

eIRB Upgrade 2023




WAKE FOREST
UNIVERSITY

The Overview

- These upgrades go into effect **May 15, 2023.**
 - You will log in the same way.
 - There are **NO** content changes to the application. The application questions remain the same.
 - **The primary changes include:**
 - As a study team member, you will navigate between smartform pages by clicking continue or using the navigation pane on the left side. This navigation pane replaces the jump-to menu from previous versions.
 - As a reviewer (IRB Staff or board member) you will be able to review the application in a continuous form or use the navigation pane to quickly get to a smartform view.
 - Reviewer notes can now be page level or question level. This will be relevant to the way the reviewer enters the comment.
 - Reviewer notes will display as a dialog between study team and reviewer with the ability to upload documents.
 - **Applications created/in process by May 12 will remain in the old format.**
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Your home page will remain the same. You'll see the same tabs mid-page and you'll create a new application by clicking the activity on the left

 Study Staff

My Roles

Board Member
SB IRB Administrator/Director
Study Staff ▾

Create

 New Application

My Web Page Links

Consent Forms ...

Folder for Jeanie Baird

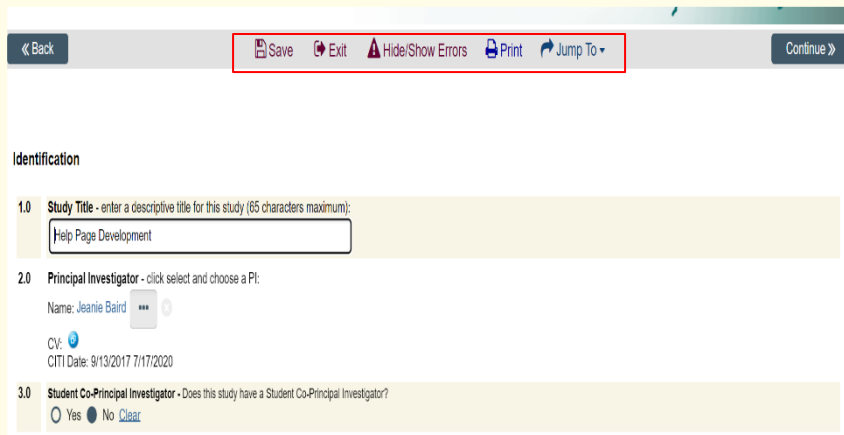
Welcome to your Personal Folder, the central resource for managing your Research Study Applications. Use the following guidelines to process your Applications:

- Process all items in your **Inbox**. Items appearing here require immediate action by the Study Team to speed your submission through the review process.
- The system will automatically notify you when action is required by you or another member of the Study Team.
- Monitor the progress of your submissions using the **Applications, Continuing Reviews, Amendments, Safety Events** and **Reports** tabs.

My Inbox	Applications	Continuing Reviews	Amendments	Safety Events	...	
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This tab displays all Applications, Amendments, Continuing Reviews and Safety Events which currently require you to perform an action. Click on the items for more information.

First page of the application in the old version



The screenshot shows the 'Identification' page of the old application. At the top, there is a grey activity bar containing buttons for 'Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', and 'Continue'. The main content area is titled 'Identification' and contains three sections: 1.0 'Study Title' with a text input field containing 'Help Page Development'; 2.0 'Principal Investigator' with a dropdown menu showing 'Jeanie Baird' and a 'CV' link; 3.0 'Student Co-Principal Investigator' with radio buttons for 'Yes' and 'No' and a 'Clear' link.

