

..... University of Kentucky E-IRB .....  
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# Application Features:

- **Controlled and secure user access**

## **Access and Roles**

**Logging onto the E-IRB requires your 'Link Blue' ID and password.**

**Everyone with a 'Link Blue' account can log in as a 'Researcher'.**

**Office of Research Integrity (ORI) and the Institutional Review Board (IRB) will have access based on their 'Role'.**

## Automated On-Line Application:

- **Automatic check for completeness**



Application can be saved at any point. Close out the application and return to 'submit' application at a later date.

Submission to 'Office of Research Integrity' checks for completeness of application. Providing instant feedback to the researcher that the application is ready for submission.

# Automated On-Line Application:

- **Question and Section Validation**

The screenshot displays an IRB application interface. On the left, a checklist of sections is shown with checkboxes and icons: Risk Level (checked), Subject Demographics (checked), Children (pencil icon), Preg/Neonate/Fetus (pencil icon), Informed Consent (checked), Study Personnel (checked), Research Description (checked), HIPAA (checked), Study Drug Information (checked), Study Device Information (checked), and Research Sites (checked). The main content area on the right is titled 'Consent and/or Authorization by a Legally Authorized Representative' and contains a large redacted area (pink box) and text explaining the consent process for participants outside of Kentucky.

Pencil appears in 'IRB Application Sections' when more information is needed.

Checkmark appears when section is complete.

Question color changes when information is needed within a section.

## Automated On-Line Application:

- **Version Control**

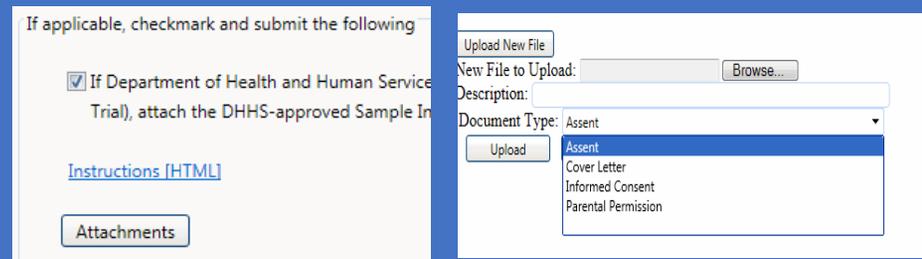
**New features in a timely manner.**

Application template will be maintained by ORI, allowing for timely changes to the application when updates are mandated by changes to federal regulations.

Past versions of the application will be retrievable.

# Automated On-Line Application:

- **Attachments**



If applicable, checkmark and submit the following

If Department of Health and Human Service (DHHS) approved (Sample Informed Consent Trial), attach the DHHS-approved Sample Informed Consent Form.

[Instructions \[HTML\]](#)

New File to Upload:

Description:

Document Type: Assent

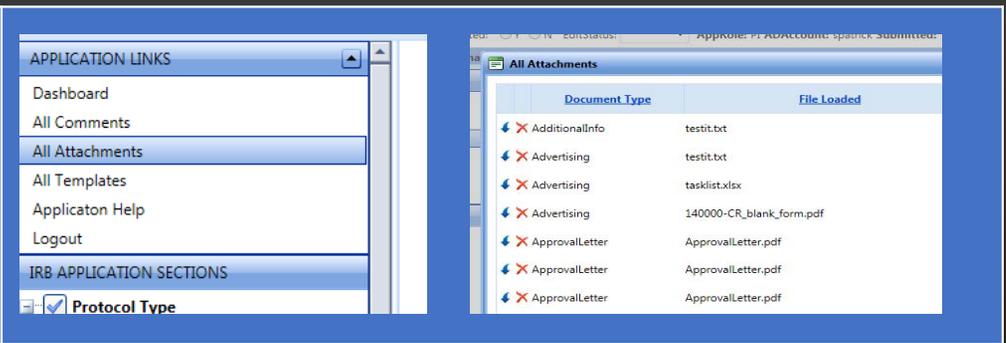
- Assent
- Cover Letter
- Informed Consent
- Parental Permission

Attach documents in the appropriate sections of the application.

View attachments on section applied or all attachments in one location on the application.

# Automated On-Line Application:

- **Attachments**



View 'all' attachments for application in one place.

Sort by 'Document Type', 'File Loaded' or 'Document Description'

# Automated On-Line Application:

- **Comments**

The screenshot displays a web application interface. On the left is a blue sidebar with navigation links: Dashboard, All Comments, All Attachments, All Templates, Application Help, and Logout. The main content area shows a 'Dashboard' tab with 'Print Protocol' and 'Change Approle' options. It displays 'ProtocolID: 41260' and 'Review Phase: IR'. Below this is a table titled 'VIEW ALL COMMENTS' with columns for Sections, ROLE, Comment, and ADACC. The table contains three rows of comments related to 'Project Information' and 'Informed Consent'.

