

How To Submit a reportable Event Form

Learn how to navigate the eIRB to submit an IRB Reportable Event Form for your research project.

- 1 After successfully logging into eIRB you should be on this landing page.

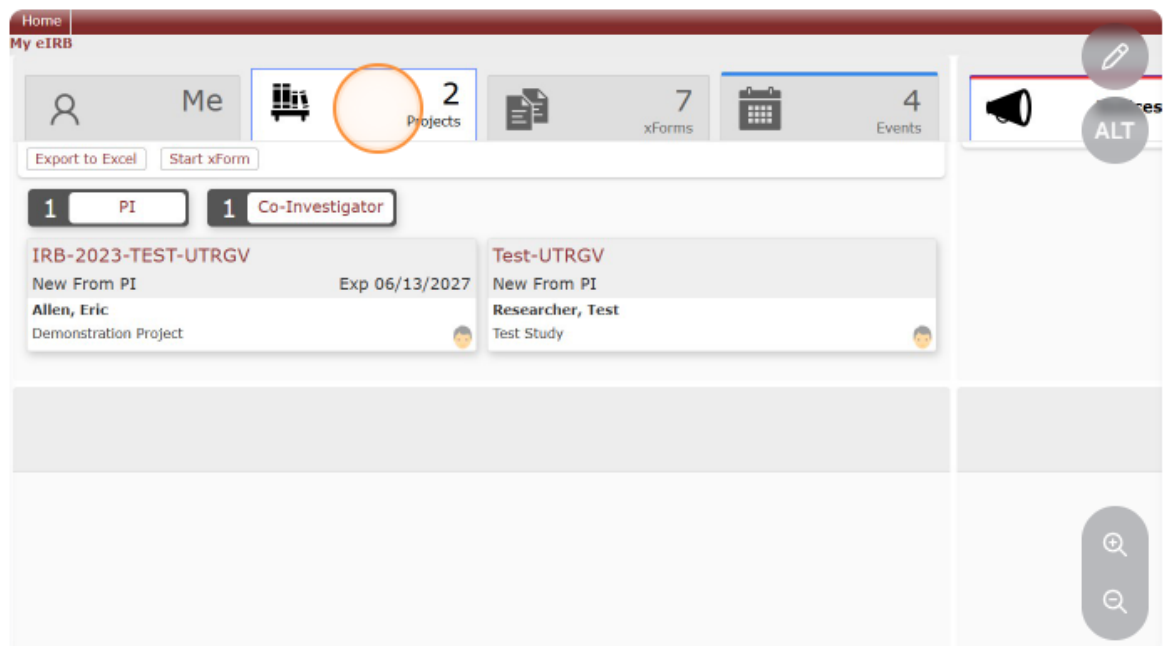
What do you want to focus on?



2 Click eIRB



3 Click "Projects"



4

Select the project that you want to submit a reportable event form for, I'm selecting mine test protocol here "IRB-2023-TEST-UTRGV"

The screenshot shows the 'My eIRB' dashboard. At the top, there's a navigation bar with 'Home' and 'My eIRB'. Below this, there are tabs for 'Me', 'Projects' (2), 'xForms' (7), and 'Events' (4). A search bar is on the right. Below the tabs, there are buttons for 'Export to Excel' and 'Start xForm'. The main area displays two project cards. The first card, 'IRB-2023-TEST-UTRGV', is circled in orange. It shows 'New From PI', 'Exp 06/13/2027', and 'Allen, Eric' as the PI. The second card, 'Test-UTRGV', shows 'New From PI', 'Researcher, Test', and 'Test Study'.

5

Click "Start xForm"

The screenshot shows the 'Project IRB-2023-TEST-UTRGV (eIRB)' form. On the left, there's a sidebar with 'Actions' (Send Email, Start xForm, xForms (1)) and 'Recent Items' (IRB-2023-TEST-UTRGV, Test-UTRGV). The 'Start xForm' button is circled in orange. The main form area displays project details in two columns. The left column includes: Project: IRB-2023-TEST, Committee: IRB, Category: Department: College of Fine Arts, Agent Types: Focus Groups, Title: Demonstration Project, Exempt Categories: External IRB FWA Number: International Research Locations: IRB approved number of participants: IRB Clinical Trial Status: Multisite Status: Name of Other Funding Source: Other Committee Oversight Status: Study Populations: VA Status: Project-Site: Site(s): UTRGV - University of Texas Rio Grande Valley, Status: New From PI, Approval: June 14, 2025 for 12 months, Initial: June 14, 2025. The right column includes: Sponsor(s): DOE (Primary), Sponsor Id: Grants: CRO: Year: 2026, Expedited Categories: Category 6. Collection of data from voice or image recordings made for research p, Funding Status: Yes, International Research Status: No, IRB Clinical Research Status: No, IRB Project Review Type: Expedited, Name of External IRB: Name of Site Relying on UTRGV: Regulatory Oversight: HHS, Thesis/Dissertation Status: None of the Above.

