# IRBMANAGER USER MANUAL

## Bluebonnet Ethical Review

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# Bluebonnet Ethical Review

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# 1. WHAT IS IRBMANAGER?

## A. Description

IRBManager is a web-based system that supports electronic submissions of new studies and modifications to Bluebonnet IRB. It is also a fully interactive client portal that includes and accepts study and customer data, documents submitted to the IRB, approvals, informed consents, expirations, electronic signatures, automated email notifications, tracking and IRB distribution. IRBManager is an open, 21 CFR, Part 11 compliant system that contains a verification process for new users.

All study documents submitted to the IRB will be maintained in the system and be accessible by Users given access to the study. It is highly recommended that you maintain your own copies of these documents outside of the system.

## B. System Capabilities

- Streamlined submission and IRB review processes
- Immediate "real time" receipt of IRB documents
- Validation component to check user data
- Direct electronic submission of forms
- Electronic signatures
- Tracking of studies and forms
- Accessible from any location that has internet access

## C. Data Security

Your privacy is important to us. To better protect your privacy we provide this notice explaining our online data practices and the choices you can make about the way your personal data is collected and used.

'Personal data' is any information relating to an identified or identifiable natural person; an identifiable natural person is one who can be identified, directly or indirectly, by reference to an identifier such as a name, an identification number, location data, or an online identifier.

**Data We Collect:**

This notice applies to all data collected or submitted in IRBManager. At a minimum, the types of personal data collected are:

- First and Last Name
- Company name

> Mailing (Physical) Address
> Email address
> Phone number

Personal data that may be collected by BBIRB on behalf of study participants are initials and study identification numbers.

**The Way We Use Data:**

We use the data you provide about you and your research study for each specific study only. We do not share this information with outside parties except for the Sponsor, CRO, or federal agencies.

We use return email addresses to answer the email we receive. Such addresses are not used for any other purpose and are not shared with outside parties.

Finally, we never use or share the personal data provided to us online in ways unrelated to the ones described above.

To prevent unauthorized access, maintain data accuracy, and ensure the correct use of information, we have put in place appropriate physical, electronic, and managerial procedures to safeguard and secure the data we collect online. All registered users accessing study information through IRBManager acknowledges that they have been given permission to access such information by the study Site, Sponsor or CRO.

Bluebonnet IRB ("BBIRB") acknowledges that, in the course of business relations, BBIRB may have access to or have disclosed to it by a research Site, Sponsor and/or CRO certain information belonging to the same. Such information may include, but not be limited to, research protocols, technical data, trade secrets, materials, certain non-public information, and other proprietary information ("Confidential Information"). BBIRB maintains such Confidential Information in the strictest confidence and will use Confidential Information only in furtherance of conducting its functions as an institutional review board. BBIRB does not divulge, furnish, or make accessible to anyone, other than its respective officers, employees, IRB Members and contracted consultants, in the regular course of business, any Confidential Information without the express written approval of the research sponsor and/or CRO or except as disclosure is required by law, regulation, rule, act, or order of any governmental authority or agency or court of competent jurisdiction. BBIRB uses all reasonable safeguards to prevent unauthorized use and/or disclosure by its officers, employees, IRB members and contracted consultants who are bound, in writing, to keep such information confidential. In addition, BBIRB adheres to all requirements of HIPAA with respect to maintaining the confidentiality of and protecting any Protected Health Information (PHI) that may be provided to BBIRB during its business activities.

![Bluebonnet Ethical Review logo]

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## 2. Login/User Accounts

### A.  Accessing IRBManager
- ➢ Access IRBManager using the direct site address: Login | IRBManager
- ➢ Enter Client ID as 'BBER' and click 'Sign In'
- ➢ This will redirect you to the BBER Login Screen
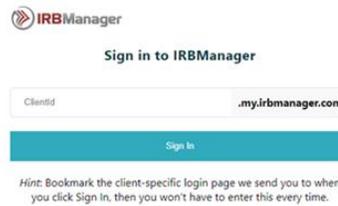


### B.  New Users – do not have an established login/password to access IRBManager
- ➢ To register click on 'Click here to register' and complete the registration process



- ➢ Once complete, click on 'Register'
- ➢ You will receive an email containing a username and link to set up a new password

**Note**: If you already have a registered account, you will be brought back to the login page – this means that they system is recognizing your email address.  You recover your password by following instructions under the section 'Forgot Password'

### C.  Existing Users/Login
- ➢ Enter your User Name: email address
- ➢ Enter your password: If you have forgotten your password refer to 'Forgot Password' section below.

