Report Form FAQ

What is the Report Form used for?

The report form is used to submit problems, events, or information to the IRB for review.

Examples of problems or events include, but are not limited to, the following:

- adverse events
- protocol deviations
- adverse device effects
- breaches of confidentiality or privacy

Examples of information include, but are not limited to, the following:

- DSMB reports
- new information about the study (e.g. from the sponsor, the FDA, other regulatory agencies, etc.)
- changes in FDA labeling, drug or device withdrawal from marketing
- incarceration of a participant
- complaints from participants that cannot be resolved by the PI
- warning or determination letters

Please see the IRB policy on Unanticipated Problems for more information about when these problems, events, and information need to be reported.

How do I access the Report Form?

The report form is built into the ERICA system. To access the report form, take the following steps:

1. Log into ERICA.
2. Open the study.
3. Click on the **Report Forms** tab.
4. Click the **File a Report Form** button.

The report form will walk you through the sections that are needed, based on your responses.

Who reviews the reports that are submitted?

An IRB Administrator and/or a member of the Unanticipated Problems (UP) Subcommittee will conduct an initial review on all reports that are submitted. If it is determined in the initial review that this report may represent an unanticipated problem involving risk to participants or others, then the convened IRB will review the report to make a final determination.

Will revisions be requested to the report form?

Sometimes. If the report form is filled out incorrectly or more information about the report is needed, the IRB staff and/or reviewers will request revisions to the report form.

How do I submit an Adverse Event?

1. Click the **File a Report Form** button.
2. On the **Report Introduction** page, select **Problem or Event**.
3. On the **Report of Problem or Event** page, select **Adverse Event**.
4. The form will then direct you through the subsequent adverse event pages.

Please see the IRB policy on Unanticipated Problems for more information about when adverse events need to be reported.

How do I submit a Protocol Deviation?

1. Click the **File a Report Form** button.
2. On the **Report Introduction** page, select **Problem or Event**.
3. On the **Report of Problem or Event** page, select **Protocol Deviation**.
4. The form will then direct you through the subsequent protocol deviation page.

Please see the IRB policy on Unanticipated Problems for more information about when protocol deviations need to be reported.

How do I know when to submit an amendment vs. a report?

If you are asking the IRB for approval of a change, submit an amendment. If you are giving the IRB new information, submit a report. If you have new information that will also require changes to your application, protocol, consent form(s), etc., submit a report AND an amendment.

How do I link an amendment to a report?

Complete the report form first. Then create the amendment that corresponds to the reported problem, event, or information. In the amendment application, on question 3.1, select the corresponding report form from the list. Submit the report form and the amendment.

How do I know which Adverse Events to submit?

Please see the IRB policy on Unanticipated Problems for more information about when adverse events need to be reported.

When do reports need to be reviewed by the convened IRB?

If it is determined in the initial review by an IRB Administrator and/or UP Subcommittee reviewer that the report may represent an unanticipated problem involving risk to participants or others, then the convened IRB will review the report to make a final determination.

How will I know if a report needs to be reviewed by the convened IRB?

All reports that need to be reviewed by the convened IRB will be assigned to the next available meeting. You will receive an email notification from the ERICA system if a report is assigned to a meeting.

Can I attach documents in the Report Form?

Yes. The report form has fields for attaching the following types of documents:

- Relevant documentation for a protocol deviation
- Adverse event documentation
  - Medwatch reports
  - CIOMS
  - Other sponsor specific forms
  - Chart notes, etc.
- Relevant documentation of new information
  - DSMB reports
  - Letters from the sponsor
  - Audit reports, etc.

Do not attach revised or updated protocols, consent forms, or other documents that have been changed in the report form. These documents must be submitted via an amendment application, which can be submitted at the same time as the report. Revised protocols, consent forms, or other documents will NOT be approved if attached in the report form.

Can I submit a report if there is a renewal or amendment currently in process?

Yes. Because some problems, events, and new information need to be submitted promptly (within in 10 working days) to the IRB, ERICA will allow you to submit a report at anytime, even if a renewal, amendment, or another report is currently in process.

How do I submit an amendment with a report?

Complete the report form first. Then create the amendment that corresponds to the reported problem, event, or information. In the amendment application, on question 3.1, select the corresponding report form from the list. Submit the report form and the amendment.

Why can't I attach my revised protocol and consent to the report?

The report form is only designed for reporting problems, events, and information, not changes to a study. In order for revised documents, such as a protocol summary or consent form to be reviewed and approved by the IRB, they must be submitted via an amendment application. The IRB will not approve revised documents that are attached in the report form and ERICA cannot put an approval stamp on documents in the report form.

Can I submit more than one report at a time?

Yes. Because some problems, events, and new information need to be submitted promptly (within in 10 working days) to the IRB, ERICA will allow you to submit a report at anytime, even if another report is currently in process. However, submitting two or more reports at the same time does not mean they will be reviewed together or by the same reviewer.

What if the sponsor wants me to submit an Adverse Event that the IRB does not require to be submitted?

According to IRB policy, only unexpected, related adverse events need to be submitted and reviewed by the IRB. If a sponsor would like you to submit an adverse event that does not meet these criteria, please give the sponsor a copy of the IRB policy for submitting adverse events and explain that the IRB will not review the event. Do not submit a report form for this event.

What if I submit new information through an amendment instead of a report?

The IRB recognizes that people will need time to transition to the report form. The IRB will accept new information that is submitted inadvertently via amendment up through February 15th, 2008. After that date, all amendments that submit new information will be withdrawn and you will be directed to submit a report of new information.

What if I need to submit an amendment with a report, but there is an amendment already in process?

Contact the IRB Administrator or Coordinator who is assigned to the amendment. Depending on how far the amendment is into the IRB process, you may be able to revise the amendment to include the additional changes as a result of the report or the IRB staff can rush final approval of the amendment so that a new amendment can be submitted. The IRB Administrator or Coordinator will discuss the options with you and help you take the appropriate actions.

What happens if the amendment needs to go to the convened board, but the report does not?

The report and amendment are reviewed separately. The report review will be completed by and IRB Administrator or the UP Subcommittee. It will not be held in a pending state until the amendment is completed. The amendment will be reviewed and approved by the

convened board as normal.

How do I report a Protocol Deviation that resulted in an Adverse Event?

The protocol deviation and adverse event should be reported separately; hence, two report forms should be submitted. You should make note in each report that the protocol deviation resulted in an adverse event.

Are there meeting submission deadlines for reports?

No. If a report needs to be reviewed at a convened IRB meeting, the IRB staff will assign the report to the next available meeting. You will receive an email notification from the ERICA system if a report is assigned to a meeting.

Where are all of my previously submitted Adverse Events and Protocol Deviations?

On a study's main workspace there is a new **Report Forms** tab. This tab includes all previously submitted adverse events and protocol deviations. All reports submitted using the new form will be located here as well. There will no longer be separate AE and Deviation tabs.