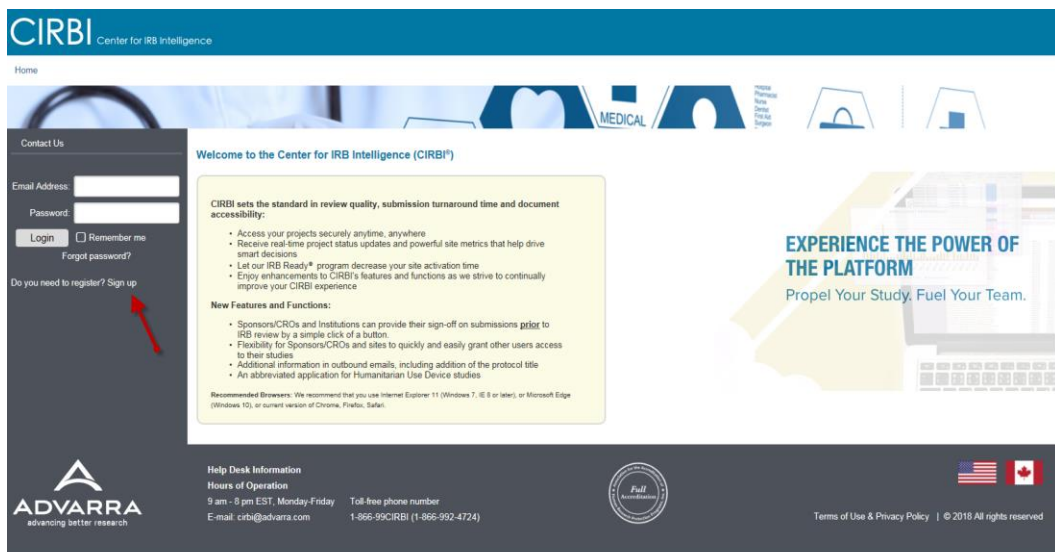


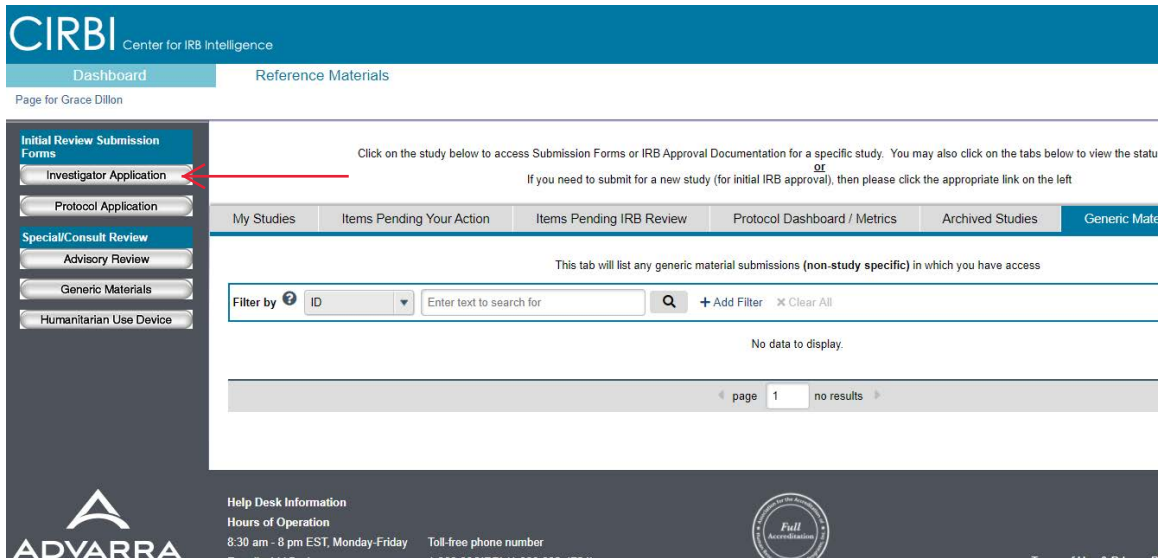
## CIRBI™ Protocol QuickSteps: Submitting an Initial Protocol Application

1. Log on to [www.cirbi.net](http://www.cirbi.net)

**NOTE:** You must be a registered user to log in and create a submission. To do so, click on “**Sign up**” under the login information.



2. In the upper right-hand corner of the screen, click on “**Dashboard**”
3. On the very left-hand side of the screen, click on the “**Investigator Application**” link.



