

## Online Application Orientation: Data entry features (1)

The screenshot displays the IRBIS Office of Human Research Ethics online submission interface. The main content area is titled "1. General Information" and contains the following sections:

- 1. Project Title \***: A text input field with a red arrow pointing to it labeled "1".
- 2. Brief Summary**: A text area with a WYSIWYG editor. A red arrow points to the editor toolbar labeled "3". Another red arrow points to the bottom-right corner of the editor labeled "4".
- 3. Is this submission similar to or related to an application already approved by a UNC-Chapel Hill IRB?**: A radio button question with "Yes" and "No" options.

At the bottom of the form, there are two buttons: "Save and Continue" and "Clear Responses". A red arrow points to the "Clear Responses" button labeled "5".

On the left side, there is a navigation menu with sections like "Dashboard", "Create New Submission", "Submissions In Progress", "All My Studies", and "Routing Inbox".

1. Some question-response text boxes do not include a WYSIWYG editor, and therefore cannot accommodate formatting.
2. Most text boxes do include a WYSIWYG editor.
3. Click to hide the WYSIWYG editor.
4. Click/drag to resize text box.
5. Click *Clear Responses* to delete ALL responses on page.

## Online Application Orientation: Data entry features (2)

The screenshot displays the IRBIS Office of Human Research Ethics application interface. On the left, the 'Item List' is expanded to show 'General Information', which is further divided into sub-sections: '1. General Information' (marked with a green checkmark and a red arrow labeled '2'), '2. Project Personnel' (marked with a red arrow labeled '1'), '3. Funding Sources', and '4. Screening Questions'. Below the 'Item List' are buttons for 'Home', 'Submit', and 'Delete Submission'. The main content area is titled '>> 2. Project Personnel' and contains instructions for listing project personnel, a 'Click here to add a response' link, and a 'Department' input field. At the bottom, there are 'Save and Continue' and 'Clear Responses' buttons, along with a note about required fields and navigation instructions.

1. Once a sub-section of General Information is completed (and saved), the **Item List** replaces the **Dashboard** in the left navigation bar.
  2. This is a “smart” application. Sections in the **Item List** will expand/contract, and will be tailored to reflect your responses, as you progress through the application. Each time you click *Save and Continue*, a green **check** appears in the **Item List**, indicating that you have completed a sub-section. When you complete all sub-sections, the section will close, and a larger **check** will appear next to the section header. All required sections (and sub-sections) must be completed before you will be allowed to *Submit* your application.
- Note:** While it is possible to use the **Item List** to skip around the application, it is recommended that you complete required sections in sequence.

## Online Application Orientation: Data entry features (3)

The screenshot shows the IRBIS application interface. The top navigation bar includes the IRBIS logo, 'Office of Human Research Ethics', and links for HOME, HELP, and LOGOUT. The main content area is titled '>> 2. Project Personnel' and contains a list of instructions for entering project personnel information. A link labeled 'Click here to add a response' is visible at the bottom of the instructions.

Some sub-forms within the application are accessed through a link.

The screenshot shows the IRBIS application interface with a pop-up form for adding a response. The pop-up form contains the following fields and options:

- Last Name \*
- First Name
- Department Name
- Address
- Fax
- Phone
- Cell/Pager
- Email \*
- Role \*
  - Principal Investigator
  - If other, please describe
- For trainee-led projects indicate your status
- Alternate Address
- Use Alternate Address?
  - Yes  No
- Send Correspondence?
  - Yes  No

Buttons for 'Save' and 'Cancel' are located at the bottom of the form.

Clicking the link [Click here to add a response](#) will open a pop-up window, with a sub-form for the addition of detailed records.

**Note:** repeat this process to enter multiple records.

## Online Application Orientation: Data entry features (4)

IRBIS Office of Human Research Ethics

HOME COMMITTEE REVIEWS ADMIN GENERAL MANAGEMENT HELP LOGOUT

Logged in as David

Item List click on section name to expand

General Information

- 1. General Information
- 2. Project Personnel
- 3. Funding Sources
- 4. Screening Questions

Home

Application Status

Submit

Delete Submission

>> 2. Project Personnel

Current Application: Quick View PDF for Printing View FAQ

1. List all project personnel beginning with principal investigator, followed by all co-investigators, faculty advisor and anyone else who has contact with subjects or identifiable data from subjects. The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated. \*

Click here to add a response

Last Name	First Name	Department Name	Role		
Tegnell	David	Ofc of Human Research Ethics	Principal Investigator	<a href="#">edit</a>	<a href="#">remove</a>
Johns	Andy	VC for Research & Economic Dev	Co-investigator	<a href="#">edit</a>	<a href="#">remove</a>

2. Center, institute, or department in which research is based if other than department(s) listed above:

Department

\* Required.

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

Save and Continue Clear Responses

Multiple records entered into the sub-form are displayed in summary form, but full details can be viewed/revised by clicking [edit](#).

