



UT Health East Texas IRBManager User Guide for Researchers and Staff

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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.



UTHealth
East Texas

Login

User Name

Password

Client

Remember Client

[Forgot Password?](#)

Copyright © 2000-2018 Tech Software. All Rights Reserved.
SteamPunk (2017.11.27).0/Release/8900be34e79f868d64aca0db505d5ab23fb9137
TP-WEB01 at 2018-06-12 11:56:08Z
Page generated in 0.003 seconds.

Section 2: Homepage/Dashboard

Upon logging in, your homepage will appear and look similar to the screen shot below:

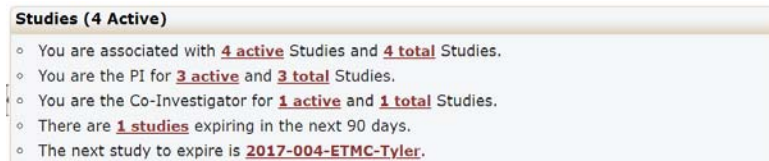
The screenshot displays the IRBManager dashboard for UT Health East Texas. The interface includes a navigation menu on the left with sections like Actions, Recent Items, Messages, Useful Links, and My Documents & Forms. The main content area is divided into several summary cards: 'Studies (4 Active)', 'xForms (4 Active)', and 'Events (6 Open)'. A 'Notices' sidebar on the right features a welcome message and the next IRB meeting date: Monday, April 2, 2018. At the bottom, a table titled 'My Studies (3 Active)' lists three studies with columns for Study ID, Site, PI, Title, Expires, and Status.

Study	Site	PI	Title	Expires	Status
2018-002-UF	University of Florida	Researcher, Test	The Effect of Obesity on Immune Responses to the Yellow Fever Vaccine	02/28/2018	Open to enrollment
2018-003-HIV	HIV Clinics	Coordinator, Test	Opioid misuse, overdose and access to behavioral health services in Orange County, Florida		New From PI
2018-004-DFT	Default Site	Researcher, Test	Yellow Fever - Testing for Levels of Exposure	02/12/2019	Open to enrollment

Your IRBManager Homepage is broken down into four main sections:

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 (4 Active)

- o You are associated with **4 active** Studies and **4 total** Studies.
- o You are the PI for **3 active** and **3 total** Studies.
- o You are the Co-Investigator for **1 active** and **1 total** Studies.
- o There are **1 studies** expiring in the next 90 days.
- o The next study to expire is **2017-004-ETMC-Tyler**.

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 (4 Active)

- o You have **0 unsubmitted** xForms.
- o You have **3 xForms** you've signed that are awaiting others' signatures.
- o You have **4 xForms** being processed at a later stage.
- o There are **2 xForms** awaiting your attention.

Once a form is submitted, it will be listed under **# xForms being processed**.

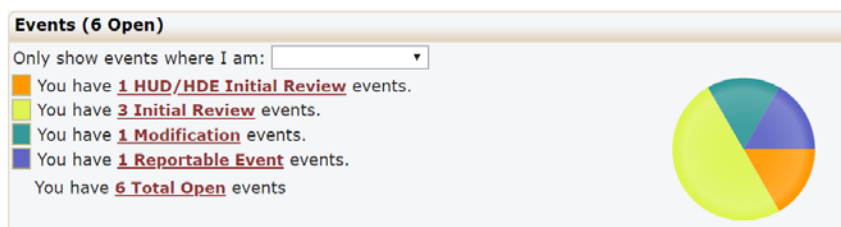


xForms (4 Active)

- o You have **0 unsubmitted** xForms.
- o You have **3 xForms** you've signed that are awaiting others' signatures.
- o You have **4 xForms** being processed at a later stage.
- o There are **2 xForms** awaiting your attention.

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.



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)						
Study	Site	PI	Title	Expires	Status	
2017-003-ETMC-Tyler	East Texas Medical Center-Tyler	Test, Investigator MD	Phase 3 Open Label Double Blind Study to see if Skittles taste better than M&M's.	08/22/2018	Open Enrollment & No Subjects Enrolled to Date	
2017-004-ETMC-Tyler	East Texas Medical Center-Tyler	Test, Investigator MD	Transcatheter Aortic Valve Replacement in Low Risk Patients	05/26/2018	Open Enrollment & No Subjects Enrolled to Date	
2017-007-ETMC-Tyler	East Texas Medical Center-Tyler	Researcher, Pat	The PREVAIL Study (PREVAIL)	10/30/2018	Open Enrollment & No Subjects Enrolled to Date	
2018-003-ETMC-Tyler	East Texas Medical Center-Tyler	Test, Investigator MD	HUD/HDE test for Full Board Deferment		New From PI	

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

Studies (4 Active)

- You are associated with **4 active** Studies and **4 total** Studies.
- You are the PI for **3 active** and **3 total** Studies.
- You are the Co-Investigator for **1 active** and **1 total** Studies.
- There are **1 studies** expiring in the next 90 days.
- The next study to expire is **2017-004-ETMC-Tyler**.