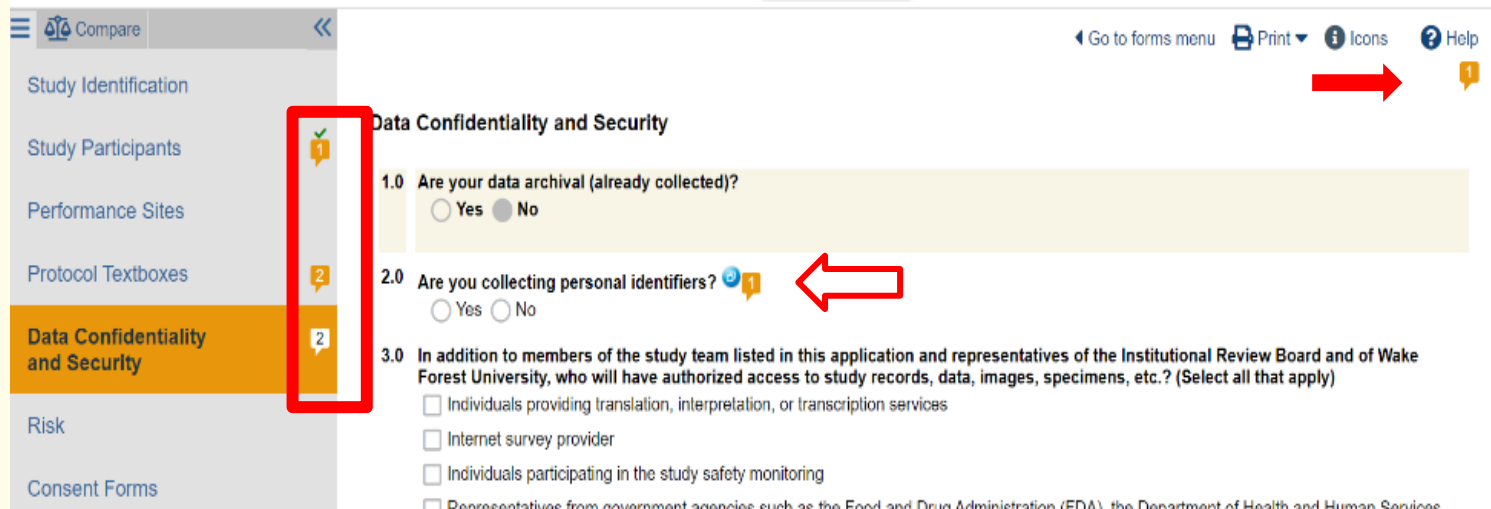
First page of the application in the new version



The screenshot shows the 'Editing: IRB00024916' page of the new application. A red arrow points to the 'Validate' button in the top menu bar. The left sidebar contains a list of menu items: 'Study Identification' (highlighted), 'Study Participants', 'Performance Sites', 'Protocol Textboxes', 'Data Confidentiality and Security', 'Risk', 'Consent Forms', 'Check Application for Errors', and 'End Section'. The main content area is titled 'Editing: IRB00024916' and contains four sections: 1.0 'Study Title' with a text input field containing 'Upgrade test 2023'; 2.0 'Principal Investigator' with a dropdown menu showing 'Jeanie Baird' and a 'CV' link; 3.0 'Student Co-Principal Investigator' with radio buttons for 'Yes' and 'No' and a 'Clear' link; 4.0 'Study Coordinator' with radio buttons for 'Yes' and 'No' and a 'Clear' link. At the bottom right, there are buttons for 'Exit', 'Save', and 'Continue'.

You'll see that in the new version, the activity bar along the top is gone, including the 'jump to' activity. All the pages of the application are listed down the left side of the page, and the buttons to exit, save and continue are on the bottom right.

The "Validate" button at the top of the menu bar can be used to check for missing data.