4. Choose “I am a clinical research site that is joining a multi-site study for which Advarra IRB will act as the central IRB. The Sponsor or CRO has or will submit the Protocol”

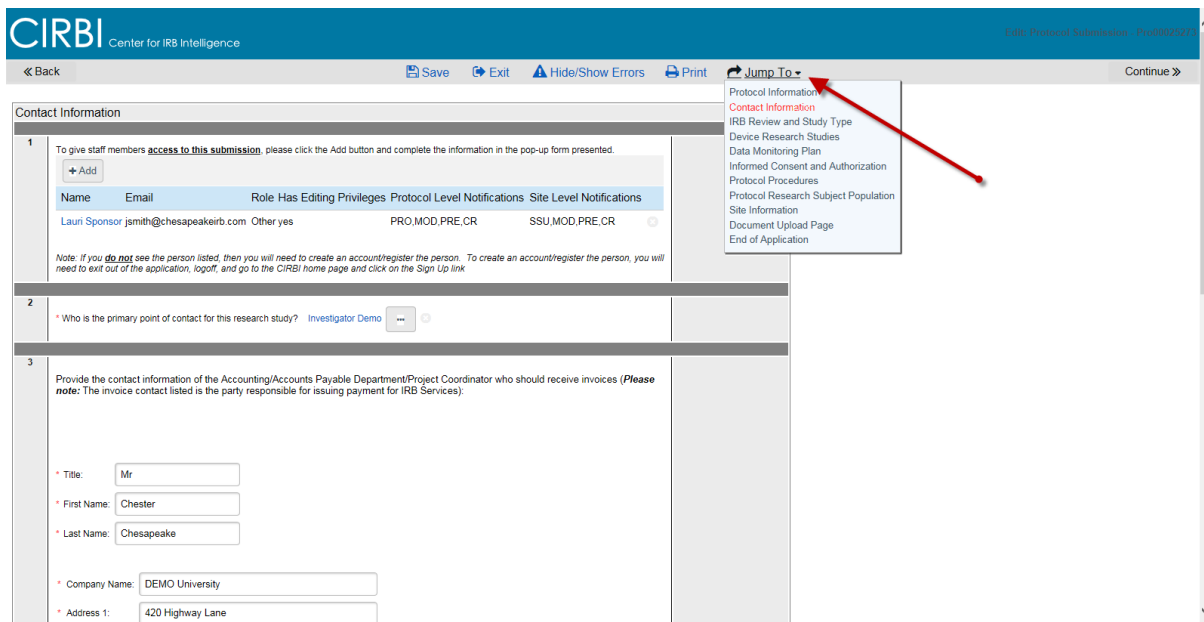
5. Click ‘Continue’ to go to the next page called “Protocol Information”

### **REMAINDER OF APPLICATION**

1. Complete the rest of the protocol application and click “**Continue**” after each completed page.

**NOTE:** Every time you click “**Continue**” it saves all the information you have entered. There is also a “**Save**” button located at the top and bottom of each page.

**TIP:** If you see a red asterisk, that field is required to be completed prior to selecting “**Continue**”. However, if you do not have the required information you can skip to the next page by clicking on “**Jump To**” at the top of the page. You will need to go back and complete ALL required fields before you can submit the application to the IRB.














The screenshot shows the CIRBI web application interface. At the top, there is a navigation bar with the CIRBI logo and the text 'Center for IRB Intelligence'. To the right of the logo, there are several utility buttons: 'Save', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', and 'Continue'. A dropdown menu is open under the 'Jump To' button, listing various sections of the application: 'Protocol Information', 'Contact Information', 'IRB Review and Study Type', 'Device Research Studies', 'Data Monitoring Plan', 'Informed Consent and Authorization', 'Protocol Procedures', 'Protocol Research Subject Population', 'Site Information', 'Document Upload Page', and 'End of Application'. A red arrow points to the 'Jump To' button. Below the navigation bar, the main content area is titled 'Contact Information'. It contains a table with columns for 'Name', 'Email', 'Role', 'Has Editing Privileges', 'Protocol Level Notifications', and 'Site Level Notifications'. The table lists one staff member: 'Lauri Sponsor', 'jsmith@chesapeakeirb.com', 'Other yes', 'PRO.MOD.PRE.CR', and 'SSU.MOD.PRE.CR'. Below the table, there is a note: 'Note: if you do not see the person listed, then you will need to create an account/register the person. To create an account/register the person, you will need to exit out of the application, logoff, and go to the CIRBI home page and click on the Sign Up link.' Below the table, there are three numbered sections: 1. 'To give staff members access to this submission, please click the Add button and complete the information in the pop-up form presented.' 2. '\* Who is the primary point of contact for this research study? Investigator Demo' 3. 'Provide the contact information of the Accounting/Accounts Payable Department/Project Coordinator who should receive invoices (Please note: The invoice contact listed is the party responsible for issuing payment for IRB Services):' This section contains a form with fields for Title (Mr), First Name (Chester), Last Name (Chesapeake), Company Name (DEMO University), and Address 1 (420 Highway Lane).

