# Project CAIR

**Standard operating procedure for adverse events**

| ***Version:*** 1.0 | **PLEASE DO NOT COPY** |
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***Purpose***

The purpose of this SOP is to define 'adverse events' and outline procedures for reporting of any adverse events.

***Scope***

This SOP applies to all project study staff and investigators.

***Allowable Exceptions***

This SOP must be followed without deviation. If there is a deviation from procedures, this shouldbe discussed with the Principal Investigator.

**Definitions:** The definitions included below are adapted from the U.S. Department of Health and Human Services' Office for Human Research Protections.

**Adverse event:** Any untoward or unfavourable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research *(modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).*

**Serious adverse event:** Any event temporally associated with the subject's participation in research that meets any of the following criteria:

1. results in death,
2. is life threatening (places the subject at immediate risk of death from the event as it occurred),
3. requires inpatient hospitalisation or prolongation of existing hospitalisation,
4. results in a persistent or significant disability/incapacity,
5. results in a congenital anomaly/birth defect, or
6. any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the outcomes listed above.

**Unexpected adverse event:** Any adverse event occurring in one or more subjects participating in a research protocol where the nature, severity, or frequency of the event is **not** consistent with either:

1. the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol–related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information; or
2. the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event *(Modified from the definition of unexpected adverse drug experience in FDA regulations at 21 CFR 312.32(a)).*

**Expected adverse event:** Any event that does not meet the definition of an unexpected adverse event. For example, pain to the HFS procedure may be considered an expected adverseevent given that it may reasonably occur in some individuals.

**Study related** (or possibly related) **adverse event:** There is a reasonable possibility that the adverse event, incident, experience or outcome may have been caused by the procedures involved in the research *(modified from the definition of associated with use of the drug in FDA regulations at 21 CFR 312.32(a)).*

**Not study-related adverse event:** Any adverse event that is solely caused by the subject's disease or condition or by other circumstances unrelated to either the research or to the subject's condition.

**Documentation Procedures:** Study staff may become aware of adverse events experienced by participants during assessment visits (e.g., day 1 or 2) and/or other contact with participants (e.g., telephone conversation). In the event that study staff become aware of one or more adverse events, as defined above, study staff will:

1. Immediately document the adverse event. Include the date on which the study team became aware of the adverse event as well as the date on which the adverse event occurred.
2. Details of the event (i.e., what happened):
    a. In the event of hospitalisation, study staff will record the name of the hospital, date of admission, and date of discharge (if applicable and the patient is not currently admitted). In addition, study staff will also attempt to ascertain the medical reason for admission.

If an adverse event that results in death occurs, study staff will attempt toobtain the cause and date of death, if known by the reporting individual. After documenting the adverse event, inform the PI of the adverse event.