.



To make the field required, check the **required box** to ensure that the signer does not skip over any required components. You can tell a field has been marked required by the **red asterisk** in the top left corner of the field. It is best practice to mark each field as required as any missed fields cannot be edited after the document is signed.

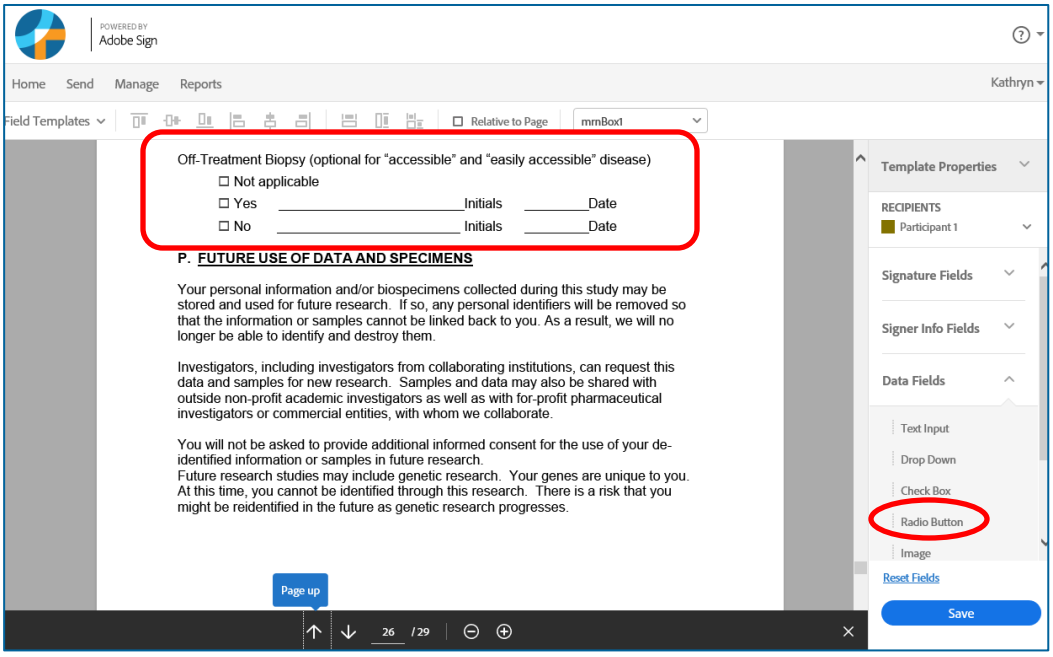
Another edit you can make it to add conditions that will hide or show fields based on previous responses in the document. One example of when you may need to set up conditions is for fields related to optional studies.

For example, optional studies will frequently have a **Yes** or **No** response and if the participant answers one of these responses, they will need to mark their initials and date next to the response given, but nothing next to the response they didn't choose. With this

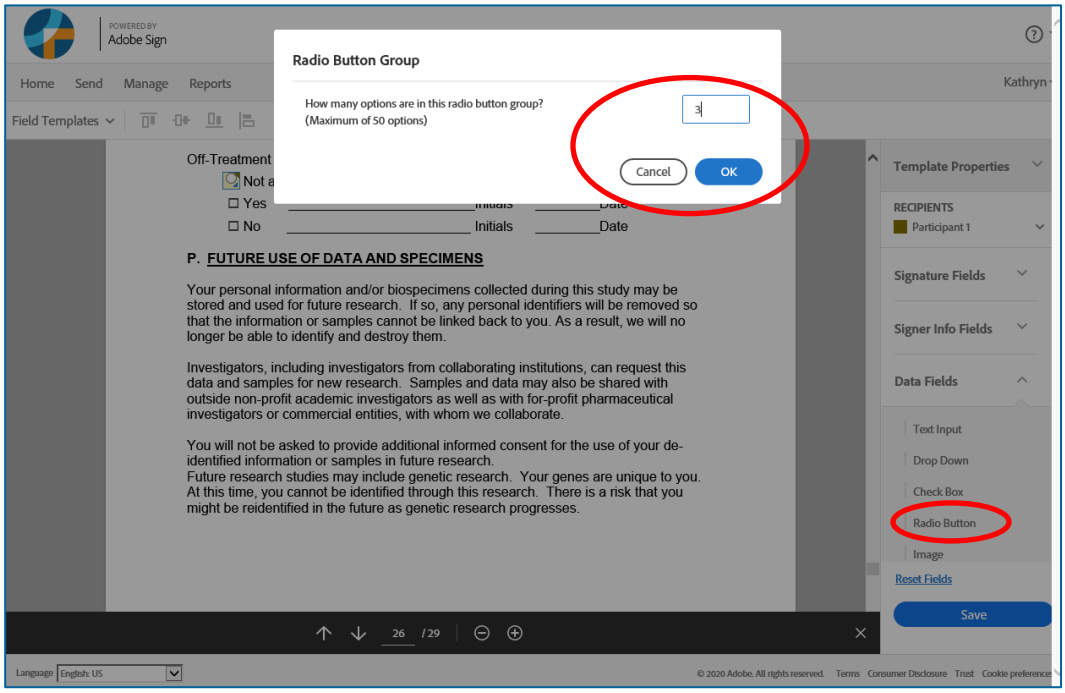
example you would add **Radio Button** fields to the optional studies section (see Section 4.11 for more information about **Radio Buttons**), and then set the **initials** and **date** fields to be conditional in relation to the **radio button** response. See the step-by-step guide below for how to set up these conditional fields with radio buttons.

Step-by-step Guide to Additional Fields with Conditions using Radio Buttons:

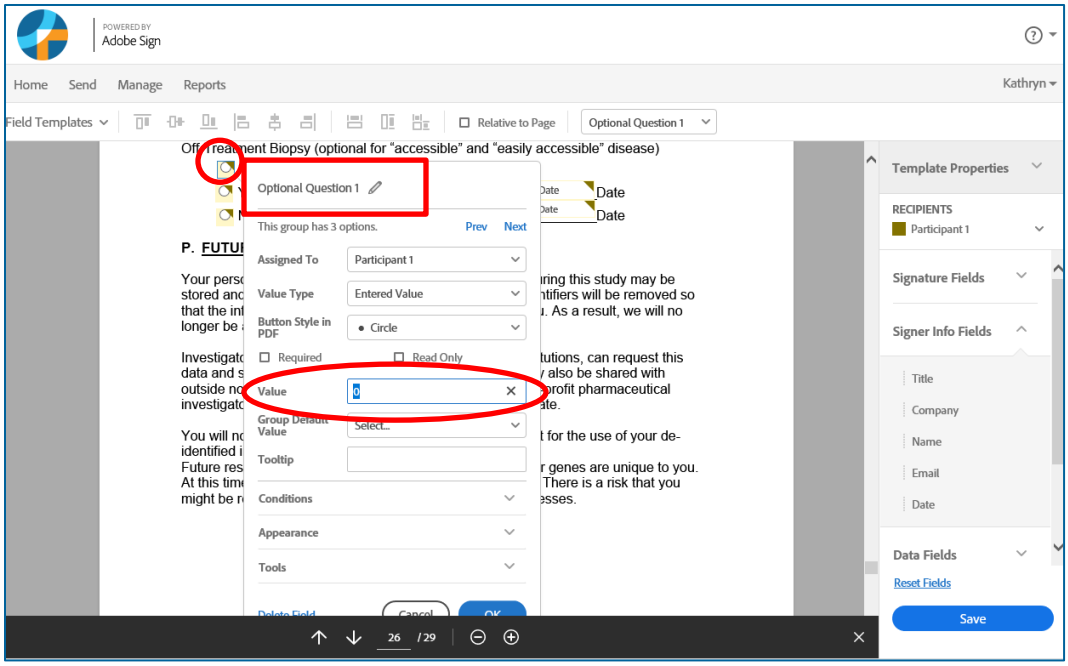
Step 1. Locate your optional question and confirm there are initials and date lines next to each response a participant could give (see example to the right). Note: some optional study questions have only one initial and date line and will therefore not need to follow this conditional response requirement.



