

WELCOME
TO THE IRB ELECTRONIC SYSTEM

Tick@lab

New Protocol Submission Training

IMPORTANT NOTE:
**Remember to Allow Pop-Ups in
your web browser.**

**If you do not allow pop-ups, the system
will not work properly.**

Tick@lab URL

<https://lar.utrgv.edu/tickatlab/default.aspx>

Log in with your UTRGV Credentials

If you are unable to log in with your UTRGV credentials please contact the Office of Research Compliance at (956) 665-2093/ (956) 665-2889/ (956) 665-3598 / (956) 882-7743. Or, you may also email the IRB to irb@utrgv.edu

We will check on your account to see if updating is required. If no account is found, you will have to complete a web form to request access.

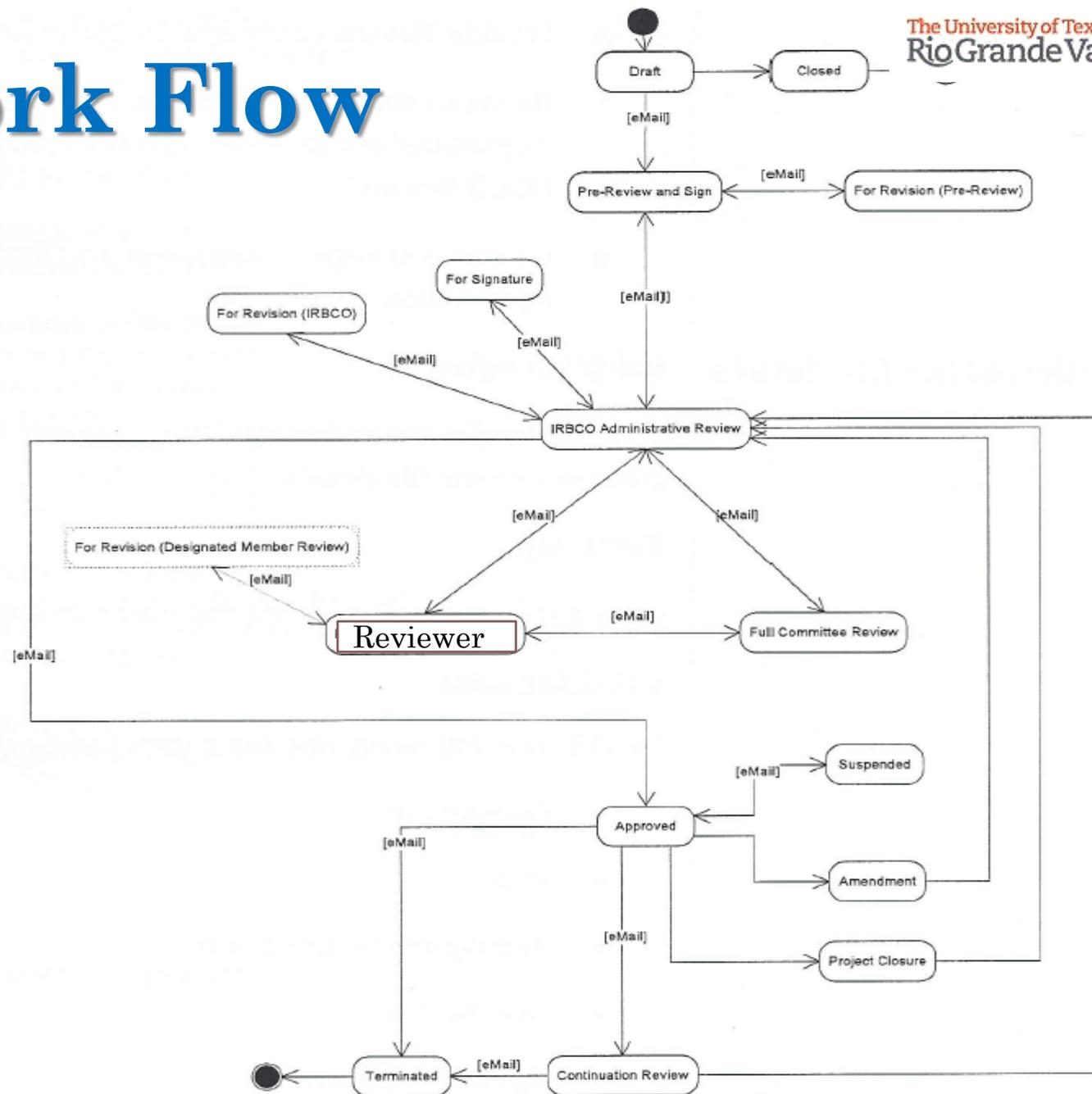
Workflow

Guide

Tick@Lab Work Flow

- New Protocol

- PI or research team will create a draft protocol.
- PI should assign personnel to the protocol with their applicable roles (Personnel Tab). Note, the PI must be assigned as a Reviewer and Signer at the bottom. As well as the Faculty Advisor if applicable.
- PI Assurance must be completed before moving to Pre-Review and Sign.
- PI should do a status change by selecting **Pre-Review and Sign**.
- PI, and Faculty Advisors (*if applicable*) must sign the protocol.
- Once signed by all Reviewers and Signers, the protocol is automatically forwarded to the IRBCO (Coordinators).
- *Exempt protocols are reviewed and approved by IRBCO.*
- *Expedited and Full Review protocols are administratively screened before being assigned to a member.*



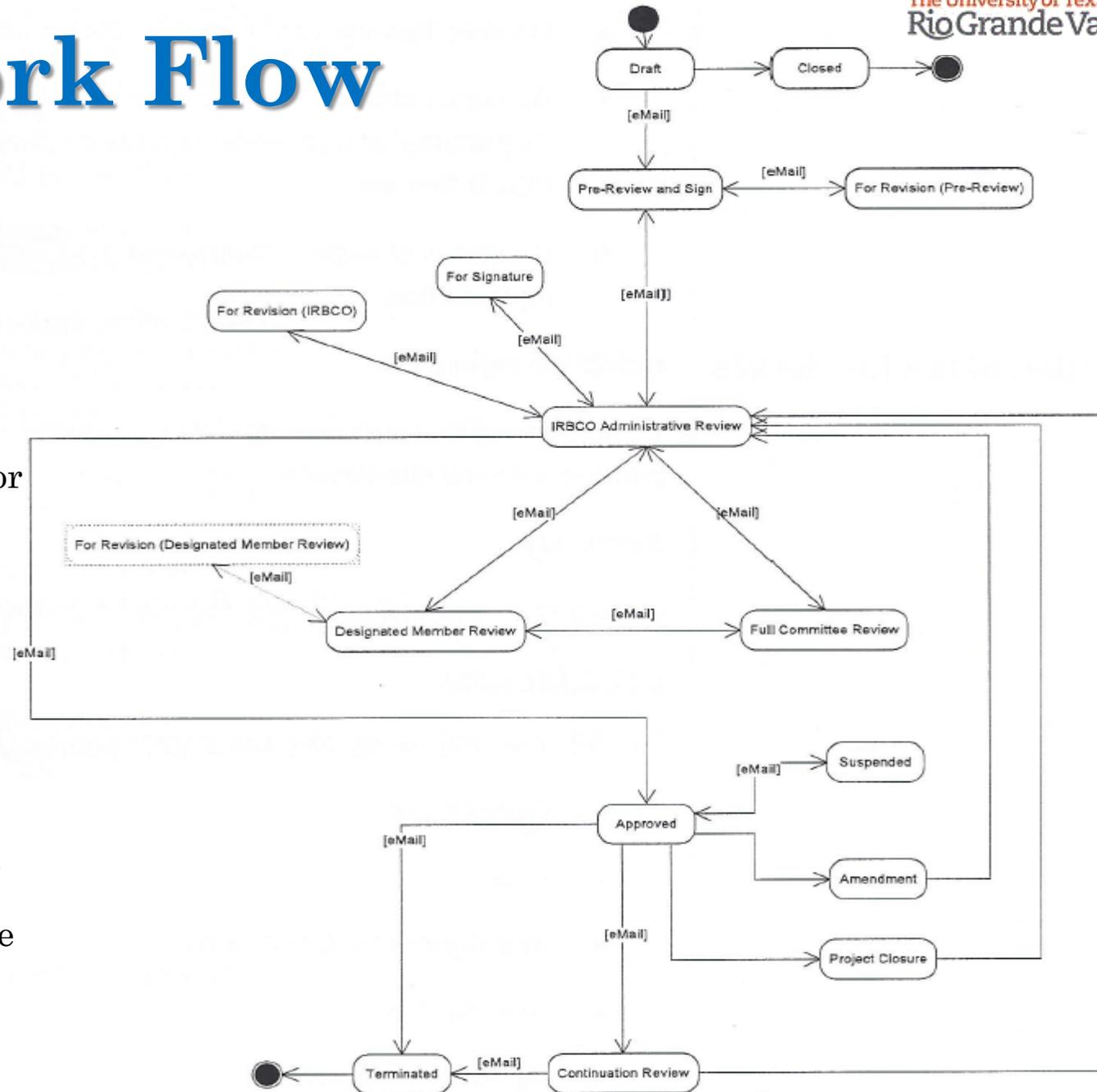
Tick@Lab Work Flow

- If no pertinent documents or information is missing the protocol is assigned to Reviewer (Board Member) for review.
- If during administrative screening any pertinent documents or information is missing, the IRBCO will send the protocol back to you for revision.

