Adverse Event Flowchart - Reporting

**From time participant is consented**:

AE observed (as defined in ACCORD SOP CR006).

Is it serious (according to seriousness criteria described in ACCORD SOP CR006)?

NO

YES

**It is a Serious Adverse Event (SAE). All SAEs must be reported on an SAE Form and emailed to** **Safety@accord.scot** **within 24 hours of becoming aware of the event.**

It is an Adverse Event (AE). This does not require expedited reporting. Record on CRF/AE log only.

Is the event related to the intervention?

YES

NO

Is the type of event expected (i.e. is expected in line with the study intervention)?

**It is a Serious Adverse Event (SAE). All SAEs must be reported on an SAE Form and emailed to** **Safety@accord.scot** **within 24 hours of becoming aware of the event.**

**It is a Serious Adverse Reaction (SAR). All SARs must be reported on an SAE Form and emailed to** **Safety@accord.scot** **within 24 hours of becoming aware of the event.**

**The event is a related and unexpected SAE (SUSAR). This must be reported on an SAE Form and emailed to** **Safety@accord.scot** **with 24 hours of becoming aware of the event.**

Related and unexpected SAEs will be reported by ACCORD on behalf of the investigator to REC within 15 days

YES

NO