### D.  Passwords
A valid password must be at least 6 characters long, be different from the user name, and contain characters from at least 3 of these groups:
- ➢ Uppercase letters

➢ Lowercase letters
➢ Numbers and Special characters (e.g. !, @, #, ~)

Note: Passwords must be different from previous 5 passwords.

### FORGOT YOUR PASSWORD

If you forgot your password, select 'Forgot Password?' on the login screen. You will be asked to provide your email address and to type an image code to retrieve your password. Within a few minutes, you will receive an email containing a link to reset your password.

### LOCKED OUT

If locked out of the system due to several failed login attempts (entering an incorrect password), select 'Forgot Password?' and follow the steps above to reset a new password.

## E. Add/Make Changes to Contacts

### REQUEST ACCESS TO IRBMANAGER FOR A NEW CONTACT

New contacts can be added to IRBManager by any registered user at any time. From the Dashboard click on 'Start xForm'. Select/submit the 'Create New Contact' form. Once this form has been submitted, (1) the new user will be created in the system and be emailed username and a link to create a password and (2) you will receive an email notification that the new contact you added in IRBManager now has new user access and has been provided with login information. You may now use this contact in new forms.

NOTE: This option is also included in some of the xForms and you will be required to complete the 'New Contact Submission' when you enter a contact name that is not recognized by the system.

### MAKE CHANGES TO CONTACTS ON YOUR STUDY

If at any time changes need to be made to include study personnel, any registered user can add users to specific studies at any time. Select the study in which you want to add or remove study personnel, under Actions (left-side tool bar) select 'Start xForm', select/submit the '**Key Personnel Change Form**'. Once this form has been submitted, the new user will be created in the system and provided access for the study.

## 3. Home Page

Upon login, you will have the ability to (1) view all studies and forms that you have submitted to the IRB, (2) view all active protocols to which you are associated, (3) submit forms to the IRB, (4) view contacts that have access to your study/site and (5) track progress/status on all information submitted to the IRB. You will also have the option to send the IRB emails through IRBManager once inside the Study Summary Page (SSP).
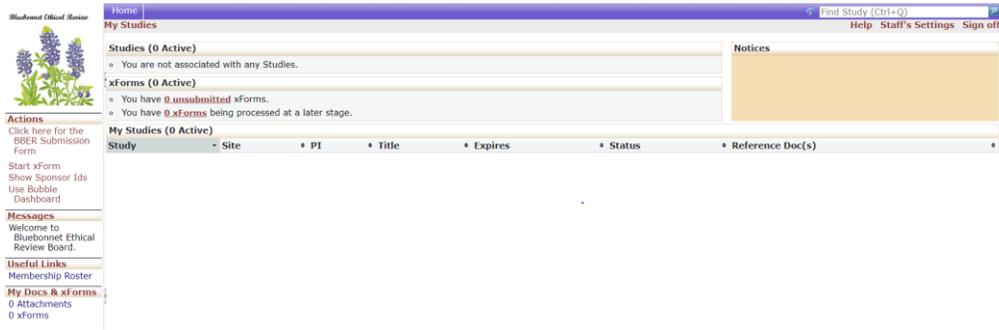
A. Top blue tool bar is HOME, you will see the following information on the HOME page:

**Note**: The information below is based off the Power Dashboard view (Not the Bubble Dashboard)

**Studies (# Active)** – allows you to view all active & closed protocol numbers (studies) submitted to BBIRB and those in which you are associated. In addition, this section will indicate any protocols that are expiring in the next 90 days.

