Adverse Event Decision Tree

What events require prompt reporting to the IRB?

Is the event an AE? — Yes → Is the AE related to research activity? — No → **STOP**

Is the event an AE? — No → Is the event related to research activity?

Is the AE related to research activity? — Yes → Is the AE unexpected? — No → **STOP**

Is the event related to research activity? — No → **STOP**

Is the event related to research activity? — Yes → Is the event unexpected?

Is the AE unexpected? — Yes → Is the AE serious? — No → **STOP**

Is the event unexpected? — No → **STOP**

Is the event unexpected? — Yes → Does the event involve risk to participants?

Is the AE serious? — Yes → **UP – Report promptly to the IRB, sponsor and applicable regulatory Authority**

Does the event involve risk to participants? — No → **PI summarizes UP, non-Ups and protocol violations/deviations at the time of the Continuing Review using the Event Report Summary Sheet**

Does the event involve risk to participants? — Yes → **UP – Report promptly to the IRB, sponsor and applicable regulatory Authority**

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