

## **The Center for IRB Intelligence (CIRBI™)**

### **Frequently Asked Questions**

#### **What is Chesapeake IRB's web based system?**

The Center for IRB Intelligence (CIRBI™) is a 100% Web based Web solution that allows full electronic submission of your study data. CIRBI simplifies the way Sponsors, CROs, and researchers submit and manage their studies.

#### **What hours will CIRBI be operational?**

The system is operational 24 hours a day, 7 days a week.

#### **Will I receive my approval documents in paper form?**

Once posted, all documentation within CIRBI is electronic and available at any time on the submission Workspace. If you require a paper copy, you can open the file and print the documents.

#### **How do I print in CIRBI?**

When printing from CIRBI, make sure your print settings are:

- Landscape
- Shrink to fit (not 100%)
- In the Options tab, print all linked documents is chosen (for printing the SmartForm or History Log)

#### **How do I upload attachments?**

To upload an attachment you will click 'Add' in the specified area and a new window will appear.

In the new window, you will click 'Browse' to find the document, and click 'Ok' to select the document. Once selected, you will click 'OK' to add the attachment.

**How do I reach the CIRBI Help Desk?**

The Help Desk phone number is 1-866-99-CIRBI (1-866-992-4724).

The e-mail address for the help desk is [cirbi@irbinfo.com](mailto:cirbi@irbinfo.com).

The hours of operation are 9 am to 8 pm ET, 5 days per week, Monday through Friday.

**Who will use CIRBI?**

All Sponsors/CRO, Investigators, Research Staff, and Institutions utilizing Chesapeake IRB's review services. Chesapeake IRB can also facilitate Canadian sites through our partnership with ethica Clinical Research, Inc.

**As a sponsor of a multi-site study, how do I instruct my selected PIs to sign-up for CIRBI?**

Sponsors and CROs are able to invite PIs to participate in a study through CIRBI. You will enter the PI or study coordinator's email address to send an invitation to come to CIRBI to fill out a site submission.

Inviting the investigators can be done as you are filling out the application or done once the study is submitted. The invitation is sent through CIRBI after you identify the investigators.

**When can I start using CIRBI?**

CIRBI is available for the submission of new studies.

**What about my current paper submissions; can I find them in CIRBI?**

There have been a number of submissions that have been transferred into CIRBI from our legacy (paper) system. However, there are still a number which have not yet been transferred. If you are not sure if it has been transferred into CIRBI, please call the CIRBI Help Desk.

**How do I find the CIRBI website?**

You will be able to access the CIRBI website at [www.cirbi.net](http://www.cirbi.net).

### **How do I obtain a temporary password?**

When you have reached the CIRBI website there is a link on the left hand side of the page that says Sign Up.

When you click the link, you will be taken to a registration page. Once you have registered, Chesapeake IRB staff will review your registration. **Please make sure your email address is valid and spelled correctly or you will not receive your registration email.**

*Please note:* Each person who registers must have a separate unique e-mail address. In addition, anyone who will be working with you on the study or who needs to be able to view the study must be a registered user in CIRBI.

### **How long will it take Chesapeake IRB to review my registration and send my temporary password?**

Sponsors and CROs will receive an e-mail with their temporary password within 24 hours. Site personnel will receive an e-mail with their temporary password immediately.

The e-mail will come to you from [cirbi@irbinfo.com](mailto:cirbi@irbinfo.com), so be sure to add the e-mail address to your 'Allowed E-mail Address' list if you have a junk mail filter.

You will be asked to create a unique password, after typing in your username (e-mail address) and temporary password, which needs to be 8 characters (letters and numbers) and is **case-sensitive**.

### **Do I need a special internet connection?**

No, any PC that has a current Windows 2000, XP, 2003, or Mac Os is able to access CIRBI. Additionally, your Web Browser should be Microsoft Internet Explorer v6 or v7.

### **Is CIRBI secure?**

CIRBI is secure and allows you to keep all study information confidential. CIRBI is FDA 21 CFR Part 11 compliant.

### **Will I need to download any programs to support CIRBI?**

No, you will not need to download any programs to support the CIRBI platform.

### **Can anyone else see my submissions?**

CIRBI has been designed to restrict access only to authorized users. The person completing the application defines the access of others to view or edit a study or site *for that specific protocol or site submission*.

### **I am a Sponsor/CRO – what documents will I need to upload for a Protocol Submission?**

You will need to upload the following – *not all of these may be applicable to your submission*:

1. Protocol document(s) – including any diaries, questionnaires and other associated protocol documents
2. Federal Funding Grant document(s) [if Federally Funded]
3. Informed Consent Form document(s)
4. Investigator’s Brochure(s) and/or Package Insert(s) [for drug studies – in the Drug Profile section of the form]
5. Product Information [for device studies – in the Device Profile section of the form]

### **I am a PI/study coordinator – what documents will I need to upload for a Site Submission?**

You will need to upload the following – *not all of these may be applicable to your submission*:

1. Principal Investigator’s CV
2. FDA Audit Documentation
3. Standard Operating Procedures (SOPs) for Informed Consent Process
4. Waiver of IRB Oversight [if you have a local IRB]
5. Additional ICF text or wording
6. Specialized ICF subject compensation wording

### **Will there be training provided for using CIRBI?**

Yes, we are providing training on CIRBI via Webinars and sharing a short demonstration of CIRBI’s capabilities. Additionally, when you are ready to begin the application, you may contact us at 1 (866) 992-4724 to work directly with you to ensure the submission goes smoothly.

**How do I get information about Webinars?** You can call our main office number at (410) 884-2900 and say you are interested in attending a Webinar. We can then e-mail the registration details so that you may attend.

**Whom do I call if I have a question?**

Call the CIRBI Help desk at 1-866-99-CIRBI and our representatives will be happy to assist you.

**Will I be losing my main point of contact?**

No, your main contact will still be the same project team, which will continue to assist with your study submission and thereafter. CIRBI is a valuable communication tool to be used throughout the life of the study. You will be able to view the study at any time from its submission through termination.

**Does CIRBI store site information?**

Yes, CIRBI stores CVs, Audit reports, and contacts for future use once they have initially been entered. This is a great advantage of using CIRBI.

**How are review timelines affected by CIRBI?**

The review timelines have been decreased significantly by elimination of the time it takes to mail documents both to and from the IRB. Our review timeline is within 7 business days of receipt of a **complete** submission. Additionally, once the review is complete it is posted on CIRBI for you to view immediately.

**Can Chesapeake view an application as soon as it is submitted to CIRBI?**

Yes, as soon as a study is submitted to CIRBI, the Project Coordinator at Chesapeake can view the study application and documents.

**Who is able to edit a submission in CIRBI?**

Only registered users you have identified on your initial application will have edit rights for the life of your specific study or site.

**How will the Principal Investigator be notified of information for their site in CIRBI?**

The PI is copied on all emails sent from CIRBI

**Where are the CIRBI backups located?**

The CIRBI site and its data is hosted, stored, and backed up by Click Commerce®. Their headquarters are in Chicago and their redundant storage facilities are in Oregon and Texas. Backup procedures include regular full and incremental backups and backups of the site are made prior to updates being made to the site.

**How can I provide feedback regarding the system?**

To share your comments and feedback regarding CIRBI please e-mail [cirbi@irbinfo.com](mailto:cirbi@irbinfo.com).

*We appreciate your business and hope that you will share your positive experience with colleagues who conduct studies.*