On October 3, 2017, the Tulane University Human Research Protection Office adopted the IRBManager Internet-based submission system. The HRPO will only accept submissions electronically through IRBManager. This Users Guide provides step-by-step instructions for each type of submission.

Web Address:
www.tulane.my.irbmanager.com

For any questions regarding IRBManager, please contact the HRPO at 504-988-2665 or email us at irbmain@tulane.edu.

Thank You!
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1.1 IRBManager

1.1 What is IRBManager?

IRBManager is an online submission, workflow, and data management system for Tulane’s Institutional Review Board. IRBManager is a fully web based system, meaning users can login anywhere they have internet access.

The electronic forms provided within this system allow users to complete submissions for IRB review. This includes forms for new studies, continuing reviews, amendments, as well as reports for unanticipated problems, adverse events, and study closures. These forms are then used to electronically route the submission through the required review process.

Through IRBManager, Investigators have access to see the studies they are conducting at Tulane, as well as any separate study-sites, if applicable. Each study’s study-site will provide a list of events submitted to the IRB. Events can be viewed as folders for the separate submission events required for each study-site such as the initial submission, amendments, and continuing reviews, etc. Each event will contain all associated forms, documents, stamped forms and letters along with a listing of review steps, which are updated to notify the investigators where the submission is within the review process. Study personnel indicated on the project application will have access to the study in IRBManager.

1.2 How to Access IRBManager

Go to https://tulane.my.irbmanager.com/

Note: Certain versions of Internet Explorer are not compatible with IRBManager. Consider utilizing Mozilla-Firefox or Google-Chrome as your browser.

1.3 Initial Login for Users with Tulane Email Accounts

Any user who previously submitted using IRBNet is automatically registered with IRBManager. If you are uncertain whether you have an IRBManager account, contact irbmain@tulane.edu.

1. To activate your account and log in, click on ‘click here’ after ‘to Login using your Tulane user name and password.’
2. The username is your Tulane email address on file (i.e., janedoe@tulane.edu).
3. The password is your Tulane password (i.e. the same password you use to sign into your Tulane account).
4. The client is ‘Tulane.’
5. Click ‘Sign In.’

Note: If you do not use your current email address on file with Tulane, you will not be able access IRBManager. **Do not create a new account. Duplicate accounts will not be linked to studies previously entered in IRBNet.** If you are unable to log in or if you need to update your email address on file, contact the HRPO Office.
1.4 How to Reset a Password

As a security precaution, IRBManager locks your account after three incorrect password attempts. If your account is locked, please email irbmain@tulane.edu or contact the HRPO office to unlock your account. (Note: Should your account lock it does not affect your Tulane email account.

2.1 Navigating the Dashboard

2.1 Actions

Under ‘Actions,’ a user can start either a Human Subjects Research or Engagement Determination Form or an Initial Application for Human Subjects Research xForm.

Note: Secondary applications including Amendments, Continuing Reviews, Closure Reports, and Unanticipated Problem or Adverse Event Reports cannot be started from this area and must be started from within the study itself. (See Section 3.3.1, ‘How to Submit an xForm’).
2.2 Recent Items
The hyperlinks under this heading will show the seven (7) most recent items viewed in IRBManager. Click on any link under ‘Recent Items’ to go directly to that item.

2.3 Messages
This heading is an area that the IRB will use for general communication to all of the users within the system.

2.4 My Documents & Forms

2.4.1 User Attachments
This heading is an area that the user can attach frequently submitted documents. For example, if a user is required to submit CVs for multiple investigators, they can use ‘Add Attachments.’

Users can also add the attachments into an xForm under the Additional Information page and select ‘My Profile.’
2.4.1 xForms

This heading is an area where users can view the xForms they submitted (i.e., where the user was the submitter, PI or Collaborator). The user can view the xForms that are in progress, as well as what stage they are currently in. Also, the user can select ‘Show Complete’ to access all of the xForms that have received an IRB determination.

![xForms Image]

2.5 Studies

A user can view a list of the studies that they are associated with from the Dashboard. The user will have access to studies if they are listed as Principal Investigator, Co/Sub-Investigator, Regulatory or Research Coordinator and/or Research Staff. Users will be able to access studies that migrated from IRBNet under ‘Studies’ as well.

