

## Quick Guide to the Submission of IND Safety Reports

### Please note:

In order to require reporting to the TTUHSC El Paso IRB, the external adverse event must exhibit all of the following characteristics:

- Non-local event reported in an externally sponsored multisite research project
- Unexpected
- Serious AND
- Have implications for the conduct of the study (e.g., it requires a significant and usually safety-related change in the protocol).

### If the event does not meet this criteria, it does not need to be submitted.

1. Log in to iRIS.
2. From the main dashboard, access “**Featured Study Operations.**” At this point, there are two options, click on “**Start a Submission Form**” or “**View My Studies.**” Both will take you to the list of studies
3. Find the study that you want to create the form for
4. On the right hand side, under Actions, select “Forms” and select the External IND Safety Report and follow the steps indicated below starting with #8
5. You may also access the form using the previous format by clicking on the “**Open**” button
6. In the *Submission Forms Column*, click on “**External Adverse Event (IND Safety Report) Form**”
7. Click “**Add New Form**”
8. Indicate the report type, date received from sponsor, date of occurrence and report number in the appropriate fields
9. Click the bar under **event/follow-up description** to access the text editor
10. Enter your event description in the text editor and click “**Apply**” when finished
11. Select the appropriate AE Category and AE Attribution from the drop-down menus
12. Click the bar under **Comments** to access the text editor
13. Enter your comments in the text editor and click “**Apply**” when finished
14. Click “**Click Add a New Document**” for any reports you would like to attach
15. Select “**Browse,**” locate the file on your computer, and select “**Open**”
16. Add version number
17. Add version date
18. Add category
19. Select “**Save Document**”
20. Repeat steps if needed
21. Click “**Save Form**”
22. Click “**Sign Off and Submit**”
23. Select “**Approve**” and enter your credentials
24. Click “**Save Sign-off**”