SECTION 1: NAVIGATING THE STUDY PAGE

From the dashboard, go to the "My Studies" section.

**Step 1:** Go to "My Studies" section, clicking on #Total Studies

Upon clicking on the chosen study, the study page will appear (as shown on next page), listing specific information. On the left side of the screen under "Actions" you can click on **Start xForm** to begin a post approval submission related to that study (for example: Amendment).
The Study Page is broken down into five main sections:

1. **Study** - Lists basic information about the study, such as:
   - **Study Number**
   - **School** – The school associated with the study
   - **Department** – The department associated with the study
   - **Agent Type** – Type of procedures or agents being used in the study
   - **Protocol Title** – Full title of study
   - **Funding Type** – External (government, industry, or other) or Internal based on funding information
   - **Type of Research** – Social/Behavioral/Education, Biomedical, or Other
   - **Comments** – General comments/study objectives
   - **Sponsor** – Study sponsor information, if applicable.
   - **Sponsor ID** – Sponsor assigned protocol number, if applicable.
   - **Grants** – Disregard this section.
   - **Year** - The year of the first review
   - **Review Category** - The level at which the study was reviewed.
   - **Population (Children, Adults, Vulnerable)** – Population type details as applicable to the study.

2. **Study Reference Documents** - documents stored within that study that depict the current informed consent(s)/HIPAA(s) being used. The accuracy of the reference document section is dependent on the study team correctly selecting the document type during the xForm submission. If the correct process was not followed, the reference documents within the study will not be correct. Ultimately the study team is responsible for ensuring that currently approved forms are being utilized at all times.

Click on the blue link to open the document.
3. **Study-Site** - Lists information about the study and study-site(s), such as:

- **Site(s)** – Primary location and supplementary sites associated with the research (if applicable).
- **Status** – Exempt Approved, Expedited Approved, Approved “full board studies”, Closed, New from PI, Administratively Closed etc.
- **Approval** – Current approval date
- **Initial Approval** – The date the study was first approved
- **Number of subjects to be enrolled at LSUHSC-NO** – Number of subjects/charts involved in the study
- **Comments** – This item will be blank unless comments have been entered
- **PI** – Principal Investigator of the project
- **Expiration** – The expiration date of the study. For studies submitted prior to 1/20/2019 (old rule), this will be listed for expedited and full board review studies. For studies submitted post 1/20/19 (new rule), this date will populate for full board studies only. This is the date the study will expire unless a continuing review is granted.
- **Other Expiration** – Annual Exempt Update (for exempt studies submitted prior to 1/20/19 (old rule)) or Annual Check-In (Exempted/Expedited) (for exempt or expedited studies submitted post 1/20/19 (new rule)). This is the due date of the annual check-in from the study team.

![Study-Site example](image)

4. **Study-Site Contacts** - Lists contacts associated with the study along with their role

5. **Events** - Lists study events, either entered manually (by IRB office) or generated from xForm submitted by the study team. The event line contains the following sections:

- **Event** – Type - The type of event (New Protocol Checklist = Initial Application, Amendment etc.)
- **Att** – Number of attachments associated with review or event. This will usually be “0” unless the event is from an xForm submitted by the study team
- **Instance/USD** – Either blank or lists summary of the event
- **Start** – Date the event was started or loaded into IRBManager
- **Complete** – Date the event was completed.

![Events example](image)

Click on the blue event link to view event details specific to the event (see next section).

**SECTION 2: NAVIGATING EVENT DETAILS**

Access the event details page by clicking on the event from the study page (as shown in the blue arrow above) OR by clicking on the link listed in the determination e-mail sent to the study team regarding an IRBManager Submission.

**General Information:** The event details page will list basic information related to the event, regardless if it is linked to an IRBManager submission, including basic study site information, event details, and event steps.
The Event Details Page is broken down into five main sections:

1. **Study-Site Information** - Lists basic information about the study, such as:
   - Study - Study Number
   - Protocol Title – Full title of study
   - PI – Principal Investigator of the project
   - Site – Primary location of study
   - Committee: Review Committee
   - Sponsor ID – Sponsor assigned protocol number, if applicable.

