

## How to create and submit a Reportable Event in iRIS?

1. Log in to iRIS
2. Click on “Start a Study Submission Form” in the “Featured Study Operations” menu.

The screenshot displays the iRIS TEST SITE interface. At the top left is the logo for iRIS TEST SITE, Oregon State University. The top right shows a user greeting: "Hello Jillian M. Coleman, your last login was 05-08-2019 14:41". Navigation links include "Help", "My Profile", and "Log out". Below the header, a "My Workspaces" dropdown is set to "Study Assistant".

Two main panels are visible:

- Featured Study Operations:** A list of actions including "Create a New Study", "View My Studies", "Start a Study Submission Form" (highlighted with a red box), "Track Approvals", and "Incomplete Forms" (with a red badge showing '1').
- Tasks:** A list of task options including "View All Tasks" (with a red badge showing '40') and "View Study Tasks" (with a red badge showing '39').

Below these panels is a "Study Assistant" section with a "Find a Study" button and a gear icon. At the bottom, a navigation bar shows "All Tasks", "Outstanding", and "Completed" tabs, with a gear icon on the right.

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3. Click on the “Forms” icon under “Actions” on the row of the applicable study

**iRIS TEST SITE** Oregon State University  
Hello Jillian M Coleman  
your last login was  
05-08-2019 14:41  
Help My Profile Log out

My Workspaces Study Assistant

Revision and Minor Change Form

40 result(s) found... 1 - 10 ▶

### IRB Studies

Recently Used Study Status

Search for RB Number, Title, Alias Search

All Draft IRB

21 result(s) found... 1 - 10 ▶

Click to open	Study Status	Review Board	RB Number	RB Expiration	Study Title	Principal Investigator	Actions					
					Study Number							
	Approved	IRB	IRB-2019-0061		Table test							
					Test	Coleman, Jillian M	History	Items	Forms	Hide	Copy	Delete
	Draft	IRB	IRB-2019-0076		Non-research support staff test							
					Test	Coleman, Jillian M	History	Items	Forms	Hide	Copy	Delete
	Pending - Submitted for Initial Review	IRB	IRB-2019-0086		Copy of Testing workflow change							
					Test	Coleman, Jillian M	History	Items	Forms	Hide	Copy	Delete
	Pending - Submitted for Initial Review	IRB	IRB-2019-0072		Creating a Non Research study with study team members							
					Creating a Non Research study with study team members		History	Items	Forms	Hide	Copy	Delete
	Pending - Submitted for Initial Review	IRB	IRB-2019-0062		Image and workflow test							
					Test	Coleman, Jillian M	History	Items	Forms	Hide	Copy	Delete

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4. Click on the “Start a new submission” icon next to the Reportable Event Form.

The screenshot shows the iRIS TEST SITE interface. At the top, there is a header with the iRIS logo, user information for Jillian M Coleman, and navigation links for Help, My Profile, and Log out. Below the header, there are tabs for My Workspaces and Study Assistant. A modal window titled "Submission Form List" is open, displaying a table of forms. The table has columns for "Version List", "Start a new Submission", and "Edit Incomplete Submissions". The "Reportable Event Form" is highlighted, and its "Start a new Submission" icon is circled in red. To the left of the modal, there are sections for "IRB Studies" and "Recently Used" with filters and search bars. To the right, there are "Actions" buttons like Forms, Hide, Copy, and Delete.

Initial	Version List	Start a new Submission	Edit Incomplete Submissions
Initial Review Submission Packet			
<b>Submission Forms</b>			
<b>Use forms below to report a change to IRB:</b>			
Convert .118 to an Initial Application			
Project Revision and Minor Change Form			
Continuing Review Application			
Final Report			
Reportable Event Form			

5. The first section provides study specific details, and you can click ‘save and continue’ to proceed with completing the form

The screenshot shows the iRIS form interface. At the top, there are buttons for "Print Friendly", "Refresh Constant Fields", "Save Section", and "Save and Continue to Next Section". The "Save and Continue to Next Section" button is highlighted with a red box. Below the buttons, there is a navigation menu with "1.0 Reportable Event" and "2.0 Event Details". The main content area shows the form details for "1.0 Study Title and PI:" with fields for "IRB Number:", "Study Title:", and "Name of Principal Investigator:". The "Save and Continue to Next Section" button is highlighted with a red box.

Print Friendly Refresh Constant Fields Save Section **Save and Continue to Next Section**

Section view of the Form Entire view of the Form

1.0 Reportable Event  
2.0 Event Details

**1.0**  
Oregon State University  
Human Research Protection Program & Institutional Review Board  
Reportable Event Form

**1.1 Study Title and PI:**

**IRB Number:**  
IRB-2019-0131

**Study Title:**  
Test for Lisa Review

**Name of Principal Investigator:**  
Tiffany Andrews

## How to create and submit a Reportable Event in iRIS?

6. Complete the information in the 'Event Details section', then when you are ready to submit, click 'save and continue'

The screenshot shows the 'Event Details' section of the iRIS form. The left sidebar has '2.0 Event Details' highlighted. The main content area is titled '2.0 Event Details' and contains four sections: 2.1 Instructions, 2.2 What was the date of the occurrence?, 2.3 When did you discover this occurrence?, and 2.4 Describe the occurrence (problem, event, deviation, etc.). At the top right, there are four buttons: 'Print Friendly', 'Refresh Constant Fields', 'Save Section', and 'Save and Continue to Next Section'. The 'Save and Continue to Next Section' button is highlighted with a red box.

7. When you reach the signoff page, click 'Sign-off and Submit'. If you are not the PI, there will be a 'notify the PI for signoff' button available.

The screenshot shows the 'Form has been Completed!' signoff page. The left sidebar has '2.0 Event Details' highlighted. The main content area is titled 'Form has been Completed!' and contains the text 'Continue to Next Screen to Submit Your Form'. At the bottom, there are two buttons: 'Exit Form' and 'Signoff and Submit'. The 'Signoff and Submit' button is highlighted with a red box.

8. The PI will click on 'approve', then 'save sign-off'. If the PI chooses to make additional edits, they can do that prior to signoff, however, if the signoff button seems to no longer be visible, they should go back to their 'Study Assistant' workspace, go to their tasks, and then click on the task called 'PI signoff' which will bring them back to the signoff page.

The screenshot shows the 'Save Signoff' page. The top section displays 'Study Title: Test for Lisa Review' and 'Submission Reference Number: 002955'. Below this, there is a table with columns 'Include in PDF Packet' and 'Submission Component Name'. The table has one row: 'Reportable Event Form' with an unchecked checkbox. At the bottom, there is a section for 'Tiffany Andrews as Principal Investigator' with 'Approve' and 'Deny' radio buttons. The 'Approve' button is highlighted with a red box. Below this, there is a 'Comments' section with a 'Click here to add comments.' link and a 'Save Signoff' button. The 'Save Signoff' button is highlighted with a red box.