**xForms (# Active)** – allows you to view all forms that have been started and submitted, along with the status of each form (i.e. those that have not yet been submitted, those being processed, those awaiting your attention, etc.)

**Events (# Open)** – allows you to view all Events (forms/requests) that have been submitted to BBIRB but have not yet been completed/distributed by the IRB.

**My Studies (# Active)** – allows you to view all active studies submitted to BBIRB. You can click on the study codes (or study number) to open the study file, which will show study information, contacts, events, attachments, etc.
**Find Study (top- right tool bar)** – allows you to search for a study per the sponsor, protocol number, PI name, etc

B. Left side tool bard, you will see the following sections:

**Actions** - allows you to select, complete and submit a new form to the IRB. Has an option to Use Bubble Dashboard (a different kind of view).

**Recent Items** – allows you to view the 7 most recent items you have accessed. You can also 'Pin' a recent item to keep it on the list. Click on the 📌 icon and it will keep this link at the top of the list. To 'Unpin', click on the icon again.

**Messages** – allows you to view system-wide messages posted by BBIRB. This section will only appear if there is a system wide message posted.

**Useful Links** – allows you to access information posted by BBIRB, such as this User Manual, Membership Roster, etc.

**My Docs & xForms** – allows you to add attachments to your user account by clicking on "Attachments" – these will be maintained on your **HOME** page and not associated with a study.

This also allows you to view xForms that you have started (in progress) and forms that you have previously submitted to the IRB. When you click on "# xForms" a list of these forms will appear and you have the option to either open the form to complete/submit, copy the form by clicking on the 🗐 icon (this will only be available when the form is allowed for copying) or click on the **X** to delete the xform.

C.    Top-right tool bar, you will see the following tabs:

**Help** – allows you a few options to see out support regarding IRBManager.

**Settings** – allows you to change specific profile information (i.e. password, phone number, address, etc.).

**Sign Off** – allows you to log out of the system (Note: System will log you off of the system after 4 hours of inactivity.)

## 4. How to Submit

### A. New Study Submissions

Under Actions (left-side tool bar) select 'Click here for the BBER Submission Form'. Prior to initial study approval, xForm is the term used to identify general forms that can be submitted anytime and are not already tied to a specific study (i.e. new study submission forms and requests to add new contacts to the system).
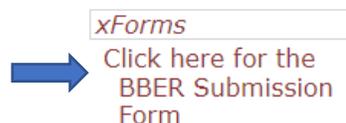
**NOTE**: The BBER Submission Form encompasses all types of submissions (Single, Multi & Additional Investigators joining a multi-investigator study).

## B. Copy a New Study Submission Form

You can copy a previously submitted New Study Submission Form (this does not apply to continuing review or other xForms), which will copy (pre-populate) questions for you. This will allow for the elimination of like data you are required to manually enter each time. The questions that will be copied will be in regard to the Investigator, site contacts and site demographics and will **NOT** copy study specific data from an old form to a new form.

As seen in the screenshots below, you will have several options on how to select a previously submitted form to copy.

**Option 1**: Clicking on # xForms from '**My Docs & xForms**' section (left hand side of screen):



**Option 2**: Clicking on the link for '**xForms** being processed at a later stage' under the '**xForms**' tab:
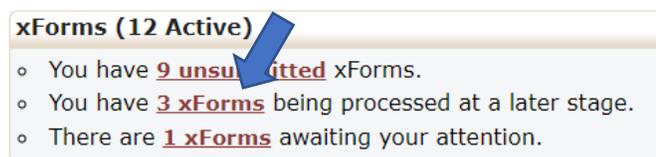


Submission Forms that can be copied, will have this icon next to it. Click on the icon and a message will appear asking if you want to proceed. Click OK. Any pages in the submission form that contain copied data will include a bold header indicating such. You may edit copied data as appropriate for the new study.

**NOTICE FOR COPY FEATURE:** If you chose to "copy" this form from a previously submitted form some or all of the answers below have been copied. Please ensure the information is accurate for *this* study and edit as appropriate.

