This questionnaire should be used to help the Principal Investigator to determine how, when, and where to report adverse events. This form is a guide to assist investigators and should not be submitted to IRB-01.

1. Did this event occur to a subject enrolled (who signed an Informed Consent and/or underwent any study interventions, including tests to determine eligibility), either at UF or at another site, on the protocol that has been approved by IRB-01?

   □ Yes, this event occurred to a subject who participated in the same exact study that has been reviewed and approved by IRB-01. Go to Question 2.

   □ No, this event occurred to a subject enrolled on a different protocol at a different site (e.g. IND safety reports). IRB-01 does not accept, process, or review these events unless the PI determines that the event unexpectedly increases the risk to past, present, or future subjects enrolled in the protocol approved by IRB-01. If you believe the event unexpectedly increases risks to subjects, please use our Adverse Event Report – Non-reportable Event form (available at http://irb.ufl.edu/irb01/forms.htm). Do not list this event in your project’s Cumulative AER Table. Do not proceed further on this form.

2. Is the adverse event Serious and Unexpected according to IRB definitions? IRB-01 considers all local deaths and non-local deaths (considered by the local PI or project Study Chair as related or possibly related to study participation) to be Serious and Unexpected. To see what IRB-01 considers serious and unexpected, please read our Adverse Event Definitions document available at: http://irb.ufl.edu/wp-content/uploads/AEDef.pdf.

   □ Yes; report this event to IRB-01 within 5 working days of when you learned about it, using the “Adverse Event Reporting Form” (available at http://irb.ufl.edu/irb01/forms.htm). Do not proceed further on this form.

   □ No, this event is not both Serious and Unexpected. Go to Question 3.

3. Is the adverse event Serious but Expected according to IRB definitions?

   □ No, go to Question 4.

   □ Yes; answer Question 3.a.

   3.a. Did this event occur to a subject enrolled locally?

      □ Yes, the event occurred to a subject enrolled locally. Please report this event to IRB-01 at Continuing Review on the Cumulative Adverse Event Summary Table (available at http://irb.ufl.edu/irb01/forms.htm). Do not proceed further on this form.

      □ No, the event occurred to a subject enrolled at another site. Answer Question 3.b.
3.b. Does this study have a DSMB or Sponsor oversight committee?

☐ **No**, there is no DSMB/sponsor oversight. Report this event to IRB-01 on the *Cumulative Adverse Event Summary Table* (available at [http://irb.ufl.edu/irb01/forms.htm](http://irb.ufl.edu/irb01/forms.htm)). Do not proceed further on this form.

☐ **Yes**, there is a DSMB/Sponsor oversight. IRB-01 does not require you to report this event. Do not list this event in your project’s *Cumulative Adverse Event Summary Table*. However, if your sponsor requires you to report this event to IRB-01, or if you determine this event unexpectedly increases the risk to past, present, or future subjects enrolled in the protocol approved by IRB-01, please submit the event on our *Adverse Event Report – Non-reportable Event* form (available at [http://irb.ufl.edu/irb01/forms.htm](http://irb.ufl.edu/irb01/forms.htm)). Do not proceed further on this form.

4. Is the adverse event **Unexpected** but not **Serious** according to IRB definitions?

☐ **No**, go to Question 5.

☐ **Yes**; answer Question 4.a.

4.a. Did this event occur to a subject enrolled locally?

☐ **Yes**, the event occurred to a subject enrolled locally. Please report this event to IRB-01 at Continuing Review on the *Cumulative Adverse Event Summary Table* (available at [http://irb.ufl.edu/irb01/forms.htm](http://irb.ufl.edu/irb01/forms.htm)). Do not proceed further on this form.

☐ **No**, the event occurred to a subject enrolled at another site. Answer Question 4.b.

4.b. Does this study have a DSMB or Sponsor oversight committee?

☐ **No**, there is no DSMB/sponsor oversight. Report this event to IRB-01 on the *Cumulative Adverse Event Summary Table* (available at [http://irb.ufl.edu/irb01/forms.htm](http://irb.ufl.edu/irb01/forms.htm)). Do not proceed further on this form.

☐ **Yes**, there is a DSMB/Sponsor oversight. IRB-01 does not require you to report this event. Do not list this event in your project’s *Cumulative Adverse Event Summary Table*. However, if your sponsor requires you to report this event to IRB-01 or if you determine the event unexpectedly increases the risk to past, present, or future subjects enrolled in the protocol approved by IRB-01, please submit the event on our *Adverse Event Report – Non-reportable Event* form (available at [http://irb.ufl.edu/irb01/forms.htm](http://irb.ufl.edu/irb01/forms.htm)). Do not proceed further on this form.
5. Is the adverse event both Expected and Not Serious?

☐ No, you do not consider the event to be both Expected and Not Serious. Please re-evaluate your classification of the adverse event. All adverse events will fall into one of three categories listed above: (1) Unexpected and Serious, (2) either Unexpected or Serious, or (3) Expected and Not Serious.

☐ Yes, this event is both Expected and Not Serious. Answer Question 5.a.

5.a. Did the event occur to a subject enrolled locally?

☐ Yes, the event occurred to a subject enrolled locally. Please report this event to IRB-01 at Continuing Review on the Cumulative Adverse Event Summary Table (available at http://irb.ufl.edu/irb01/forms.htm). Do not proceed further on this form.

☐ No, the event occurred to a subject enrolled at another site. IRB-01 does not require you to report this event. Do not list this event in your project’s Cumulative Adverse Event Summary Table. However, if your sponsor requires you to report this event to IRB-01 or if you determine this event unexpectedly increases the risk to past, present, or future subjects enrolled in the protocol approved by IRB-01, please submit the event on our Adverse Event Report – Non-reportable Event form (available at http://irb.ufl.edu/irb01/forms.htm).
Table 2: UF IRB-01 AE Cumulative Table Reporting Algorithm

Start Here:
Serious + Unexpected?
(All Local Deaths & Non-Local Related or Possibly Related Deaths)

No → Local?

No → Serious OR Unexpected?
(not both)

No → Do not submit
IRB does not process or review

Yes → DSMB or Sponsor Oversight

Yes → DSMB or Sponsor Oversight

No → Submit on Cumulative AE Table with Continuing Review

Yes → Unexpected AND Related / Possibly Related?

No → Submit "Unanticipated Problem Form" within 5 working days of discovery

Yes → Reviewed by Full Board or Chair as appropriate

Go to Table 1

Legend:

PI submission to IRB
IRB Action
Decision Point