



Cayuse Human Ethics: Incidents/Reportable Events

Incidents/Reportable Events

What needs to be reported

How to create and submit an incident

On the Dashboard, click here to view your studies

The dashboard shows a top navigation bar with 'Dashboard', 'Studies', 'Submissions', 'Tasks', 'Meetings', 'Reporting', and 'More'. The 'Dashboard' tab is active. Below the navigation bar, there are three summary cards: 'In-Draft' (8), 'Awaiting Authorization' (0), and 'Under Review' (2). A blue callout box with the text 'On the Dashboard, click here to view your studies' points to the 'View All' link under the 'My Studies' section. The 'My Studies' section lists several studies with IRB numbers and dates. The 'My Tasks' section lists tasks like 'Complete Submission' for various IRB numbers. The 'Submissions by Type' section shows counts for different submission types like 'Renewal', 'Initial', 'Modification', etc. At the bottom, there are sections for 'Approved Studies', 'Studies Expiring in 30 days', and 'Expired Studies'.

Click on the Study for which an Incident will be entered

The 'Studies' page shows a table of studies. A blue callout box with the text 'Click on the Study for which an Incident will be entered' points to the study entry with IRB# IRB-FY2020-00000000. The table has columns for IRB#, Study Title, Status, PI, Exp Date, Admin Check-in Date, and Create Date. The 'Status' column shows various statuses like 'Unsubmitted', 'Under Review', 'Expired', and 'Requires Changes'. A blue arrow points from the callout box to the study entry. At the bottom right, there is a red circle with a white question mark and the number 6.

IRB#	Study Title	Status	PI	Exp Date	Admin Check-in Date	Create Date
IRB-FY2021-00000000		Unsubmitted		N/A	N/A	02-16-2021
IRB-FY2020-00000000		Unsubmitted		N/A	N/A	10-16-2019
IRB-FY2019-00000000		Unsubmitted		N/A	N/A	04-18-2019
IRB-FY2019-00000000		Under Review		N/A	N/A	04-03-2019
IRB-FY2019-00000000		Unsubmitted		N/A	N/A	03-01-2019
IRB-FY2019-00000000		Unsubmitted		N/A	N/A	12-21-2018
IRB-FY2019-00000000		Expired		12-11-2019	N/A	12-11-2018
IRB-FY2019-00000000		Requires Changes		N/A	N/A	12-11-2018
IRB-FY2018-00000000		Unsubmitted		N/A	N/A	08-22-2018


Role: Researcher

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Under Review

IRB-FY2019-

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Approval Date: N/A Expiration Date: N/A Organization: PROVOST - Vice Provost for Research (VPR) Active Submissions: [Initial](#)
 Admin Check-In Date: N/A Closed Date: N/A Current Policy: Post-2018 Rule [Withdrawal](#)
 Sponsors: N/A

Personal Flags:

Key Contacts:

Team Member	Role	Number	Email
	Principal Investigator		
	Primary Contact		

6 ?

Click "New Submission" then click "Incident"


IRBResearcher

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1 In-Draft Submission is with researchers 2 Awaiting Authorization Submission is awaiting certification or approval 3 Pre-Review Submission is being prepared for review 4 Under-Review Submission is with reviewers

Unsubmitted

Incident
 IRB-FY17-9 - The Sample Study Test

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PI: N/A Current Analyst: N/A Decision: N/A Policy: Pre-2018 Rule Required Tasks: [Complete Submission](#)
 Review Type: N/A Review Board: N/A Meeting Date:

Approvals Task History Attachments

Research Team

Name	Role	Result	Date
No entries.			

6 ?

Click here to begin editing the Incident report

Incident Report

- Complete all questions
- When finished, click COMPLETE SUBMISSION
- Recommend submitting all minor study deviations once per year for Exempt/Expedited studies

The screenshot shows the 'Assessing the Event' section of an incident report. The left sidebar has a 'COMPLETE SUBMISSION' button highlighted with a blue arrow. A blue callout box points to this button with the text: 'When finished, click "COMPLETE SUBMISSION" to send to the PI for certification'. The main content area is titled 'Assessing the Event' and includes a 'Check all that apply:' section with checkboxes for 'Breach of Confidentiality', 'Complaint by a research subject', 'Death of research subject', and 'Other:'. Below this is a 'Date of Event' field with a calendar icon.

Incident Submission

Preview Only

Sections

Incident Report

* Type of Report:

- ☐ Unanticipated Problem or Adverse Event
 - Internal or External
 - Internal Subject Death even if anticipated if occurs within 30 days of study procedures
 - Adverse Device Effects
- ☐ Protocol deviation/violation
 - Alteration to approved study procedures
 - Change in research to eliminate an immediate hazard to a subject.
- ☐ Report(s) to or from oversight entity
- ☐ Report of study lapse
- ☐ Accident/incident
 - Data Breach
 - Self Report of Noncompliance
- ☐ Subject Complaint
- ☐ Subject incarceration
- ☐ Subject withdrawal
- ☐ Pertinent publication/public announcement
- ☐ Notification of audit/inspection/inquiry
- ☐ Miscellaneous

Get Help – IRB Staff Consultations

- Virtual Office Hours
 - Wednesdays at 11am –12:00pm
 - By appointment
- IRB Chat via Teams
- IRB Help Line:
 - 937-775-4462
- Email: irb-rsp@wright.edu

