

eIRB Updates

2023

Smart Forms Overview

eIRB will continue to use Smart Forms.

- Types of entries in eIRB Smart Forms:
 - Text Entries
 - Date Entries
 - Multiple Choice
 - Choose Multiple
 - Select an item from data in the system
 - Add document
 - Add data to be displayed in table

*Biosketch and CITI Certification dates displayed below are read-only for review purposes. To upload a Biosketch activity on the Application Workspace. CITI dates are handled by the Office of Research. Email sstanfie@wful

1.0 **Other Team Members** - add any other team members (other project assistants, students, support staff)

Last	First	E-Mail	CITI Date	ICH
There are no items to display				

2.0 **Department Team Members** - add any department team members that may need access to Consent Form. Please Note that this role is for view only and that edits to a study cannot be made by people with this role.

Last	First	E-Mail	CITI Date	ICH
There are no items to display				

3.0 **Co-Investigators** - click Add and select any Co-Investigators for this study:
This Co-Investigators list needs be as complete (as possible), because once you save t

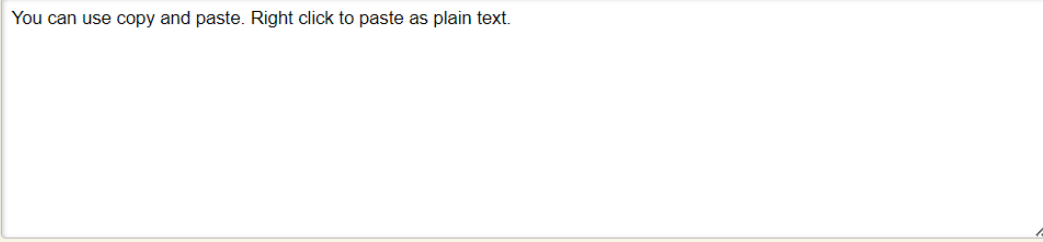
Last	First	Email	Biosketch	CITI Date (Biomedical)	CITI Date (Non-Biomedical)
There are no items to display					

This image includes entries in which an item can be selected based on data in the system.

5.0

* **Abstract** - enter a summary, purpose, and rationale for this study. Please include the objectives, interventions, methods, and outcome measures

You can use copy and paste. Right click to paste as plain text.



Text fields are straightforward. Entries can be copied and pasted, but it is advisable that when you have copied the data, right-click on the text entry field. You will see the option to paste as plain text. This will keep unwanted characters out of your entry.

Abstract Documents:

+ Add

Name	Modified	Version
There are no items to display		

Biosketch and CITI Certification dates displayed below are read-only for review purposes. To upload a biosketch, save the activity on the Application Workspace. CITI dates are handled by the Office of Research. Email ssstanfie@wfubmc.edu (WF

1.0 **Other Team Members** - add any other team members (other project assistants, students, support staff, etc.):



Last	First	E-Mail	CITI Date	ICH-GCP Date
There are no items to display				

To add a document, click the **+Add** button. A dialog box will now open from the right. For some fields, you may be able to drag a document from your computer to this field.

Some fields allow you to **select from data that already exist in the system**. To find the correct information, start typing and a list will appear (the more letters you type, the more refined the search). You can also click the ellipsis (highlighted in red) next to the field and search from the entire list.

1. The Welcome back message appears when you reopen an application.
2. Validate allows you to check for missing data.
3. The side panel replaces Jump To and shows what pages need to be completed.
4. Exit, Save, and Continue appear at the bottom of the page. Navigate to another page by clicking the page names in the left side panel.

Wake Forest School of Medicine

Human Subjects Research

Study Identification

Research Facilities

Sponsorship

Limited IRB Review

Ancillary Reviews - Winston-Salem

Check for Errors

End Section

1 Welcome back! Continue where you left off.

2 Validate

3

4

Editing: IRB0009

Go to forms menu Print Help

Study Identification - Exempt

*If a study team member does not appear in the appropriate list, you will need to request this role for him/her. [Click here to go to the FAQ section](#); use the Request User Roles button to request the appropriate role(s).

*Biosketch and CITI Certification dates displayed below are read-only for review purposes. To upload a Biosketch, Save the application, click Exit, and use the "Upload Team Member Biosketch" activity on the Application Workspace. CITI dates are handled by the Office of Research. Email sstanfie@wfubmc.edu (WFUHS) if you have questions about a certification date.

1.0 **Other Team Members** - add any other team members (other project assistants, students, support staff, etc.):

Last	First	E-Mail	CITI Date	ICH-GCP Date	Biosketch
There are no items to display					

2.0 **Department Team Members** - add any department team members that may need access to Consent Forms or other documentation only:
Please Note that this role is for view only and that edits to a study cannot be made by people with this role

Last	First	E-Mail	CITI Date	ICH-GCP Date	Biosketch
There are no items to display					

3.0 **Co-Investigators** - click Add and select any Co-Investigators for this study:
This Co-Investigators list needs be as complete (as possible), because once you save the page, the Co-Investigators will receive a request to ATP to this study

Last	First	Email	Biosketch	CITI Date (Biomedical)	CITI Date	Bel
There are no items to display						

Exit Save Continue


5. Reviewers Notes will no longer appear in the page header. You will find an orange message box.

The red dot above the orange icon indicates that no comment has been entered yet.