Administrative review and Reviewer - Review comments will be provided within the protocol, located on the respective tab. The protocol will be pushed back to you For Revision.

Amendments and Continuations

After a protocol has been approved, the PI may draft and submit an Amendment or Continuation.



Document Status Types

- **Draft** – This means your submission is in Draft Mode and is not yet submitted.
- **Pre-Review & Sign** – This means your submission is in the pre-review stage, all reviewers and signers (*as designated by you on the Personnel tab*) must review before signing.
- **Signatures** – This means your submission is in the signing stage, all reviewers and signers (*as designated by you on the Personnel tab*) must sign the protocol.
- **IRBCO Administrative Review** – This means your submission is being reviewed by IRB Coordinators
- **For Revision** – This means your submission is being sent back to you for revisions (*may be based on feedback from Coordinators, a Designated Member, or the Full Committee*)
- **Reviewer** – This means that your submission has been assigned to a designated IRB Member for review, and is currently under review by them.
- **Full Committee Review** – This means that your submission has been pushed for Full Review by either the Coordinators or a Designated IRB Member. Note, in this stage the project will be added to a meeting agenda and will be visited by the board at a convened meeting.
- **Approved** – This means your submission has been approved. An approval memo will be published at the file level.

Steps on how to submit an IRB application.

The University of Texas
Rio Grande Valley

Launch Pad My tick@lab

Home

Protocols

Compliance Support

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Help

UTRGV Research Compliance

tick@lab

System Information: a-tune tick@lab 3.0
Build: 3269.2 Config Version: 013 Language: English

Investigator and Member IRB

Your session will expire in:
87 min 33 sec

Profile Refresh Logout

PROTOCOLS IRB

TASKS Tasks Cases

REPORTS CUSTOM REPORTS Custom Report

Select IRB under the "Protocol" ribbon.

- Please select the Institutional Review Board (IRB) tab to work with Human Subjects Research Protocols.
- This system allows the user to submit Animal Use Protocols (AUP) as well as Human Subjects Research Protocols

- Home
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- Compliance Support
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- Switch to mobile
- Help
- UTRGV Research Compliance

tick@lab

System Information: a-tune tick@lab 3.0
Build 3269.2 Config Version: 013 Language: English

Investigator and Member IRB

2. Click on "Apply Filter"

FILTER SEARCH

Apply filter Reset filter

Hide Show

Select the desired filter criteria below and click "Apply Filter" to customize your view.

Operation between different filter criteria: AND
Operation between multiple selections within the same criterion: OR

My Filter Sets:

- Approved Protocols (For all users)
- Pending Protocols (applicationwide default)**

File-General File-History

1. Once on the IRB tab, please select "Pending Protocols" from "My Filter Sets".
 - Pending Protocols lists all protocols that are either pending submission or are currently undergoing the review process.
 - Approved Protocols lists all protocols that have been approved by the IRB.

CLICK HERE TO VIEW, CREATE AND EDIT YOUR PROTOCOLS.

3. Click here to Expand Files. By default Tick@lab collapses all files. You need to expand files in order to see the folders that contain your protocol.

- Home
- Protocols
- Compliance Support
- Tasks
- Reports
- Switch to mobile
- Help
- UTRGV Research Compliance
- tick@lab

IRB

FILTER & SEARCH

Apply filter Reset filter

Hide | Show

Select the desired filter criteria below and click "Apply Filter" to customize your view.

Operation between different filter criteria: AND
Operation between multiple selections within the same criterion: OR

My Filter Sets: Pending Protocols (For all users)

File-General File-History Document

CLICK HERE TO VIEW, CREATE AND EDIT YOUR PROTOCOLS.

+ New Export to Excel

This is an example of how a list of all projects you are part of, would look like

4. Click here to start a new application.

| IRB# | File title | File created | File status | Last file status change | Expiration date | Document title | Last document change | Last document checkout | Current document status/progress | Last document status change | 1st approved | Principal investigator | Version | Next Annual Review Date |
|-------------|--------------------------------------|--------------|-------------|-------------------------|-----------------|----------------|----------------------|------------------------|----------------------------------|-----------------------------|--------------|------------------------|---------|-------------------------|
| IRB-20-0228 | Training Materials | 22-Jul-2020 | Initiated | 22-Jul-2020 | --- | --- | 22-Jul-2020 | 22-Jul-2020 | Draft | 22-Jul-2020 | --- | IRB, Investigator | 1.0 | --- |
| IRB-20-0227 | Protocol A (Exp Behav) | 22-Jul-2020 | Amendment | 22-Jul-2020 | 21-Jul-2021 | --- | 22-Jul-2020 | 22-Jul-2020 | IRBCO Administrative Review | 22-Jul-2020 | 22-Jul-2020 | IRB, Investigator | 10.0 | --- |
| IRB-20-0226 | Testing attachment adding and rem... | 09-Jun-2020 | Initiated | 09-Jun-2020 | --- | --- | 10-Jun-2020 | 10-Jun-2020 | IRBCO Administrative Review | 10-Jun-2020 | --- | IRB, Investigator | 9.0 | --- |

Investigator and Member IRB

Your session will expire in:
87 min 33 sec

Profile Refresh Logout

Popup - Google Chrome
lar-test.test-utrgv.net/ticketlab_test/popup.aspx?Commlid=-1598658504&EventId=InitiateFileWizard.Start

Close window X

Initiate File and Document Wizard

Document Template

File Properties

Location

DOCUMENT TEMPLATE

Please select the document template you like to use.

Document Template*: Institutional Review Board Protocol (IRB)

→ Next

6. Click "Next" to continue.

5. Select IRB from the drop down menu on "Document Template"

Popup - Google Chrome
lar-test.test-utrgv.net/tickatlab_test/popup.aspx?CommId=-1598658504&EventId=InitiateFileWizard.Start

Initiate File and Document Wizard

Document Template

File Properties

Location

Please provide a meaningful short description for the file.

Title Training Materials

Protocol Number: IRB-20-0228

← Back → Next

7. Type the title of your project in the Title text box.

8. Take note of your project number, and click "Next" to continue.

10. Click on “Close Window”
to automatically save.

Popup - Google Chrome
lar-test.test-utrgv.net/ticketlab_test/popup.aspx?CommlId=-1598658504&EventId=InitiateFileWizard.Start

Initiate File and Document Wizard

Document Template
File Properties
Location

Save and open document

Please select "UTRGV" below.

Location

+ UTRGV

Back Save and open document

Close window X

9. Select “UTRGV” under
location, and click on “Save and
open document”.

- This is how the application for a new project will look like.
- The questions on the application are organized by topics on the left side of the form.

The screenshot shows the IRB application interface for 'IRB: IRB-20-0228 "Training Materials", (v.1.0), Initiated/Draft'. The left sidebar contains a navigation menu with the following items: Home, Protocols, Compliance Support, Tasks, Reports, Switch to mobile, Help, UTRGV Research Compliance, and tick@lab. The main content area is titled 'GENERAL INFORMATION' and contains several questions. A red box highlights the left sidebar, and a red arrow points from a text box to the 'GENERAL INFORMATION' tab.

11. Click through the tabs and answer the questions on each tab.

The main content area includes the following questions:

- 1. Please provide a brief (1-5 sentences) overview of your study, including (1) the purpose, (2) your subject population(s), and (3) the methods used. (*)**
Write for a general audience, do not use jargon or names of instruments/measures/methods that individuals outside your field will not know. Please note this is just an overview, detailed information is required under the "Project information" tab.
 Answer
- 2. External site for this project**
Note: UTRGV owned
Note: If for your research
 Yes
Please attach an outside site letter (using the UTRGV template) for each external site.
 No
- 3. Is this a multi-site research project?**
A multi-site research project refers to the same protocol for human subjects research conducted at multiple (2 or more) research institutions in collaboration with UTRGV. For non-exempt human subjects research that include multiple sites, cooperative agreements will be needed (i.e., Single IRB, or Reliance Agreement).
 Yes
 No
- 4. Are you collaborating with someone from another institution?**
This question refers to non-multi-site research projects. I.e., someone will be helping you conduct your research, however their affiliated institution is not a site where research will be conducted.
 Yes
 No

Save Often, Tick@lab does not save information automatically.
Make sure you save information after completing each tab.