6 Click "IRB Reportable Event Form"

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Start Form on Project-Site IRB-2023-TEST-UTRGV

Filter: 

Select xForm to start

Action	Form (Click to start)	Description
	IRB Reportable Event Form (Draft)	IRB Reportable Event Form






7 Answer funding reporting question, in this example I clicked the "No".

IRB Reportable Event Form -- Data Entry

Allen, Eric
Email: eric.allen@utrgv.edu Phone:

Faculty Advisor [View Audit](#)
Note: If blank, there is no faculty advisor listed for this project.

Name Role

Sponsor/Funding Agency (if applicable) [View Audit](#)
DOE

Has the event(s) been reported to the sponsor/funding agency? (Required) [View Audit](#)

☐ Yes
☒ No
☐ N/A

Has the event(s) been reported to the Data Safety Monitoring Board? (Required) [View Audit](#)

☐ Yes
☐ No
☐ N/A

Has the event(s) been reported to the FDA? [View Audit](#)
(Required)

☐ Yes
☐ No
☐ N/A

Date of event(s) being reported: (Required) [View Audit](#)






8 Answer the DSMB question, in this example I selected "No".

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IRB Reportable Event Form -- Data Entry

Sponsor/Funding Agency (if applicable) View Audit
DOE

Has the event(s) been reported to the sponsor/funding agency? (Required) View Audit
☐ Yes
☒ No
☐ N/A

Has the event(s) been reported to the Data Safety Monitoring Board? (Required) View Audit
☐ Yes
☒ No
☐ N/A

Has the event(s) been reported to the FDA? (Required) View Audit
(Required)
☐ Yes
☐ No
☐ N/A

Date of event(s) being reported: (Required) View Audit

Date of awareness of event(s): (Required) View Audit

9 Answer the FDA question, in this example I clicked "No".

Has the event(s) been reported to the sponsor/funding agency? (Required) View Audit
☐ Yes
☒ No
☐ N/A

Has the event(s) been reported to the Data Safety Monitoring Board? (Required) View Audit
☐ Yes
☒ No
☐ N/A

Has the event(s) been reported to the FDA? (Required) View Audit
(Required)
☐ Yes
☒ No
☐ N/A

Date of event(s) being reported: (Required) View Audit

Date of awareness of event(s): (Required) View Audit

Location of event(s): (Required) View Audit
For example: UTRGV, external site (give full site name), UTRGV affiliate entity (give full entity name)

10 Click the calendar icon.

Has the event(s) been reported to the Data Safety Monitoring Board? (Required) [View Audit](#)

☐ Yes
☒ No
☐ N/A

Has the event(s) been reported to the FDA? (Required) [View Audit](#)

☐ Yes
☒ No
☐ N/A

Date of event(s) being reported: (Required) [View Audit](#)

Date of awareness of event(s): (Required) [View Audit](#)

Location of event(s): (Required) [View Audit](#)

For example: UTRGV, external site (give full site name), UTRGV affiliate entity (give full entity name)

How many participants did this event(s) affect? (Required) [View Audit](#)

11 Enter the appropriate date.

Has the event(s) been reported to the Data Safety Monitoring Board? (Required) [View Audit](#)

☐ Yes
☒ No
☐ N/A

Has the event(s) been reported to the FDA? (Required) [View Audit](#)

☐ Yes
☒ No
☐ N/A

Date of event(s) being reported: (Required) [View Audit](#)

Date of awareness of event(s): (Required) [View Audit](#)

Location of event(s): (Required) [View Audit](#)

For example: UTRGV, external site (give full site name), UTRGV affiliate entity (give full entity name)

How many participants did this event(s) affect? (Required) [View Audit](#)

12 Click the caldenar icon.

Has the event(s) been reported to the Data Safety Monitoring Board? (Required) [View Audit](#)

☐ Yes
☒ No
☐ N/A

Has the event(s) been reported to the FDA? (Required) [View Audit](#)

☐ Yes
☒ No
☐ N/A

Date of event(s) being reported: (Required) [View Audit](#)

6/2/2026 

Date of awareness of event(s): (Required) [View Audit](#)