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

Studies (4 Active)

Study	Site	Title	Expires	PI	Status
2017-003-ETMC-Tyler	East Texas Medical Center-Tyler	Phase 3 Open Label Double Blind Study to see if Skittles taste better than M&M's.	08/22/2018	Test, Investigator MD	Open Enrollment & No Subjects Enrolled to Date
2017-004-ETMC-Tyler	East Texas Medical Center-Tyler	Transcatheter Aortic Valve Replacement in Low Risk Patients	05/26/2018	Test, Investigator MD	Open Enrollment & No Subjects Enrolled to Date
2017-007-ETMC-Tyler	East Texas Medical Center-Tyler	The PREVAIL Study (PREVAIL)	10/30/2018	Researcher, Pat	Open Enrollment & No Subjects Enrolled to Date
2018-003-ETMC-Tyler	East Texas Medical Center-Tyler	HUD/HDE test for Full Board Deferment		Test, Investigator MD	New From PI

Once in the study, click on **<Start xForm>** on the left side of your screen under "Actions."

UTHealth East Texas

Home Find Study (Ctrl+Q) Study 2017-003-ETMC-Tyler (IRB) Help Investigator's Settings Sign off

Actions

- Send EMail
- Start xForm xForms (0)
- Done

Recent Items

- 2017-003-ETMC-Tyler
- 2017-007-ETMC-Tyler

Messages

Welcome to IRBManager at ETMC

Useful Links

- 2017 IRB Meeting Dates

My Documents & Forms

- 0 User Attachments
- 2 xForms

Study

Study: 2017-003 Sponsor(s): *Not Funded (Primary)

Committee: IRB Sponsor Id:

Category: Grants:

Department: Next Review:

Last Review: CRO:

Agent Types: Clinical Tests • Collection of clinical specimens • Interview • Prospective Chart Review • Questionnaire/Survey Year: 2017

Title: Phase 3 Open Label Double Blind Study to see if Skittles taste better than M&M's.

Risk Category: Comments: Control group will consist of 45 subjects. Blinded group will consist of 45 subjects. Neither the research staff or the subjects will know if they are receiving skittles or M&M's for the treatment of afternoon blues.

Study-Site

Site(s): ETMC-Tyler - East Texas Medical Center-Tyler PI: Test, Investigator MD

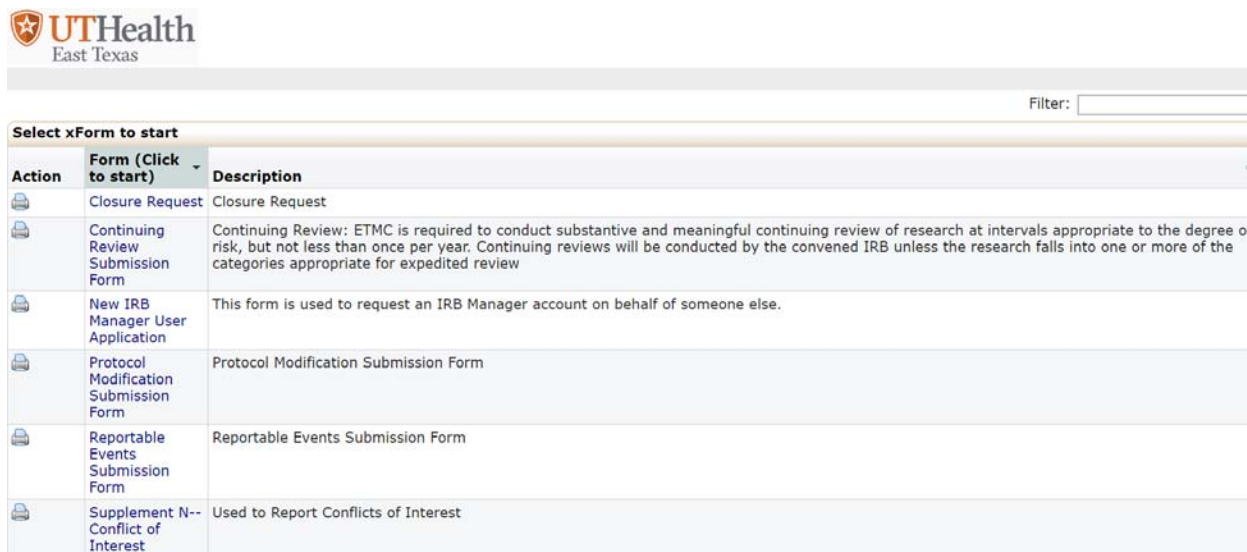
Status: Open Enrollment & No Subjects Enrolled to Date Additional: N

Approval: August 23, 2017 for 12 months Expiration: August 22, 2018







Initial Approval: August 23, 2017 Other Expirations:

Comments:

After clicking <Start xForm> you will see a screen similar to the below image.