Step 2. Add **Radio Buttons** by dragging **Radio Button** over from the **Data Fields** drop down list. Enter the number of options available. This question has 3 options (Not applicable, Yes, No), so enter **3** options. If your optional question only has 2 responses (e.g., Yes or No), enter 2 options. Position the radio buttons to fit directly over the applicable responses on the consent form – make sure they line up with the correction location and are **Assigned To** be completed by the participant. Next add 2 fields for **initials** and 2 fields for **dates**, placing them on the initials and date lines next to the **Yes** and **No** options on the consent form (see Section 4.4 for details about **Initials** fields; see Section 4.5 for details about **Date** fields).

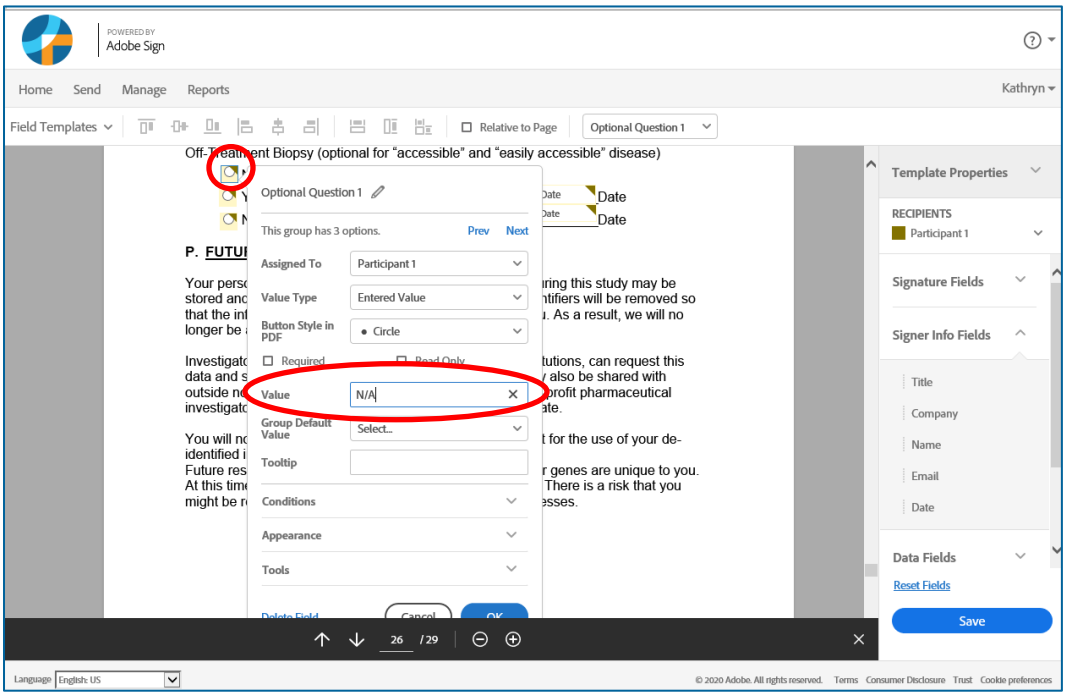


Step 3. Double-click or right click to edit the radio button you added in Step 2. First, change the name of the **Radio Button** to fit the optional question number or description. In this example we've named the question **Optional Question 1**. We could've also named it **Off-Treatment Biopsy Optional Question** as another way of identifying the question. Adding a name will help you

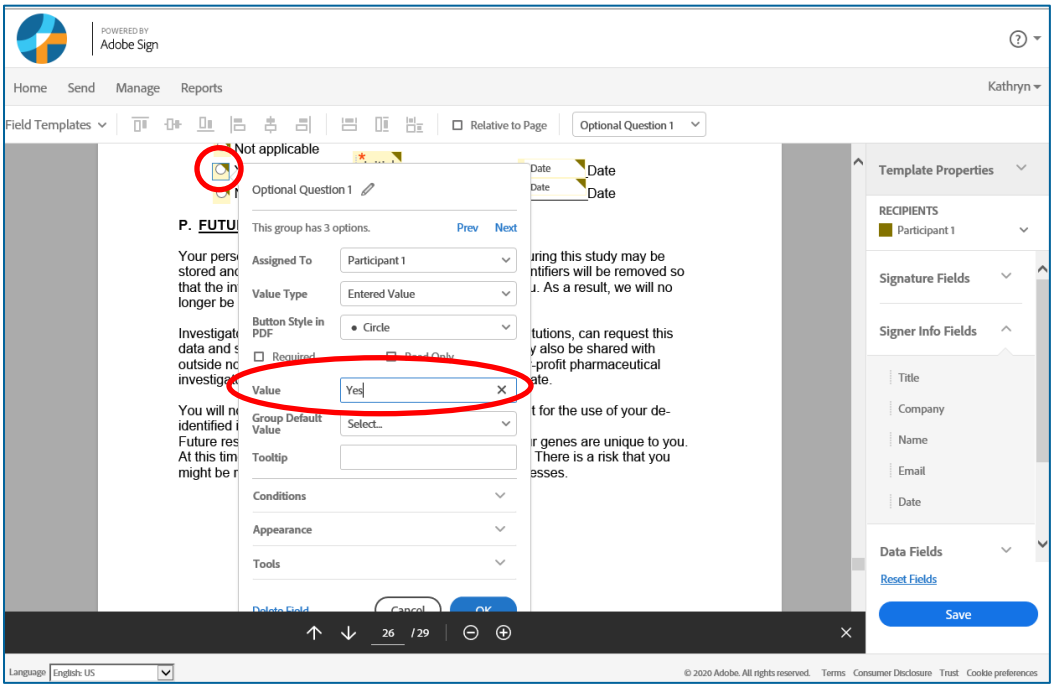


identify the condition later in future steps.

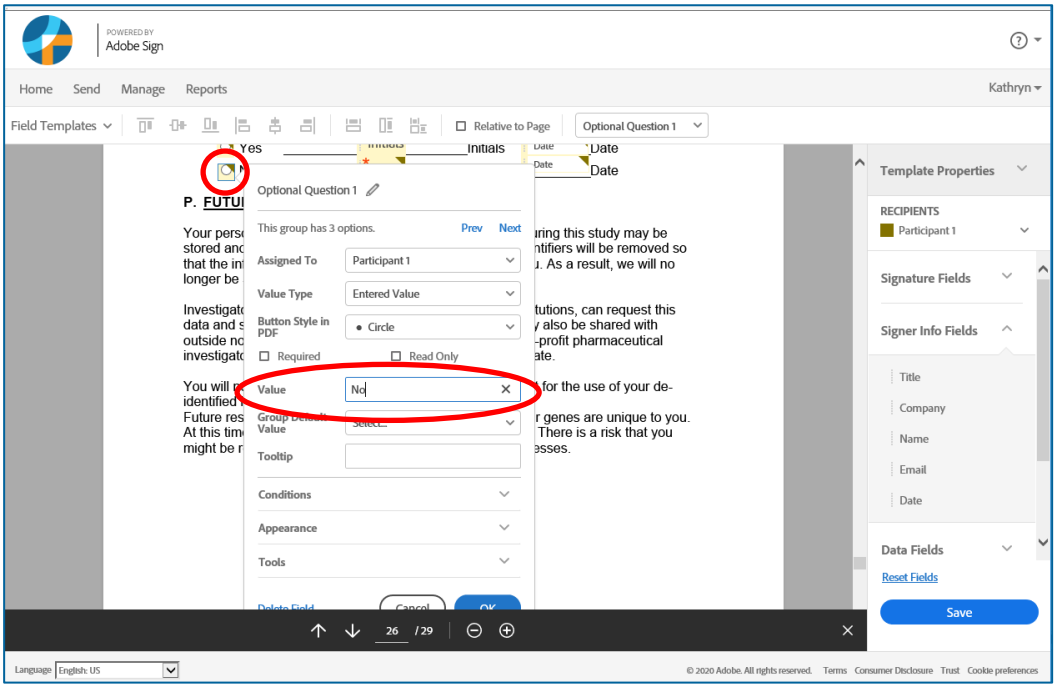
Step 4. Next you will notice the first **radio button** you are editing has a value of **0** (red oval on screenshot above). Each **Radio Button** in Adobe Sign Fields automatically defaults to the order it was entered. In this case with 3 responses, the default values are **0**, **1**, and **2** (for **Not applicable**, **Yes**, **No**). Change the value of each response to fit the response it corresponds with by typing into the value box. In this screenshot, we changed the **0** to be **N/A**.