Location of event(s): (Required) [View Audit](#)

For example: UTRGV, external site (give full site name), UTRGV affiliate entity (give full entity name)

How many participants did this event(s) affect? (Required) [View Audit](#)

13 Enter the appropriate date.

Has the event(s) been reported to the Data Safety Monitoring Board? (Required) [View Audit](#)

☐ Yes
☒ No
☐ N/A

Has the event(s) been reported to the FDA? (Required) [View Audit](#)

☐ Yes
☒ No
☐ N/A

Date of event(s) being reported: (Required) [View Audit](#)

6/2/2026 

Date of awareness of event(s): (Required) [View Audit](#)



Location of event(s): (Required) [View Audit](#)

For example: UTRGV, external site (give full site name), UTRGV affiliate entity (give full entity name)

How many participants did this event(s) affect? (Required) [View Audit](#)

- 14 Click in the text box and enter the "Location of event(s)".

☐ N/A

Has the event(s) been reported to the FDA? (Required) [View Audit](#)

☐ Yes
☒ No
☐ N/A

Date of event(s) being reported: (Required) [View Audit](#)

6/1/2026

Date of awareness of event(s): (Required) [View Audit](#)

5/12/2026

Location of event(s): (Required) [View Audit](#)

For example: UTRGV, external site (give full site name), UTRGV affiliate entity (give full entity name)

How many participants did this event(s) affect? (Required) [View Audit](#)

Study status: (Required) [View Audit](#)

☐ Currently in progress (open to enrollment)
☐ Closed to enrollment (participants in follow-up)

- 15 Enter the number of affected participants.

Date of awareness of event(s): (Required) [View Audit](#)

5/12/2026

Location of event(s): (Required) [View Audit](#)

For example: UTRGV, external site (give full site name), UTRGV affiliate entity (give full entity name)

UTRGV lab in building.....

How many participants did this event(s) affect? (Required) [View Audit](#)

Study status: (Required) [View Audit](#)

☐ Currently in progress (open to enrollment)
☐ Closed to enrollment (participants in follow-up)

Which type of event are you reporting? (select all that apply) (Required) [View Audit](#)

☐ Serious Adverse Event
☐ Unanticipated Problem
☐ Protocol Deviation
☐ Adverse Event
☐ Noncompliance

Identify all actions taken by the research team to mitigate risk or to protect participants. (Required) [View Audit](#)

16 Select what you are reporting, in this example I selected "Protocol Deviation".

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How many participants did this event(s) affect? (Required) View Audit

3

Study status: (Required) View Audit

☐ Currently in progress (open to enrollment)

☐ Closed to enrollment (participants in follow-up)

Which type of event are you reporting? (select all that apply) (Required) View Audit

☐ Serious Adverse Event

☐ Unanticipated Problem

☐ Protocol Deviation

☐ Adverse Event

☐ Noncompliance

Identify all actions taken by the research team to mitigate risk or to protect participants. (Required) View Audit

Note: If none, please enter N/A.

Identify any implemented actions/activities to eliminate immediate risks to participants, without IRB approval. (Required) View Audit

Note: If none, please enter N/A.

17 Review the guidance/examples to aid in answering the question.

Study status: (Required) View Audit

☐ Currently in progress (open to enrollment)

☐ Closed to enrollment (participants in follow-up)

Which type of event are you reporting? (select all that apply) (Required) View Audit

☐ Serious Adverse Event

☐ Unanticipated Problem

☒ Protocol Deviation

☐ Adverse Event

☐ Noncompliance

Protocol Deviation Assessment View Audit

Did the Protocol Deviation involve the study visit and window? (Required)

Examples include:

i. Missed or Out-of-Window Visits: Scheduling study visits outside the mandatory protocol window (e.g., a 3-day window is missed by 2 days).

ii. Missed Procedures/Labs: Failure to perform required tests (e.g., electrocardiogram, blood work, questionnaires) at scheduled visits.

☒ Yes

☐ No

Did the Protocol Deviation involve informed consent? (Required)

Examples include:

i. Incorrect Consent Form: Using an outdated or non-IRB-approved version of the informed consent form.

ii. Documentation Errors: Missing signatures, dates, or missing documentation of the consent process.

iii. Timing Issues: Performing study-related procedures before the participant has signed the informed consent document.