**Note:** By clicking on the underlined link to active or total studies, the user will be able to view the details of their associated studies. Users will be able to access studies based on their role in the study. Users will be notified at 30, 45 and 60 days of the expiration of a study to allow for preparation of a Secondary Application.
1. The ‘Active Studies’ include all associated studies with the following statuses:
   a. Active
   b. Active-Opened to Enrollment
   c. Active-Closed to Enrollment
   d. Active-in Data Analysis
   e. Active-Long Term Follow-Up Only
   f. Exempt

   **Note:** Studies that are Suspended are also located here.

2. The ‘Total Studies’ are all the studies the user is associated with, including studies that have been Administratively Closed. This includes studies that were closed at the request of the PI or due to study expiration.

   **Note:** If a user had access to a study via Full, Write or Read access in IRBNet but was not listed on Application Part 1, they will not have access to the study in IRBManager. To regain access to a study, it is recommended that an Amendment be submitted to add research staff to an active study.

2.6 xForms

The xForms section shows the forms or applications currently being processed at this time.

**Note:** An xForm is an electronic, web-based form.

**xForms (5 Active)**

- You have [2 unsubmitted] xForms.
- You have [3 xForms] being processed at a later stage.
- There are [1 xForms] awaiting your attention.

In this view of the DASHBOARD:

1. The user has two (2) unsubmitted xForms. This shows the user started two xForms, but clicked ‘Save for Later’ or closed out of the form without submitting the form.
   
   **Note:** By clicking on the link, the user can go directly to a list of unsubmitted xForms.

2. The user has three (3) xForms being processed at a later stage. This shows that the user has submitted three forms that are currently awaiting review and signature by the PI (or other necessary party) or are being processed by the IRB.
   
   **Note:** By clicking on the link, the user can go directly to a list of xForms being processed at a later stage and see what stage the xForm is in currently.

3. The user has xForms in error (not shown in screenshot). This shows the user has some forms that have errors. This is a software issue and the user must notify the HRPO office if they receive this notification.
   
   **Note:** By clicking on the link, the user can go directly to the xForm(s) in error. Please contact HRPO office for assistance with xForms in Error.
4. The user has one (1) xForm currently awaiting their attention. This shows that the user has one xForm that currently needs action by the user (i.e., review and signature required, revisions requested by the IRB, etc.).

   **Note:** By clicking on the link, the user can go directly to the xForms that need the user’s attention.

2.7 Events

The events section of the DASHBOARD shows the total number of open events and the number of events categorized by name, such as Initial, Continuing Review, Amendment, Protocol Deviation or Closure. The dropdown box following ‘Only show events where I am’ will allow a user to filter the events according to their role in the associated study.

2.8 My Studies

All the active studies a user is associated with will appear here.

   **Note:** A study is not created when a user submits an xForm. A study is created when the IRB determines that the study is ready for review. From the DASHBOARD, a user can view the following information regarding their studies, including:

1. The project number.
2. The main site where the project is taking place. (Note: If the project is taking place at more than one site, the project will be listed twice with each site listed.)
3. The PI name.
4. The project title.
5. Expiration date of the project (if blank the study has not yet been approved).
6. Status
   a. Pending (if not yet approved)
   b. Active
   c. Exempt
   d. Deferred
   e. Expired
   f. Suspended

   **Note:** Closed studies will not display here. In addition, the status will depend on whether the project is still under initial review or if elsewhere within the project’s lifecycle.
Note: By clicking on the blue link under ‘Study,’ the user can go directly to the project.

By clicking the small arrow to the right of ‘Study, Site, PI, Title, Expires, and Status,’ a user can sort the studies accordingly.

1. Project can be sorted by Project Number
2. Site can be sorted alphabetically
3. PI is sorted alphabetically
4. Title is sorted alphabetically
5. Expiration dates are sorted by numerical date
6. Status is grouped and sorted alphabetically

2.9 Help

The Help page is currently disabled. Please use this manual, email irbmain@tulane.edu, or contact the HRPO office for assistance.

2.10 [Account Users] Settings

This section allows the user to edit their profile settings. [Account Users] will be replaced with the user’s first name. By clicking on [Account Users] Settings, a user will access ‘My Settings.’