	Sections	ROLE	Comment	ADACC
Select	Project Information	ORI	Please revise your protocol information	wmdl22
Select	Project Information	PI	I like my title the way it is.	spatric
Select	Informed Consent	PI	There will be a change to this form before next month.	spatric
Select	Informed Consent	ORI	You must make the change before Continuation Review.	spatric

Researchers may view comments made between them and ORI in each section or in one place.

IRB and ORI may view each others' comments on application.

ORI may view 'all' comments.

# Automated On-Line Application:

- **Signatures(Assurances)**

Department Authorization: individual, such as PI's Department Chair or Equivalent, who holds authority to support the PI's ability to effect.

Select a role and signee:  
Please Select A Role...

Please Select A Role...  
Department Authorization  
Faculty Advisor (or equivalent)  
Review by Other

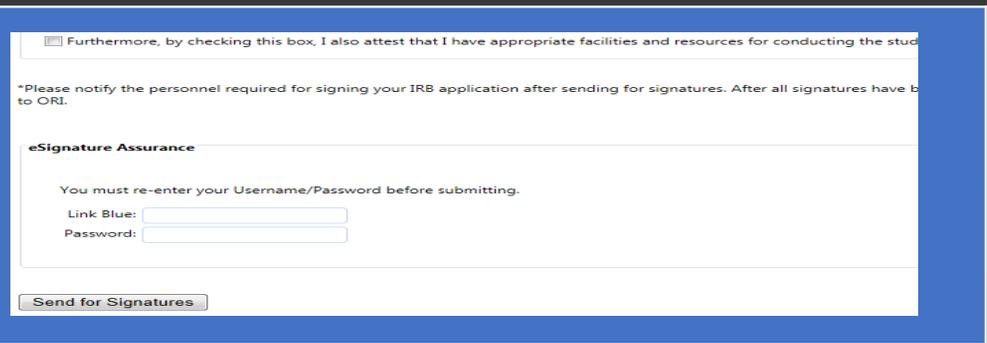
First Name	Last Name	Role	Department	Date Signed	
×	Sheri	Patrick	Principle Investigator	Information Services	

Researchers may assign signatures according to departmental policies.

Required signees will get a 'task' in their dashboard to electronically sign application.

# Automated On-Line Application:

- **Signatures(Submission)**



Furthermore, by checking this box, I also attest that I have appropriate facilities and resources for conducting the study.

\*Please notify the personnel required for signing your IRB application after sending for signatures. After all signatures have been obtained, notify ORI.

**eSignature Assurance**

You must re-enter your Username/Password before submitting.

Link Blue:

Password:

Once the required signatures from the Researcher's department have been obtained, the Principle Investigator may 'Submit' application to ORI by using their 'Link Blue' ID and password.

# Automated On-Line Application:

- **Routing Application**

The screenshot displays the ORI Dashboard interface. On the left, a navigation menu lists various options under the heading 'ORI DASHBOARD'. The main content area is divided into two sections. The top section, titled 'My Team's Tasks', features two tabs: 'Unassigned IR's' and 'Unassigned CR's'. Below these tabs is a table with three columns: 'Task', 'Protocol', and 'Phase'. The table contains one row with the following data:

Task	Protocol	Phase
ScreenProtocol	2013-41266	IR

Below the table, there is a dropdown menu labeled 'ORI1'. The bottom section, also titled 'My Team's Tasks', has two tabs: 'Protocols' and 'Reportables'.

The researcher submits the application and immediately the application appears on ORI's dashboard to be screened.

# Automated On-Line Application:

- **Copy Application**

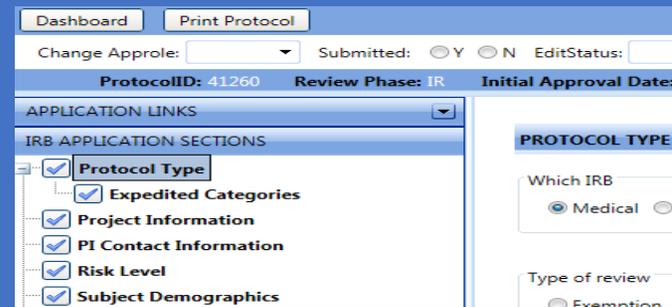
The screenshot shows the 'PROTOCOL APPLICATION DASHBOARDS' interface. On the left is a navigation menu with categories: 'PI DASHBOARD', 'APPLICATIONS IN PROGRESS', 'CREATE NEW', and 'MANAGE STUDY PERSONNEL'. The 'Copy Protocol' option is highlighted under the 'PI DASHBOARD' category. The main content area is titled 'Copy Protocol' and contains a table with columns 'Protocol', 'Type', and 'Title'. Below the table are three rows, each with a 'Select' button, a protocol ID, a type, and a title.

	Protocol	Type	Title
Select	2013-41264	MEDXP	A protocol to create MR
Select	2013-41262	MEDXP	An approved protocol (MR)
Select	2013-41285	MEDXP	A protocol to create CR

Use the 'Copy Protocol' feature to duplicate similar applications. The new application will require researcher to view and save each section as verification that the section is valid for the new application.

# Automated On-Line Application:

- **Printing Application**



Print the application to a pdf file anytime during or after the creation of the application.