UT Health East Texas IRBManager User Guide for Researchers and Staff

Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Logging into the System</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>Homepage/Dashboard</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>How to Submit a New Protocol</td>
<td>6</td>
</tr>
<tr>
<td>4</td>
<td>How to Submit a Continuing Review, Modification, Reportable Event or Closure</td>
<td>7</td>
</tr>
<tr>
<td>5</td>
<td>How to Change your password</td>
<td>9</td>
</tr>
<tr>
<td>6</td>
<td>How to Sign a Conflict of Interest Disclosure form (COI)</td>
<td>9</td>
</tr>
</tbody>
</table>
Section 1: Logging into IRBManager

1. Go to this website: https://uthealtheasttexas.my.irbmanager.com

2. Enter the User Name (usually the email address you provided to the IRB office) and Password that you were provided (you will be given the option to change your password).

3. Select <Login> to continue.
Section 2: Homepage/Dashboard

Upon logging in, your homepage will appear and look similar to the screen shot below:
1. **Studies** - Summary of your studies (Studies that are closed or have not been submitted will NOT appear in "Active")

   Under "Studies" you will see the number of active and the total studies you are associated with. By clicking on either #active or #total will show a list of your studies you are associated with. This section lists the specific roles you have for each study (PI, Sub-I, Coordinator; etc.). This section also provides you with the next study to expire and all of the studies expiring in the next 90 days.

   ![Studies Section](image)

2. **xForms** - Summary of your xForms. Xforms are submission forms (mod, CR, initial, reportable event, exemption, etc.)

   Forms you are currently working on will be listed under #unsubmitted xforms. You can work on multiple forms at the same time, and save them for completing at a later time. If you click on this link, you will find a list of the forms you are working on but have not yet been submitted.

   ![xForms Section](image)

   Once a form is submitted, it will be listed under #xForms being processed.
3. Events
Once a form has been submitted and accepted into IRBManager, an event is created. To see what events are open (i.e.; Modifications, Initial Reviews, etc.) look under the events section and you will be able to check the status of that event. The "only show events where I am:" dropdown will allow you to sort the events by the role (i.e. Principal Investigator, Co-Investigator, Coordinator) that you have within the study.

![Events (6 Open)](image)

4. My Studies - Listing of your studies
You can filter your list of studies on the particular item you choose to filter (i.e.; PI Name, Expiration Date, etc.). When the filter feature is turned on, a yellow dashed box surrounds the data. To remove the filter, click again on your original filter item. You can click on the Study number of any study to view the study details.

![My Studies (4 Active)](image)
Section 3: How to Create a New Protocol

Start on your Homepage and look to the left hand column:

a) If you want to create a new study in the system for the IRB to review, click on <Click here to submit a new protocol >. This includes a protocol that would receive regular IRB review either through expedited or full board review.

b) If you want to create a new Humanitarian Use Device (HDE) submission, click on <Click here to start new HDE protocol>.

c) If you want to create a new protocol that meets Exemption Criteria, click on <Click here to start an Exemption protocol>.

d) If you want to start a form for Reviews Preparatory to Research, click on, <Click here to start a new Preparatory to Research protocol>.
Section 4: How to Create a Continuing Review, Modification, Reportable Event, or Closure form for Studies that have already received Initial IRB review and approval

For all other submissions----To submit a request on an active study that is already approved, click on # active Studies, from your homepage

then click on any Study # under the "Study" column.

Once in the study, click on <Start xForm> on the left side of your screen under "Actions."
After clicking `<Start xForm>` you will see a screen similar to the below image.

**Note:** The screen above represents SOME of the available forms. (screenshot is for example only). To complete one of forms above, you must be in the specific study for which you want to complete the form.

Select the xForm needed by clicking on the form's title----by hovering over the blue hyperlink.
Section 5: How to Change your Password
To Change Your Password and other Settings
After logging in select <settings> at the top right hand side of the page; you will then have the option to change your password, contact information, update your profile, etc.

Section 6: How to Sign a Conflict of Interest Disclosure
Below are the different stages involved in the review of a new or continuing review protocol.
Stage 1—Xform is drafted by the coordinator and upon completion the coordinator submits for PI review
Stage 2—PI reviews the Xform submission for completion and accuracy
Stage 3—After the PI has reviewed the submission for completion the form moves to the next stage which is the Conflict of Interest stage. In this stage, all individuals listed on the protocol will be required to sign into the protocol and disclose whether or not they have a conflict of interest related to this specific project.
Stage 4—Once everyone on the protocol has signed a COI disclosure for this submission then the submission moves to the IRB review stage.

The Conflict of Interest stage and disclosures are only required of new initial review protocols and continuing review protocols.
Each individual listed on a protocol that is submitted for initial review or continuing review will receive an email letting them know that their disclosure is needed with information provided as to study title, protocol number, and Principal Investigator. Please log into IRBManager and follow the following steps to complete the COI disclosure.

From your homepage look for the following:
Forms that require your sign off will be listed under #xForms awaiting your attention.
After you click on the under **# xForms awaiting your attention** link, it will bring up a list of forms.

Click on the blue link to the form to complete the stage of the form that requires your attention.

Once the submission form opens scroll to the very bottom of the form and you will see information explaining the Conflict of Interest Policy. If you DO NOT have a conflict of interest related to this specific research study then hit the “Next” button. Then on the following page, you will hit the “Submit” button and you are then finished.

If you DO have a conflict of interest to report related to this specific research study then hit the link that says “Report Conflict”. A new window will open and a blank COI disclosure form will appear ready for you to report your conflict to the IRB.

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If you have any questions about IRBManager please contact the UT Health East Texas IRB office at: [irb@uthet.com](mailto:irb@uthet.com) or 903-535-6525

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<thead>
<tr>
<th>Form</th>
<th>Identifier</th>
<th>Owner</th>
<th>Stage</th>
<th>Status</th>
<th>Started</th>
<th>Requires Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETMC Submission Form</td>
<td>Initial Submission-- Expedited Review with Supplements to Table</td>
<td>Bush, Lisa MS (<a href="mailto:kbush@etmc.org">kbush@etmc.org</a>)</td>
<td>Financial Conflict of Interest</td>
<td>Awaiting Signature(s)</td>
<td>1 hours ago</td>
<td>Yes</td>
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<tr>
<td>ETMC Submission Form</td>
<td>Initial Submission-- Expedited Review with Supplements to Approve with Mods</td>
<td>Bush, Lisa MS (<a href="mailto:kbush@etmc.org">kbush@etmc.org</a>)</td>
<td>PI Signature for Coordinator Submission</td>
<td>Work in progress</td>
<td>10/27/2017</td>
<td>No</td>
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</tbody>
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