The screenshot shows the Tick@lab interface for an IRB protocol. The 'Action' dropdown menu is open, showing options: 'Enable Editing', 'Save Edits', 'Save New Version', 'Print', 'Compare version', and 'Validate & Save'. The 'Enable Editing' option is circled in red, and an arrow points to it from a text box. Another arrow points to the 'Save Edits' option from a second text box. The interface also shows a sidebar with navigation options like Home, Protocols, Animal Orders, etc., and a main content area with tabs for 'Review', 'Attachments', and 'Action'. A table below the dropdown shows investigator information.

| Last name | First name |
|-------------|----------------|
| Coordinator | IRB-IACUC TEST |

12. Enable Editing: enables you to edit the document.

Click on "Save Edits" under the "Action" button located in each tab.

- Note, you have 3 ways to save forms:
 - Done Editing: saves the file and checks the document in so that another person could check it out and edit it. (Done Editing will only show after you first enable editing)
 - Save Edits: saves the document and allows you to keep working on it.
 - Save New Version: saves a separate and new version of the file (duplicate).

Personnel

How to add project team members to your protocol

From the “Personnel” Tab on the left, go into each of the questions and click “Edit selection” to assign personnel as Co-Investigators, Key Personnel, Faculty Advisor and Reviewer and Signers from the Pop-up window.

The screenshot shows the IRB system interface for protocol IRB-20-0228. The left sidebar has the "Personnel" tab selected. The main content area is divided into sections for different roles, each with an "Edit selection" button highlighted in a red box:

- PRINCIPAL INVESTIGATOR**: The Principal Investigator is responsible for all work conducted under this protocol and can edit the information. If this is a student project, the student is considered the "Principal Investigator" and should list a "Faculty Advisor" below.

| Last name | First name |
|-----------|--------------|
| IRB | Investigator |
- CO-INVESTIGATOR**: Co-PIs can edit the information on this protocol.

| Last name | First name |
|-----------|------------|
|-----------|------------|
- OTHER STUDY PERSONNEL**: Other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way.

| Last name | First name |
|-----------|------------|
|-----------|------------|
- FACULTY ADVISOR**: Students performing research, as part of their course work, should have a Faculty Advisor. Please enter the Faculty Advisor name in here.

| Last name | First name | (for IRB internal use only) |
|-----------|------------|-----------------------------|
|-----------|------------|-----------------------------|
- REVIEWERS AND SIGNERS**: Individuals listed here need to pre-review and sign the protocol. Required signers include: the Principal Investigator (PI) and Faculty Advisor (if the PI is a student).

| Last name | First name |
|-----------|------------|
|-----------|------------|

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IRB: IRB-20-0228 "Training Materials", (v.1.0), Initiated/Draft

← Back to overview Review Attachments Action Workflow

General Information Edit selection

| Last name | First name |
|-----------|--------------|
| IRB | Investigator |

CO-INVESTIGATOR ?

Co-PIs can edit the information on this protocol.

Edit selection

| Last name | First name |
|-----------|------------|
|-----------|------------|

OTHER STUDY PERSONNEL ?

Other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way.

Edit selection

| Last name | First name |
|-----------|------------|
|-----------|------------|

FACULTY ADVISOR ?

Students performing research, as part of their course work, should have a Faculty Advisor. Please enter the Faculty Advisor name in here.

Edit selection

| Last name | First name | (for IRB internal use only) |
|-----------|------------|-----------------------------|
|-----------|------------|-----------------------------|

REVIEWERS AND SIGNERS ?

Individuals listed here need to pre-review and sign the protocol. Required signers include: the Principal Investigator (PI) and Faculty Advisor (if the PI is a student).

Edit selection

| Last name | First name |
|-----------|------------|
|-----------|------------|

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tick@lab
System Information: a-tune tick@lab 3.0
Build: 3269.2 Config Version: 013 Language: English
Investigator and Member IRB
Your session will expire in: 87 min 33 sec
Profile Refresh Logout

- If the PI is a student, a Faculty Advisor must be assigned in the Faculty Advisor section. Advisors are also required to pre-review and sign the application. Therefore, it is also important to ensure the advisor is assigned as a Reviewer and Signer.
- If the PI is not a student, only the PI needs to be assigned as a Reviewer and Signer to complete the pre-review and sign process.

Personnel Selection

FILTER & SEARCH

Apply filter Reset filter

Click a team to show the list of team members. Selection of the root-node "Teams" will show all persons. Use the name-filter to search by name within the selected team (or within all users).

Name:

Teams

Apply current selection

1. Type the Name of the person you want to add (first or last name only, not both) then click on "Apply filter", or
2. You can click on Teams to select from the list, then click on "Apply current selection"

Note 1: You can add as many personnel as you want.

Note 2: If you cannot find a researcher from the list, there is a slight possibility that the researcher does not have access to Tick@Lab and will need to submit an Access Request to get an account created.

Personnel Notes

- Only Reviewers and Signers may view the project and documents.
- Only Reviewers and Signers who are also listed as the PI or Co-I's can modify protocol content.
- The PI on the project should always be designated as a Reviewer and Signer.
- Other personnel such as research assistants or coordinators do not have write access.
- All Reviewers and Signers must sign the document before you submit to the IRB Coordinators (IRBCO).

Attachments

How to add attachment to your protocol

IRB: IRB-20-0228 "Training Materials", (v.1.0), Initiated/Draft

[← Back to overview](#)[Review](#)[Attachments](#)[Action](#)[Workflow](#)

You can add attachments by using any of the "Attachments" button.

Please include your attachments on their respective tabs. This is will facilitate the review process once you submit.

E.g. Attach your consent form documents on the Informed Consent tab. Attach your recruitment materials on the Recruitment tab. Attach your data collection materials on the Project Information tab.

- Home
- Protocols
- Compliance Support
- Tasks
- Reports
- Switch to mobile
- Help
- UTRGV Research Compliance
- tick@lab

System Information: a-tune tick@lab 3.0
Build 3269.2 Config Version: 013 Language: English

Investigator and
Member IRB

Your session will expire in:
87 min 33 sec

Profile Refresh Logout

Popup - Google Chrome
lar-test.test-utrgv.net/ticketlab_test/popup.aspx?CommId=493531827&EventId=AttachmentPopUp.Start

Close window X

Attachments

General Information

- VA Study Approvals
- Personnel
- Training
- Protocol/Forms Links
- Drugs and/or Devices
- Retrospective Data Collection
- Prospective Collection of Biological Specimens
- Project Information
- Human Subjects Information
- Risks and Benefits
- Informed Consent
- HIPAA
- Protection Of Data
- Recruitment
- PI Assurance Statement
- Workflow History

All

Apply to document

GENERAL

+ Add Reset

File: Choose File No file chosen

Description:

ATTACHMENTS

No. of entries: 0

| Last Changed | File | Description |
|--------------|------|-------------|
|--------------|------|-------------|

No. of entries: 0

1. Click on "Choose File" and upload file from computer or other devices.

Clicking on the "All" button will show you the application attachments on all tabs. However, you must choose a tab you want to attach to, you will not be able to attach on the All tab.

Popup - Google Chrome
lar-test.test-utrgv.r...entId=AttachmentPopUp.Start

Close window X

Attachments

- General Information
- VA Study Approvals
- Personnel
- Training
- Protocol/Forms Links
- Drugs and/or Devices
- Retrospective Data Collection
- Prospective Collection of Biological Specimens
- Project Information
- Human Subjects Information
- Risks and Benefits
- Informed Consent
- HIPAA
- Protection Of Data
- Recruitment
- PI Assurance Statement
- Workflow History
- All

3. Click "Apply to document"

Apply to document

GENERAL

+ Add **Reset**

File: Choose File No file chosen

Description:

2. Add a description

ATTACHMENTS

No. of entries: 0

| Last Changed | File | Description |
|--------------|------|-------------|
|--------------|------|-------------|

No. of entries: 0

How to locate an attachment...

The screenshot shows the IRB application interface for "IRB: IRB-20-0228 'Training Materials', (v.1.0), Initiated/Draft". The left sidebar contains navigation options: Home, Protocols, Compliance Support, Tasks, Reports, Switch to mobile, Help, and UTRGV Research Compliance. The main content area has a top navigation bar with buttons for "Back to overview", "Review", "Attachments", "Action", and "Workflow". The "Attachments" button is circled in red, and a red arrow points from it to a text box. Below the navigation bar, the "General Information" tab is selected, and a paperclip icon is visible next to it. The main content area displays the "GENERAL INFORMATION" section with a text input field and a question: "1. Please provide a brief (1-5 sentences) overview of your study, including (1) the purpose, (2) your subject population(s), and (3) the methods used. (*)".

