

# Online Application Features (1)

## Data Entry

>> 1. General Information Reference ID: 261066

1. Project Title \*

My Project Application

2. Brief Summary. Provide a brief non-technical description of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. Please ensure your summary is clear and concise so that reviewers can readily identify the content. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH. \*

Purpose:

Participants:

Procedures (methods):

[Tips and Techniques on using the HTML Editor](#)

3. Is this new study similar or related to an application already approved by a UNC-Chapel Hill IRB? Knowing this will help the IRB in reviewing your new study. \*

Yes  No

If yes, provide IRB study number here (and explain in the COVER MEMO why this is relevant to the current study and why it would be useful for the IRB to know).

\* Required.

To navigate the Application, press continue or any link in the Item List to your left.

[Save and Stay](#) [Save and Continue](#)

Most, but not all, textboxes are rich text formatted. The Tips and Techniques hyperlink has additional information on using the online text editor.

Red asterisk indicates a response is required.

Pull corner to expand.

Responses to radio buttons or checkboxes may open additional questions or textboxes.

## Online Application Features (2)

### Look-ups

Look-ups provide access to personnel and sponsor records maintained in University data bases. IRBIS facilitates search of these databases, and selection and mapping of records into the IRB application, thereby saving data entry time, and ensuring data consistency across integrated systems, campus-wide.

For example, at **General Information / Project Personnel:**

1) Click "[Click here to add personnel](#)" link to open the personnel data entry form.

>> 2. Project Personnel Reference Id: 147236

1. Will this project be led by a STUDENT (undergraduate)

Yes  No

2. List all project personnel beginning with print

- List ONLY those personnel for who are IRE
- If this is Community Based Part
- If your extended research team

The table below will access campus directory inform

[Click here to add personnel](#)

**NOTE: The IRB database will link automatically to separate instructions about COI disclosures. The I**

Personnel Search - Windows Internet Explorer

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The table below will access campus directory information

UNC-Chapel Hill Personnel Search

Enter the last name of the person you are looking for:

PID:

First Name:

Last Name:

Last Name \*

First Name

Address

Phone \*

UNC Email \*

Department Name

\* Required.

lication, press continue or any link in the Item List to yo

y

3) Type the study team member's name or PID to search the campus directory, then:

- Select the relevant record to auto-populate the **Project Personnel** data entry form.
- Please confirm the PID and information for all personnel as there may be multiple similar names.

2) Click the look-up icon (magnifier) to open the **Personnel Search** pop-up.

# Online Application Features (3) Attachment Requirements

meter Measurements on the Evaluation of Pulmonary Hypertension

>> D.1. Obtaining informed consent from subjects Reference Id: 143622

The standard consent process is for all subjects to sign a document containing all the elements of informed consent. If you will be requesting a waiver answer "not applicable" for any of the following questions.

1. Will children under the age of majority in their locale (18 years in NC) be enrolled in your study?

Yes  No

2. Will adult subjects be enrolled in your study?

Yes  No

Required document(s): Adult Consent Form

1) Responses to some questions additionally require the attachment of a document.

2) Accumulated document requirements are listed at the **Consent Forms and Attachments** sections. Requirements are marked with a **red X** until "satisfied" (**green check**).

>> 1. DOWNLOAD CONSENT FORM TEMPLATE

Click the template name to either download the selected consent form template to your computer OR indicate why you are not providing the template 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
- HIPAA Authorization
- Stored Specimens without Identifiers

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

File Name	Document Type
<a href="#">HIPAA Authorization.docx</a> Uploaded by: Celeste Cantrell On: 07/08/2021 At: 09:42 AM	HIPAA Authorization
<a href="#">Stored Specimens without identifiers.docx</a> Uploaded by: Celeste Cantrell On: 07/08/2021 At: 09:43 AM	Stored Specimens without Identifiers

3) Requirements are "satisfied" by uploading documents of a corresponding Document Type.

# Online Application Features (4)

## Other Attachments

>> 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:

**CONSENT-RELATED MATERIALS**

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

Attachment:  No file chosen

New Documents Only

To upload documents that may not be listed as required but should be reviewed, there is a list of different types of documents in the Consent section and in the Attachment section.

>> 2. UPLOAD ATTACHMENTS :

Use this section to upload attachments listed above. Select the appropriate Document Type for the attachment you want to upload. Click Browse unique file name. [\(Why is this important?\)](#) You can also upload additional materials not listed or multiple versions of items already listed. Do not use this section to replace documents already listed below under "Revise/Replace Previously Uploaded Attachments."

Document Type:

- Focus Group Guide
- Interview Questionnaire Survey
- Observation Guide
- Other Questionnaire Survey
- Pencil and Paper Questionnaire Survey
- Telephone Questionnaire Survey

**OTHER APPROVALS AND AGREEMENTS**

- Biostatistician Signoff
- Certificate of Confidentiality
- COI Validation Form
- Data Use Agreement

Attachment:  No file chosen

New Documents Only