Click the orange icon to read Reviewer Notes and to respond as needed.

Human Subjects Research	1
Study Identification	6
Research Facilities	1
Sponsorship	
Clinical Trials	
Protocol	6
Risk/Benefit	1
Patient Population	11
Safety, Confidentiality, and Privacy	1
Consent Process	23
Ancillary Reviews - Winston-Salem	2
Waiver of Authorization - Part 1	

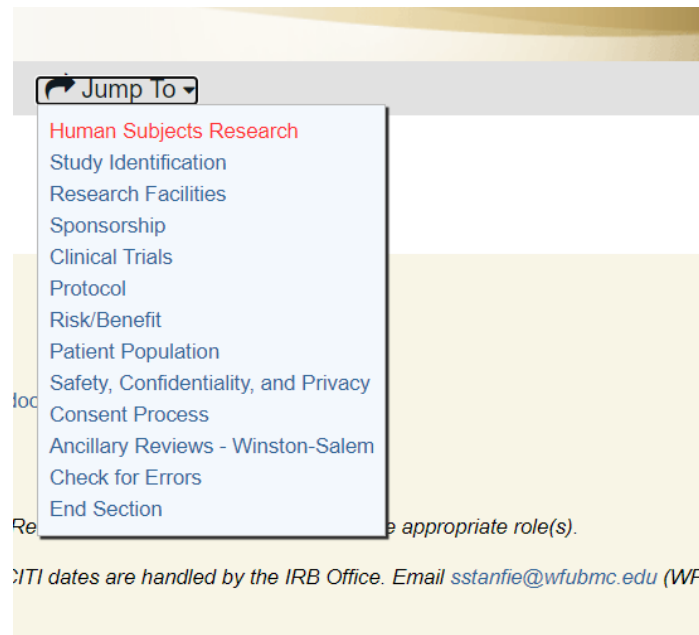
Risk/Benefit

- 1.0 **Risk:** *Minimal Risk means that the risks of harm anticipated in the proposed research are not greater -- considering probability, general population in daily life or during the performance of routine physical, laboratory, or psychological exams or tests. [45 C.F.R. 46.104]*
- * Select a Risk Category:  **5**
- Category**
- 1) This research involves no more than minimal risk to subjects.
- 2) This research involves more than minimal risk to subjects and the risk(s) represent a minor increase over minimal risk.
- 3) This research involves more than minimal risk to subjects and the risk(s) represent more than a minor increase over minimal risk.
- 2.0 **Benefit:** *A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject or the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit.*
- * Select a Benefit Category:
- Category**
- This research is not expected to directly benefit individual subjects, but is likely to yield generalizable knowledge.
- This research involves the prospect of direct benefit to the individual subject.

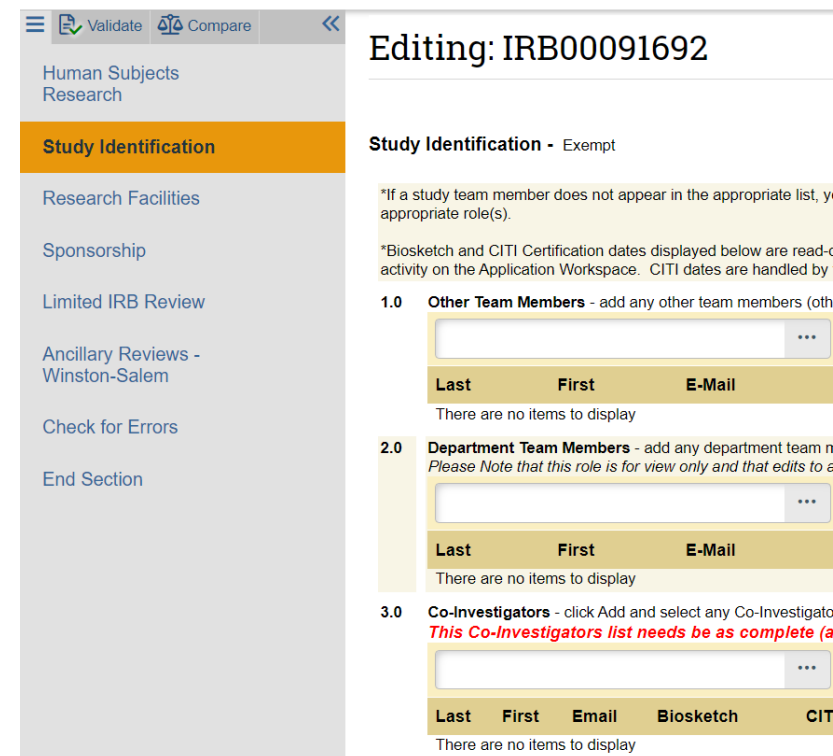
Comparison

The updates include a left side panel of the pages that need to be completed for the study. No longer will “Jump To” appear at the top of the page. Pages will update in real time to reflect any new pages that will need to be completed (based on information added to application).