IRB: IRB-20-0228 "Training Materials", (v.1.0), Initiated/Draft

← Back to overview Review Attachments Action Workflow

General Information 

VA Study Approvals

Personnel

Training

Protocol/Forms Links

Drugs and/or Devices

Retrospective Data Collection

Prospective Collection of Biological Specimens

Project Information

Human Subjects Information

Risks and Benefits

Informed Consent

HIPAA

Protection Of Data

Recruitment

PI Assurance Statement

Workflow History

Please respond

GENERAL INFORMATION

Irbp.Tab.GeneralInformation.HelpText.Label

1. Please provide a brief (1-5 sentences) overview of your study, including (1) the purpose, (2) your subject population(s), and (3) the methods used. (*)

Write for a general audience, do not use jargon or names of instruments/measures/methods that individuals outside your field will not know. Please note this is just an overview, detailed information is required under the "Project information" tab.

Answer

2. Will subjects be recruited or data collected at an external site(s)?

External site for this question refers to any non-research site where subjects will be recruited, consented and/or where data will be collected.
Note: UTRGV owned clinics are not external sites.
Note: If for your research you will be meeting subjects at a public place, this would not be considered an external site.

Yes
Please attach an outside site letter (using the UTRGV template) for each external site.

No

3. Is this a multi-site research project?

How to remove attachments...

The screenshot shows the UTRGV Research Compliance interface for an IRB protocol. The top navigation bar includes a back arrow, a title "IRB: IRB-20-0228 'Training Materials', (v.1.0), Initiated/Draft", and buttons for "Back to overview", "Review", "Attachments", "Action", and "Workflow". The "Attachments" button is highlighted with a red arrow. A red-bordered text box with white text is overlaid on the interface, stating: "You can remove attachments by using the 'Attachments' button." The main content area shows a form with sections for "General Information", "Project Information", "Human Subjects Information", "Risks and Benefits", "Informed Consent", "HIPAA", "Protection Of Data", "Recruitment", "PI Assurance Statement", and "Workflow History". The "Attachments" button is located in the top navigation bar, between the "Review" and "Action" buttons.

Attachments

General Information

VA Study Approvals

Personnel

Training

Protocol/Forms Links

Drugs and/or Devices

Retrospective Data Collection

Prospective Collection of Biological Specimens

Project Information

Human Subjects Information

Risks and Benefits

Informed Consent

HIPAA

Protection Of Data

Recruitment

PI Assurance Statement

Workflow History

All

Apply to document

GENERAL

+ Add Reset

File: Choose File No file chosen

Description:

ATTACHMENTS

No. of entries: 1

| Last Changed | File | Description |
|--------------|-----------------------------|-------------|
| 22-Jul-2020 | 2. Application Requirements | |

No. of entries: 1

Edit Attachment

Delete Attachment

javascript:__doPostBack('AAttachmentPopUp.100608APO17-...')

Right click on top of the name of the file and select "Delete Attachment"

Note: by changing the workflow, the attachments will be locked and can no longer be deleted. I.e., while in draft mode and pre-review revision mode you may delete any attachments that you do not need. However, once you submit to the IRBCO Administrative Review attachments will be locked.

Validating and Saving

- Once you have completed the application, then you need to Validate and Save your application.
- Mandatory questions are marked with (*) at the end of the questions.

IRB: IRB-22-0136 "Testing LAC/Assignments", (v.5.0), Initiated/Full Committee Review

← Back to overview Review Attachments

For IRB Use

Personnel

Project Information

General Information

Human Subjects Information

Recruitment

Protection Of Data

Risks and Benefits

Informed Consent

HIPAA

Training

Protocol/Forms Links

PI Assurance Statement

Document History

Please respond to all questions.

GENERAL INFORMATION

Irbp.Tab.GeneralInformation.I

1. What level of review do you require? ?

The qualification is subject to determination made by ORC or the IRB. For more information on the different levels of review, please visit [here](#).

Exempt Review

2. Will research procedures take place at an external site? ?

An external site refers to any non-UTRGV site in which research activities are not covered by site's own IRB. Note: UTHHealth RGV clinics are not considered external sites. However, use of these sites still require an internal permission letter. If for your research you will be meeting subjects at a public place, this would not be considered an external site.

Yes
Please attach a site letter (see Templates and Forms on our website for copies of our template letters) for each external site.

No

Done Editing
Save Edits
Save New Version
Print
Compare version
Validate & Save

“Validate & Save” is a feature to check for any incomplete mandatory questions.

Application Validation...

The screenshot shows the IRB application interface for "IRB: IRB-20-0228 'Training Materials', (v.1.0), Initiated/Draft". The left sidebar contains navigation options: Home, Protocols, Compliance Support, Tasks, Reports, Switch to mobile, Help, and UTRGV Research Compliance. The main content area displays the "GENERAL INFORMATION" section. At the top, there are buttons for "Review", "Attachments", "Action", and "Workflow". A red box highlights two validation error messages: "Questionnaire validation error: No item selected for mandatory field '1. Please provide a brief (1-5 sentences) overview of your study, including (1) the purpose, (2) your subject population(s), and (3) the methods used.' Location: tab 'General Information' > section 'General Information'" and "Questionnaire validation error: No item selected for mandatory field 'The principal investigator agrees to!'. Location: tab 'PI Assurance Statement' > section 'PI Assurance Statement'". Below the errors, the "GENERAL INFORMATION" section is visible, with a red arrow pointing to the first question: "1. Please provide a brief (1-5 sentences) overview of your study, including (1) the purpose, (2) your subject population(s), and (3) the methods used. (*)". A text box for the answer is present but empty.

Pending Mandatory questions.

The screenshot shows the same IRB application interface as above, but now the validation is successful. A green box at the top displays the message: "Successful validation: All mandatory fields are filled in." Below this, the "PI ASSURANCE STATEMENT" section is visible. A red arrow points to the statement: "The Principal Investigator undertakes the primary responsibility for protecting the rights and welfare of research participants and must be familiar with the ethical principles of human subject protection requirements of federal regulations, Federal Wide Assurance, and IRB policy and procedures." Below the statement, there is a list of bullet points regarding the PI Assurance Statement, and a radio button labeled "I have read and agree to follow the PI Assurance statement above." is selected.

All required questions are answered.

Pre-Review, Signatures and Submission

Submitting the protocol into Workflow

Important Notes before Moving Forward with Signatures

Please keep these notes in mind:

- Pre-Review and Sign is not IRB review, the project is not yet submitted.
- All Reviewers and Signers which you have designated on the Personnel tab must sign.
- Once a person signs, the next signer can view and sign the application but will not be able to edit it.
- If edits are required after someone has signed, the reviewer requesting such revisions must select “For Revision (Pre-Review)” from the workflow button and leave their comments. However, this will erase all previously obtained signatures.
- After edits have been made, the protocol must be submitted to ‘Pre-Review and Sign’ and everyone who is listed as a Reviewer and Signer must sign again using the ‘Signatures’ option on the Workflow button.

Pre-Review and Signature Steps

1. Designate Reviewers and Signers on the Personnel tab
2. Push for 'Pre-Review and Sign' using the Workflow button at the top.
3. Click on 'Signatures' using either the Workflow button at the top. Or, right click on the document and select 'Signatures' from the context menu.
4. Sign by entering your password, and click on close window at the top of the pop-up window.

This will leave the document available for others to sign. Once all signatures have been obtained the protocol will automatically be submitted to the IRB Coordinators (IRBCO). When this happens you will see the status change from 'Pre-Review and Sign' to 'IRBCO Administrative Review'. **That is your confirmation that the project has been successfully submitted.**

- Once you have validated your application then you need to submit the application to workflow for Pre-review and Signature. A copy of the workflow process has been included at the end of this presentation.

The screenshot shows the IRB application interface for "IRB-20-0228 'Training Materials', (v.1.0), Initiated/Draft". The left sidebar contains navigation options like Home, Protocols, Compliance Support, Tasks, Reports, Switch to mobile, Help, and UTRGV Research Compliance. The main content area has a top navigation bar with "Back to overview", "Review", "Attachments", "Action", and "Workflow" tabs. The "Workflow" tab is selected, and its dropdown menu is open, showing "Pre-Review and Sign" and "Closed" options. A red arrow points to the "Pre-Review and Sign" option. A red box highlights the instruction: "For submission please click on the 'Workflow tab and Select 'Pre-Review and Sign'". Below the workflow menu, there is a text editor with a toolbar and a question: "2. Will subjects be recruited or data collected at an external site(s)?".

