## Adverse or Unanticipated Events Report Form

Please complete this form to report unanticipated or adverse events occurring in the course of your research. For brief definitions\* of such events see the end of this form. For more explanation and timelines for reporting see the ‘Marjon Ethics policy and code of conduct’.

**All forms and templates, and application deadlines, are provided via the** [staff intranet](http://staffnews/course/view.php?id=18&section=2http://staffnews/course/view.php?id=18&section=2) **and** [PGR Dashboard](https://www.marjon.ac.uk/research/postgraduate-research/pgr-dashboard/)**.**

# Title of Research Project

# Review Details

Ethics Application Code:

Original Approval Date:

Previous Renewal Date(s):

# Investigator Information

Principle investigator (or student’s name)

Name:

Department:

Institutional email:

Are co-investigators involved? (if student application, insert supervisor’s name)

If YES, please provide the names and institutional contact details of co-investigators, describe the decision-making processes for collaborative research studies and if Terms of Reference exist, attach them to the application.

# Location

Did the event occur at Plymouth Marjon University?

If YES, please specify the precise location.

If the event occurred off-site, specify the location, and specify if anybody from the site has been notified.

# Description of Adverse / Unanticipated Event

Date of the event:

Describe the event:

What action (if any) has been taken, or will be taken, by the research site, and by whom?

If the event involved the loss or a breach of personal data, on what date was this reported to the Data Protection Officer?

What action (if any) has been taken, or will be taken, by the research team?

# Statement of Principal Investigator

I am aware of and understand the circumstances and/or information related to the adverse/unanticipated event referred to on this form. I have assessed the significance of this event with respect to participants involved in this research and as a result, I believe that:

The study should continue without change to the protocol:

The study should continue without change to the Information and Consent Forms:

**If you answered NO to either question, please enclose the revised protocol/information sheet/consent form, for review by the Ethics Panel.**

Signature of Investigator:

Date:

Signature of Supervisor (if applicable):

Date:

## Definitions

## Unanticipated events

An ‘unanticipated’ event is any incident, experience or outcome that meets all the following three criteria:

* Unexpected in terms of its nature, severity or frequency, or the research population being studied the research conducted to date under the protocol;
* Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience or outcome may have been caused by the procedures involved in the research);
* Suggests that the research places participants or others at a greater risk of physical, psychological, economic or social harm than was previously known or recognised.

Examples of unanticipated events include:

* Loss of a laptop computer containing confidential information about participants or others.
* A spouse physically abused by his or her partner for taking part in the study.
* Publication in the literature or a Data and Safety Monitoring Report that indicates an unexpected change in the balance of risks and benefits in the study.
* Finding that laboratory reports on blood or other samples were in error.

## Adverse Events

An **Adverse Event** is any unfavorable change in current status (including mental, emotional or psychological) in a person participating in a research study. This change may or may not be causally related to the study protocol. Unexpected adverse events are those in which the event is inconsistent with the risk information in the current protocol or is occurring more frequently than anticipated. **Internal adverse events** are those experienced by participants enrolled in the project at the University of St Mark and St John. **External adverse events** are those experienced by participants enrolled at other institutions or in a study for which the University of St Mark and St John is not the coordinating center.

Examples of serious adverse events include:

* Inadvertent disclosure of confidential information which presents an immediate risk to a participant such as from spousal or child abuse.
* Hospitalisation (initial or prolonged).
* Disability.
* Congenital abnormality.

Sources:

[www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/#Q1](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/#Q1)

<http://www.research.utoronto.ca/forms/>