Overview
This is the form one uses to report events that occur during the tenure of an IRB. For researchers using restricted data, the most typical events are (a) notification of an inspection visit; (b) reporting the results of an inspection visit; (c) correcting an error in a scheduled continuing review (SCR).

Process
Click on the study that you want to create an AE/ORIO for:

Notification of an inspection visit
1. Submit an AE/ORIO
2. Choose ORIO
3. Choose Notification of audit/inspection/inquiry
4. Answer the questions you are presented

Reporting the results of an inspection visit
1. Submit an AE/ORIO
2. Chose ORIO
3. Choose Report to or from an oversight entity
4. Answer the questions you are presented

Correcting an error in a Scheduled Continuing Review
Answer questions in the application as follows:

1.2 Type of Report
Select: Other Reportable Information or Occurrence (ORIO)

1-2. Other Reportable Information or Occurrence (ORIO)
1-2.1 ORIO Types
Select: Protocol deviation/violation

1-2.2 Does this report include follow-up…
Select: no

6. Reports submitted to or received from an oversight entity

6.1 Protocol Deviation/Violation involving:
Select: Single Isolated Event

6.2 General Information
6.2.1 Date Deviation/Violation occurred:
Enter: date of last SCR
6.2.2 Date Deviation /Violation came to the attention of the study team:
Enter: date when you became aware of the error (This date should be close to the time you are filing the ORIO.)

6.2.3 From what source did the study team receive the information:
Enter: your own response

6.2.4 Date subject was enrolled (if applicable):
Enter: n/a

6.2.5 Subject identifier
Enter: n/a

6.3 Description of Event or Information
Enter: SCR submission indicated that study involved analysis of de-identified data. IRB issued an exempt determination based on the reported study status. However, because the project involved restricted use data, considered to be potentially-identifiable, the study should have remained in expedited review.

6.4 Investigators’ Assessment
10.4.1 Harm to subjects
Select: no

10.4.2 Impact on data integrity
Select: no

6.5 Investigators’ Response
Enter: Describe amendment to protocol

6.6 Additional Information
Enter: Any other information you wish to include

6.7 Supporting documentation
Enter: not required

Click FINISH
Click on Error Check Button
Click on Ready to Submit Inbox
Submit Adverse Event/ORIO

Wait for response. The IRB panel may decide that this study can be treated as “Exempt and Not Regulated.” They will give you an Exemption #7. Make sure the restricted data contract allows for this. If it does not, respond via ‘post correspondence tab’ in left navigation bar.