

Document Management: Consent Forms Overview

- Consent forms are required by your responses to application questions.
- Because your consent form templates are tailored to your specific study, the **Consent Forms** section is not presented until all preceding application sections have been completed.

At Step 1--

Download template:

- Download/save required consent form template(s) to your computer—and edit;
- or
- Otherwise satisfy document requirement(s).

Scroll to slide #2 for Step 1 details

At Step 2--

Upload edited template:

- Assign **Document Type**;
- *Browse* computer for your edited template; and
- *Upload Consent Form*

Scroll to slide #3 for Step 2 details

At Step 3--

Manage documents uploaded at Step 2 (now listed at Step 3):

- Download to edit
- Replace with a revised version
- Rename your file
- View Version History
- Delete document

Scroll to slide #4 for Step 3 details

Application Consent Forms Reference ID: 132091

Current Application: [Quick View \(HTML\)](#) [PDF](#) [View Revisions](#) [Delete Submission](#)

The consent form templates listed below have been automatically created according to the answers you provided on the application. This means that some consent form sections have been added and others deleted to fit the study circumstances you have described. You will still need to edit with study-specific details, following the steps below:

>> 1. DOWNLOAD CONSENT FORM TEMPLATE

Click the template name to either download the required consent form template to your computer **OR** indicate why you are not providing the form at this time.

Next, edit the template, providing study specific details. Save to your computer. Assign each form a unique file name. ([Why is this important?](#))

GENERATE REQUIRED CONSENT FORMS

- ✓ [Adult Consent Form](#)
- ✗ [Text for Consent Embedded in Survey](#)

GENERATE FORMS NOT LISTED ABOVE

[View list](#)

>> 2. UPLOAD NEWLY-CREATED CONSENT FORMS

Use this section to upload your newly-created consent forms not already listed below. Select the appropriate *Document Type*; click *Browse* to locate the edited consent form on your computer; and click *Upload Consent Form*.

Use step 2 the first time only for each form; once uploaded, revise and replace using step 3 below.

Document Type:

Attachment: [Browse...](#)

New Documents Only

[Upload Consent Form](#)

NOTE: If you need to create a consent form to use with an additional group or cohort, download a copy in step #3 below, make the necessary changes, save to your computer with a unique file name and upload in step #2 above.

>> 3. REVISE/REPLACE PREVIOUSLY UPLOADED CONSENT FORMS

Click the file name to: download, replace, rename, delete, or view version history.

File Name	Document Type
Adult Consent Form test 022513.docx	Adult Consent Form

Uploaded by: David Tegnell On: 07/17/2015 At: 01:58 PM

Document Management: Consent Forms

Step 1 (Download template)

- Consent requirements are listed at the top of **Step 1**.
- Click [blue linked file name](#) to access actions pop-up

Click [Click here to download](#) to access/save the editable consent form template to your computer

Check a box to alternatively satisfy a consent requirement

- Click [Why is this form required?](#) to display the application question triggering the requirement;
- Click the [trigger-question link](#) to jump to the application where you may review/revise your response and remove the requirement, if appropriate

>> 1. DOWNLOAD CONSENT FORM TEMPLATE

Click the template name to either download the required consent form template to your computer **OR** indicate why you are not providing the form at this time.

Next, edit the template, providing study specific details. Save to your computer. Assign each form a unique file name. ([Why is this important?](#))

GENERATE REQUIRED CONSENT FORMS

- ✓ [Adult Consent Form](#)
- ✗ [Text for Consent Embedded in Survey](#)

Consent Form Template: ✗

[Click here to download](#)

I am not using this template because:

- Full waiver of consent requested in application (Section D.3.)
- Waiver of written consent requested in application (Section D.2.)
- Not Yet Available / Not Applicable
- Consent form no longer in use (enrollment closed)

More Information:

[Why is this form required?](#)

Your response to the following question triggered this requirement:

- [D.2. Waiver of written documentation of informed consent](#)
- Consent statement incorporated into a survey itself

IRBIS indicates whether a requirement has been satisfied:

- **Green checkmark** = requirement satisfied
- **Red X** = requirement not satisfied

If you do not find your form listed as a requirement, click [View list](#) to display all other templates in the library

- Click any [blue linked document type](#) to display its application trigger-question.
- Click the [question link](#) to jump to the application where you may review/revise your response, and add a requirement, as appropriate

GENERATE REQUIRED CONSENT FORMS

- ✓ [Adult Consent Form](#)
- ✗ [Text for Consent Embedded in Survey](#)

GENERATE FORMS NOT LISTED ABOVE

[View list](#)

- [Assent Form Ages 15-17](#)
- [Assent Form Ages 7-14](#)
- [Consent Addendum for Current Subjects](#)
- [Focus Group Consent](#)

A response to the following question would trigger this requirement:

- [A.4. Study design, methods and procedures](#)
- [Focus groups](#)

