

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 review 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. IRB-01 does not require you to submit these events. If the sponsor requires you to submit this event to IRB-01 (e.g. perhaps the IND # is the same), 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 deaths 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/docs/AEDef.doc>.
 - 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*. Do not proceed further on this form. Go to Question 4.
 - 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*, which is submitted at Continuing Review/Study Closure. 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, please use our *Adverse Event Report – Non-reportable Event* form (available at <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. You must do both of the following: (a) you must submit an Unanticipated Problem Reporting form (available at: <http://irb.ufl.edu/docs/frm-upr.doc>); and (b) you must also report this event to IRB-01 at Continuing Review on the *Cumulative Adverse Event Summary Table*. Do not proceed further on this form. Go to Question 5.
- 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*, which is submitted at Continuing Review/Study Closure. 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, please use our *Adverse Event Report – Non-reportable Event* form (available at <http://irb.ufl.edu/irb01/forms.htm>). Do not proceed further on this form.

5. Is the adverse event both Expected and Not Serious?

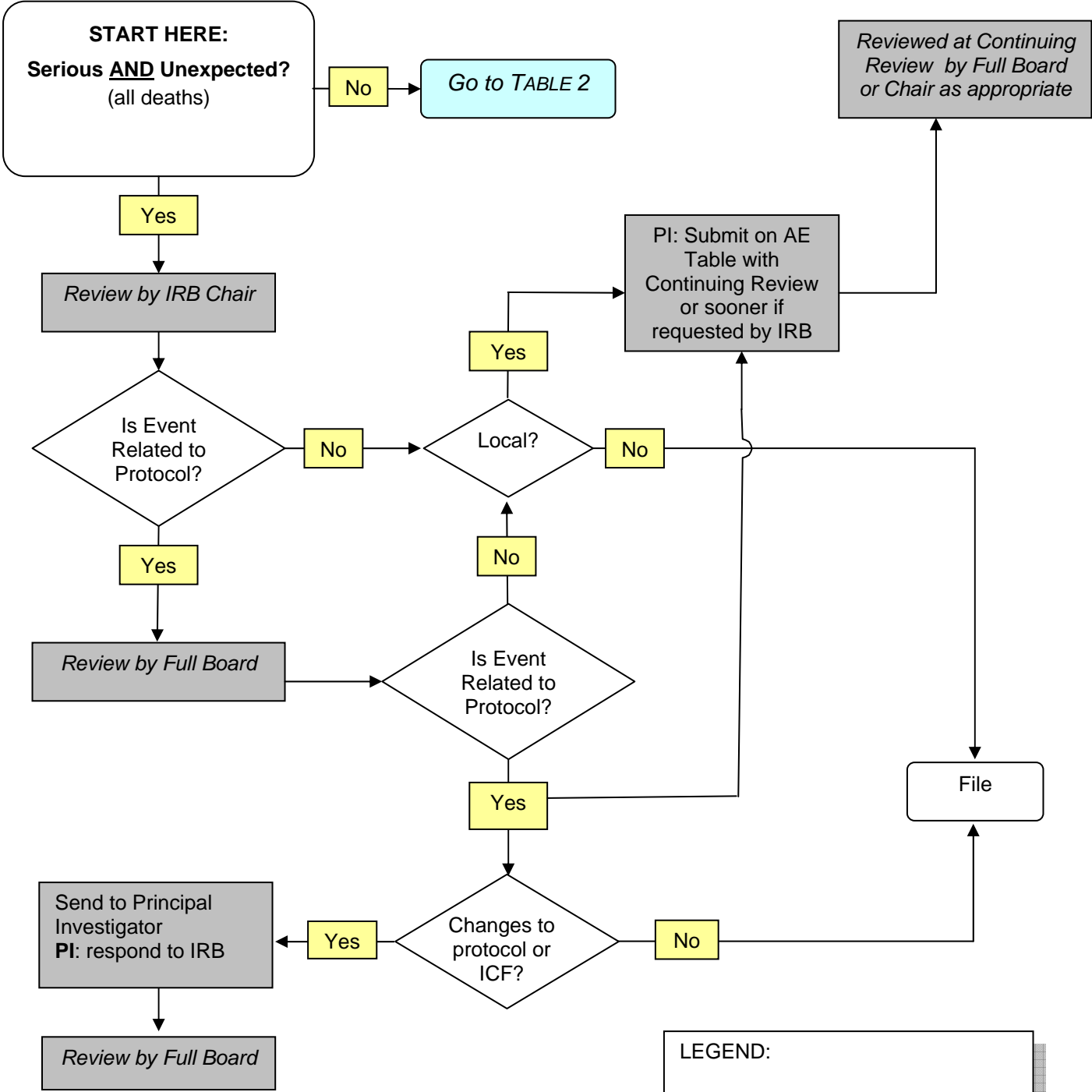
- No**, you do not consider the event to be both Expected and Not Serious. Please re-evaluate your classification of the adverse event. All adverse events will fall into one of three categories listed above: (1) Unexpected and Serious, (2) either Unexpected or Serious, or (3) Expected and Not Serious.
- 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*. 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, please use our *Adverse Event Report – Non-reportable Event* form (available at <http://irb.ufl.edu/irb01/forms.htm>).