☐ Yes

☐ No

Did the protocol deviation involve safety and regulatory compliance? (Required)

18 Review the guidance/examples to aid in answering the question.

Did the Protocol Deviation involve the study visit and window? (Required)
Examples include:

- i. **Missed or Out-of-Window Visits:** Scheduling study visits outside the mandatory protocol window (e.g., a 3-day window is missed by 2 days).
- ii. **Missed Procedures/Labs:** Failure to perform required tests (e.g., electrocardiogram, blood work, questionnaires) at scheduled visits.

☒ Yes
☐ No

Did the Protocol Deviation involve informed consent? (Required)
Examples include:

- i. **Incorrect Consent Form:** Using an outdated or non-IRB-approved version of the informed consent form.
- ii. **Documentation Errors:** Missing signatures, dates, or missing documentation of the consent process.
- iii. **Timing Issues:** Performing study-related procedures before the participant has signed the informed consent document.

☒ Yes
☐ No

Did the protocol deviation involve safety and regulatory compliance? (Required)
Examples include:

- i. **Eligibility Criteria Errors:** Enrolling subjects who do not meet inclusion criteria or meet exclusion criteria.
- ii. **Incorrect Dosing/Administration:** Errors in dosing, timing, or administration of the study drug/device.
- iii. **Prohibited Concomitant Medication:** Participant taking a medication forbidden by the protocol.
- iv. **Late Reporting:** Failure to report Adverse Events (AEs) or Serious Adverse Events (SAEs) within the required timeframe to the IRB/Sponsor.

☐ Yes
☐ No

Did the protocol deviation involve documentation and/or administrative errors? (Required)
Examples include:

- i. **Missing Data:** Incomplete Case Report Forms (CRFs) or missing source documentation.
- ii. **Insecure Data Management:** Improper storage of PHI (Protected Health Information) or loss of data.

19 Review the guidance/examples to aid in answering the question.

LABORATORY ERRORS:

- i. **Incorrect Consent Form:** Using an outdated or non-IRB-approved version of the informed consent form.
- ii. **Documentation Errors:** Missing signatures, dates, or missing documentation of the consent process.
- iii. **Timing Issues:** Performing study-related procedures before the participant has signed the informed consent document.

☒ Yes
☐ No

Did the protocol deviation involve safety and regulatory compliance? (Required)
Examples include:

- i. **Eligibility Criteria Errors:** Enrolling subjects who do not meet inclusion criteria or meet exclusion criteria.
- ii. **Incorrect Dosing/Administration:** Errors in dosing, timing, or administration of the study drug/device.
- iii. **Prohibited Concomitant Medication:** Participant taking a medication forbidden by the protocol.
- iv. **Late Reporting:** Failure to report Adverse Events (AEs) or Serious Adverse Events (SAEs) within the required timeframe to the IRB/Sponsor.

☐ Yes
☒ No

Did the protocol deviation involve documentation and/or administrative errors? (Required)
Examples include:

- i. **Missing Data:** Incomplete Case Report Forms (CRFs) or missing source documentation.
- ii. **Insecure Data Management:** Improper storage of PHI (Protected Health Information) or loss of data.
- iii. **Unapproved Procedures:** Implementing recruitment procedures or protocols not approved by the IRB.

☐ Yes
☐ No

Please provide a detailed description of the protocol deviation(s). (Required)
Note: Please ensure that your response includes a sequential timeline, individual(s) involved if known, and location(s).

20 Review the guidance/examples to aid in answering the question.

i. *Incorrect Consent Form:* using an outdated or non-IRB-approved version or the informed consent form.
ii. *Documentation Errors:* Missing signatures, dates, or missing documentation of the consent process.
iii. *Timing Issues:* Performing study-related procedures before the participant has signed the informed consent document.

☒ Yes
☐ No

Did the protocol deviation involve safety and regulatory compliance? (Required)

Examples include:

i. *Eligibility Criteria Errors:* Enrolling subjects who do not meet inclusion criteria or meet exclusion criteria.
ii. *Incorrect Dosing/Administration:* Errors in dosing, timing, or administration of the study drug/device.
iii. *Prohibited Concomitant Medication:* Participant taking a medication forbidden by the protocol.
iv. *Late Reporting:* Failure to report Adverse Events (AEs) or Serious Adverse Events (SAEs) within the required timeframe to the IRB/Sponsor.

☐ Yes
☒ No

Did the protocol deviation involve documentation and/or administrative errors? (Required)

Examples include:

i. *Missing Data: Incomplete Case Report Forms (CRFs) or missing source documentation.*
ii. *Insecure Data Management: Improper storage of PHI (Protected Health Information) or loss of data.*
iii. *Unapproved Procedures: Implementing recruitment procedures or protocols not approved by the IRB.*

☐ Yes
☒ No

Please provide a detailed description of the protocol deviation(s). (Required)
Note: Please ensure that your response includes a sequential timeline, individual(s) involved if known, and location(s).

