HAUREC Form 104; Adverse Event Reporting Form

Complete entire form. Do not leave any blanks

REC Protocol #:		**PI Institution:**	
Principal Investigator:		**Phone:** **Email:**	
Report prepared by:		**Phone:** **Email:**	
Study Title:			
Study Sponsor:			
Date of Adverse Event:	**Subject's Initials or Study #:**	**Type of Report:** ☐ Initial ☐ Follow-up	
Brief Description of Adverse Event (including diagnosis):			

Location of Adverse Event:

_____

Research involves a: ☐ Drug
☐ Device
☐ Procedure

Name of Drug, Device or Procedure:

_____

Is the drug/device investigational: ☐ Yes

_____

☐ No _____

Has the Adverse Event been reported to:
☐ Sponsor, Date of report
☐ REC, Date of report

Adverse Event appears to be (check one):
☐ Not related ☐ Unlikely ☐ Possibly related
☐ Probably related ☐ Related ☐ Unknown

Expectedness: ☐ Expected ☐ Not expected

Severity of Adverse Event:
☐ Mild ☐ Moderate ☐ Severe
☐ Fatal

Outcome of Adverse Event:
☐ Death (due to event) ☐ Death (due to other causes)
☐ Hospitalization ☐ Extended Hospitalization
☐ Congenital Abnormality ☐ Recovered
☐ Not yet recovered

Recovery of Subject:
☐ Complete ☐ Moderate ☐ Minimal
☐ None ☐ Not yet resolved ☐ Unknown

Was this Adverse Event addressed in the protocol and consent form?	☐ Yes ☐ No ☐ N/A
Was this Adverse Event addressed in Investigators Brochure?	☐ Yes ☐ No ☐ N/A
Are changes required to the protocol?	☐ Yes ☐ No ☐ N/A
Are changes required to the consent form?	☐ Yes ☐ No ☐ N/A
If changes are **required**, please attach a copy of the revised protocol/consent form *with changes highlighted with a bright coloured highlighter.*	
If changes are **not required**, please explain as to why changes to the protocol /consent form are not necessarily based on the event.	

From the data obtained or from currently available information, do you see any need to reassess the risks and benefits to the subjects in this research. ☐ Yes ☐ No

_____ _____

P.I. Signature Date