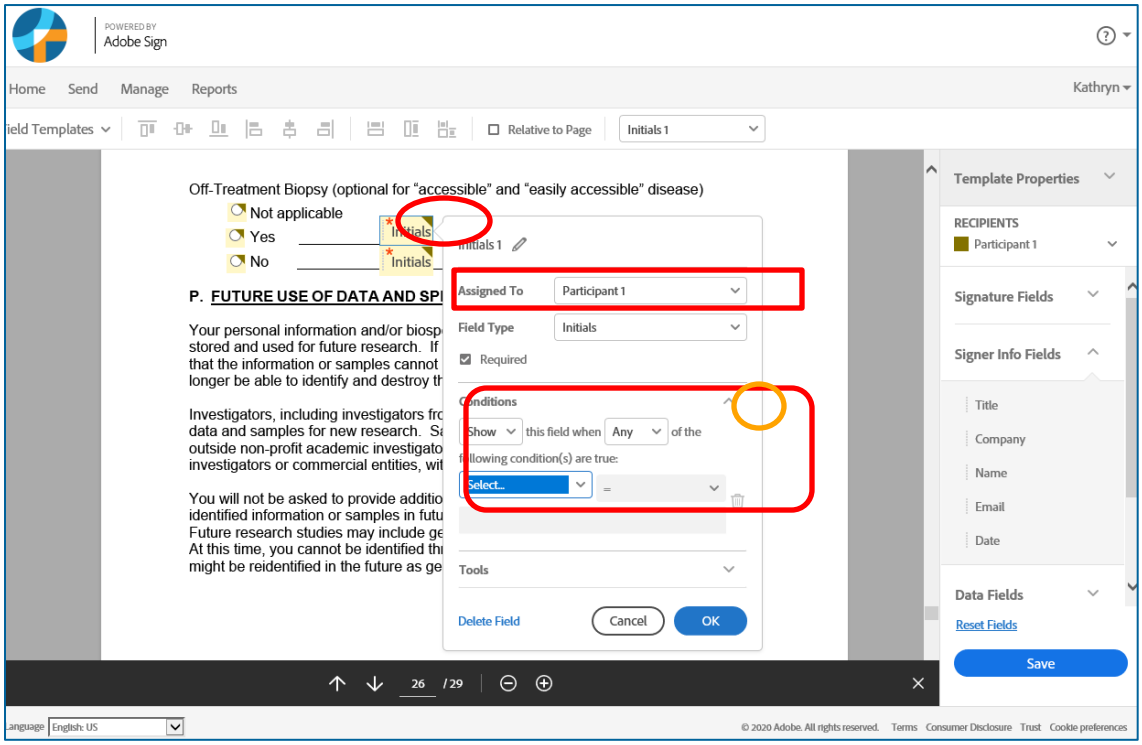
Continue to follow this step for the remaining **Radio Button** responses. Double-click or right click on the next **Radio Button** next to **Yes** and change the value listed to be **Yes**. Click OK.



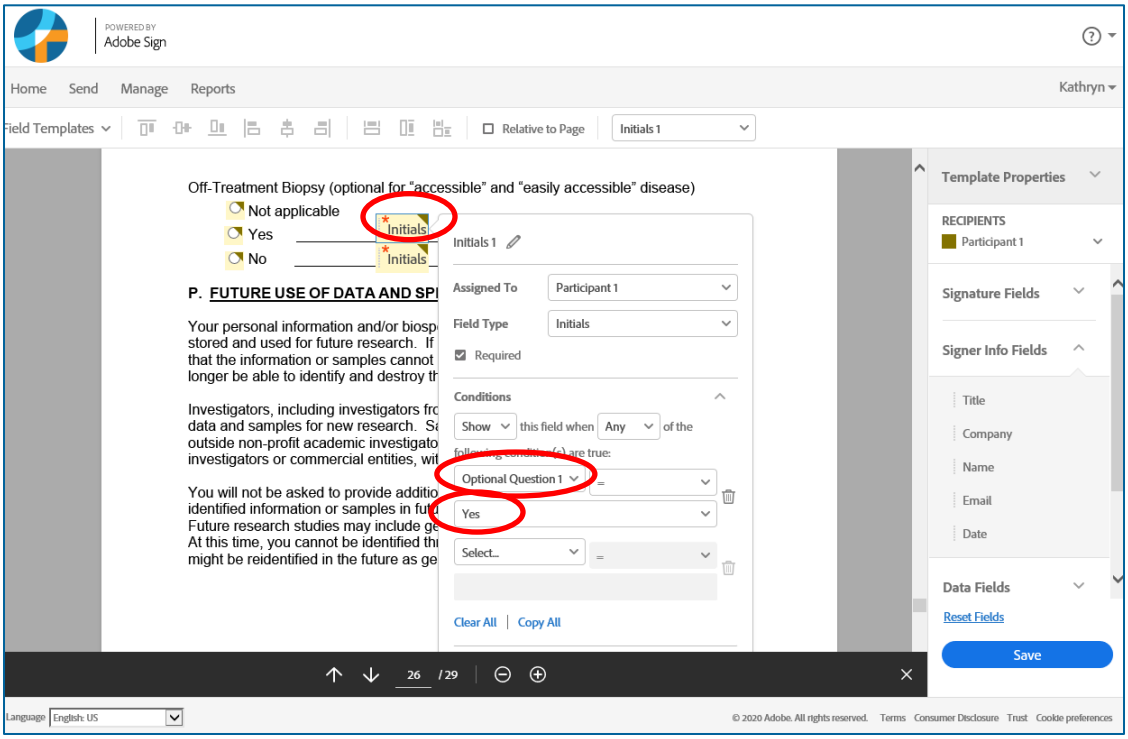
Double-click or right click on the next radio button next to **No** and change the value listed to be **No**. Click OK.



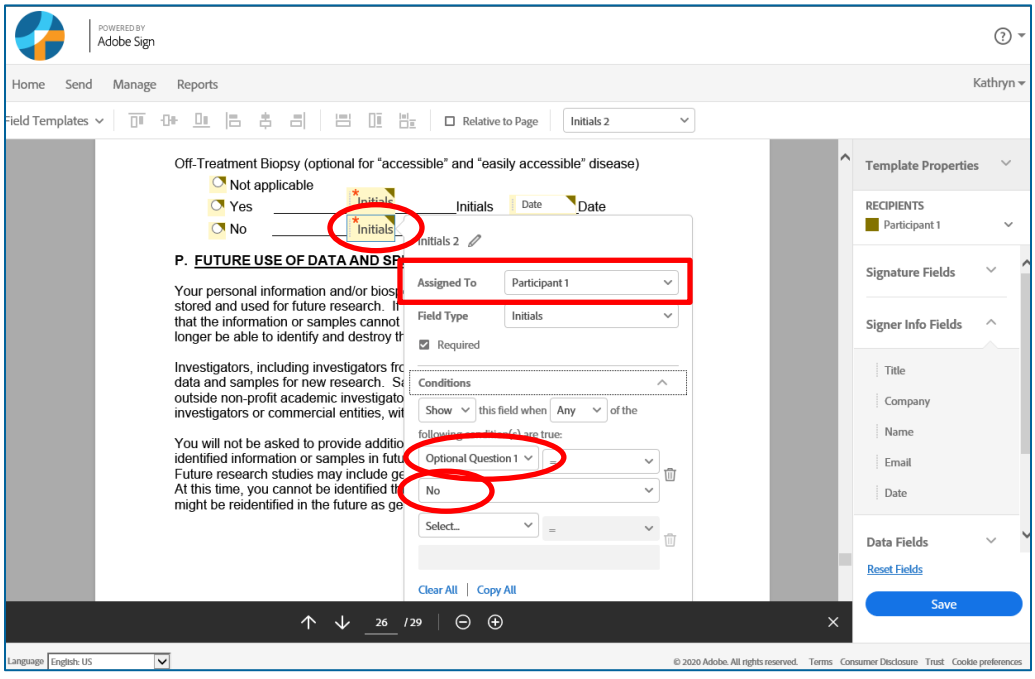
Step 5. Double-click or right click on the first initials field corresponding with the **Yes** response and on the same line as the **Yes Radio Button**. Check that the field has been **Assigned To** the participant. Next click the **grey arrow** (circled in orange) next to Conditions to show more details. Leave the **show** and **any** as they are selected already.



