**Procedures for Reporting Adverse Events**

**Purpose**

To describe the obligations and procedures for those conducting research under the auspices of Trinity College Dublin, to report Adverse Events and Unanticipated Problems to the relevant Research Ethics Committee.

**Definitions**

An *Adverse Event* is any unfavourable change in the well-being (including physical, psychological, economic, or social harm) of an individual or individuals participating in research.

A *Local Adverse Event* is an adverse event experienced by individual or individuals participating in research that is conducted under the primary auspices of Trinity College Dublin, and which has received full ethical review by a Trinity College Dublin Research Ethics Committee (REC). The term *Local Adverse Event* is not applied to adverse events associated with research for which full ethical review was first provided by an external organisation (such as a hospital ethics committee), and which also received secondary approval by a Trinity College Dublin REC.

A *Serious Adverse Event* is an adverse event that:

* Results in death; or
* Is life threatening; or
* Requires in-patient hospitalization or prolongation of existing hospitalization; or
* Results in persistent or significant disability or incapacity; or
* Causes congenital malformation/birth defect or
* Any other adverse event that, based upon appropriate professional judgement, is a significant event that may jeopardize the health (physical, psychological, economic, or social) of the research participant or researcher and may require medical or other intervention to prevent one of the outcomes listed above.

An *Unanticipated Problem* is an incident, experience or outcome, not considered an adverse event. The *Unanticipated Problem* nonetheless places an individual or individuals at greater risk of harm (including physical, psychological, economic, or social) than was anticipated previously, or has implications for the conduct of the research or the integrity of the research data. An unanticipated problem should satisfy all of the following criteria:

* **Unexpected** (in terms of nature, severity, or frequency) given a) the research that was described in the ethics application (including additional documents such as the Participant Information Leaflet, the Consent Form, the Research Protocol etc); and b) the characteristics of the research participant populations being studied; **and**
* **Related or possibly related** to participation in the research. Possibly related means that there is a reasonable possibility (given the nature of the event, the mediating physical/psychological condition, or temporal relationship) that the incident, experience or outcome may have been caused by the procedures involved in the research or specific research field; **and**
* Suggests that the research **places research participants or others at a greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognised.

A *Local Unanticipated Problem* is an unanticipated problem experienced by individual or individuals participating in research that is conducted under the primary auspices of Trinity College Dublin, and which has received full ethical review by a Trinity College Dublin Research Ethics Committee (REC). The term *Local Unanticipated Problem* is not applied to unanticipated problems associated with research for which full ethical review was provided by an external organisation (such as a hospital ethics committee), and which also received approval by a Trinity College Dublin REC.

For randomised double-blind studies, Adverse Events and Unanticipated Problems will be assessed as though the participant was randomised to the study intervention.

**Reporting Obligations and Procedures**

*Responsibilities*

The designated Principal Investigator in respect of research for which approval was granted, following *full ethical review* by a Research Ethics Committee (REC) of Trinity College Dublin, will be responsible for identifying and reporting Adverse Events and Unanticipated Problems. In the case of student research projects, the Academic Supervisor is the person responsible for reporting Adverse Events and Unanticipated Problems. During an absence of the Principal Investigator, an appropriately qualified, experienced and trained researcher may report Adverse Events and Unanticipated Problems, if they have been delegated this responsibility and this has been recorded appropriately by the Principal Investigator.

*Reporting and reactive requirements for Local Adverse Events and Local Unanticipated Problems*

1. A *Local Serious Adverse Event* must be reported within twenty four hours of the event being known, using the Adverse Event Reporting Form. Any other local adverse events or local unanticipated problems must be reported within five working days of the event being known, using the Adverse Event Reporting Form [on web version add link to form]. If there is uncertainty concerning the severity of an Adverse Event, the ‘worst case’ assessment should be used for reporting purposes.
2. If a safety issue is identified, the Principal Investigator or designate must act immediately to protect participants from any immediate threat to their health and safety. This may require suspension of the research.
3. Ongoing information regarding the status of an individual or individuals affected by a local adverse event or local unanticipated problem, must be obtained and recorded.
4. In the event that the classification of the (local) event or problem changes (e.g., from an adverse event to a serious adverse event; or, from an unanticipated problem to an adverse event), this must be reported using the Adverse Event Update Form [on web version add link to form].
5. Any adverse events or unanticipated problems which are not local must be reported within fourteen working days of the event being known, using the Adverse Event Reporting Form.
6. Adverse events or unanticipated problems must be reported to any agency sponsoring the research, and/or partner organisations listed in the ethics application.
7. A summary list of adverse events and unanticipated problems must be included in the Annual Review and in the Final Report (i.e., associated with the ethics application).

**In respect of research for which full ethical review was provided by an external organisation (such as a hospital ethics committee), the reporting and reactive requirements of the external organisation should be followed. In the event that full ethical review was also provided by a REC of Trinity College Dublin, the requirements listed above will apply. In general, if the approval of more than one organisation has been obtained for a study, a formal agreement stipulating the reporting and reactive requirements should be put in place before the research commences.**

**In respect of any Adverse Event or Unanticipated Problem that occurs in the context of research for which approval was granted, following full ethical review, by a Research Ethics Committee (REC) of Trinity College Dublin, that REC must be informed in writing by means of the Adverse Event Reporting Form, in accordance with the requirements listed above.**

*Screening and Review of Adverse Events and Unanticipated Problems*

1. The completed Adverse Event Reporting Form (or Adverse Event Update Form) must be submitted via the Research Ethics Application Management System (REAMS). The Chair of the relevant Research Ethics Committee (REC) will receive a notification that the form has been submitted.
2. The Chair of the relevant REC will immediately review the submission and request any required clarification, missing documentation or additional information.
3. The Chair of the relevant REC (and any other members of the REC delegated to do so) will review the Adverse Event Reporting Form and any supporting documentation, to determine if action is required. Such action may include escalation to other relevant office holders within the College (e.g., the Head of School; the Dean of Research; the Secretary). The Chair of the relevant REC will retain a documentary record of any actions taken in respect of the submission of an Adverse Event Reporting Form.
4. The Chair of the relevant REC may choose to act immediately on the basis of the information provided (e.g., to suspend the research), should it appear that this is necessary. In such circumstances the matter should be reported immediately to those undertaking the research, the Research Ethics Program Committee, and any other relevant office holders within the College (e.g., the Head of School; the Dean of Research; the Secretary), and any agency sponsoring the research, and/or partner organisations listed in the ethics application.