Under My Settings, a user can:

1. Change their password
2. Change their profile
3. Change their phone number
4. Change their address
5. View last 25 logins
6. Create an email signature
7. Manage linked client

2.10.1 Change Password

The HRPO staff requests that users do not change their password as Tulane uses a Single Sign On system. If a user changes their password to one other than their Tulane email password, it could affect a user’s access to studies.

2.10.2 Change My Profile

Click on the ‘Change My Profile’ link.

This view will appear:
1. Update name, degree or specialty.
2. Click ‘Update.’

The HRPO staff requests that users do not change their email address as Tulane utilizes a Single Sign On system. If a user changes their email address to one other than their Tulane email, it could affect a user’s access to studies.

2.10.3 My Phone Numbers

1. Click on ‘My Phone Number(s)’ link.

This view will appear:

<table>
<thead>
<tr>
<th>Numbers</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Action</td>
<td>Primary</td>
<td>Type</td>
<td>Number</td>
</tr>
<tr>
<td>📞</td>
<td>☑️</td>
<td>Business</td>
<td>3-2693</td>
</tr>
</tbody>
</table>

2. Click the icon that appears to be a hand holding a piece of paper.

This view will appear:

2.10.4 My Address

1. Click on ‘My Address(es)’ link.

This view will appear:
2. Click the icon that looks like a hand holding a piece of paper. This view will appear:

3. Add/Update the address.
4. Click ‘Add Address’.

2.10.5 Log In Information

Clicking on this link will provide a list of the time and date of the last 25 times a user logged into IRBManager.
3.1 Managing Forms in IRBManager (i.e., xForms)

IRBManager uses web-based forms called xForms. Users submitting to the Tulane IRB will submit the xForm appropriate to the type of request (i.e., New Project, Amendment, Continuing Review, Protocol Deviation, Closure).

3.1 Human Subjects Research or Engagement Determination Form

Use this form for a determination if an activity is research, if research is Human Subjects Research or if the involvement in research qualified as Engagement in research.

1. This is one of three options seen on the Dashboard (the view when a user logs in seen above), under the ‘Action’ menu on the far left.
2. Click here to begin the Human Subjects Research or Engagement Determination Worksheet.
3. Complete the xForm.
4. A determination will be provided at the end of the form.
5. If you need a formal letter, submit the form for processing.
3.2 Initial Application for Human Subjects Research

Use this form for requesting an Initial protocol to be reviewed under Exempt, Expedited, Facilitated or Convened Criteria.

1. This is one of three options seen on the Dashboard (the view when a user logs in seen above), under the ‘Action’ menu on the far left.
2. Click here to begin the Initial Application for Human Subjects Research.
3. Complete the xForm, attaching all necessary documents, and submit.

**Note:** ‘Start xForm’ allows a user to start either of the above-referenced forms. Click on the name of the form to start the appropriate xForm (see below).

---

### Select xForm to start

<table>
<thead>
<tr>
<th>Action</th>
<th>Form (Click to start)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Human Subjects Research and Engagement Determination Worksheet</td>
<td>Use this form to submit the Human Subjects Research and Engagement Determination Worksheet</td>
</tr>
<tr>
<td></td>
<td>Initial Application for Human Subjects Research</td>
<td>Use this form to submit the Initial Application for Biomedical and Social/Behavioral Research(Exempt, Expedited, Facilitated, and Full Board)</td>
</tr>
</tbody>
</table>

3.3 Secondary Application for Human Subjects Research

Use this form to submit an amendment or continuing review for an approved, existing study.

1. On the home page under ‘My Studies,’ click on the study number for the study that needs amending or renewal.
2. Click on ‘Start xForm.’
   Select the appropriate submission type. The types of submissions that can be submitted on this xForm are as follows:
   a. Continuing Review Submission – Submitted to renew or extend the approval period for minimal risk or greater than minimal risk studies that were reviewed under Expedited criteria or the Convened IRB. Amendments to the currently approved study can also be submitted at the time of continuing review.
   b. Amendment Submission ONLY – Submitted to Amend, Modify, Add or Remove currently approved study procedures, study staff, consent procedures/processes, etc., that occur between approval periods. Amending a study will not extend the current approval period.
   c. Continuing Review Submission for Exempt Research – Submitted to renew or extend the approval period for minimal risk studies that were reviewed under Exempt criteria. Amendments to the currently approved study can also be submitted at the time of continuing review.
   d. Amendment Submission for Exempt Research ONLY – Submitted to Amend, Modify, Add or Remove currently approved study procedures, study staff, consent procedures/processes, etc., that occur between approval periods. Amending a study will not extend the current approval period.
e. Facilitated Continuing Review – Submitted to extend the approval period for studies where IRB oversight has been deferred to another University / Institution.

f. Facilitated Amendment – Submitted to Amend, Modify, Add or Remove currently approved study procedures, Tulane study staff, consent procedures/processes, etc., that occurs between approval period where IRB oversight has been deferred to another University / Institution.