Under **the following condition(s) are true**, select the name of the field you want to refer to. In this case we select **Optional Study 1** (the name we gave the group of **radio buttons** in Step 3). Keep the next field as **=**. The next field will auto-select the first response corresponding with the first **radio button** we named in step 4 - **N/A**. Because this first **initials** line corresponds to the **Yes** response, change the selection here to be **Yes**. Click **OK**.

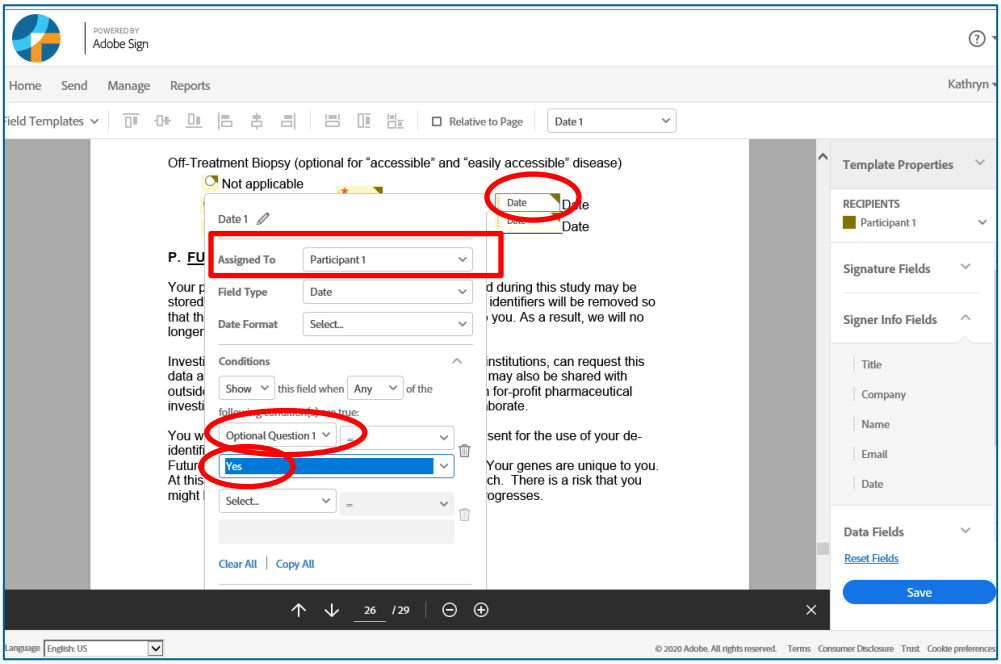


Follow the same process for the second **initials** field. Double-click or right click on the second **initials** field corresponding with the **No** response and **No Radio Button**. Check that the field has been **Assigned To** the participant. Next, click the **grey arrow** next to Conditions to show more details. Leave the **show** and **any** as they are selected already. Under **the following condition(s) are true**, select **Optional Study 1**. Keep the **=** as is. Again, the next field will auto-select the first response

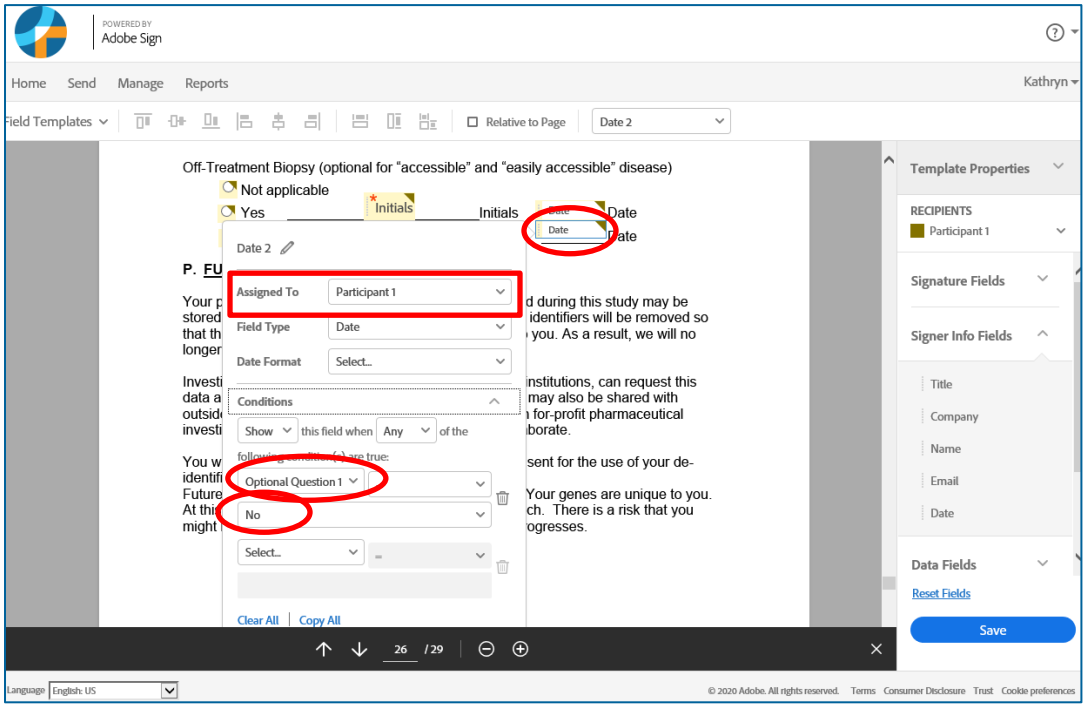


corresponding with the first **radio button** we named in step 4 - **N/A**. Because this second **initials** line corresponds to the **No** response, change the selection here to be **No**. Click **OK**.

Step 6. Repeat the same steps as step 5, but with the **date fields** corresponding with each response line. Double-click or right click on the first **date** field corresponding with the **Yes** response and **Yes Radio Button**. Check that the field has been **Assigned To** the participant. Next, click the **grey arrow** next to Conditions to show more details. Leave the **show** and **any** as they are selected already. Under **the following condition(s) are true**, select **Optional Study 1**. Keep the **=** as is. The next field will auto-select the first response corresponding with the first **radio button** we named in step 4 - **N/A**. Because this first **date** line corresponds to the **Yes** response, change the selection here to be **Yes**. Click **OK**.



Follow the same process for the second **date** field. Double-click or right click on the second **date** field corresponding with the **No** response and **No Radio Button**. Check that the field has been **Assigned To** the participant. Next, click the **grey arrow** next to Conditions to show more details. Leave the **show** and **any** as they are selected already.



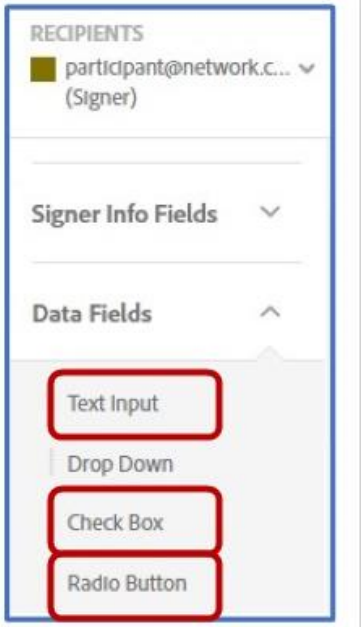
Under **the following condition(s) are true**, select **Optional Study 1**. Keep the **=** as is. Again, the next field will auto-select the first response corresponding with the first **radio button** we named in step 4 - **N/A**. Because this second date line corresponds to the **No** response, change the selection here to be **No**. Click **OK**.

