IRBManager Quick Start Guide
Dashboard Overview and Status of xForm

SECTIONS OF YOUR DASHBOARD

Upon logging in, your Dashboard will appear similar to the screen below:

Your Dashboard is broken down into five main sections:

1. **Studies** - Summary of your studies (Studies that are closed or have not been submitted will NOT appear in “Active”)

By clicking on either #active (approved and open) or #total (active, closed, and new), you can view the studies with which you are associated. This section lists the specific roles you have for each study (PI, Co-Investigator, Coordinator; etc.). This section also provides you with the next study to expire and all of the studies expiring in the next 90 days.
2. **xForms - Summary of your xForms**

   a. **Unsubmitted** - xForms that you started but have not submitted for processing will be listed under **# unsubmitted xforms**.

      ![xForms (12 Active)]

      You have 0 unsubmitted xForms.
      - You have 12 xForms being processed at a later stage.
      - You have 1xForm in error.
      - There are 4 xForms awaiting your attention.

      If you no longer wish to move forward with an unsubmitted form, please click on the **# unsubmitted** link to be brought to the next page:

      ![xForms (12 Active)]

      You have 12 xForms being processed at a later stage.
      - You have 1xForm in error.
      - There are 4 xForms awaiting your attention.

      Next, click on the "X" under the “Action” column to delete this form.

   b. **Being Processed** - xForms that you submitted and are being processed will be listed under **# xForms being processed**. You will be able to check on the status of a form after you have submitted it by clicking on this link. The current stage the form is in will be listed under the “Stage” column. For example, "IRB Coordinator Administrative/Expedited Review" means that the form is under review by the IRB.

      ![xForms (12 Active)]

      You have 12 xForms being processed at a later stage.
      - You have 1xForm in error.
      - There are 4 xForms awaiting your attention.

   c. **Awaiting Attention** – xForms that require you to take additional action (signature or make requested revisions) will be listed under **# xForms awaiting your attention**. After you click on this link, a list of forms pending action will appear. The current stage the form is in will be listed under the “Stage” column. For example, “PI Signature For Coordinator Submission” means that the form requires your signature. You can click on the form link, electronically sign the application, and "submit" for processing.

      ![xForms (12 Active)]

      You have 0 unsubmitted xForms.
      - You have 12 xForms being processed at a later stage.
      - You have 1xForm in error.
      - There are 4 xForms awaiting your attention.

   NOTE: If you notice a form designated as “You have #xForm in error,” please contact the IRB Office for assistance.
3. **Events**

Once a form has been submitted and accepted into IRBManager (after moving through the stages required prior to loading) an event is created. **To see what events are open (i.e.; Amendments or Initial Applications (green arrow)),** look under the events section and you will be able to check the status of that event. **Only reference this section for forms you submitted using IRBManager.** Other events listed (particularly Amendments and Initial Applications submitted before May 2018 and March 2019, respectively) may be outdated/not accurate of current events.

4. **My Studies** - Listing the studies with which you are associated.

You can filter your list of studies by clicking on the title of a particular column (i.e.; PI, Expires, Status etc.). To remove the filter, click again on your original filter item. **Studies that are closed or have not been submitted will NOT appear here.**

The **reference document** section refers to documents stored within that study that depict the current informed consent/HIPAA being used. This accuracy of the reference document section is dependent on the study team correctly selecting the document type during the xForm submission. Ultimately, the study team is responsible for ensuring that currently approved forms are being utilized at all times.

For more details on this process, visit the [amendment overview and attachments guide](#).

5. **Actions** – Starting an xForm for Specific Initial Submission

You can start an **xForm** by clicking on a link on the left side of your screen under "**Actions.**"

By clicking on a prompt shown below, you will be brought to a specific form:

- **“Does My Study Require IRB Review?”** – Directs you to the Human Subjects Research (HSR) Determination Request form (xForm). Select this option if you are UNSURE if your activity meets the definition of HSR or requires IRB review ([green arrow on next page](#)).