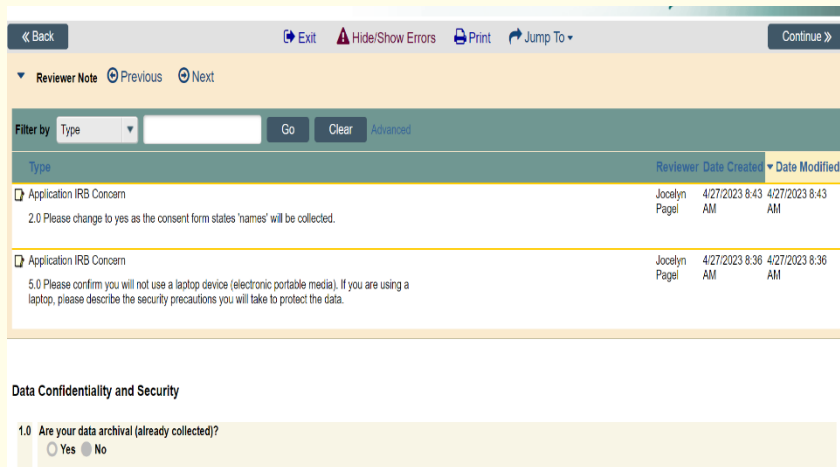


The screenshot displays the 'Data Confidentiality and Security' section of the application. The left-hand menu is highlighted, showing the 'Data Confidentiality and Security' section with an orange concern icon and the number '2'. The main content area shows three questions: 1.0 'Are your data archival (already collected)?' with 'Yes' and 'No' radio buttons; 2.0 'Are you collecting personal identifiers?' with 'Yes' and 'No' radio buttons and an orange concern icon with the number '1'; and 3.0 'In addition to members of the study team listed in this application and representatives of the Institutional Review Board and of Wake Forest University, who will have authorized access to study records, data, images, specimens, etc.? (Select all that apply)'. A red arrow points to the top right of the page, and another red arrow points to the orange concern icon next to question 2.0.

The comments will no longer be stacked at the top of each page.

- 1. You will see the orange concern icons in the left-hand menu of application pages.**
- 2. You will also see them on each page, either at the top right of the page or next to the specific question the concern is addressing.**

Old Version



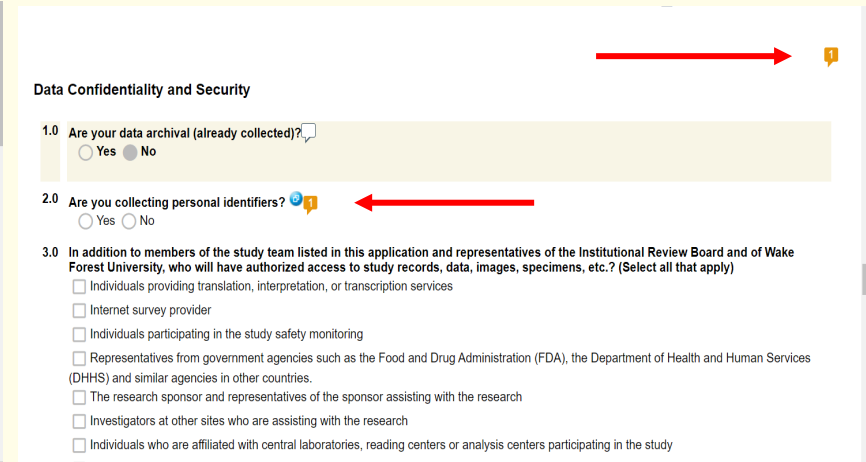
The screenshot shows the 'Old Version' of the application interface. At the top, there is a navigation bar with buttons for '<< Back', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', and 'Continue >>'. Below this is a 'Reviewer Note' section with 'Previous' and 'Next' buttons. A 'Filter by' dropdown menu is set to 'Type', with 'Go' and 'Clear' buttons, and a link to 'Advanced'. Below the filter is a table with columns for 'Type', 'Reviewer', 'Date Created', and 'Date Modified'. The table contains two entries, both by 'Jocelyn Pagel'. The first entry is 'Application IRB Concern' with a description '2.0 Please change to yes as the consent form states 'names' will be collected.' and dates '4/27/2023 8:43 AM'. The second entry is 'Application IRB Concern' with a description '5.0 Please confirm you will not use a laptop device (electronic portable media). If you are using a laptop, please describe the security precautions you will take to protect the data.' and dates '4/27/2023 8:36 AM'. Below the table is a section titled 'Data Confidentiality and Security' with a question '1.0 Are your data archival (already collected)?' and radio buttons for 'Yes' and 'No'.