4. Complete the xForm and submit.

3.4 Event Reports, Closures and Correspondence Submissions

Use this form to submit an Event Report, including Protocol Deviations, Event Requiring Reporting by a Study Sponsor, an Unanticipated Problem or Adverse.

1. On the home page under ‘My Studies,’ click on the project number for the project that requires the reporting of an event to the IRB.
2. Click Start an xForm
3. Select the Event Reports, Closures and Correspondence Submissions xForm.
4. Select the appropriate submission type. The type of submissions that can be submitted using this xForm are as follows:
   a. Event Reports – Submitted to report protocol deviations by the study team or subjects, adverse events causing an increase in risk or study team, breach of confidentiality, study procedures being conducted prior to IRB approval being obtained, non-compliance, etc.
      i. A link to the Event Reporting Form is located within the xForm.
      ii. Click the link to download the form.
      iii. Complete and Save the Event Reporting Form.
      iv. Attach the completed form where it states to ‘Add Attachment.’
      v. Submit the form for review
   b. Correspondence – Submitted to notify the IRB of study related information ie, safety reports, memorandums, sponsor communications, etc.
      i. Attach the documents where it states to ‘Add Attachment.’
      ii. In the Additional Information Section, please provide explanation of the documents being submitted to the IRB for review.
      iii. Submit the form for review.
   c. Closures – Submitted to close a study following the completion of all study procedures, data analysis and preferably, following the acceptance of any pending publications.
      i. A link to the Closure form is embedded within the xForm for ease of access to the user.
      ii. Click the link to download the form.
      iii. Complete and Save the Closure Form.
      iv. Attach the completed form where it states to ‘Add Attachment.’
      v. Submit the form for review.

3.5 Completing an xForm

After entering basic study details, the questions in the xForms are directed by the answers given. For example, research involving retrospective data analysis will not ask
about investigational drug intervention in research and vice versa. Changing responses on the form will enable subsequent questions that were hidden or hide questions that are no longer applicable.

1. To navigate an xForm, click ‘Next’ to move on to the next page of the xForm. Click ‘Previous’ to move to an earlier page. Click ‘Save for Later’ to stop working on the form. The xForm can then be reopened by going to the xForm link under ‘My Documents and Forms’ or ‘Unsubmitted xForms’ on the DASHBOARD.

2. Most questions on the form are required (the question will be labeled ‘Required’). Optional questions will indicate they can be skipped in the question text. All required questions on the form must be completed before submitting. If they are not, a red error message will appear. The system will not allow the user to continue until the field has been populated.

3. All required questions on a page must be completed before clicking ‘Next’. To skip to another page on the form without answering all questions on the page at that time, use the navigation drop down at the top of the page.

3.6 Attaching Documents

To attach a document:

1. Click ‘Add Attachment’ on specified attachment questions. Attachment questions will populate for submission of the Protocol, Consent/Assent Form(s) or Institutional Agreements (for Facilitated Reviews). The HRPO templates for the Protocol, Consent and Assent forms are embedded in these questions for the convenience of the user.

2. Enter name for the attachment. To use the name of the uploaded file, leave this field blank.

3. Select the type of attachment if that option is available. On some questions, only a certain type of document is intended to be attached, and the type is pre-set.

4. Click the ‘Select’ button to locate the file on the computer. Files can also be attached from Dropbox or Box.

5. Click ‘Attach’ to finish the process.
3.6.1 Submitting the xForm

**Note:** Before submitting an xForm, review the form completely. Changes cannot be made once an xForm is submitted unless the IRB requests changes.

After all pages on the form are complete, the submission screen will appear. Click ‘Submit.’

