ADVERSE EVENT FORM

ID NUMBER: ☐☐☐☐☐☐☐ FORM CODE: A E R DATE: 10/06/2017 Version 1.0

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐

Instructions: *This form should be completed each time an adverse event is recorded for the study. See the QxQ for details on which adverse events are reported. The form should be updated when the adverse event has been resolved.*

1. Description of adverse event

☐A = Otitis externa (outer ear infection) → **Go to Item 2**

☐B = Cerumen impaction or ear foreign body requiring removal by physician → **Go to Item 2**

☐C = Death from any cause → **Go to Item 2**

☐D = Other

1a. Specify other _____

2. Source of reporting

☐A = Participant

☐B = Record review

☐C = Family member

☐D = Physician

☐E = Other → **Complete notelog**

3. Start date of adverse event ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

4. Severity of adverse event

☐A = Mild

☐B = Moderate

☐C = Severe

5. Relationship of adverse event to study procedures

☐A = Unrelated

☐B = Possibly

☐C = Definitely

6. Did the participant discontinue the study due to the adverse event or serious adverse event?

☐Y = Yes

☐N = No

7. Adverse event resolution status

☐A = Ongoing→**Go to Item 9**

☐B = Resolved

☐C = Fatal→**Go to Item 9**

☐D = Unknown→**Go to Item 9**

8. Date adverse event was resolved ☐☐/☐☐/☐☐☐☐
Month Day Year

Instructions: An adverse event is serious if it results in any of the following outcomes: death, a threat to life, requires (inpatient) hospitalization, likely causes persistent or significant disability or incapacity, likely associated with a congenital anomaly or birth defect, requires treatment to prevent one of the outcomes listed above, other than for pre-existing conditions detected as a result of participation in this study.

9. Did adverse event meet the criteria for a serious adverse event?

☐Y = Yes

☐N = No→**Go to item 10**

9a. Did the adverse event cause hospitalization or prolong hospitalization?

☐Y = Yes

☐N = No

9b. Did the adverse event result in persistent or significant disability/incapacity?

☐Y = Yes

☐N = No

9c. Did the adverse event result in a congenital anomaly or birth defect?

☐Y = Yes

☐N = No

9d. Was the adverse event life threatening?

☐Y = Yes

☐N = No

9e. Was the adverse event fatal?

☐Y = Yes

☐N = No

9f. Was the adverse event another medically important condition?

☐Y = Yes

☐N = No

10. Was the adverse event unexpected according to the study protocol?

☐Y = Yes

☐N = No→**End form**

11. Describe reportable adverse event or problem in detail. Record tests and lab data, including dates. A narrative description is REQUIRED for unexpected and possibly or definitely related serious adverse events.