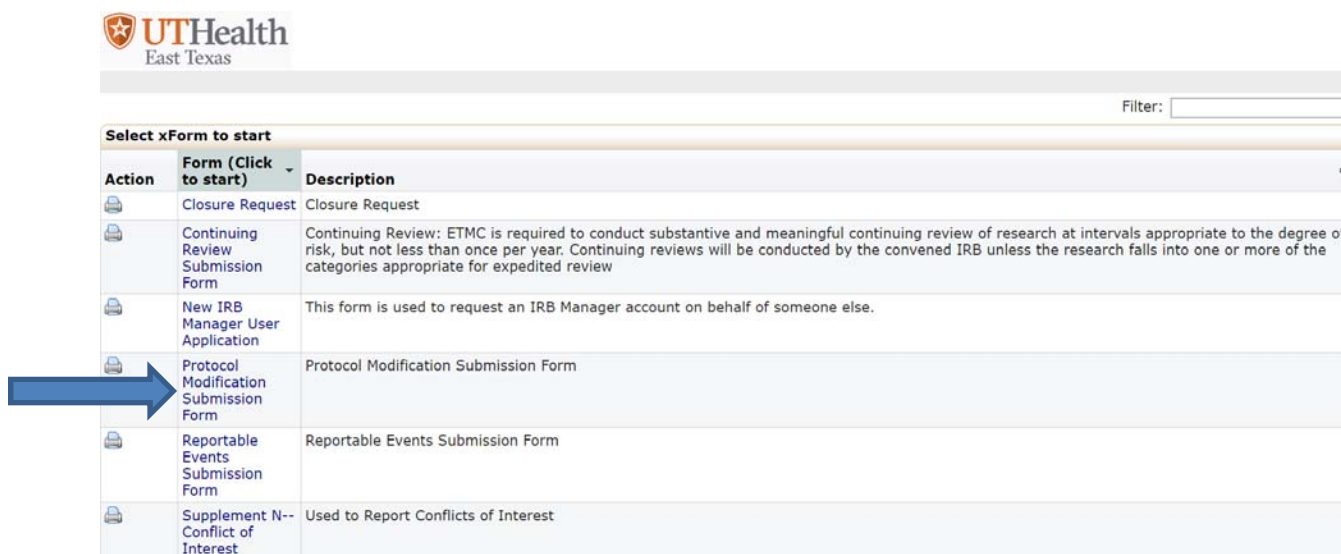


The screenshot shows the UTHealth East Texas logo at the top left. Below it is a search bar labeled "Filter:". Underneath is a section titled "Select xForm to start" which contains a table with three columns: "Action", "Form (Click to start)", and "Description".







Action	Form (Click to start)	Description
	Closure Request	Closure Request
	Continuing Review Submission Form	Continuing Review: ETMC is required to conduct substantive and meaningful continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. Continuing reviews will be conducted by the convened IRB unless the research falls into one or more of the categories appropriate for expedited review
	New IRB Manager User Application	This form is used to request an IRB Manager account on behalf of someone else.
	Protocol Modification Submission Form	Protocol Modification Submission Form
	Reportable Events Submission Form	Reportable Events Submission Form
	Supplement N-- Conflict of Interest	Used to Report Conflicts of Interest

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.



This screenshot is identical to the one above, but includes a blue arrow pointing to the "Protocol Modification Submission Form" title in the "Form (Click to start)" column.

Action	Form (Click to start)	Description
	Closure Request	Closure Request
	Continuing Review Submission Form	Continuing Review: ETMC is required to conduct substantive and meaningful continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. Continuing reviews will be conducted by the convened IRB unless the research falls into one or more of the categories appropriate for expedited review
	New IRB Manager User Application	This form is used to request an IRB Manager account on behalf of someone else.
	Protocol Modification Submission Form	Protocol Modification Submission Form
	Reportable Events Submission Form	Reportable Events Submission Form
	Supplement N-- Conflict of Interest	Used to Report Conflicts of Interest

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.

Form	Identifier	Owner	Stage	Status	Started	Requires Approval
 ETMC Submission Form	Initial Submission--Expedited Review with Supplements to Table	Bush, Lisa MS (lkbush@etmc.org)	Financial Conflict of Interest	Awaiting Signature(s)	1 hours ago	Yes
ETMC Submission Form	Initial Submission--Expedited Review with Supplements to Approve with Mods	Bush, Lisa MS (lkbush@etmc.org)	PI Signature for Coordinator Submission	Work in progress	10/27/2017	No

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.

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