Old View



New View



Comparison

Reviewer notes are now at the item level, not in the page header.

Old View

Reviewer Note Previous Next

Filter by Type [dropdown] [input] Go Clear Advanced

Type	Reviewer D
Application IRB Concern Under 8.0, please add 5, and 7 as the protocol states retrospective data will be collected and QOL surveys will be given to the subjects.	Jon 3/28/2023 Schwaiger 11
Application: Concern Addressed (change made) - - edited	- 3/28/2023 11:07 AM

Human Subjects Research

1.0

- Principal Investigator** - click the select button and choose a PI:
Glenn Gaston
Email: Glenn.Gaston@orthocarolina.com
Biosketch: Gaston CV Expires 03.24.2025.pdf(0.02)
CITI Date: 5/23/2022
ICH-GCP: 10/23/2022
Training:

**If a study team member does not appear in this list, you will need to request this role for him/her. [Click here to go to the FAQ section](#); use the Request User Roles button to request the appropriate role(s).*

To upload a Biosketch: Save the application, click Exit, and use the "Initial Team Member Biosketch" activity on the Application Workarea. CITI dates are handled by the IRB Office. Email estefan@dufuhm.edu

New View

- Human Subjects Research 1
- Study Identification 8
- Research Facilities 1
- Sponsorship
- Clinical Trials
- Protocol 6
- Risk/Benefit 1**
- Patient Population 11
- Safety, Confidentiality, and Privacy 1
- Consent Process 23
- Ancillary Reviews - Winston-Salem 2
- Waiver of Authorization - Part 1

Risk/Benefit

1.0

Risk: Minimal Risk means that the risks of harm anticipated in the proposed research are not greater -- considering probability and magnitude of harm -- than those ordinarily encountered in daily life or during the performance of routine physical, laboratory, or psychological exams or tests. [45 CFR 46.102(h)(1)]

Select a Risk Category: 1

Category

1) This research involves no more than minimal risk to subjects.

2) This research involves more than minimal risk to subjects and the risk(s) represent a minor increase over minimal risk.

3) This research involves more than minimal risk to subjects and the risk(s) represent more than a minor increase over minimal risk.

2.0

Benefit: A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit.

Select a Benefit Category:

Category

This research is not expected to directly benefit individual subjects, but is likely to yield generalizable knowledge.

This research involves the prospect of direct benefit to the individual subject.

Comparison

Check for missing data by clicking Validate. Green checks indicate data is complete. Red circles indicate that data may be missing for an item.

Old View

The 'Old View' interface includes a navigation bar with 'Back', 'Exit', 'Hide/Show Errors', 'Print', and 'Jump To'. Below this is a 'Reviewer Note' section with 'Previous' and 'Next' buttons. A filter section allows filtering by 'Type' with 'Go' and 'Clear' buttons. The main content area shows a message: 'Application: Concern Addressed (change made) 3/28/2023 11:07 AM edited'. A red box highlights the 'Hide/Show Errors' button, with an arrow pointing to a message box at the bottom of the page.

Human Subjects Research

Error/Warning Messages

Message

Application IRB Concern: Author: Jon Schwaiger Change the response to question 5 to this: To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, and stored separately from the data. The linkage file will be kept secure, with designated study personnel. Following data collection subject identifying information will be electronically deleted or destroyed. Data access will be limited to study staff. Data and records will be kept with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

New View

The 'New View' interface features a 'Validate' button (highlighted with a red box) and a 'Compare' button. The main content area is titled 'Error/Warning Messages (16)' and lists various messages with status indicators (green checkmarks or red circles). A red box highlights the status indicators for several messages.

Human Subjects Research

Study Identification

- Is Investigational Drug This is a required field; therefore, you must provide the required information.
- Is Investigational Device This is a required field; therefore, you must provide the required information.
- WFUHS Coordinating Site This is a required field; therefore, you must provide the required information.
- Covid-19 obtain ICF This is a required field; therefore, you must provide the required information.

Research Facilities

Sponsorship

- Investigator Initiated This is a required field; therefore, you must provide the required information.

Limited IRB Review

- Protocol Doc This is a required field; therefore, you must provide the required information.
- What interventions This is a required field; therefore, you must provide the required information.
- PHI Accessed This is a required field; therefore, you must provide the

Editing: IRB00091692

Human Subjects Research

1.0 * **Principal Investigator** - click the select button
Amy Dawson ...
Email: apdawson@wakehealth.edu
Biosketch: ADawson biosketch 1210202
CITI Date: 1/2/2022
ICH-GCP:
Training:
**If a study team member does not appear in the User Roles button to request the appropriate n*
To upload a Biosketch, Save the application, c are handled by the IRB Office. Email sstanfie@

2.0 * **Study Coordinator** - click the select button
Amy Dawson ...
Email: apdawson@wakehealth.edu
Biosketch: ADawson biosketch 1210202
CITI Date: 1/2/2022
ICH-GCP:
Training:

3.0 * **Study Short Title** - enter a short descriptive
Sample - Another

4.0 * **Study Full Title** - enter the full study title: