EARS SAE and AE capture form V1

EARS ID	
DATE	...../...../.....
Data Collection Week:	

The following question should be asked by the Health Trainer at the end of each data collection session:

"Since the last session, have you been ill or noticed anything change in your physical or mental health?"

Responses should be recorded in detail below, giving description of the complaint and the participant's thoughts on what caused the change in health:

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Suspected Adverse Event? YES / NO

If 'YES', report to the Trial Manager at the next Team meeting.

Suspected Serious Adverse Event? YES / NO

If 'YES' report to the trial manager IMMEDIATELY.

Reported to:.....

By:.....

Time:.....

Date:.....

Definitions:

ADVERSE EVENT

The definition of an adverse event is: "Any untoward medical occurrence in a patient which does not necessarily have a causal relationship with this treatment" (Section1.2, ICH GCP, 2006). This includes "any unfavourable and unintended sign .... symptom or disease temporally associated with the study intervention". This may include, for example, a cold or an accident (Section1.2, ICH GCP, 2006).

SERIOUS ADVERSE EVENT

The definition of a serious adverse event is one that fulfils at least one of the following criteria:

Is fatal – result in death (NOTE: death is an outcome, not an event)

Is life-threatening

Requires inpatient hospitalisation or prolongation of existing hospitalisation

Results in persistent or significant disability/incapacity

OR

Is a congenital anomaly/birth defect

If any clinical trials staff are in doubt whether to report an occurrence as a SAE contact the Trial Manager or Principal Investigator.