**Note:** The form will not move to the next stage if ‘Submit’ is not clicked.

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3.7 Checking the Status of an xForm

On the left side of the screen under ‘My Documents & Forms,’ select the xForms to see a list of all the xForms a user is associated with (either as a PI, Submitter, or Collaborator).
• **Action:** If a form can be deleted or copied for an amendment, those options will display in this column. **Note:** An xForm can only be deleted when in data entry.

• **Form:** Name of the form

• **Identifier:** This is generally the study ID# or the study title

• **Owner:** The owner of the form will be the user who started the xForm until an event is created and then the form is owned by the study. **Note:** An event will be created within IRBManager after the pre-review has been assigned to a Regulatory Compliance Specialist.

• **Stage:** This is the current stage that the form is in.

3.8 Stage Types and Definitions

Review Stages

• **HSR and Engagement Determination Data Entry:** The form is currently with the user to complete or make changes

• **Initial Submission Data Entry:** The form is currently with the user to complete or make changes

• **Secondary Submission Data Entry:** The form is currently with the user to complete or make changes.

• **PI attestation for Coordinator’s submission:** If the PI did not complete the xForm, this is the stage when the PI reviews the submission and determines if modifications are necessary or the form is ready for submission to the IRB.

• **Faculty Advisor Attestation:** If the PI is a student, this is the stage when the form will be sent to the Faculty Advisor listed on the form to review the submission and determine if modifications are necessary or the form is ready for submission to the IRB.

• **Department Head Attestation:** If the PI is Faculty/Staff, this is the stage when the form will be sent to the Department Head listed on the form to review the submission and determine if the submission is ready for submission to the IRB.
  
  o **Note:** If the Department Head is a member of the study team, the Dean of the School that the research will be conducted under should be listed as the Department Head.

• **HRPO Submission Intake:** The form has been reviewed, signed and has now been submitted to the HRPO for review.

• **HRPO Regulatory Compliance Specialist Review:** The HRPO Office will screen the application for completeness and either request further information/documentation or assign for review.

• **Consultant Review:** The HRPO will request additional reviews of the submission if applicable. These reviews can include:
  
  o **Research Compliance Review:**
  o **Sponsored Projects Administration Review:** To verify the submission and negotiation of industry sponsored studies contracts.
- **COI**: To verify the institutional requirements for Conflict of Interest have been completed.
- **University Privacy Officer**: To determine adherence to HIPAA regulations in research, including data sharing and data transfer.
- **General Counsel of Research**: To review all legal requirements for research.
- **Global Affairs Office**: To verify adherence to guidelines for research conducted internationally.

- **Under Expedited Review**: The submission is being reviewed at the expedited level
- **Under Full Board Review**: The submission is being reviewed by the convened board
- **Post Non Full Board Review Processing**: The IRB has completed the review and the HRPO Office is preparing the decision notification to the research team.

A user can also check the status of the xForm from within the event (see 3.2, ‘Finding an xForm on an Event’).

**Note**: The xForm will be ‘owned’ by the type of event with which it is associated (i.e. initial submission, continuing review, amendment [once the amendment is submitted])

### 3.9 Decision Notification

Once the IRB Office or the IRB reviewer(s) have completed their review, the research team will receive an email detailing the IRB decision. If approved or deferred for modifications, the appropriate approval/determination letter will be attached.

### 4.0 Navigating the Study Page

From the DASHBOARD, access a study page for each study. Click on the blue study number link to access this page.

#### 4.1 Study

This section notes all sorts of basic information about the study, such as:

- Study number
- Sponsor (if applicable)
- Committee: The board, Biomedical or Social Behavioral, that will conduct the review of a study.
- Sponsor ID: This will be blank as functionality not used
- Category of study: This will be blank as functionality not used
- Grants (if applicable)
- Department: This will reflect the department entered on the initial application
• Last Review: This is the level at which the study was last reviewed (i.e., Exempt, Expedited or Full Board)

• Next Review: This is level at which the study will be reviewed at the next Continuing Review (i.e., Exempt, Expedited or Full Board)

• Agent Type: The type of research being conducted; (ex. Non-FDA Approved, Investigational Drug)

• Title: The title of the study as entered on the initial application

• Year: The year of first review

• Risk Level: This will reflect if the study is minimal risk or greater than minimal risk.

• Comments: A description of the project as entered on the initial application.

4.2 Study-Site

This section notes information about the study and the study-site, such as:

• Site(s): The primary location of the research

• PI: Principal Investigator of the project

• Status: Active, Expired, Closed, etc.