Step 7. Repeat steps 1-6 for any remaining optional questions with **initials** and **date** lines next to each response. Remember that optional questions with only one **initial** and **date** line next to both or all responses will not need to follow this conditional response requirement.

4.8 Other Commonly Used Fields

You may need to use a few other data fields in a typical consent document. The most common fields are **Text Input**, **Check Box**, and **Radio Button**. All three of these fields can be found under the **Data Fields** drop down. When and where you use each of these may depend on the elements of your specific consent.

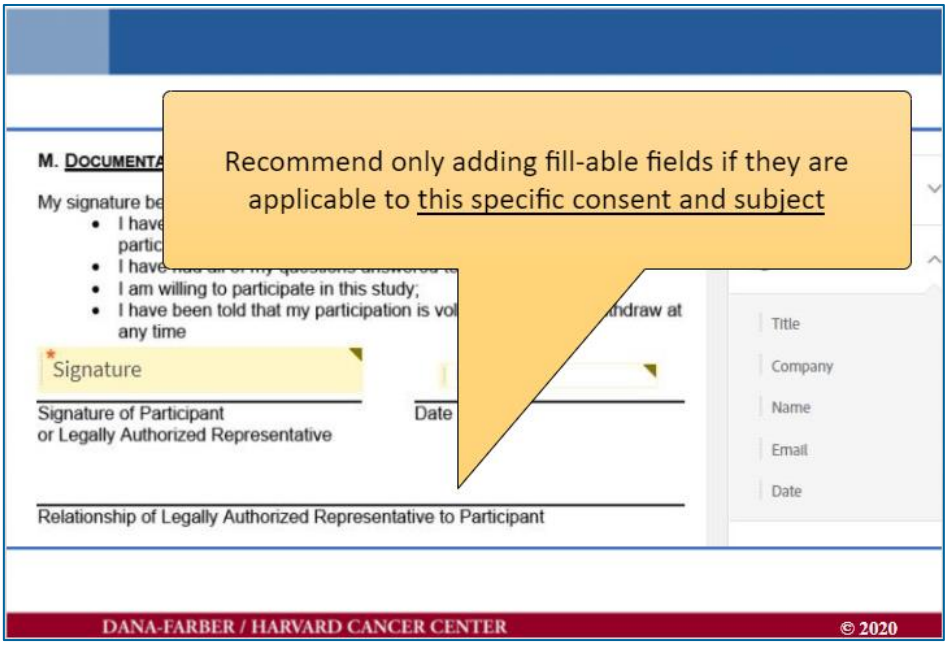
The **text input** field allows for manual entry of text, values, dates, etc. For example, the date the consent discussion was initiated on many consent forms will often be a different date than the signature date, so a **text input** field should be used instead of a date field. We'll discuss how to format the specific field for date the consent discussion was initiated in Section 4.9. Another example of using a **text input** field is in the top right corner of the consent to add the participant's name and MRN. If you are sending a one-off consent, you can add the participant's name and MRN to the pdf before uploading the document into Adobe Sign. However, if you are creating a template, you want to make this field a pre-fill option (to be completed by you or the person sending the form) on each page of the consent document. See Section 4.6 for more information about how to assign a field as needing pre-fill.



Check boxes are used if there's only a single option, or if more than one option can be selected. For example, **check boxes** should be placed at the end of a typical consent form where the person obtaining informed consent confirms elements of the consent process. Additional information about **check boxes** is in Section 4.10.

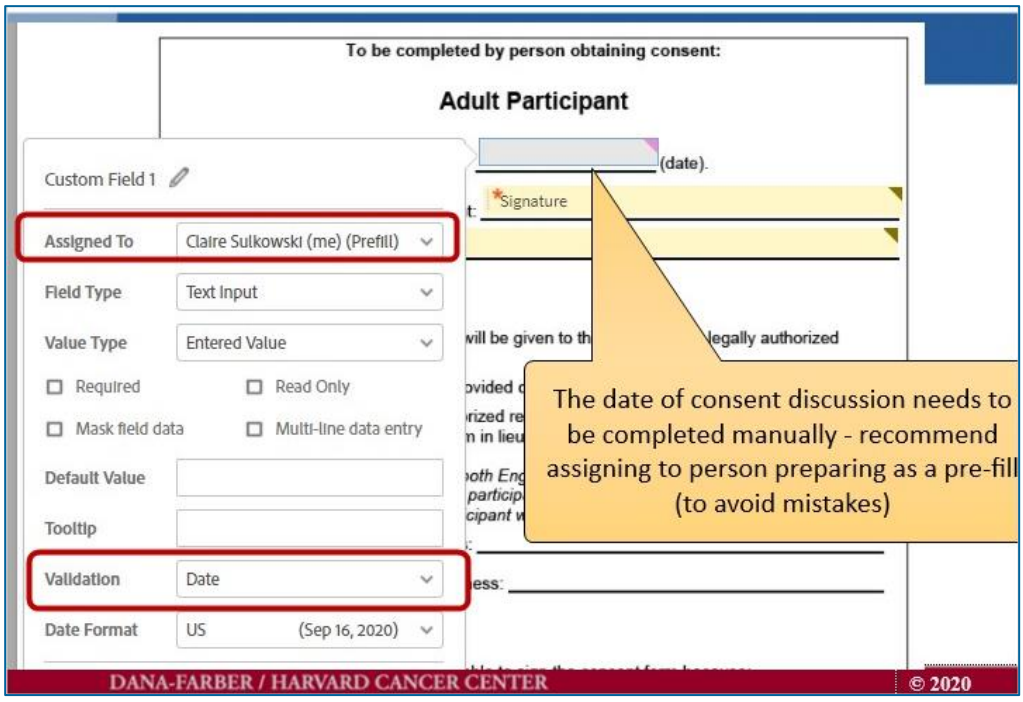
Radio buttons must be used when there are two or more options and the signer must only select one. One example of this is when a participant must select a yes or no for participation in an optional study. Additional information about **radio buttons** is in Section 4.11.

Section 1 of this guidance referenced requirements for any 3rd party signing on behalf of the subject, indicating they would need a verified email address document in the subject's chart. To avoid mistakes or confusion, we recommend not adding any fill-able fields or check boxes to the consent form if they are not applicable to the specific study. An example of this is the line asking the relationship of the LAR to the participant. Only add a text input field here IF in fact a LAR is being used for the subject's consent.



4.9 Text Input – Date Consent Discussion Initiated

DF/HCC consent forms contain a field asking for the Date the consent discussion was initiated. The date of this discussion could be a different day than when the investigator or person obtaining consent is ready to sign the consent form.



As mentioned previously, a **Date** field pulled under the **Signer Info Fields** is always associated or attached to the signature, meaning it will automatically populate when the signature field is completed.

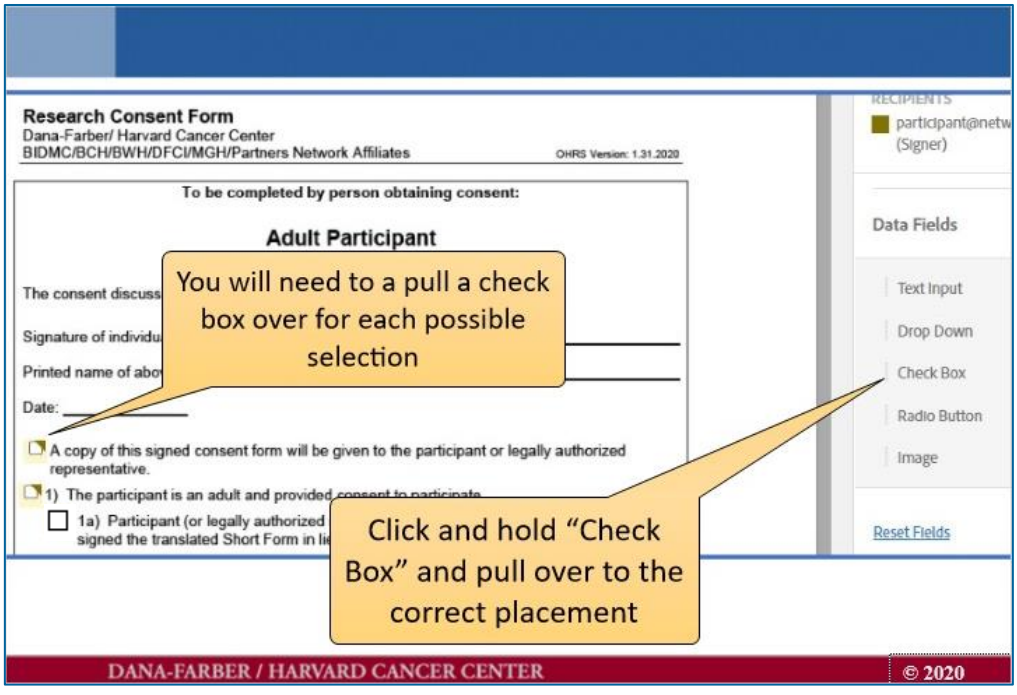
Therefore, you will need to add a **Text Input** field for the DF/HCC consent section asking for the Date the consent discussion was initiated.

