

## **PhEAST Working Practice Document 013** **Title: Serious Adverse Events Reporting**

PES has an excellent safety record in previous trials whilst participants with PSD, who usually have severe stroke, will have multiple adverse events and SAEs. Hence, we will limit recording to:

- All Serious Adverse Events during days 0-9.
- All Procedure/device-related Adverse Events and Serious Adverse Events over days 0-14.
- All fatal Serious Adverse Events over days 10-90.

### **Definition of a Serious Adverse Event (SAE):**

This is any adverse event occurring following study mandated procedures, having received the study intervention or control that results in any of the following outcomes:

- Death
- A life-threatening adverse event
- Inpatient hospitalisation or prolongation of existing hospitalisation
- A disability / incapacity
- A congenital anomaly in the offspring of a participant
- Medically important

### **Definition of an Adverse Device Effect (ADE) / Serious Adverse Device Effect (SADE):**

#### **Adverse Device Effect (ADE):**

- Adverse event related to the use of an investigational medical device
- Includes any adverse event resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the implantation, the installation, the operation, or any malfunction of the investigational medical device
- Includes any event that is a result of a use error or intentional abnormal use of the investigational medical device.

#### **Serious Adverse Device Effect (SADE):**

- Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

#### **Unanticipated Serious Adverse Device Effect :**

- Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.
- A list of anticipated adverse events / serious adverse events is listed within the trial protocol.

**Serious Adverse Events and device-related adverse events (within the above time scales) must be reported via the SAE form on REDCap within 24 hours of knowledge of the event.**

The initial form can be completed by a research nurse / coordinator / SLT, who will be able to sign the form online. Once signed and saved as complete, this will send an email notification through to the Principal Investigator, who will need to review the information online and sign the online form to say whether they agree. The Chief Investigator will also receive an email to review the SAE, once reviewed more information may be requested from the site – the trial manager will contact the site if this is the case.

Review by the Principal Investigator should take place within 24 hours of the SAE being reported. They should review the entire form, and also assess causality and severity of the SAE. It is good practice to have a sub-PI on the delegation log who can assess these events in case of annual leave, sickness etc.

**Causality Assessment:**

1. Not related to device = SAE
2. Unlikely / Improbably related to device = SAE
3. Possibly related to device = (U)SADE serious adverse device effect
4. Probably related to device = (U)SADE serious adverse device effect
5. Definitely related to device = (U)SADE serious adverse device effect

**For SAEs that take place within the potential treatment period (days 1-9), whether randomised to PES or not, they should be reported as at least unlikely in order to keep the SAE adjudicators blinded.**

**This is for any SAE that could be related to the device / treatment (whether they have received this or not).**