• Approval: Current approval date

• Expiration: The expiration date for expedited and full review projects (this is the day the project will expire unless a continuing review is granted)

• Initial Approval: The date that the project was first approved

• Comments: This will blank unless comments have been entered

4.3 Contacts

This section lists the contacts associated with the study along with their role, phone number and email address.

<table>
<thead>
<tr>
<th>Contacts (2)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Role</td>
</tr>
<tr>
<td>Test Generic Coordinator</td>
<td>Research Coordinator</td>
</tr>
<tr>
<td>Test Generic PI</td>
<td>Co-Investigator</td>
</tr>
</tbody>
</table>
4.4 Events

This section lists all the IRB ‘Events’ or submissions that have been or are being conducted for the study. The event line contains the following sections:

- Event: The type of event (Initial Submission, Amendment, Study Closure, Non-Compliance, etc.)
- Att: Number of attachments associated with that event or review.
- Instance/UDF: Usually this will be blank. If the event is an amendment, a summary of the amendment appears here.
- Start: The date the event was started or loaded into IRBManager
- Complete: The date the event was completed
- Last Mtg: This shows the last meeting this event or review was submitted to. Even if a submission is expedited, it shows up on a meeting agenda as an expedited review report.

Click on any blue event link to view the event details specific to the event. (See Section 5.0)

4.5 Event Details

Event Details are specific to the event or submission.

The event details contain the following:

4.5.1 Study Site:
- Study: Study IRB number
- Study-Site: Location where the project is taking place
- PI: Principal investigator’s name

4.5.2 Event:
- Type: The type of event, which could include New Submission, Continuing Review, Adverse Event/Unanticipated, etc.)
- Instance/UDF: Usually this will be blank. If an amendment, a summary of the amendment appears here.
- Started: The date the event first started
• Completed: The date the event was completed

4.5.3 Steps:
This shows the actions that take place as part of the event with the dates. Each event will have the steps listed with a planned date (not used except for steps that involve the full board review of a study), actual date.

For example, in this event, the following has occurred:
• The IRB received the New Submission on 08/21/2017
• The IRB staff completed an internal review for completion on 08/21/2017
• The Project was assigned to reviewers on 08/21/2017
• The Expedited Reviewer returned the review on 08/23/2017
• The Expedited approval has not yet been reported to the board
• The PI has not yet been notified of approval

When the IRB has completed these actions, the Complete column will be marked ‘yes’ and a completion date will show in the Actual column.

Ensure ‘Hide Skipped’ is checked, otherwise, steps not applicable to that project will appear.

4.6 Actions in the Event Details
Actions in the event details screen are as follows:
• Attachments: This shows the attachments related to the event detail
• Generated Docs: This shows the approval documents associated with the study

• xForms: This shows the form used to create the event

• Done: This returns the user to the next most logical page depending on previous actions

4.7 Helpful Hints

For any further questions regarding a project status or using IRBManager, contact the HRPO Staff at irbmain@tulane.edu or by phone at (504) 988-2665.

4.7.1 System Requirements:

• Supported Operating Systems (OS) and Browsers
  o The system is compatible with the following operating systems: Current versions of Windows, Linux, OS X (Mac) and iOS (iPad/iPhone) and Android (Google)
  o 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.
  o **Note:** We have found that the Internet Explorer browser does cause issues when attempting to sign off on xForms. Tulane’s default browser is Internet Explorer. When a PI, Faculty Advisor or Department Head click ‘Sign’ to sign off on an xForm, at the top of the pop-up box, it states the type of browser that the signer is utilizing for easy identification. A change to the default browser may alleviate any future issues.
  o **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.

4.7.2 Email Notifications:

• Email notifications will be sent to the study team from IRBManager via irbmain@tulane.edu.

• All signatories (i.e., the PI, Department Head, Faculty Advisor, etc) will receive an email with a link to the xForm they are being requested to review and sign off on.
  o **Note:** The Tulane default browser is Internet Explorer. When a signatory attempts to sign off on a study while in the default browser the signature is not being accepted. Please set the default browser on the computer to Google Chrome or Firefox to ensure this issue does not affect the submission process.

• Email notifications will be sent to the study team when the determination of an event has been completed.