You can either **pre-fill** the date information prior to sending the document to the participant or you can assign this field to the person obtaining informed consent to complete. You can create a pre-fill field by changing the **signer** responsible for the field and selecting yourself to prefill the information. See Section 4.6 for details on how to change the assigned recipient of a field.

Make sure the field is marked as **Required** and that you've set the text format to capture a date. To format the **Text Input** Field into the date format, select the **Validation** drop down in the edit window and select **Date**. Note that there are many other formatting options under **Validation** that you may need to utilize at some point.

4.10 Checkboxes – How to Add and Edit

Check boxes can be added to the consent template by clicking and dragging them onto the document from the **Data Fields** drop down list. **Check boxes** are not grouped together, rather they are independent fields and must be added and modified individually.



Check boxes can be used in several instances on a consent form template. One example is under the section "To be completed by person obtaining consent" section typically found at the end of the consent form. In this section, add **check boxes** for the first two attestations in that documentation section "A copy…etc." and "1) The participant is an adult…etc." The person obtaining consent will need to attest that a signed consent form will be given to the participant, which will

happen automatically via Adobe Sign, and will also need to attest that the participant is an adult providing consent.

See Section 4.8 about avoiding potential mistakes with check boxes you may not need on the "To be completed by the person obtaining consent" section.

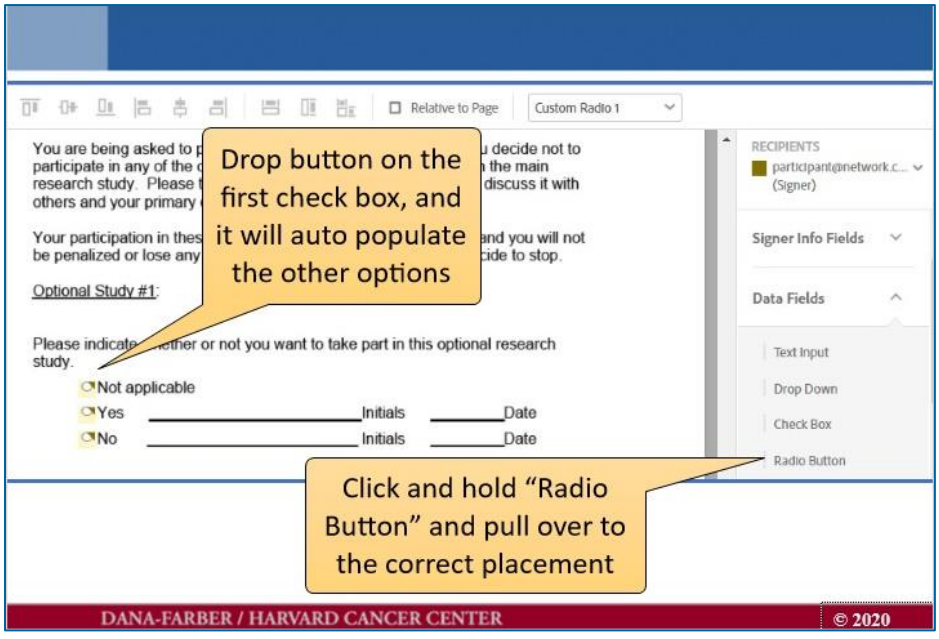
Note that **Check boxes** should not be used for questions with multiple option where only one option can be selected as the answer. For example, optional study questions typically have a Yes or No response for the participant to indicate participating in or declining optional studies. For this type of question/answer, use a **Radio Button** (see Section 4.11).

You will always want to confirm who is assigned to complete the **check box** and mark the field as **required**. As described in Section 4.7, you can edit these functions of the **check box** by double-clicking or right-clicking on the field.

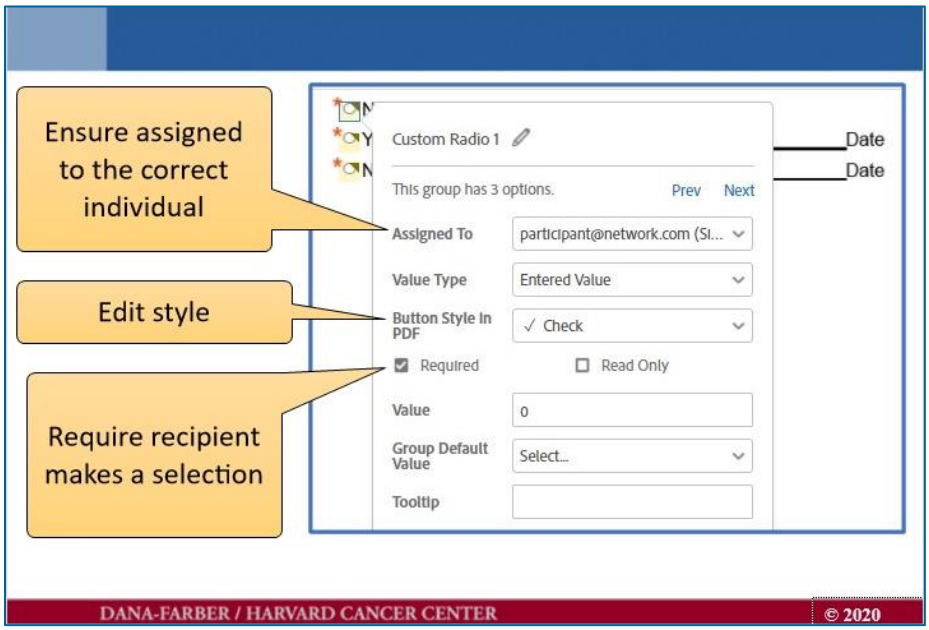
4.11 Radio Buttons – How to Add and Edit

Radio buttons can be added by clicking and dragging them onto the document from the **Data Fields** drop down list. **Radio buttons** are added in groups and are linked to allow only one selection within a group, so they are typically used for optional questions in a consent form.

When you drag a **radio button** field onto the form, you need to enter the number of options available. For example, the screen here displays an optional study with 3 options of **Not applicable**, **Yes**, and **No**. Based on these responses, you would select one **radio button** dragged onto the form and you'd enter **3** for the number of options. Optional questions with only Yes and No as the options would have one **radio button** dragged onto the form with **2** options selected.