Home

Protocols

Tasks

Reports

Switch to mobile

Help

UTRGV Research Compliance

Utopia

System Information: a-tune: rct@rak 2.0
Build: 3289.2 Config: Version: 011 Language: English

IRB: IRB-20-0228 "Training Materials", (v.1.0), Initiated/Draft

← Back to overview

Review Attachments Action Workflow

General Information

VA Study Approvals

Personnel

Training

Protocol/Forms/Links

Drugs and/or Devices

Retrospective Data Collection

Prospective Collection of Biological Specimens

Project Information

Human Subjects Information

Risks and Benefits

Informed Consent

HIPAA

Protection Of Data

Recruitment

PI Assurance Statement

Workflow History

Please provide the names of all personnel who will oversee or conduct work under this protocol.

PRINCIPAL INVESTIGATOR

The Principal Investigator is responsible for all work conducted under this protocol and can edit the information. If this is a student project, the student is considered the "Principal Investigator" and should list their name as such.

Edit selection

| Last name | First name |
|-----------|--------------|
| IRB | Investigator |

CO-INVESTIGATOR

Co-PIs can edit the information on this protocol.

Edit selection

| Last name | First name |
|-----------|------------|
| | |

OTHER STUDY PERSONNEL

Other individuals who contribute to the protocol.

Edit selection

| Last name | First name |
|-----------|------------|
| | |

You may add a comment if you want and/or click “Ok”. Then, please click the “Back to overview” button. This button will take you back to the protocols page where projects are listed.

This is how your application will look like in your “Pending Protocols” files after it has been sent for Pre-Review and Signature.

The screenshot shows the IRB application interface. On the left is a navigation sidebar with options: Home, Protocols, Compliance Support, Tasks, Reports, Switch to mobile, Help, and UTRGV Research Compliance. The main content area is titled "IRB" and includes a "FILTER & SEARCH" section with buttons for "Apply filter" and "Reset filter", and a "Hide | Show" toggle. Below this is a section for "My Filter Sets" with a dropdown menu and icons for adding and deleting filter sets. There are also buttons for "File-General", "File-History", and "Document". A section titled "CLICK HERE TO VIEW, CREATE AND EDIT YOUR PROTOCOLS." contains "+ New" and "Export to Excel" buttons. A message states: "Documents are organized into files (folders). Click on the file to see the document(s) stored in the file." Below this is a table with 3 entries. The first entry is highlighted with a red box, and a sub-table titled "Documents/Versions in File" is shown below it, also with a red box around the "Pre-Review and Sign" status.

| IRB# | File title | File created | File status | Last file status change | Expiration date | Document title | Last document change | Last document checkout | Current document status/progress | Last document status change | 1st approved | Principal investigator | Version | Next Annual Review Date |
|-------------|--------------------|--------------|-------------|-------------------------|-----------------|----------------|----------------------|------------------------|----------------------------------|-----------------------------|--------------|------------------------|---------|-------------------------|
| IRB-20-0228 | Training Materials | 22-Jul-2020 | Initiated | 22-Jul-2020 | --- | --- | 22-Jul-2020 | 22-Jul-2020 | Pre-Review and Sign | 22-Jul-2020 | --- | IRB, Investigator | 2.0 | --- |

| Document title | Version | Last document change | Last document checkout | Document status | Last document status change | Principal investigator | Checked-out by |
|----------------|---------|----------------------|------------------------|---------------------|-----------------------------|------------------------|----------------|
| --- | 2.0 | 22-Jul-2020 | 22-Jul-2020 | Pre-Review and Sign | 22-Jul-2020 | IRB, Investigator | --- |
| --- | 1.0 | 22-Jul-2020 | 22-Jul-2020 | Draft | 22-Jul-2020 | IRB, Investigator | --- |

1st way to access the Signatures function: Protocols Page

| IRB# | File title | File created | File status | Last file status change | Expiration date | Document title | Last document change | Last document checkout | Current document status/progress | Last document status change | 1st approved | Principal investigator | Version | Next Annual Review Date |
|-------------|--------------------|--------------|-------------|-------------------------|-----------------|----------------|----------------------|------------------------|----------------------------------|-----------------------------|--------------|------------------------|---------|-------------------------|
| IRB-20-0228 | Training Materials | 22-Jul-2020 | Initiated | 22-Jul-2020 | --- | --- | 22-Jul-2020 | 22-Jul-2020 | Pre-Review and Sign | 22-Jul-2020 | --- | IRB, Investigator | 2.0 | --- |

Documents/Versions in File

| Document title | Version | Last document change | Last document checkout | Document status | Last document status change | Principal investigator | Checked- |
|----------------|---------|----------------------|------------------------|---------------------|-----------------------------|------------------------|----------|
| --- | 2.0 | 22-Jul-2020 | 22-Jul-2020 | Pre-Review and Sign | 22-Jul- | | --- |
| --- | 1.0 | 22-Jul-2020 | 22-Jul-2020 | Draft | | | --- |

Context menu options:

- Open document
- Print PDF
- For Revision (Pre-Review)
- Signatures** (highlighted in red)

| | | | | | | | | | | | | | | |
|-------------|--------------------------------------|-------------|----|--|--|-----|-------------|-------------|-----------------------------|-------------|-------------|-------------------|------|-----|
| IRB-20-0227 | Protocol A (Exp Behav) | 22-Jul-2020 | Ap | | | --- | 22-Jul-2020 | 22-Jul-2020 | Approved | 22-Jul-2020 | 22-Jul-2020 | IRB, Investigator | 15.0 | --- |
| IRB-20-0226 | Testing attachment adding and rem... | 09-Jun-2020 | | | | --- | 10-Jun-2020 | 10-Jun-2020 | IRBCO Administrative Review | 10-Jun-2020 | --- | IRB, Investigator | 9.0 | --- |

First open your project by clicking on the gray row as shown above. This will open up the document level where you application is located. Then, right-click on the document as shown in this red box and select **Signatures**.

- All pre-reviewers and signers listed on the protocol must sign in order to move on to the next step in the workflow. They may all use this step, or the next to sign.
- For PIs who are students, the pre-review and signature process will be completed once both the student PI and the Faculty Advisor have signed.

2nd way to access the Signatures function: Within the application

The screenshot shows the IRB application interface for 'IRB: IRB-20-0228 "Training Materials", (v.2.0), Initiated/Pre-Review and Sign'. The left sidebar contains a navigation menu with 'Home', 'Protocols', 'Tasks', and 'Reports'. The main content area has a top navigation bar with 'Back to overview', 'Review', 'Attachments', 'Action', and 'Workflow'. The 'Workflow' dropdown menu is open, showing 'For Revision (Pre-Review)' and 'Signatures'. The 'Signatures' option is highlighted with a red box. A red arrow points from the 'Signatures' box to a text box below it.

Home
Protocols
Tasks
Reports

General Information
VA Study Approvals
Personnel
Training

Back to overview Review Attachments Action Workflow

For Revision (Pre-Review)
Signatures

GENERAL INFORMATION

Irbp.Tab.GeneralInformation.HelpText.La

To sign a project click on "Workflow" and select "Signatures"

If you are a Faculty Advisor you can sign the project after reviewing all tabs, then by clicking on "Workflow" and select "Signatures".

How to Sign

After clicking on Signatures using either method mentioned on previous slides, a pop-up box will appear as shown on this slide.

1. To sign a project you will need to enter your Tick@lab password.

2. Click "Sign"

← Back to overview

IRB Protocol Submission Certification
By electronically signing this IRB application, I certify that I am the Principal Investigator (PI) or Faculty Advisor for the research project described in this application. I will immediately report any unexpected or unanticipated problems or incidents that occur during the study. I will report in writing any findings which develop during the course of the study which may affect the risks and benefits to the participants. I will not begin my research until I have received approval from the IRB. I will abide by the IRB requests to report on the status of the study. I will maintain the records and documents of this research. If there is a grant associated with this research, it completely reflects what is contained in this application. If the above conditions are not met, I understand that approval of this research could be suspended or terminated.

As the PI signing this protocol submission:

I attest that the information provided in this application is true and accurate. I will immediately report any unexpected or unanticipated problems or incidents that occur during the study. I will report in writing any findings which develop during the course of the study which may affect the risks and benefits to the participants. I will not begin my research until I have received approval from the IRB. I will abide by the IRB requests to report on the status of the study. I will maintain the records and documents of this research. If there is a grant associated with this research, it completely reflects what is contained in this application. If the above conditions are not met, I understand that approval of this research could be suspended or terminated.