- [HIPAA Authorization](#)
- [Information or Fact Sheet](#)
- [Parental Permission Form](#)
- [SSN Collection for payments](#)
- [SSN Collection for use as identifier](#)
- [Short Form](#)
- [Stored Specimens with Identifiers](#)
- [Stored Specimens without Identifiers](#)
- [Text for Online Consent Form](#)
- [Verbal/Phone Consent](#)

Document Management: Consent Forms

Step 2 (Upload new document)

After you have edited your consent template:

1. Save the file to your computer, using a unique file name (for instructions, click [Why is this important?](#)).
2. From the drop-down list, select the **Document Type** corresponding to the requirement listed in **Step 1**.
3. Browse for and *Upload* your edited consent form.

>> 1. DOWNLOAD CONSENT FORM TEMPLATE

Click the template name to either download the required consent form template to your computer OR indicate why you are not providing the form at this time.

Next, edit the template, providing study specific details. Save to your computer. Assign each form a unique file name. ([Why is this important?](#))

GENERATE REQUIRED CONSENT FORMS

- ✓ [Adult Consent Form](#)
- ✗ [Text for Consent Embedded in Survey](#)

GENERATE FORMS NOT LISTED ABOVE

- [View list](#)

>> 2. UPLOAD NEWLY-CREATED CONSENT FORMS

Use this section to upload your newly-created consent forms not already listed below. Select the appropriate *Document Type*; click *Browse* to locate the edited consent form on your computer; and click *Upload Consent Form*.

Use step 2 the first time only for each form; once uploaded, revise and replace using step 3 below.

Document Type:

Attachment: Browse...

New Documents Only

[Upload Consent Form](#)

NOTE: If you need to create a consent form to use with an additional group or cohort, download a copy in step #3 below, make the necessary changes, save to your computer with a unique file name and upload in step #2 above.

>> 2. UPLOAD NEWLY-CREATED CONSENT FORMS

Use this section to upload your newly-created consent forms not already listed below. Select the appropriate *Document Type*; click *Browse* to locate the edited consent form on your computer; and click *Upload Consent Form*.

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Document Type:

CONSENT-RELATED MATERIALS

- Adult Consent Form
- Assent Form Ages 15-17
- Assent Form Ages 7-14
- Consent Addendum for Current Subjects
- Debriefing
- External Consent Form
- Focus Group Consent
- Foreign Language Consent Form
- HIPAA Authorization
- Information or Fact Sheet

Attachment: Browse...

New Documents Only

[Upload Consent Form](#)

IMPORTANT: Upload only New documents at **Step 2**. Do not use this step to upload revised (replacement) documents.

- Documents uploaded at **Step 2**, will be listed at **Step 3**.
- If the **Document Type** matches the corresponding **Step 1** requirement, the requirement will be satisfied (**Red X** will be converted to **Green check**, **Step 1**).

Document Management: Consent Forms Step 3 (Revise/replace existing document)

>> 2. UPLOAD NEWLY-CREATED CONSENT FORMS

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Use step 2 the first time only for each form; once uploaded, revise and replace using step 3 below.

Document Type:

Attachment: [Browse...](#)

New Documents Only

[Upload Consent Form](#)

NOTE: If you need to create a consent form to use with an additional group or cohort, download a copy in step #3 below, make the necessary changes, save to your computer with a unique file name and upload in step #2 above.

>> 3. REVISE/REPLACE PREVIOUSLY UPLOADED CONSENT FORMS

Click the file name to: download, replace, rename, delete, or view version history.

File Name	Document Type
Adult Consent Form test 022513.docx Uploaded by: David Tegnell On: 07/17/2015 At: 03:51 PM	Adult Consent Form

>> 3. REVISE/REPLACE PREVIOUSLY UPLOADED CONSENT FORMS

Click the file name to: download, replace, rename, delete, or view version history.

File Name	Document Type
Adult Consent Form test 022513.docx	Adult Consent Form

Manage Uploaded Consent Form (Mouse over links for instructional text)

[Download](#) [Replace](#) [Rename](#) [Version History](#) [Delete](#)

[Continue](#)

At **Step 3**, you may manage existing documents, as follows:

- [Download](#) a document for editing
- [Replace](#) an a document
- [Rename](#) your file (without otherwise revising)
- [Delete](#) a document no longer in use
- View [Version History](#)

To access the actions pop-up, click the [blue linked file name](#), then select desired action.

>> 1. DOWNLOAD CONSENT FORM TEMPLATE

Click the template name to either download the required consent form template to your computer OR indicate why you are not providing the form at this time.

Next, edit the template, providing study specific details. Save to your computer. Assign each form a unique file name. [\(Why is this important?\)](#)

GENERATE REQUIRED CONSENT FORMS

<input checked="" type="checkbox"/> Adult Consent Form
<input type="checkbox"/> Text for Consent Embedded in Survey