2. **Events Information** - Lists event details, including the following sections:
   - Type - The type of event (New Protocol Checklist = Initial Application, Amendment, etc.)
   - Instance/UDF – Either blank or lists summary of the event
   - Committee: Disregard
   - Review Type - The level at which the event was reviewed.
   - Started – Date the event was started or was loaded in IRBManager
   - Complete – Completion date of event

3. **E-mails** - Lists e-mails sent to the study team related to the event.

4. **Step Information** – displays actions associated with the event and respective dates. Each event type has specific steps that may list planned as well as actual dates linked to each step.

5. **Actions** – Actions on event details screen are as follows:
   - Attachments – Attachments associated with event (generally “0” if this wasn’t done through IRBManager). If an xForm was submitted and determination letter was issued, it would be listed in this section.
   - XForm: shows the form used to create the event (only applicable for IRBManager xForm Submissions – see section 3). If event is related to non IRBManager submission, it will say “0”
   - Done – returns user to previous page.
SECTION 3: DETERMINATION LETTER AND XFORM

**xForm**: An application submitted through IRBManager is referred to as "xForm." Select xForms are available at this time (for example: Initial Applications (medical chart reviews ONLY) and amendments). Visit our [website](#) for a list of submissions that can currently be done using an xForm.

If you submitted an xForm, you will receive updates regarding the submission through e-mail notifications. You can also check the status of the xForm by visiting your dashboard. Visit our website for guidance on navigating your dashboard.

**DETERMINATION LETTERS**

Once a final determination is issued for the submission, you will receive an e-mail which includes a link to the event details page (as listed in section 2) to access the determination letter. The email will be similar to the one below:

*EXTERNAL EMAIL: EVALUATE*

Hello-

The determination letter for the submitted Medical Chart Review ONLY Application for the study below is now available for your files.

IRB Number: 19-764-TOURO

Protocol Title: medical chart review only

PI: Rome, Kadie Test

Determination: Exempt

To access the determination letter, please click on the following link, then click on "Attachments" on the left-hand side of the page, and the determination letter will be located under the "Generated Documents" header. The attachments associated with the application will be available under the "Attachments" header in this same section. [https://lsulsc-no.my.irbmanager.com/Events/81fa5d26-977e-4b51-9029-fe42ca596e97](https://lsulsc-no.my.irbmanager.com/Events/81fa5d26-977e-4b51-9029-fe42ca596e97)

Thank you.

**OPTION 1**: Click on the link in the determination e-mail to be brought to the event details page.

**OPTION 2**: From the study page, click on the blue event link to view event details related to the xForm (see section 2).

You will be brought to the Event Details Page.

- Click on Attachments on the left side of the page under "Actions"
Upon clicking on **Attachments**, you will be brought to a screen similar to the one below:

The attachments listed under the “Attachments” column are the documents submitted with the xForm by the study team (**red arrow**).

The documents listed under the “Generated Documents” column are documents generated by IRBManager system based on the IRB’s final determination (**purple arrow**). Click on the blue link to open any of the documents.

**Viewing the xForm**

From the Event Details Page (see Section 2), click on **xForms (#)** on the left side of the page under “Actions”.

If the event is linked to an xForm submitted by the study team (IRBManager Submission), there will be a number next to xForms (**blue arrow**). If there is no number listed, it means that the event was entered manually by the IRB office based on a traditional submission (non-electronic submission).

Upon clicking on **xForms (#)**, you will be brought to a screen similar to the one below:

By clicking on the blue link under the Form name, the completed xForm will open.

Scroll to the bottom xForm to download a pdf as needed (see next page)
If you have any questions about IRBManager please visit our [website](#) or contact the LSUHSC-NO Office of Research Services by e-mail:

IRBOffice@lsuhsc.edu