## DOCUMENT UPLOAD PAGE

1. Next to the last page of the application is called the “Document Upload Page”. This is where you upload any supporting documents such as the Protocol, IB, Informed Consent Form, etc.
2. Upload the documents in the appropriate areas.

Document Upload Page

Please attach all documentation necessary for IRB review in the correct areas as outlined below

| 1   | Protocol Document:  <br><input type="button" value="+ Add"/><br><table border="1"> <thead> <tr> <th>Name</th> <th>Created Date</th> </tr> </thead> <tbody> <tr> <td> Upload Revision Koala.jpg</td> <td>4/24/2018 11:59 AM</td> </tr> </tbody> </table> | Name     | Created Date |  Upload Revision Koala.jpg | 4/24/2018 11:59 AM |   |  |  |  |  |
|---|--|----------|--------------|---|--------------------|---|--|--|--|--|
| Name  | Created Date   |          |              |   |                    |   |  |  |  |  |
|  Upload Revision Koala.jpg | 4/24/2018 11:59 AM   |          |              |   |                    |   |  |  |  |  |
| 2   | Recruitment Materials:  <br><input type="button" value="+ Add"/><br><table border="1"> <thead> <tr> <th>Name</th> <th>Type</th> <th>Category</th> <th>Document</th> </tr> </thead> <tbody> <tr> <td colspan="4">There are no items to display</td> </tr> </tbody> </table>   | Name     | Type         | Category  | Document           | There are no items to display                       |  |  |  |  |
| Name  | Type   | Category | Document     |   |                    |   |  |  |  |  |
| There are no items to display   |  |          |              |   |                    |   |  |  |  |  |
| 3   | Other Protocol Material(s) - including any diaries, questionnaires or other associated protocol documents:  <br><input type="button" value="+ Add"/><br><table border="1"> <thead> <tr> <th>Name</th> <th>Created Date</th> </tr> </thead> <tbody> <tr> <td colspan="2">There are no items to display</td> </tr> </tbody> </table>       | Name     | Created Date | There are no items to display   |                    |   |  |  |  |  |
| Name  | Created Date   |          |              |   |                    |   |  |  |  |  |
| There are no items to display   |  |          |              |   |                    |   |  |  |  |  |
| 4   | Informed Consent Form(s):  <br><input type="button" value="+ Add"/><br><table border="1"> <thead> <tr> <th>Name</th> <th>Created Date</th> </tr> </thead> <tbody> <tr> <td colspan="2">There are no items to display</td> </tr> </tbody> </table>  | Name     | Created Date | There are no items to display   |                    | Please provide a Word document and <u>add</u> a PDF |  |  |  |  |
| Name  | Created Date   |          |              |   |                    |   |  |  |  |  |
| There are no items to display   |  |          |              |   |                    |   |  |  |  |  |
| 5   | Translated Material(s):<br><input type="button" value="+ Add"/><br><table border="1"> <thead> <tr> <th>Name</th> <th>Created Date</th> </tr> </thead> <tbody> <tr> <td colspan="2">There are no items to display</td> </tr> </tbody> </table>  | Name     | Created Date | There are no items to display   |                    |   |  |  |  |  |
| Name  | Created Date   |          |              |   |                    |   |  |  |  |  |
| There are no items to display   |  |          |              |   |                    |   |  |  |  |  |
| 6   | Drug/Biologic Profile(s):<br><input type="button" value="+ Add"/>  |          |              |   |                    |   |  |  |  |  |

**NOTE:** If you have multiple files, you can ‘Drag and Drop’ from your computer into the CIRBI SmartForm.

### **END OF APPLICATION Page**

3. Select either ‘Submit Application’ **or** ‘Save Application, but DO NOT submit’.
4. Click **“Continue”**.
  - a. If you chose ‘Submit Application’, you will see the “Acknowledgement of Receipt” page.
  - b. If you chose ‘Save Application, but DO NOT submit’, you will see the “Not Submitted Notice” page.
5. Click “Finish” to exit