- **“Initial Application”** – Directs you to the IRB Initial Application form (xForm), which is available for specific types of initial submissions. The list of application types will continue to expand over time. If the options listed are not applicable to your proposed study, do not continue with the xForm. You must submit a standard application to the IRB office using a traditional application (not IRBManager), found [here](#). ([red arrow on next page](#))
However, if you click on "Start xForm" directly, you will be brought to a screen similar to the one below that lists all of the available initial submission types, including the ones mentioned previously:

Then select the type of xForm you wish to submit by clicking on the form's title (purple link)

The list of submission types will continue to expand over time. If the options listed are not applicable to your proposed study, do not continue with the xForm.

***See Next Page for Details on how to Check the Status of an xForm***
STATUS OF XFORM

Visit your dashboard and check the status of your xForm by using one of the options listed below:

OPTION 1: Visit the xForms section of your dashboard. Click on the #xForms in any of the subsets displayed to determine the stage of each form, which will be listed under the “Stage” Column

a. Unsubmitted - xForms that you started but have not submitted for processing will be listed under # unsubmitted xforms.
b. Being Processed - xForms that you submitted and are being processed will be listed under # xForms being processed.
c. Awaiting Attention – xForms that require you to take additional action (signature or make requested revisions) will be listed under # xForms awaiting your attention.

When you click on #xForms, a screen will appear similar to the one below, which will tell you the following:

- xForm type - type of xForm submitted
- Owner - the submitter (if an event has not been created in IRBManager) or the IRB Number with the event the form has been moved through the stages required for loading into IRBManager (PI/department head signatures and accepted in the administrative pre-review stage).
- Stage – see definitions later in this guide
- Time it has been in that stage
OPTION 2: Click on the #xForms under My Docs & xForms tab on left side of menu:

When you click on #xForms, a screen will appear similar to the one below, which shows you the same information, but it includes all xForms associated with you as a user (submitter), including completed forms, those currently requiring your attention and those being processed at a later stage.

To filter through which ones require your attention, click “Notifications View” to see ones that are pending action on your end:
The xForms that appear are those requiring action by your specifically:

Stage Types and Definitions – All Submission Types
(User refers to the person who is viewing the dashboard (the submitter)):

- **Data Entry for ______ Application** - The form is currently with the user to complete the application but has not been submitted to the IRB.
- **Data Entry for ______ Application ( # time)** – The form is with the user. It was submitted to the IRB and revisions/additional training have been requested. The user can now make the requested revisions/complete training and once completed, can resubmit the form for IRB review.
- **PI Signature For Coordinator Submission** – The form is with the PI. This is the stage when the PI reviews the submission and determines if modifications are necessary (returned to the user) or if the form is ready for submission to the IRB.
- **Request for KDS Modules/COI to be Assigned** – The form is with the IRB. Required training modules and/or COI profiles for the application were requested for assignment from the appropriate office. Assignment requests are being processed.
- **COI Management** – The form is with the COI Office. An annual disclosure for someone associated with the application has been flagged and is under review by the COI office.
- **Final Signature** – The form is with the IRB. The IRB recommendation has been sent to the signator for final determination. Once this stage is completed, a notification of determination will be sent to the entire study team.
- **Coordinator Corrections** – The form is with the IRB. The signator returned the form to the IRB staff to make revisions or request that the study team revise the form prior to final determination.

Stage Types and Definitions – Amendment Specific Submission Type
(User refers to the person who is viewing the dashboard (the submitter)):

- **New PI Signature for Coordinator Submission** - The form is with the new PI. The type of change requested is a change in PI, which requires that the new PI reviews the submission and provides his/her certification for the submission.
- **New PI Department Head Signature** – The form is with the Department Head. The change in PI amendment requires that the Department Head (which the user listed in the form) reviews the submission and determines if he/she is willing to provide his/her certification and send the form to the IRB for review.
- **IRB Coordinator Administrative/Expedited Review** – The form is with the IRB for administrative review (screens the application for completeness) and the reviewer can either request further information/documentation from the user or determine the review type (exempt, expedited, or full board) and assign for review.
- **Training Verification** – The form is with the IRB being reviewed for fulfillment of training/documentation for change in personnel/change in PI portion of the amendment.
- **Post Training Ver Administrative/Expedited Review** – The form is with the IRB. The training verification is complete and is undergoing administrative review (screening the application for completeness) and the reviewer can either request further information/documentation from the
user, send the form for final signature (expedited or exempt review), or assign the full board reviewer, as applicable.