• The email will include the determination letter and stamped consent/assent form(s), if applicable.
4.7.3 Additional Training:

Should a study team, class section, organization or department wish to request additional training in the IRB Submission process and the electronic submission system:

- Please contact the HRPO office at irbmain@tulane.edu.
- Please provide the name of a point of contact, email address and telephone number.
- Please provide the number of people that will attend the training and a proposed location.
  - **Note:** Access to a laptop and projector would be beneficial.
  - **Note:** The HRPO Conference Room can be made available with prior notice.
- Please provide 2-3 proposed dates and times for the training to be conducted.
- Please provide a list of questions and/or issues being encountered to ensure the training can be tailored to the needs of the group.
APPENDIX 1:
5.1 Frequently Asked Questions

Why can’t my study team see the xForm I created?

The only members of the study team that have access to an unsubmitted xForm are the PI and the submitter of that xForm. The rest of the study team will be able to view the xForm once a determination is made.

Should a study team member other than the submitter and the PI require access to an xForm while it is being completed, the submitter or PI can add that person as a ‘Collaborator’ of that form. The Collaborator functions exactly like the ‘Read/Write/Full’ access from IRBNet.

A Collaborator can be granted the following permissions:

- View Only
- Edit
- Edit and Manage
- Edit, Manage and Submit

This function is form specific. Collaborators will only be able to see each form they are added to. Collaborator access does not carry over to other xForms created in a study.

Why can’t my PI sign off on an xForm?

There are a couple of reasons that this may be happening:

1st: Check the web browser that PI is using. We have found that some investigators cannot sign off on xForms if they utilize Internet Explorer as their default browser. Also, we have learned that Tulane’s University default browser is Internet Explorer. A solution would be to update the default browser to Firefox or Chrome and sign off on the xForm.

2nd: Once the PI signs off on the xForm, they must select “NEXT”, then they must select “SUBMIT”. Without selecting “Next” and “Submit” the signature will not be accepted and the xForm will remain in the PI Attestation Stage.

Does everyone on my study team need to receive email notifications?

The short answer is yes.

The HRPO was weighed the Pros and Cons of providing email notifications to all approved members of the entire study team to ensure everyone is aware of the status of study Events. We have determined that notifying everyone on the study team when modifications/revisions have been requested, and when the IRB Determination Letters and Stamped Consent Forms have been provided. While this may be inconvenient for some researchers, we are deeply apologetic if it causes any undue stress. We have found that majority of the research community wants the entire study staff to have access to the notifications in an attempt to provide requested modifications timely and to ensure that all study team members are aware of and have access to the IRB determinations.
I am trying to add a member to the study team and the xForm is saying “contact not found”, what does that mean?

If you are receiving the “contact not found” message that usually means that the person you are attempting to add has not logged into IRBManager to activate their User Account. While everyone with a Tulane email address and password has access to IRBManager, each User must sign into the system to active their account. Unfortunately, if a contact is not found that researcher cannot be added to the study team until their email address can be added to the xForm in the appropriate Personnel field, depending on if an Initial or Secondary Application is being submitted.

I submitted an Amendment Only Secondary Application, however, the xForm was returned with the request that I submit a Continuing Review?

If you will be requesting changes (an amendment) within 45 DAYS of the expiration date or at the time of the Continuing Review Submission, select the appropriate Continuing Review Submission option. Do NOT create an Amendment Submission ONLY xForm and a Continuing Review xForm. The xForms will be returned.

I submitted an Initial Application, the xForm was returned requesting a modification to the consent form. When I send it back, what should I do with the old form that I was asked to change?

When modifications to a document attached to the xForm are requested, for an Initial Application, you should remove the old version of the document from the section. Please note that any documents you upload become a part of the study record as an attachment. Helpful hint, the documents that are attached to the xForm are the documents that will be reviewed by the IRB. You don’t want the documents that require modifications to be sent to the reviewers, as this could cause a delay in the final determination.

When is an xForm considered submitted to the HRPO/IRB office?

An xForm is not considered submitted to the HRPO/IRB office until it reaches the HRPO Intake Stage. Prior to this stage the form is pending signatures from the PI and/or the department head. Until the form is signed by the appropriate individual(s) it is not considered submitted. This is especially important for Greater Than Minimal Risk submissions that require Full Board review and for Protocol Deviations and Adverse or Serious Adverse Events that must be reported within a certain timeframe.