TABLE 1: UF IRB-01 Adverse Event Reporting Algorithm

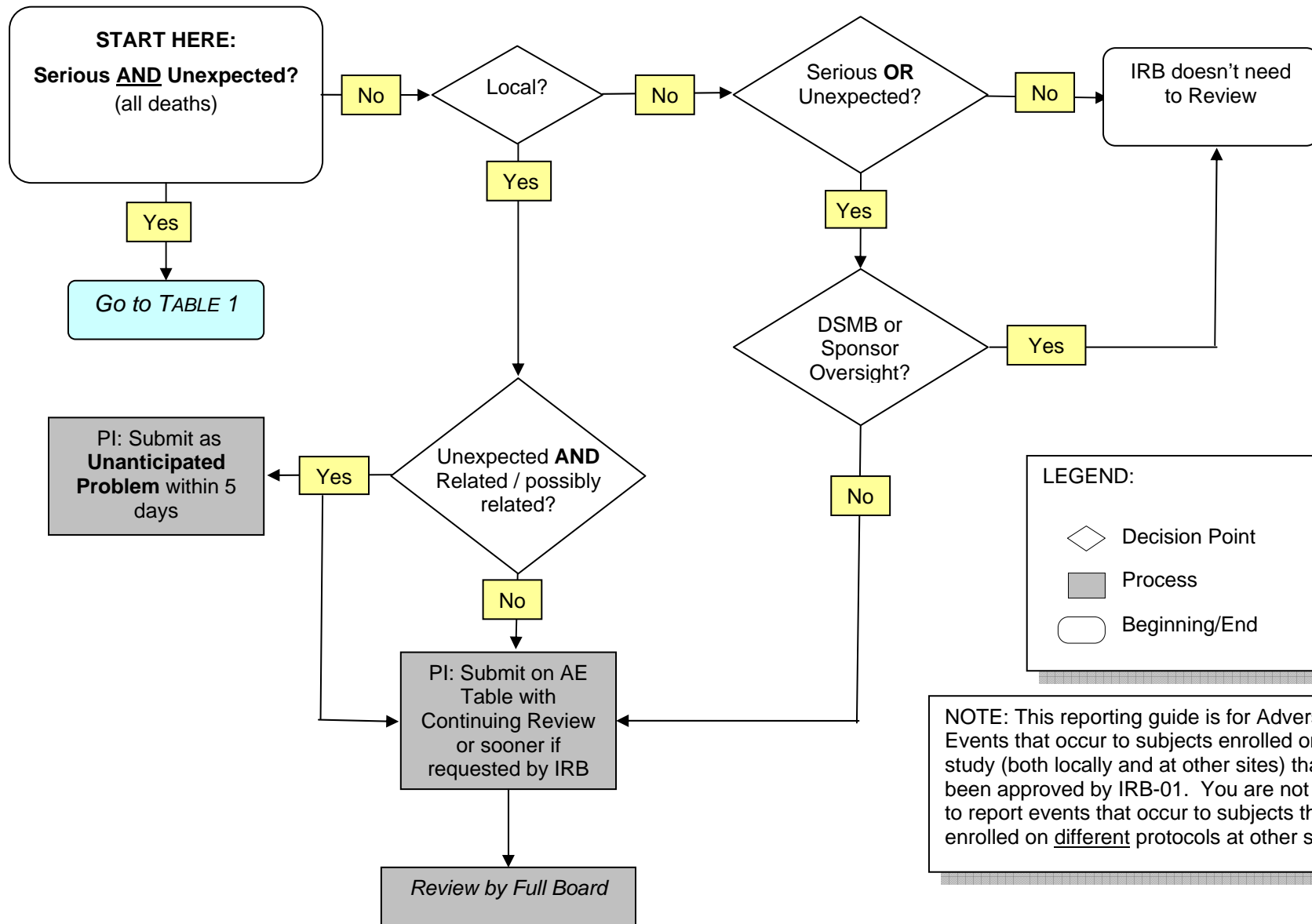


NOTE: This reporting guide is for Adverse Events that occur to subjects enrolled on the study (both locally and at other sites) that has been approved by IRB-01. You are not required to report events that occur to subjects that are enrolled on different protocols at other sites.

LEGEND:

- ◇ Decision Point
- Process
- Beginning/End

TABLE 2: UF IRB-01 Adverse Event Reporting Algorithm



LEGEND:

- ◇ Decision Point
- Process
- Beginning/End

NOTE: This reporting guide is for Adverse Events that occur to subjects enrolled on the study (both locally and at other sites) that has been approved by IRB-01. You are not required to report events that occur to subjects that are enrolled on different protocols at other sites.