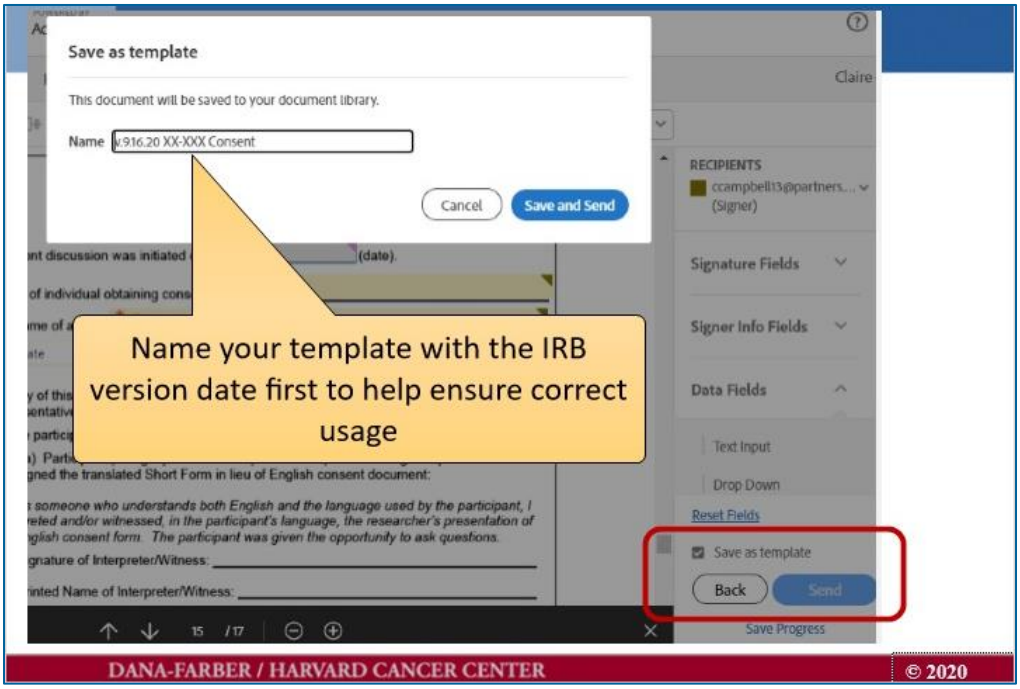
Once you've selected the number of options, position the **radio buttons** to fit directly over the applicable responses on the consent form – making sure they line up with the correct location.



By double-clicking or right-clicking the **radio buttons** you can change the style of the **radio button** to match the consent form itself - for example, if you want it to appear as a box rather than a circle. You can also confirm that the **radio buttons** are assigned to the appropriate **Recipient** (see Section 4.6 for details on assigning recipients). Finally, make sure the radio buttons are **Required** if the signer must select one of the options.

4.12 Review and Save Template

Once you are finished adding and editing Adobe Sign fields, review the consent document thoroughly one last time before sending. Ensure all fields are placed correctly in their applicable locations and assigned to the correct recipient. Ensure all required fields have a red asterisk.



If you're adding a template to your Adobe Sign template library in advance for use later, you can now save your template in the library.

If you're creating an Adobe Sign consent template by using the consent form you will send the very first time

you send a consent form to a participant to sign in Adobe Sign, you can save your document as a template for future.

Note that only the template-owner / original creator of a template can edit the template. This means if someone who created the template leaves your group, you or your group's manager will need to contact DFCI IS to have that account removed and templates removed.

No matter which method you choose, make sure to name the template consent and accompanying documents with the protocol number, type of document, and date posted for use. An example of this format is *XX-XXX Consent Form Posted for Use 01OCT2020*.

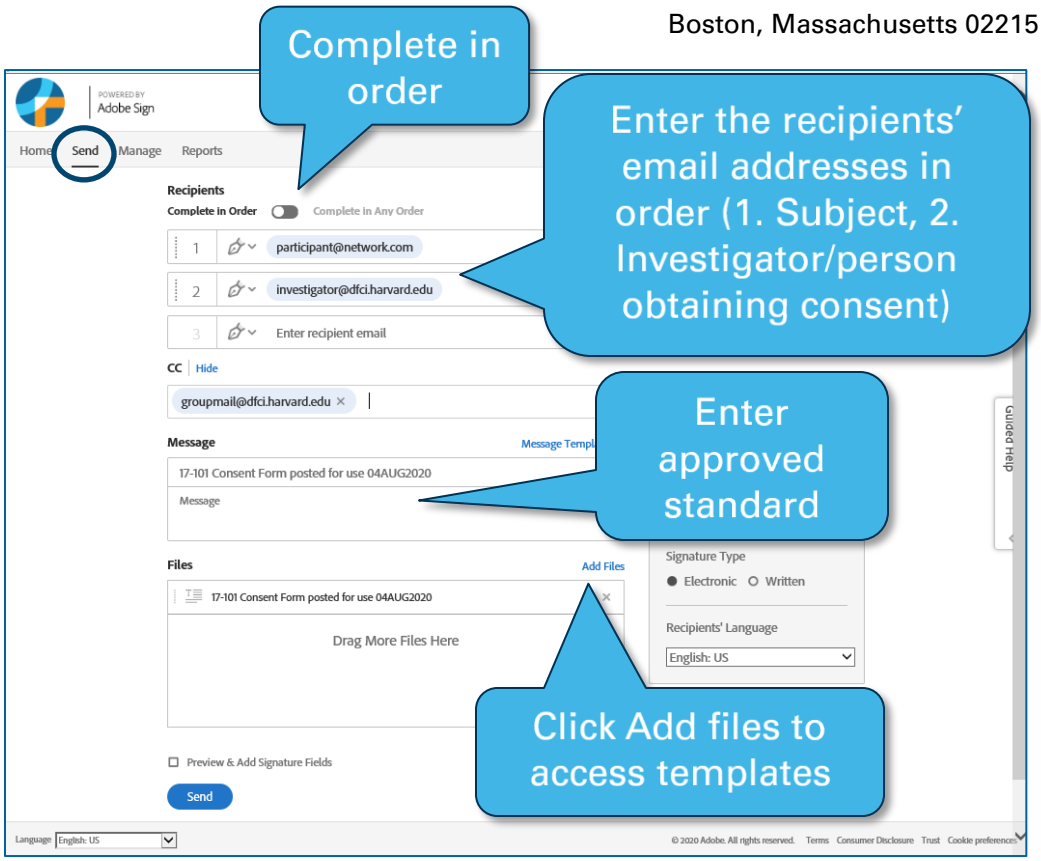
Keep in mind that study teams are responsible for ensuring templates are revised or deleted when a new version of the consent form is IRB approved and posted to OncPro.

If a new consent is posted to OncPro and the fields on your previously created consent template have not changed, you can transfer the fields you created on the first template over to the new template. Please see Adobe Sign's instructions about creating a layer template for more information about how this is down. An alternative to the layer template option it to start a new template from scratch (see Sections 4.1 and 4.2).

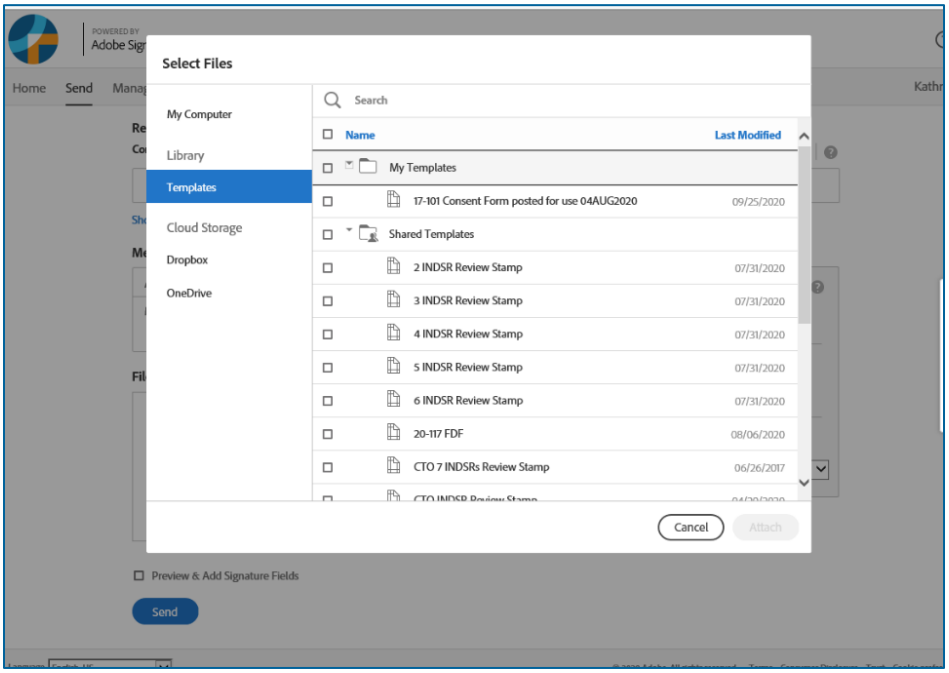
5. Using an Adobe Sign Consent Template Already Created

After you've signed into Adobe Sign (see Section 3 of this guidance), start on the **Send** page.