## C. Collaborator Feature

You have the ability to collaborate with colleagues to assist with the completion of any xForms. On the top of the page, you will see an icon to add collaborators:


Collaborators

When this feature is selected, you will enter the email address of the person (or persons) in which you with to collaborate with.  (**Note**, Collaborators must already be registered Users in the system, refer to Section 1 for instructions.) You will select the type of permission (Access) you want them to have.



**View Only**: Allows the collaborator to only View the submission form (can be used when certain personnel require reviewing prior to submitting to the IRB)

**Edit**: Allows the collaborator to only Edit the form prior to submitting to the IRB

**Edit and manage**: Allows the collaborator to Edit and manage the xForm prior to submitting to the IRB

**Edit, manage, and submit**: Allows the collaborator to Edit, manage and submit the submission to the IRB (without any approval from the original creator of the xForm).

You can add Notes for the collaborators, as well as copy you on the email (click on CC Me) then select '**Add**' to send the email.  Collaborators will then receive an invitation via email with a direct link to the xForm.  Collaborators will only be able to access the form through this link.

## D.  Study Specific xForms (after initial approval)

Once you have study approval, modifications to the research can be submitted utilizing study specific xForms.  These study specific xForms can only be found on the Study Summary Page (SSP).  Once you are on your SSP, you can click on the link (left hand side of screen) 'Start xForm' (see Blue arrow below).  This will pull up the list of all study specific xForms (i.e. Modifications Request Form, Protocol Deviations, IRB Continuing Review Form, Adverse Event Form, etc.)

**NOTE**: **Sponsors/CROs managing a multi-investigator study** will see an additional section between 'Protocol' and 'Protocol Site' labeled 'Other Sites' that includes a list of all PIs along with the PIs site name. The Sponsor/CRO (aka Project Manager) details will also be included in this list as a protocol site. Be sure to select the Project Manager name/site from this list to ensure you are accessing the appropriate Study Summary Page (SSP) prior to submitting a form.

**Tip**: You can collapse (hide) any of the other Tabs by selecting the green arrow next to each Tab.

## E.  Attaching Files to Forms

There are multiple options to attach files to forms... (1) within the upload browser, browse and select a file located on your computer and attach or (2) drag/drop single or multiple attachments by selecting the document(s) from your computer or from email and drag the document(s) over to the attachments file and drop them. Your documents will automatically attach to the file.  You will have options to utilize platforms like Dropbox or box to select files and attach as described above.

# 5.  How To Find Your Study Documents

## A.  Access to Study Summary Page [SSP]

There are two ways to access your study. Active studies are available on your **HOME** page listed under 'My Studies' and you can locate specific protocols by using the 'Find Study' search feature located on the **HOME** tool bar. To access the study file, select the protocol number under 'My Studies'.

## B. Access to Study File (View and retrieve your approval documents)

On the Study Summary Page (SSP) view [See Study Summary Page View above], you can view all protocol, PI and site details and the events (forms) that have been submitted under 'Submissions' tab. Click the event link to view the steps that have been/will be taken by the IRB. The IRB completion dates of each Step are found under 'Actual' date.

## C. Submissions/Events

Submissions (or Events) are defined as xForms/requests you are submitting to the IRB (see Submission/Event View below).  Once you have submitted an xForm to the IRB and the IRB has completed the first step (after Submission Received step) on the xForm (i.e. Quality Assurance) the Submission will appear on your SSP.

**NOTE**: The submission will not load into the system (appear on the SSP) until the IRB has completed the Quality Assurance step.

## D. Attachments

To view attachments to any Event, you must be in the Study Summary Page (SSP) and have the specific Event open. [See Submission/Event View below] On the left side tool bar, click on 'Attachments' to review the documents you have submitted and the actions taken by the IRB. You can also retrieve your attachments by clicking on the column labeled 'ATT' and selecting the number listed below it. This will take you directly to the Attachment page view. BBIRB approval documents will be posted under a sub-heading labeled 'BBIRB Approval Documents'. The system accepts all file types with no size limits.

## E. Steps

Steps are defined as actions to be taken by BBIRB on an Event. You may view the steps (action/status) being taken on a form anytime by opening the form under 'Events'. (Remember that an Event is the form/request that has been submitted.) Steps exist to provide you with a "real time" status on Events.