Type	Reviewer	Date Created	Date Modified
Application IRB Concern 2.0 Please change to yes as the consent form states 'names' will be collected.	Jocelyn Pagel	4/27/2023 8:43 AM	4/27/2023 8:43 AM
Application IRB Concern 5.0 Please confirm you will not use a laptop device (electronic portable media). If you are using a laptop, please describe the security precautions you will take to protect the data.	Jocelyn Pagel	4/27/2023 8:36 AM	4/27/2023 8:36 AM

Data Confidentiality and Security

1.0 Are your data archival (already collected)?
☐ Yes ☐ No

New Version



The screenshot shows the 'New Version' of the application interface. At the top right, there is a red arrow pointing to an orange icon. Below this is a section titled 'Data Confidentiality and Security'. The first question is '1.0 Are your data archival (already collected)?' with radio buttons for 'Yes' and 'No'. The second question is '2.0 Are you collecting personal identifiers?' with radio buttons for 'Yes' and 'No', and an orange icon next to it. The third question is '3.0 In addition to members of the study team listed in this application and representatives of the Institutional Review Board and of Wake Forest University, who will have authorized access to study records, data, images, specimens, etc.? (Select all that apply)'. Below this question is a list of checkboxes for various roles: 'Individuals providing translation, interpretation, or transcription services', 'Internet survey provider', 'Individuals participating in the study safety monitoring', 'Representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.', 'The research sponsor and representatives of the sponsor assisting with the research', 'Investigators at other sites who are assisting with the research', and 'Individuals who are affiliated with central laboratories, reading centers or analysis centers participating in the study'.

Data Confidentiality and Security

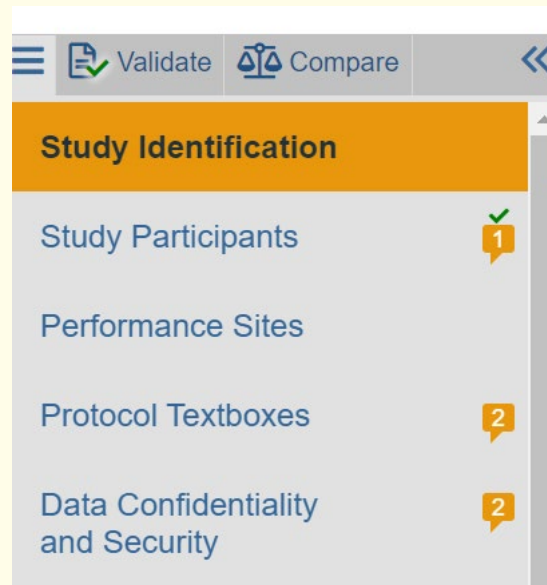
1.0 Are your data archival (already collected)?
☐ Yes ☐ No

2.0 Are you collecting personal identifiers?
☐ Yes ☐ No

3.0 In addition to members of the study team listed in this application and representatives of the Institutional Review Board and of Wake Forest University, who will have authorized access to study records, data, images, specimens, etc.? (Select all that apply)

- ☐ Individuals providing translation, interpretation, or transcription services
- ☐ Internet survey provider
- ☐ Individuals participating in the study safety monitoring
- ☐ Representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.
- ☐ The research sponsor and representatives of the sponsor assisting with the research
- ☐ Investigators at other sites who are assisting with the research
- ☐ Individuals who are affiliated with central laboratories, reading centers or analysis centers participating in the study

There will be an orange icon at the top right for page level concerns, and an orange icon next to the actual question for question level concerns. Click the icon to open the concern.



When the concern has been resolved by the IRB admin, a green check will appear above the orange box.



As always, please reach out to us with any questions/concerns you may have.

irb@wfu.edu