- **Expedited Consultation with Full Board Member** – The form is with the IRB. The IRB has requested an additional review of the submission by a consultant prior to determining review type.
- **Expedited MRSA Review** – The form is with the IRB. The form was previously reviewed under the expedited process and given the recommendation of Modification Required to Secure Approval (MRSA). The study team re-submitted the form and is now undergoing expedited review to ensure that the requested changes were made.

**Stage Types and Definitions – Amendment Specific Submission Type Continued:**
(Users refers to the person who is viewing the dashboard (the submitter)):

- **Full Board Pre-Review** – The form is with the IRB. The submission is being reviewed by the convened full board meeting.
- **Post Full Board Action** – The form is with the IRB. The submission was reviewed at the full board meeting and and the IRB office is preparing the decision notification for the research team.
- **Administrative Review of FB MRSA** – The form is with the IRB. The form was previously reviewed at a full board meeting and given the recommendation of Modification Required to Secure Approval (MRSA). The study team re-submitted the form and it is now back with the IRB office for administrative review to ensure that the requested changes were made.
- **Post Full Board/Flag for COI Management** - The form is with the COI Office. The form was previously reviewed at a full board meeting and given the recommendation of approval. However, an annual disclosure for someone associated with the amendment application (change in personnel or change in PI) has been flagged by the COI Office and is under review.

**Stage Types and Definitions – Initial Application Specific Submission Type:**
(Users refers to the person who is viewing the dashboard (the submitter)):

- **Department Head Signature** - This is the stage when the Department Head (which the user listed in the application form) reviews the submission and determines if he/she is willing to provide his/her certification and send the form to the IRB for review.
- **Administrative Pre-Review** – The form is with the IRB for administrative pre-review (screens the application for accuracy and completeness) and the reviewer can either request further information/documentation from the user or determine the review type (exempt, expedited, or full board) and assign for review.
- **Training Verification Pre-Review** – The form is with IRB and is being reviewed for fulfillment of study team training/documentation/COI requirements prior to IRB Specialist Review Set-Up.
- **IRB Specialist Review Set-Up** - The form is with IRB for Specialist Review Set-Up. The IRB Specialist will determine the review type and assign the review for the application.
- **Under Exempt Review** - The form is with the IRB. The submission is under IRB Exempt Review.
- **Post Exempt Review Processing** - The form is with the IRB. The Exempt Review is complete and the IRB office is preparing the decision notification for the research team.
- **MRSA Review** – The form is with the IRB. The form was previously reviewed and given the recommendation of Modification Required to Secure Approval (MRSA). The study team re-submitted the form and is now undergoing administrative MRSA review to ensure that the requested changes were made.
- **Training Verification Post-Review** – The form is with the IRB. The form is being reviewed for training/documentation/COI deficiencies previously noted during the training verification pre-review stage.
ADDITIONAL DASHBOARD TOOLS

Account User Settings – Update Phone Number:

The IRBOffice Staff requests that you do not alter your e-mail address or password as a LSU Health (@lsuhsc.edu) user since we use a single sign on system. If you make changes to this information, it could alter your access to studies.

However, if you wish to update your phone number go to your Settings tab and select “My Phone Number,” as pictures below.

Next, click on the hand next to the phone number you wish to edit and then update the phone number, clicking “update phone” when finished.

Starting a Form for an Initial Submission: click on Start xForm on the left side of your screen under "Actions."
Then select the Initial xForm by clicking on the form's title:

The IRBManager initial application form (xForm) is available for specific types of initial submissions. The list of application types will continue to expand over time. If the options listed are not applicable to your proposed study, do not continue with the xForm. You must submit a standard application to the IRB office using a traditional application (not IRBManager), found here.

**Starting a Form for an Active Study from your Dashboard:** click on # active Studies:

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 image below. Select the type of xForm you wish to submit by clicking on the form's title. **This screen will represent forms that are currently available.** When more post-approval applications become available for use, they will be viewable here.

**PLEASE NOTE:** To complete the submission for an approved study, you must be in the specific study for which you want to complete the form.

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If you have any questions about IRBManager please contact the LSUHSC-NO Office of Research Services by e-mail: IRBOffice@lsuhsc.edu