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## SUBMISSION/EVENT VIEW



## EVENT VIEW



## F. Filtering/Searching

There are a couple of ways to search for study files and/or Events within your SSP.

You can filter for similar Events by clicking somewhere inside the row of the column in which you want to search (search for all Modification Submissions). The result will place a yellow highlighted border around all the records that contain the same name (see Search View below).

You can also search for specific Event topics by clicking the top of the Instance field where a search bar will appear. You can enter specific information into any of the search fields, such as entering Amendment 3 into the Instance field and this will pull up all Events with those combination of words. (see Search View below).

**Search View**



## 6. Form and Navigation Tips

### A. Form Navigation Buttons at the top of each page of the xForms

**Collaborators** - allows you to select a colleague to assist with the completion/submission of a form.  Refer to Section 4.C above for more details.

**Page titles/headers** - allows you to "jump" between pages of the xForm before completing all required questions on a page. Click on the drop down to choose the page you wish to jump to. If all required questions are not completed when you submit, you will receive a message that the form is not complete.



**Page numbers** - shows "Page x of y" on each page of the form

**Next** - saves the current page and takes you to the next page in the form (all Required questions on the page must be answered to move forward when using Next).

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## B. Form Navigation Buttons at the bottom of each page of the xForms

**Previous** - takes you back to the previous page

**Next** - saves the current page and takes you to the next page in the form

**Save for Later** - saves the progress in the current form to finish later (if you meant to move to the next page, you can click on the browser's back button and click the 'Next' button)

**More** – allows you to view specific types of questions (Attachment Questions, Questions with Notes or Changed Responses) as well as view the submission form as a PDF.

## C. Required Fields

Questions that required are indicated as *(Required)*.  This means that you have to provide an answer before submitting the form or moving to the next page.

When "Required" fields are left blank, an error message will alert you in red text as to which questions have information missing.

## D. Attachments

When an attachment is required or may be necessary, the question will provide you with the option to upload a file. This will be evident for those questions that contain an upload browser. The system accepts all file types with no size limits.

For those questions that may require more than one attachment, the system will allow for multiple files to be uploaded one at a time. If for some reason you are not allowed to upload more than one attachment, please contact the IRB Office for assistance.

To attach a file, click on Add Attachment (the upload browser), enter the name of the file, or in some cases you may also have to select the Type of attachment.  Click on 'Select Files' and locate the file from your computer files then click 'Attach'. You will then see the attachment on the form view.

## E. Notes

Need to make a quick note related to a question to return to later (i.e. as a reminder) or need to submit comments/questions to the IRB in regards to the question? In the top right corner of each question select Add Note , this will allow you to enter a comment.  Click Save and the comment will appear on the question.  If you require edits to your comments, click on the icon and this will allow you to edit your comments.  If you don't need the comment you can click on the to delete the comment.

### F. Signatures

Bluebonnet does **not** require signatures on any of the xForms.  In the BBER Submission Form, there is an option for the person completing the form to allow for the investigator to review and sign off on the submission form prior to IRB submission, if needed.  To sign a form electronically the PI will be sent an email instructing them to perform a final review of the form and to enter his/her password, which will represent his/her signature.

## 7. System Requirements

### A. Supported Operating Systems (OS) and Browsers

The system is compatible with the following operating systems: Current versions of Windows, Linux, OS X (Mac) and iOS (iPad/iPhone) and Android (Google)

The system is compatible with the following internet browsers: The current (N), previous (N-1), and previous-previous (N-2) versions of Internet Explorer (IE) 8>, Firefox, Chrome and Safari on supported OS

NOTE: Beta versions of browsers are not supported. IRBManager may, and likely will, work in many unsupported browser/operating system configurations, but will not provide anything beyond cursory support if the issue cannot be reproduced in a supported OS/browser configuration.

## 8. Help & Support

For general questions and assistance with forms or system navigation contact the IRB Office at 512-300-8832 or send an email to support@bbirb.com