As the Faculty Advisor signing this protocol submission:

I attest that I reviewed the above application and find the research is scientifically and scholarly sound and that competencies and resources are adequate. As the Faculty Advisor, I understand that my responsibilities are:

- Confirm the competency of the researcher(s) to conduct this research and protect participants.
- Confirm that the researcher(s) has:
 - * The resources needed to protect research participants and adequately pursue and complete the project.
 - * Access to a population that will allow recruitment of the required number of participants within the proposed recruitment period.
 - * Sufficient time to conduct and complete the research within the agreed research period.
 - * Adequate numbers of qualified staff for the foreseen duration of the research.
 - * Adequate facilities for the foreseen duration of the research.
 - * A process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions.
 - * Availability of medical or psychological resources that participants might require as a consequence of the research.
- Confirm that the research has scientific merit.

By signing this protocol submission, I understand that I am exposing participants to risk.

| Name | Comment | Signed |
|-------------------|---------|--------|
| IRB, Investigator | | |

Please note that the e-approval authentication uses regular user domain authentication mechanisms! Standard organizational constraints (e.g. retry counts) apply!

Password*:

Comment

✓ Sign X Cancel

This is how a signed protocol will look like

The screenshot displays the IRB system interface for protocol IRB-20-0228 "Training Materials", (v.3.0), Initiated/IRBCO Administrative Review. The interface includes a sidebar with navigation options like Home, Protocols, Compliance Support, Tasks, Reports, and Help. The main content area shows a workflow history table with the following data:

| File Version | Document Version | Status | Performed by | Effective date | Comment |
|--------------|------------------|-----------------------------|-------------------|----------------|--|
| 0.1.0 | 1.0 | Draft | IRB, Investigator | 22-Jul-2020 | |
| 0.2.0 | 2.0 | Pre-Review and Sign | IRB, Investigator | 22-Jul-2020 | thank you |
| ✓ 0.2.0 | 2.0 | Signature | IRB, Investigator | 22-Jul-2020 | |
| 0.3.0 | 3.0 | IRBCO Administrative Review | --- | 22-Jul-2020 | Automatic status change after signature. |

A red box highlights the 'Signature' row, and a red arrow points from this row to the explanatory text below.

A check mark will indicate your project has been signed. If multiple Signers are designated, every signature will generate a new row noting signature (see next slide).

This is how a protocol signed by a faculty advisor would look like.

IRB: IRB-20-0229 "Protocol B (FA Behav Exp)", (v.5.0), Initiated/IRBCO Administrative Review

← Back to overview Review Attachments Action

General Info

Click "Back to Overview"

| File Version | Document Version | Status | Performed by | Effective date | Comment |
|--------------|------------------|-----------------------------|-------------------|----------------|---|
| 0.1.0 | 1.0 | Draft | IRB, Investigator | 22-Jul-2020 | |
| 0.2.0 | 2.0 | Pre-Review and Sign | IRB, Investigator | 22-Jul-2020 | advisor, please review my application. |
| 0.3.0 | 3.0 | For Revision (Pre-Review) | --- | 22-Jul-2020 | Sending this project back for revisions. Thank you. |
| 0.4.0 | 4.0 | Pre-Review and Sign | IRB, Investigator | 22-Jul-2020 | For signature |
| ✓ 0.4.0 | 4.0 | Signature | IRB, Investigator | 22-Jul-2020 | |
| ✓ 0.4.0 | 4.0 | Signature | IRB, FA/OP | 22-Jul-2020 | Reviewed and signed! |
| 0.5.0 | 5.0 | IRBCO Administrative Review | --- | 22-Jul-2020 | Automatic status change after signature. |

After all required signatures are obtained, the system will auto-submit to 'IRBCO Administrative Review'. For this a new row will be generated, as shown above noted as file version 5.0.

- Home
 - Protocols
 - Compliance Support
 - Tasks
 - Reports
 - Switch to mobile
 - Help
 - UTRGV Research Compliance
 - tick@lab
- System Information: a-tune tick@lab 3.0
Build: 3269.2 Config Version: 013 Language: English

FILTER & SEARCH

Apply filter Reset filter

Hide Show

Select the desired filter criteria below and click "Apply Filter" to customize your view.

Operation between different filter criteria: AND
Operation between multiple selections within the same criterion: OR

My Filter Sets: Pending Protocols (applicationwide default)

File-General File-History Document

CLICK HERE TO VIEW, CREATE AND EDIT YOUR PROTOCOLS.

New Export to Excel

Once all signatures have been obtained, the document status will change to "IRBCO Administrative Review" (IRBCO stands for IRB Coordinator)

| Current document status/progress | Last document status change | 1st approved | Principal investigator | Version | Next Annual Review Date |
|----------------------------------|-----------------------------|--------------|------------------------|---------|-------------------------|
| IRBCO Administrative Review | 22-Jul-2020 | --- | IRB, Investigator | 3.0 | --- |

Documents/Versions in File

| Document title | Version | Last document change | Last document checkout | Document status | Last document status change | Principal investigator | Checked-out by |
|----------------|---------|----------------------|------------------------|--------------------------------------|-----------------------------|------------------------|----------------|
| --- | 3.0 | 22-Jul-2020 | 22-Jul-2020 | IRBCO Administrative Review and Sign | 22-Jul-2020 | IRB, Investigator | --- |
| --- | 2.0 | 22-Jul-2020 | 22-Jul-2020 | Draft | 22-Jul-2020 | IRB, Investigator | --- |
| --- | 1.0 | 22-Jul-2020 | 22-Jul-2020 | | 22-Jul-2020 | IRB, Investigator | --- |

- You will get an email that the application has been submitted for review, but you may also verify proper submission here.

How to Revise a Submitted Protocol

Returned to you for Revision

Once your application goes to the IRBCO for review, one of the following will happen:

- Approved by IRBCO (aka IRB Coordinators)
- Referred to a IRB Member for review – aka (Reviewer)
- Referred to the Full Committee Review
- Returned to you For Revisions

| IRB-20-0228 | Training Materials | 22-Jul-2020 | Initiated | 22-Jul-2020 | --- | --- | 22-Jul-2020 | 22-Jul-2020 | For Revision (IRBCO) | 22-Jul-2020 | --- | IRB, Investigator | 4.0 | --- |
|----------------------------|--------------------|----------------------|---------------------------|------------------------|-----------------------------|------------------------|----------------|-------------|----------------------|-------------|-----|-------------------|-----|-----|
| Documents/Versions in File | | | | | | | | | | | | | | |
| Document title | Version | Last document change | Last document checked out | Document status | Last document status change | Principal investigator | Checked-out by | | | | | | | |
| --- | 4.0 | 22-Jul-2020 | 22-Jul-2020 | For Revision (IRBCO) | 22-Jul-2020 | IRB, Investigator | --- | | | | | | | |
| --- | 3.0 | 22-Jul-2020 | 22-Jul-2020 | IRBCO Administrator... | 22-Jul-2020 | IRB, Investigator | --- | | | | | | | |
| --- | 2.0 | 22-Jul-2020 | 22-Jul-2020 | Pre-Review and Sign | 22-Jul-2020 | IRB, Investigator | --- | | | | | | | |
| --- | 1.0 | 22-Jul-2020 | 22-Jul-2020 | Draft | 22-Jul-2020 | IRB, Investigator | --- | | | | | | | |

If your protocol application gets returned to you for revisions:

- You will get an email that reviewer comments need to be addressed and the protocol needs to be revised.
- Requested revisions, approval notices, and renewal reminders will also be sent by email to you as PI.

- 📄 Billing
- 📋 Tasks
- 🏠 Cage Management
- 🏢 Administration
- 📊 Reports
- 🗄️ Master Data
-
- 📱 Switch to mobile
- 🔍 Help

TEST Administrator
 Your session will expire in:
89 min 44 sec

👤 Profile
🔄 Refresh
🔌 Logout

+ New Application
📄 Export to Excel

Documents are organized into files (folders). Click on the file to see the document(s) stored in the file.

No. of entries: 1897

« <
1
2 3 4 5 6 7 8 9 10 ... > »

| IRB# | File created | File status | Last file status change | Expiration date | Last document change | Last document checkout | Current document status/progress | Last document status change | 1st approved |
|-------------|--------------|-------------|-------------------------|-----------------|----------------------|------------------------|----------------------------------|-----------------------------|--------------|
| IRB-22-0136 | 28-Jun-2022 | Initiated | 28-Jun-2022 | --- | 18-Jul-2022 | 18-Jul-2022 | Full Committee Review | 28-Jun-2022 | --- |

Documents/Versions in File

📄

🔗 Enable Editing

| Document title | Document status | Last document status change | Principal investigator | Checked-out by |
|-----------------------------|-----------------------|-----------------------------|-----------------------------|----------------|
| IRBCO Administrative Review | Full Committee Review | 28-Jun-2022 | Coordinator, IRB-IACUC TEST | --- |
| IRBCO Administrative Review | Reviewer | 28-Jun-2022 | Coordinator, IRB-IACUC TEST | --- |

- In order to make changes to a document in Tick@lab you need to enable editing the document first. During the time a document is enable editing, no other person can edit your document.
- Right-click on the document and select “enable editing document.”