21 Click in the text box to enter the appropriate information.

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Examples include:

i. *Missing Data: Incomplete Case Report Forms (CRFs) or missing source documentation.*
ii. *Insecure Data Management: Improper storage of PHI (Protected Health Information) or loss of data.*
iii. *Unapproved Procedures: Implementing recruitment procedures or protocols not approved by the IRB.*

☐ Yes
☒ No

Please provide a detailed description of the protocol deviation(s). (Required)
Note: Please ensure that your response includes a sequential timeline, individual(s) involved if known, and location(s).

Identify all actions taken by the research team to mitigate risk or to protect participants. (Required) [View Audit](#)
Note: If none, please enter N/A.

Identify any implemented actions/activities to eliminate immediate risks to participants, without IRB approval. (Required) [View Audit](#)
Note: If none, please enter N/A.

22 Select in all of the applicable text boxes and enter correct information.

☐ Yes
☒ No

Please provide a detailed description of the protocol deviation(s). (Required)
Note: Please ensure that your response includes a sequential timeline, individual(s) involved if known, and location(s).

Blood work was taken at a different time interval because.....

Identify all actions taken by the research team to mitigate risk or to protect participants. (Required) View Audit
Note: If none, please enter N/A.

Identify any implemented actions/activities to eliminate immediate risks to participants, without IRB approval. (Required) View Audit
Note: If none, please enter N/A.

Identify any remaining or potential increased risk(s) to participants. (Required) View Audit
Note: If none, please enter N/A.

23 Select in the text box and enter applicable information or enter N/A.

Identify all actions taken by the research team to mitigate risk or to protect participants. (Required) View Audit
Note: If none, please enter N/A.

The PI did.....

Identify any implemented actions/activities to eliminate immediate risks to participants, without IRB approval. (Required) View Audit
Note: If none, please enter N/A.

Identify any remaining or potential increased risk(s) to participants. (Required) View Audit
Note: If none, please enter N/A.

24 Select in the text box and enter applicable information or enter N/A.

(Required)
Note: If none, please enter N/A.

The PI did.....

Identify any implemented actions/activities to eliminate immediate risks to participants, without IRB approval. (Required) [View Audit](#)
Note: If none, please enter N/A.

The PI implemented.....

Identify any remaining or potential increased risk(s) to participants. (Required) [View Audit](#)
Note: If none, please enter N/A.

What is the impact on participants' participation after the event(s)? (select all that apply) (Required) [View Audit](#)

☐ Participant stopped research participation
☐ Participant had already completed research

25 Identify the participant status.

Identify any remaining or potential increased risk(s) to participants. (Required) [View Audit](#)
Note: If none, please enter N/A.

N/A

What is the impact on participants' participation after the event(s)? (select all that apply) (Required) [View Audit](#)

☐ Participant stopped research participation
☐ Participant had already completed research
☐ Participant continued research participation
☐ Participant withdrew from further participation
☐ Participant continued participation/follow-up only
☐ Investigator withdrew Participant from participation
☐ Other

You must click "Next" and then "Submit" to send this form to the UTRGV IRB.

[Next](#) [Save for Later](#) [More](#)

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2026.S.8472.2/Release/103042z | GCWBWS1 | 2026-05-02 22:15:56Z | D.3329
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- 26 Click "Next" If you have missed any question it will be highlighted below.

Identify any remaining or potential increased risk(s) to participants. (Required) [View Audit](#)

Note: If none, please enter N/A.

N/A

What is the impact on participants' participation after the event(s)? (select all that apply) (Required) [View Audit](#)

- ☐ Participant stopped research participation
- ☐ Participant had already completed research
- ☒ Participant continued research participation
- ☐ Participant withdrew from further participation
- ☐ Participant continued participation/follow-up only
- ☐ Investigator withdrew Participant from participation
- ☐ Other

You must click "Next" and then "Submit" to send this form to the UTRGV IRB.

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2026.S.0472.0/Saleses/102042c | GCWBSWS1 | 2026-06-03 22:15:58Z | 0.190a
Powered By ORR Manager

- 27 Click "Submit" to move the application to the next stage (e.g. PI review, Faculty advisor review, or IRB review)

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Form Complete

Form Completed

You've completed the form. You can now either save the form for later revision, or submit it.

[Go Back](#) [Save for Later](#) [Print](#) [Submit](#)