## Online Application Orientation: Data entry features (5)

IRBIS Office of Human Research Ethics

HOME COMMITTEE REVIEWS ADMIN GENERAL MANAGEMENT HELP LOGOUT

Item List click on section name to expand

General Information

- 1. General Information
- 2. Project Personnel
- 3. Funding Sources
- 4. Screening Questions

Home

Application Status

Submit

Delete Submission

>> 3. Funding Sources

Current Application: Quick View PDF for Printing View FAQ

1. Is this project funded (or proposed to be funded) by a contract or grant that is sponsored by an organization external to UNC-Chapel Hill? \*

Yes  No

2. Is this study funded by UINC-CH (e.g., department funds, internal pilot grants, trust accounts)?

Yes  No

3. Is this research classified (e.g. requires governmental security clearance)?

Yes  No

4. Is there a master protocol, grant application, or other proposal supporting this submission (check all that apply)?

- Grant Proposal
- Industry Sponsor Master Protocol
- Student Dissertation or Thesis Proposal
- Investigator Initiated Master Protocol
- Other Study Protocol

\* Required.

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

Save and Continue Clear Responses

Depending on your response, secondary questions may be displayed, e.g., if you indicate that your project is funded, you will be prompted to indicate the source(s) of that funding.

1. Is this project funded (or proposed to be funded) by a contract or grant that

Yes  No

Check all the funding source types that apply:

- Federal
- Foundation
- Industry
- Local Govt
- State (NC)
- State (Non-NC)

Funding Source(s) or Sponsor(s)

[Click here to add a response](#)

OR

[Click here if currently not available](#)

Is there any additional information that your sponsor will expect to see in the provided)?

Please review the FAQ section for Time and Techniques on using the HTML

## Online Application Orientation: Data entry features (6)

IRBIS Office of Human Research Ethics  
 HOME ADMIN GENERAL MANAGEMENT HELP LOGOUT

IRB Number: 11-0051 PI: David Tegnall  
 Study Title: A Survey of State Legislators and City Council Members

Item List click on section name to expand

- General Information
- Part A. Questions Common to All Studies
  - A.1. Background and Rationale
  - A.2. Subjects
  - A.3. Inclusion/exclusion criteria
  - A.4. Study design, methods and procedures
  - A.4.A. Biomedical methods and procedures
  - A.5. Benefits to subjects and/or society
  - A.6. Risks and measures to minimize risks
  - A.7. Data and safety monitoring
  - A.8. Data analysis
  - A.9. Identifiers
  - A.10. Confidentiality of the data
  - A.11. Data sharing and transmission
  - A.12. Post-study disposition of identifiable data or human biological materials
- Part B. Direct Interaction

Once you've completed editing your Application, it can be resubmitted at anytime by clicking the resubmit button at bottom left of the screen. Once resubmitted, no further edits can be made unless the Application is returned to pi again.

>> A.1. Background and Rationale

Current Application: View Stipulations Quick View (HTML) PDF View Revisions View FAQ

1. Provide a summary of the background and rationale for this study (i.e., why is the study needed?). If a complete background and literature review are in an accompanying grant application or other type of proposal, only provide a brief summary here. If there is no proposal, provide a more extensive background and literature review, including references.

INTRODUCTION: The evaluation of subjects with suspected colonic disease includes endoscopic imaging by colonoscopy and radiologic imaging such as aircontrast barium enema, or CT colonography. The PillCam® platform offers an alternative approach for endoscopic visualization of the colon using capsule endoscopy, an ingestible device which contains imagers, light sources, a power source and a radio frequency transmitter. Advantages of the PillCam® platform include the elimination of the need for sedation, the minimally invasive, painless nature of the exam, and the ability to pursue normal daily activities immediately following the procedure. Furthermore, compared to standard colonoscopy, the PillCam® platform may be more readily accepted by patients and thereby improving compliance with colorectal cancer screening recommendations.

Please review the FAQ section for Tips and Techniques on using the HTML Editor.

2. State the research question(s).

Stipulation:  
Please answer this

At any point, you may (progressively) generate either an HTML or PDF version of your application. The latter can be printed and shared with study team members.

IRBIS Office of Human Research Ethics  
 HOME ADMIN GENERAL MANAGEMENT HELP LOGOUT

IRB Number: 11-0051 PI: David Tegnall  
 Study Title: A Survey of State Legislators and City Council Members

Item List click on section name to expand

- General Information
- Part A. Questions Common to All Studies
  - A.1. Background and Rationale

Once you've completed editing your Application, it can be resubmitted at anytime by clicking the resubmit button at bottom left of the screen. Once resubmitted, no further edits can be made unless the Application is returned to pi again.

>> A.1. Background and Rationale

Current Application: View Stipulations Quick View (HTML) PDF View Revisions View FAQ

1. General Information

1. Project Title  
A Survey of State Legislators and City Council Members

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 reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content.

Purpose: Revised purpose statement.

Participants: State legislators in the fifty states and City Council members from the 100 largest cities in America.

Procedures (methods): An online survey.

3. Is this submission similar to or related to an application already approved by a UNC-Chapel Hill IRB?  
No

2. Project Personnel

1. List all project personnel beginning with principal investigator, followed by all co-investigators, faculty advisor and anyone else who has contact with subjects or identifiable data from subjects. The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated.

Last Name	First Name	Department Name	Role
Tegnall	David	Ofc of Human Research Ethics	Principal Investigator
Harden	Jeff	Political Science	Co-investigator