Remember, only one person at a time can work on an application.

- Others can view in read-only mode, while the document is during enable editing mode.

Done Editing (operational mode): Means it is available to edit.

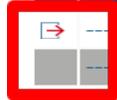
Documents/Versions in File

| Document title | Version | Last document change | Last document checkout | Document status | Last document status change | Principal investigator | Checked-out by |
|---|---------|----------------------|------------------------|----------------------|-----------------------------|------------------------|-------------------|
|  --- | 4.0 | 22-Jul-2020 | 22-Jul-2020 | For Revision (IRBCO) | 22-Jul-2020 | IRB, Investigator | IRB, Investigator |
| --- | 3.0 | 22-Jul-2020 | 22-Jul-2020 | IRBCO Administrat... | 22-Jul-2020 | IRB, Investigator | --- |
| --- | 2.0 | 22-Jul-2020 | 22-Jul-2020 | Pre-Review and Sign | 22-Jul-2020 | IRB, Investigator | --- |
| --- | 1.0 | 22-Jul-2020 | 22-Jul-2020 | Draft | 22-Jul-2020 | IRB, Investigator | --- |

Enable Editing (read-only mode): Means someone is working on the document.

IRB-20-0228 Training Materials 22-Jul-2020 Initiated 22-Jul-2020 --- --- 22-Jul-2020 22-Jul-2020 For Revision (IRBCO) 22-Jul-2020 ---

Documents/Versions in File

| Document title | Version | Last document change | Last document checkout | Document status | Last document status change | Principal investigator | Checked-out by |
|---|---------|----------------------|------------------------|----------------------|-----------------------------|------------------------|-------------------|
|  --- | 4.0 | 22-Jul-2020 | 22-Jul-2020 | For Revision (IRBCO) | 22-Jul-2020 | IRB, Investigator | IRB, Investigator |
| --- | 3.0 | 22-Jul-2020 | 22-Jul-2020 | IRBCO Administrat... | 22-Jul-2020 | IRB, Investigator | --- |
| --- | 2.0 | 22-Jul-2020 | 22-Jul-2020 | Pre-Review and Sign | 22-Jul-2020 | IRB, Investigator | --- |
| --- | 1.0 | 22-Jul-2020 | 22-Jul-2020 | Draft | 22-Jul-2020 | IRB, Investigator | --- |

Once you have enable editing on the document, then you can navigate through all the revisions requested by using the review button.

The screenshot displays the IRB system interface for a protocol titled "IRB: IRB-20-0228 'Training Materials', (v.4.0), Initiated/For Revision (IRBCO)". The interface includes a left-hand navigation menu with options like Home, Protocols, Compliance Support, Tasks, Reports, and UTRGV Research Compliance. The main content area shows a form with several sections. The "Review" button in the top navigation bar is highlighted with a red box. The form contains three questions: 1. A text entry field for a study overview with a rich text editor. 2. A radio button question about external sites. 3. A radio button question about multi-site research projects.

Click on “Review” button to see all feedback from the reviewer.

Click "All" to see the feedback left on all tabs at once, instead of moving from tab to tab.

IRB Review: IRB 20-0228 "Training Materials", (v.4.0), Initiated/For Revision (IRBCO)

Generate Report

| Tab | Subject | Author | Responses | Started on |
|---------------------|---------------------|--------|-----------|----------------------|
| Training | Training | --- | 1 | 22-Jul-2020 10:56... |
| General Information | General Information | --- | 1 | 22-Jul-2020 10:55... |

To open the feedback items double click on the subject.

- As illustrated in the red box above, you will find a list of items requested by reviewers for the entire protocol.
- To view the feedback, please click on each topic under the "Subject" column to open the message.

IRB: IRB-20-0228 "Training Materials", (v.4.0), Initiated/For Revision (IRBCO)

3. Click "Close Window"

1. You may leave a response in the text box as shown below. However, if changes are requested within the application, a response is not enough. You will also need to go to the relevant tab on the main application and make the required change(s) there.

2. Click "Save & Back"

If a document has to be uploaded as a response, you must go back to the "attachments" tab and upload the document in the respective section.

IRB Review: IRB-20-0228 "Training Materials", (v.4.0), Initiated/For Revision (IRBCO)

Close window X

Generate Report

| Tab | Subject | Author | Responses | Started on |
|---------------------|---------------------|--------|-----------|----------------------|
| Training | Training | --- | 2 | 22-Jul-2020 10:56... |
| General Information | General Information | --- | 2 | 22-Jul-2020 10:55... |

- After reviewing and addressing all items, click “close window”.
- Every time a researcher makes modification to a form a new version is activated in the system. The creation of versions allows the IRB Coordinators and Board Members to streamline the review process by conducting automatic comparisons among versions.

Don't forget to save your changes before submitting!

The screenshot displays a web application interface for IRB review. The main header shows the protocol ID: "IRB: IRB-22-0136 'Testing LAC/Assignments', (v.5.0), Initiated/Full Committee Review". Below the header, there are navigation buttons: "Back to overview", "Review", "Attachments", "Action" (highlighted with a red box), and "Workflow". The "Action" dropdown menu is open, showing options: "Done Editing", "Save Edits" (highlighted with a red box), "Save New Version", "Print", "Compare version", and "Validate & Save".

The left sidebar contains a navigation menu with the following items: Home, Protocols, Animal Orders, Animal Management, Compliance Support, Billing, Tasks, Cage Management, Administration, Reports, Master Data, Switch to mobile, and Help. At the bottom of the sidebar, it identifies the user as "TEST Administrator" and shows a session expiration timer: "Your session will expire in: 89 min 49 sec".

The main content area is divided into sections for "For IRB Use" (Personnel, Project Information, General Information, Human Subjects Information, Recruitment, Protection Of Data, Risks and Benefits, Informed Consent, HIPAA, Training, Protocol/Forms Links, PI Assurance Statement, Document History) and "IRB PROTOCOL CLASSIFICATION". Below this, there are sections for "Risk Level" (No more than minimal, More than minimal), "Review process used for this version of the protocol:" (Exempt, Expedited, Full Board), and "Type of Research" (Faculty Research).

Resubmitting a Protocol

Submitting back to Workflow, after making required revisions

You have two options to submit your revised protocol back to Workflow.

Option #1: Within the application

The screenshot shows the IRB application interface for "IRB: IRB-20-0228 'Training Materials', (v.4.0), Initiated/For Revision (IRBCO)". The top navigation bar includes "Back to overview", "Review", "Attachments", "Action", and "Workflow". The "Workflow" dropdown menu is open, showing options: "IRBCO Administrative Review", "Closed", and "Withdrawn". The "IRBCO Administrative Review" option is highlighted with a red box. Below the navigation bar, the "General Information" tab is active, showing a list of sections: "VA Study Approvals", "Personnel", "Training", "Protocol/Forms Links", "Drugs and/or Devices", "Retrospective Data Collection", "Prospective Collection of Biological Specimens", "Project Information", "Human Subjects Information", "Risks and Benefits", "Informed Consent", "HIPAA", "Protection Of Data", "Recruitment", "PI Assurance Statement", and "Workflow History". The main content area displays a question: "1. Please provide a brief (1-5 sentences) overview of your study, subject population(s), and (3) the methods used. (*)". The question text is: "Write for a general audience, do not use jargon or names of instruments/...". Below the question is a text editor with a toolbar and a text area containing "Blah, Blah...". A red box highlights the "Workflow" dropdown and the "IRBCO Administrative Review" option. A red arrow points from the text box to the "Workflow" dropdown. A red box also highlights the text box.

1. Click "Workflow" and select "IRBCO Administrative Review" from the list box.

File Insert Format Table



Please use this box to communicate with the next Workflow user.

Comment:

Effective date*:

You may leave a comment inside the text box, then please click "Ok"

< IRB: IRB-20-0228 "Training Materials", (v.5.0), Initiated/IRBCO Administrative Review

- Home
- Protocols
- Compliance Support
- Tasks
- Reports
- Switch to mobile
- Help
- UTRGV Research Compliance
- tick@lab
- System Information: a-tune tick@lab 3.0
Build 3269.2 Config Version: 013 Language: English

← Back to overview

Review

Attachments

After selecting IRBCO Administrative Review from the workflow menu, click on “Back to overview”

- General Information
- VA Study Approvals
- Personnel
- Training
- Protocol/Forms Links
- Drugs and/or Devices
- Retrospective Data Collection
- Prospective Collection of Biological Specimens
- Project Information
- Human Subjects Information
- Risks and Benefits
- Informed Consent
- HIPAA
- Protection Of Data
- Recruitment

1. Please provide a brief (1-5 sentences) overview of your study, including (1) the purpose, (2) your subject population(s), and (3) the methods used. (*)

Write for a general audience, do not use jargon or names of instruments/measures/methods that individuals outside your field will not know. Please note this is just an overview, detailed information is required under the "Project information" tab.