The first section is **Recipients**. Always make sure the **Complete In Order** toggle is set when you are sending a consent document so that the potential participant is required to sign before the investigator or person obtaining consent. In the **Recipients** section, enter the participant's email address in the first box, then add a second recipient field for the email address of the investigator or person obtaining consent. Always make sure to double-check that you are entering the correct participant contact information in the recipients section. A carbon copy or **CC** field is located directly below the initial recipient email boxes. You can use the **CC** field to send a copy of the signed consent to a study team mailbox or other research team member.



The next section is a **Message** field that allows you to enter custom language to appear in the email notifications sent to both signers (the participant and the Investigator or person obtaining consent). Note that any language entered in the **Message** field is a communication to the research subject. Centrally confirmed DFCI language for the **Message** field is available on the DF/HCC website. Any changes to this language must be reviewed and approved by the IRB of record for each protocol separately. Additional instructional language for participants with step-by-step Adobe Sign instructions has also been centrally confirmed by DFCI and can be sent to the subject. These instructions are also listed on the DF/HCC Website. See section 1 for more information about IRB approvals needed for the Adobe Sign process with consents.



Consent templates previously created can be accessed on the **Send** page by clicking **Add Files**. A new **Select Files** window will appear showing any templates created for your own use under **My Templates** and templates your group created that you have access to under **Shared Templates** (See Section 4.1 for details

about adding Templates within your group). If you are using a previously saved template, you should NOT be uploading a consent form PDF into Adobe Sign. The template you select in the above step replaces the need to upload a separate PDF consent form.

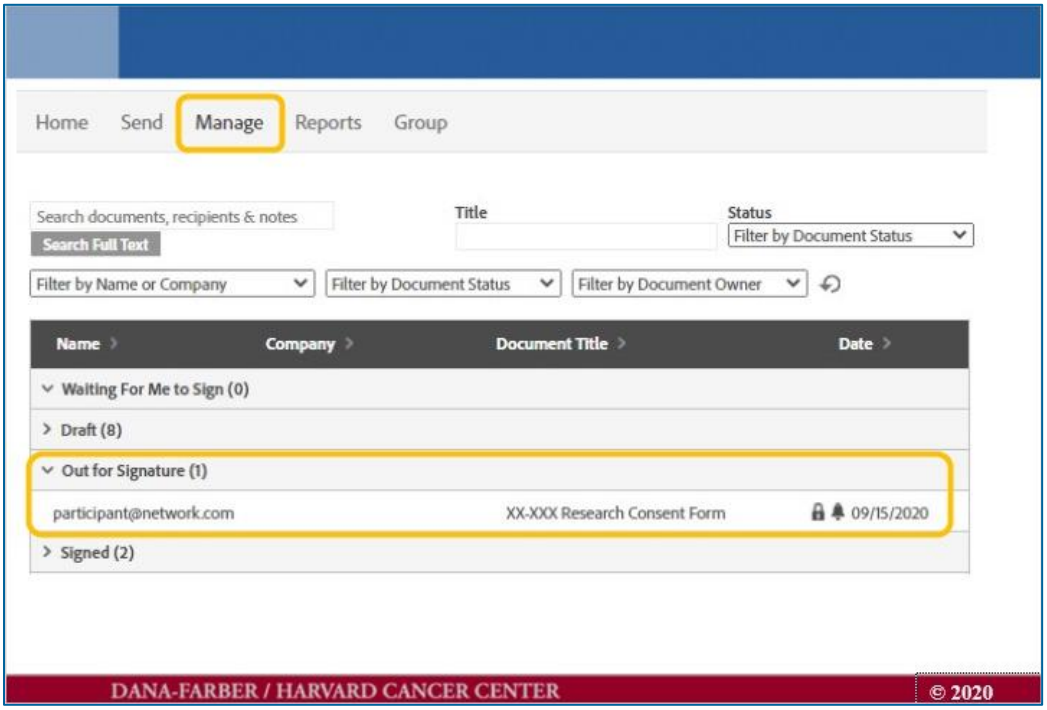
Note that only the template-owner / original creator of a template can edit the template. This means if someone who created the template leaves your group, you or your group's manager will need to contact DFCI IS to have that account removed and templates removed.

Confirm the consent template you are about to attach is the most recently approved and posted for use version on OncPro. **Attach** the consent and any supplementary forms you downloaded. **Click Preview & Add Signature Fields** to pre-fill any required pre-fill items and confirm the fields are assigned to the appropriate recipient (See Section 4.6 of this guidance document for more information about assigning recipients). Always make sure to double-check that the correct participant information is on the document before sending. Once you have reviewed all fields, click **Send**.

6. Other Helpful Tips for the Adobe Sign Consent Process

6.1 Adobe Sign Reminders

Once you have sent your document for signature, you will be able to track its progress. If you are the sender, you will automatically receive email updates when each recipient completes and signs their part of the consent form. You can also login to the Adobe Sign and go to the **Manage** tab to check on the status and send an automated reminder to the recipient whose signature is currently outstanding.



To send a reminder, select the correct document, add the centrally confirmed standard language from the DF/HCC Website and click

send reminder. Keep in mind that if it is the participant who still needs to sign the consent form, you should put the centrally confirmed language from the DF/HCC Website in the **Message** field of the **Reminder**. Any additional language sent with the reminder must be approved by the IRB. Details about how often you plan to send reminders should be included in the updated recruitment plan you describe as part of your amendment to the IRB.

Remember – do not schedule any screening procedures until you have received the fully signed consent form.

6.2 Saving an Adobe Signed Consent Form

The complete and signed consent form will automatically be sent to the participant, fulfilling the requirement in DF/HCC Policy CON-100 to provide them with a copy of the signed consent.

The sender, or another designated study team member, will need to save a copy of the signed form to the participant's research file for appropriate record-keeping. Additionally, signed research consents must be sent to DFCI's Health Information Services (HIS) for documentation in the participant's Epic Medical Record. DFCI study teams can email the Adobe Signed consent form to HIS: DFCIHIS_ScanningDocuments@DFCI.harvard.edu. Be sure the consent is labeled with the potential patient's name and medical record number (MRN), or if either is missing from the consent document, include this in the body of your email to HIS. The HIS team will upload the consent form into the medical record.

6.3 Consent Errors

Once the consent is sent and signed in Adobe Sign, the document will be completed and finalized, and you will not be able to go back and edit it. This is also true of partially signed consent forms (e.g., a participant makes an error before the investigator has signed.)

The Adobe Sign certificate information on the fully signed consent and the content of the document may not be changed once the document is signed.

Any errors on a completed and signed Adobe Sign document cannot be corrected as the document and certificate is certified and tamper proof. If you notice any errors on the document, you will need to send a new consent document for completion and signature and delete the previous document.

6.4 Difficulty with Signing Forms

If a participant notifies you that they are unable to sign the consent via Adobe Sign, contact your research manager or the CTO, do not contact IS.

If an investigator or other DFCI staff member notifies you that they are unable to sign the consent via Adobe Sign, ensure they are following the appropriate instructions on the DFCI IS Intranet Page for Adobe Sign page. If they are still experiencing difficulty signing the consent, contact IS.

7. References

DFCI October 2020 Adobe Sign for Consent Training
CFR Title 21, Part 11 – Electronic Signatures
DF/HCC Policy CON-100
DFCI Centrally Confirmed Language for Adobe Sign Message
DFCI Centrally Confirmed Step-by-Step Adobe Sign Instructions for Participants
DFCI IS Intranet Page for Adobe Sign
DFCI Adobe Sign URL
Adobe Sign's Instructions on Creating a Layer Template
DFCIHIS Email Address for Signed Documents