IRBIS: Instructional Guide

How to Submit Applications for UNCW IRB Approval through the Online IRBIS System
Getting to IRBIS
Begin at the UNCW homepage

(www.uncw.edu)
Click on the “Research” Tab
Select “Human Subjects Protection” under the Compliance Tab
Find the IRBIS link in the third paragraph and click on it.
Logging Into IRBIS
This brings you to the IRBIS system.

Click “Continue to Login”
Enter your usual UNCW Username and Password, and click Sign In.
Starting a New Protocol
Welcome to the IRBIS home screen. Some of the things you can do from here include:

- Begin a New Study
- Submit a Renewal
- File a Closure Form
- View, Edit, and Submit Draft Protocols that you have saved.
To begin a new application, click the **New Study** tab on the left hand column.
General Information
Begin by entering your general study information.
If you need to exit IRBIS, just click the “Save and Stay” button before leaving the screen. When you return to IRBIS, your saved application will be located in the “In Draft” tab on your Dashboard on the left of your IRBIS homepage.
After entering basic questions and a brief summary of your study, you will see this screen. **Please note** – the sections listed under General Information on the left do not represent the complete application. IRBIS has not built your application yet. Once you enter all of the general information questions into IRBIS, it will build an appropriate application based on the information you provide.
2. Project Personnel
List ALL members of the research team. Prior to listing your personnel, please ensure they have completed the required human subjects training. You should include anyone involved in the design of the study or who will interact with subjects in any way, particularly when obtaining consent from subjects.

First, you will be asked if the project is LED by a student (undergraduate or graduate.) If you click yes, you will be prompted to indicate the type of student (undergrad, etc.) If your answer is no, this question will not appear.
To proceed, click the “Click here to add a response” under #2.

NOTE: The IRB database will link automatically to Citi Training database and the UNCW Conflict of Interest (COI) database. Once the study is certified by the PI, all personnel listed (for whom we have email addresses) will receive separate instructions about COI disclosures. The IRB will communicate with the personnel listed above or the PI if further documentation is required.
This dialog box will appear to select the Principal Investigator.
Once you click in the Last Name entry field, a search pop-up should appear.

You can begin by typing only the last name. If the PI has a common last name, you may also type the first name to avoid a long list of results.

When your search results appear, click on the PI’s name.
When you select the desired name, the name and other specifics from the university directory will populate in the appropriate fields.
The layout for subsequent personnel will be similar, and will still enable a search box. However, you must assign a role to each member. Then press Save.
Note: You may enter the name of a non-UNCW researcher if you are collaborating with someone from another institution. To do this, search by the individual’s last name (or any last name). Select the option to add a person not listed. You may have to scroll down to the end of the list of names to find this option if you searched on a common name.

Please do not list individuals who will seek approval through their home institution’s IRB.
IRBIS will customize the application as you respond to questions.

If you are conducting a simple study, you will be presented with a shorter application than one built for a more complex study.

Continue through the application and respond to all relevant questions.
IRBIS APPLICATION TIPS:

Consent Forms

• The Consent Form function in IRBIS does not work properly yet.

• Please continue to refer to the Research Compliance - Forms/Templates website for approved consent and assent-permission templates

http://uncw.edu/research/compliance/forms.html

• Please upload your consent forms along with the other regular attachments to your application.

• Please remember that you may use any custom consent format you like, but if you do not use the UNCW approved templates, you must also complete and submit an Informed Consent Checklist to demonstrate that you included all of the required elements of consent.
IRBIS APPLICATION TIPS:

Consent Forms – Ignore Consent Instructions

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<thead>
<tr>
<th>Item List</th>
<th>click on section name to expand</th>
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<tbody>
<tr>
<td>✓ General Information</td>
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<td>✓ Exemptions</td>
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<td>✓ Part A. Questions Common to All Studies</td>
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<td>✓ Part B. Direct Interaction</td>
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<td>✓ Part C. Existing Data, Records, Specimens</td>
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<td>✓ Data Security Requirements</td>
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<td>✓ Consent Forms</td>
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**Application Consent Forms Reference ID: 100092**

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?)*

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.
IRBIS APPLICATION TIPS:

Uploading Attachments

• You can browse to any file on your computer and upload it as an attachment to your application.

• After browsing to your file, be sure to select the document type to activate the upload function.

• Surveys, debriefing scripts, recruitment ads, interview questions and other supporting documentation should all be uploaded as attachments.

• If you are using numerous survey/questionnaire instruments, we prefer that you scan them into one file and upload that file, to minimize the number of attachments the IRB has to open.
IRBIS APPLICATION TIPS:
Uploading Attachments

1 – Select document type
2 – Browse to desired file
3 – Upload attachment
Once all questions are answered and all attachments are uploaded this icon will light up yellow and red at the bottom left hand side of your screen. When you are ready, press the **Proceed to Submit** button.
If you are not the PI, this screen will be the first you see. This will submit the protocol to your PI for certification and will be sent to the IRBIS system for review only after the PI approves it.
IRBIS SUBMISSION TIPS: Responding to Stipulations

INSTRUCTIONS: Please review and respond to the stipulations found below.

1) Click the Go to Question button below each stipulation to navigate to the associated application question, make any requested changes to the application, consent forms or attachments, and click Save and Continue to return to the View Stipulations screen.

2) At View Stipulations, below each stipulation, click the Respond button to open a textbox. Briefly describe your response to each stipulation, even if only stating "changes made," or explain why you cannot comply with the IRB's request.

3) Only when all changes AND responses are completed, will you be permitted to resubmit. Please click the yellow Proceed to Resubmit button, at bottom of left navigation bar.

Number of Stipulations: 1

Consent Forms

A consent form is required for this study. Please upload a consent form.

Go to Consent Forms

Add/Edit Response below

Consent form is uploaded.
IRBIS SUBMISSION TIPS:

Responding to Stipulations

• After you submit your application, the IRB will conduct an initial review. If clarification is needed or information is missing, the IRB will return the application to you with stipulations. You will receive an email notifying you that stipulations were noted in your application.

• The email will contain instructions on how to respond to the stipulations.

• You do not have to provide a lengthy explanation for your response. Just correct the section in question and say, “Corrected” or “Added” or whatever is most applicable.

• Save your response

• When all stipulations have been addressed, resubmit your study.
IRBIS SUBMISSION TIPS:

Copying an Approved Protocol

• Once your application is approved, you can make a copy of it if you conduct a similar study in the future.

• Log in to IRBIS and select “My Studies” under the “All My Studies” heading in the Dashboard on the left.

• You will see a “Copy” option at the far right of the study details.
IRBIS SUBMISSION TIPS:
Modifying, Renewing and Closing an Approved Study

• When your application is approved by the IRB, you must conduct the study in accordance with the approved application. Any changes that you need to make must be approved before you change the methods, procedures or personnel. You can log into IRBIS and modify a study any time after it has been approved.

• IRB policy requires that you notify the IRB when you complete a study. There is a Closure Report in IRBIS that you can access by opening your study.

• If there is an adverse event or unanticipated problem, you must report it to the IRB immediately. There is a Report of an Unanticipated Problem in IRBIS.
IRBIS SUBMISSION TIPS:
Modifying, Renewing and Closing an Approved Study
IF YOU NEED HELP WITH IRBIS

Contact:

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