Answer

*

Blah, Blah...

2. Will subjects be recruited or data collected at an external site(s)?

External site for this question refers to any non-research site where subjects will be recruited, consented and/or where data will be collected.
Note: UTRGV owned clinics are not external sites.
Note: If for your research you will be meeting subjects at a public place, this would not be considered an external site.

Yes
Please attach an outside site letter (using the UTRGV template) for each external site.

No

3. Is this a multi-site research project?

A multi-site research project refers to the same protocol for human subjects research conducted at multiple (2 or more) research institutions in collaboration with UTRGV. For non-exempt human subjects research that include multiple sites, cooperative agreements will be needed (i.e., Single IRB, or Reliance Agreement).

Yes

Option #2: From the Protocols page

Open the project by clicking on the text in the gray row as shown below. This will open up the document level shown in the red box.

| Document title | Version | Last document change | Last document checkout | Document status | Last document status change | Principal investigator | Checked-out by |
|----------------|---------|----------------------|------------------------|----------------------|-----------------------------|------------------------|----------------|
| --- | 4.0 | 22-Jul-2020 | 22-Jul-2020 | For Revision (IRBCO) | 22-Jul-2020 | IRB, Investigator | --- |
| --- | 3.0 | 22-Jul-2020 | 22-Jul-2020 | IRBCO Administrat... | 22-Jul-2020 | IRB, Investigator | --- |
| --- | 2.0 | 22-Jul-2020 | 22-Jul-2020 | Pre-Review and Sign | 22-Jul-2020 | IRB, Investigator | --- |
| --- | 1.0 | 22-Jul-2020 | 22-Jul-2020 | Draft | 22-Jul-2020 | IRB, Investigator | --- |

Next, at the document level right-click on the latest version of your application. From the menu select “IRBCO Administrative Review”.

Documents/Versions in File

| Document title | Version | Last document change | Last document checkout | Document status | Last document status change | Principal investigator | Checked-out by |
|----------------|---------|----------------------|------------------------|-----------------------------|-----------------------------|------------------------|----------------|
| --- | 4.0 | 22-Jul-2020 | 22-Jul-2020 | For Revision (IRBCO) | 22-Jul- | gator | --- |
| --- | 3.0 | 22-Jul-2020 | 22-Jul-2020 | IRBCO Administrative Review | | gator | --- |
| --- | 2.0 | 22-Jul-2020 | 22-Jul-2020 | Pre-Review and S | | gator | --- |
| --- | 1.0 | 22-Jul-2020 | 22-Jul-2020 | Draft | | gator | --- |

IRB-20-0227 Protocol A (Exp Behav) 22-Jul-2020 21 --- 22-Jul-2020 22-Jul-2020 Closed 22-Jul-2020 22-Jul-2020

Right click on document and select “IRBCO Administrative Review”.

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|-------------|--------------------|-------------|-----------|-------------|-----|-----|-------------|-------------|-----------------------------|-------------|-----|----|
| IRB-20-0228 | Training Materials | 22-Jul-2020 | Initiated | 22-Jul-2020 | --- | --- | 22-Jul-2020 | 22-Jul-2020 | IRBCO Administrative Review | 22-Jul-2020 | --- | II |
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Documents/Versions in File

| Document title | Version | Last document change | Last document checkout | Document status | Last document status change | Principal investigator | Checked-out by |
|----------------|---------|----------------------|------------------------|-----------------------------|-----------------------------|------------------------|----------------|
| --- | 5.0 | 22-Jul-2020 | 22-Jul-2020 | IRBCO Administrative Review | 22-Jul-2020 | IRB, Investigator | --- |
| --- | 4.0 | 22-Jul-2020 | 22-Jul-2020 | For Revision (IRBCO) | 22-Jul-2020 | IRB, Investigator | --- |
| --- | 3.0 | 22-Jul-2020 | 22-Jul-2020 | IRBCO Administrative Review | 22-Jul-2020 | IRB, Investigator | --- |
| --- | 2.0 | 22-Jul-2020 | 22-Jul-2020 | Pre-Review and Sign | 22-Jul-2020 | IRB, Investigator | --- |
| --- | 1.0 | 22-Jul-2020 | 22-Jul-2020 | Draft | 22-Jul-2020 | IRB, Investigator | --- |

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|-------------|------------------------|---------|--------|---------|---------|-----|---------|---------|--------|---------|---------|----|
| IRB-20-0227 | Protocol A (Fxn Behav) | 22-Jul- | Closed | 22-Jul- | 21-Jul- | --- | 22-Jul- | 22-Jul- | Closed | 22-Jul- | 22-Jul- | TI |
|-------------|------------------------|---------|--------|---------|---------|-----|---------|---------|--------|---------|---------|----|

You may verify that your project was submitted by looking at the document status column. The status should show “IRBCO Administrative Review”.

Once your revisions are completed and received, your project will be revisited. Your project may be approved after that, depending on where it is in the workflow. If your revisions are not sufficient or something was missed, the protocol will be pushed back to you for revision.

Approved Projects are located under "Approved Protocols" in the My Filter Sets area.

| IRB# | File title | File created | File status | Last file status change | Expiration date | Document title | Last document change | Last document checkout | Current document status/progress | Last document status change | 1st approved | Principal investigator | Version | Next Annual Review Date |
|-------------|---------------------------|--------------|-------------|-------------------------|-----------------|----------------|----------------------|------------------------|----------------------------------|-----------------------------|--------------|------------------------|---------|-------------------------|
| IRB-20-0229 | Protocol B (FA Behav Exp) | 22-Jul-2020 | Initiated | 22-Jul-2020 | --- | --- | 22-Jul-2020 | 22-Jul-2020 | Pre-Review and Sign | 22-Jul-2020 | --- | IRB, Investigator | 4.0 | --- |
| IRB-20-0228 | Training Materials | 22-Jul-2020 | Initiated | 22-Jul-2020 | --- | --- | 22-Jul-2020 | 22-Jul-2020 | IRBCO Administrative Review | 22-Jul-2020 | --- | IRB, Investigator | 5.0 | --- |

| Document title | Version | Last document change | Last document checkout | Document status | Last document status change | Principal investigator | Checked-out by |
|----------------|---------|----------------------|------------------------|----------------------|-----------------------------|------------------------|----------------|
| --- | 5.0 | 22-Jul-2020 | 22-Jul-2020 | IRBCO Administrat... | 22-Jul-2020 | IRB, Investigator | --- |

Once approved, you will receive an email notification and your application will disappear from the 'Pending Protocols' list.

This is how your approved protocol will appear on the IRB tab 'Approved Protocols' filter

The screenshot shows the IRB system interface. On the left is a navigation sidebar with options: Home, Protocols, Compliance Support, Tasks, Reports, Switch to mobile, Help, and UTRGV Research Compliance. The main content area is titled 'IRB' and includes a 'FILTER & SEARCH' section with 'Apply filter' and 'Reset filter' buttons. Below this, there's a 'My Filter Sets' dropdown menu where 'Approved Protocols (For all users)' is selected and highlighted with a red box. Underneath are filters for 'File-General', 'File-History', and 'Document'. A section titled 'CLICK HERE TO VIEW, CREATE AND EDIT YOUR PROTOCOLS.' contains '+ New' and 'Export to Excel' buttons. A message states: 'Documents are organized into files (folders). Click on the file to see the document(s) stored in the file.' Below this is a table with 15 columns: IRB#, File title, File created, File status, Last file status change, Expiration date, Document title, Last document change, Last document checkout, Current document status/progress, Last document status change, 1st approved, Principal investigator, Version, and Next Annual Review Date. The first row of data is highlighted with a red box, showing IRB-20-0228, Training Materials, 22-Jul-2020, and a status of 'Approved'. Below the table is a section for 'Documents/Versions in File' with a table containing columns: Document title, Version, Last document change, Last document checkout, Document status, Last document status change, Principal investigator, and Checked-out by. The data row shows '---', 6.0, 22-Jul-2020, 22-Jul-2020, Approved, 22-Jul-2020, IRB, Investigator, and ---. At the bottom, it says 'No. of entries: 1'.

*****Your project has been APPROVED*****