**Adverse Event Reporting**

**What to Report**

The principal investigator(s) (PI) must report all adverse events to the IRB in a timely manner. An adverse event is an event that occurs within a research protocol that

* causes physical or psychological harm to the participants and/or
* leads to an increased probability or magnitude of physical or psychological harm to participants and/or
* leads to a loss of confidentiality and/or privacy to the participant and/or others such as the participant’s family.

The PI should classify adverse events by whether they are

* **anticipated** (listed in the protocol and/or consent form as approved by the IRB) or **unanticipated**
* **serious** (see 21 CFR 312.32; for example, death, life threatening, in-patient hospitalization or prolongation of existing hospitalization, persistent or significant incapacity or substantial disruption of the ability to conduct normal life function, congenital anomaly / birth defect. Additionally, attempted suicide, psychotic breaks, or breach of confidentiality that could lead to arrest, deportation, or loss of job or standing in the community; contact the Chair of the IRB if you have questions) or **minor**
* **related** to or caused by the research protocol or **unrelated**

**When to Report**

The reporting time depends on how the PI has classified the adverse event.

* The PI must report all adverse events that are both serious and related to the research protocol within 24 hours of discovering the event.
* The PI must report all adverse events that are unanticipated and related to the research protocol but not serious within five days of discovering the event.
* The PI must report all other adverse events (those unrelated to the research or those that are anticipated as specified in the protocol, minor and related) at the conclusion of the study or with the request for re-approval, whichever comes first.

**How to Report**

The principal investigator should submit the Adverse Event Report to the Chair of the IRB at irb@udayton.edu.

**Consequences of Adverse Events**

The chair of the IRB, or his or her designee, will review all adverse event reports within two weekdays of receipt.

For serious, related and unanticipated adverse events, the chair or designee will determine whether an emergency meeting of the IRB is required to review the event or a full IRB review is required at the next scheduled IRB meeting. The chair or designee will also determine whether the protocol’s approval should be temporarily suspended pending IRB review of the adverse event. For minor, related and unanticipated adverse events, or adverse events that are recurring, the full IRB will review the event at the next scheduled meeting. For all other adverse events (those unrelated to the research or those that are anticipated as specified in the protocol, minor and related), the chair or designee will acknowledge receipt of the report and will file it.

When the IRB reviews the adverse event report, it will vote on one or more of the following actions which will be reported to the principal investigator and recorded in the IRB minutes:

* no action
* require additional training in the protection of human research participants
* modification of the protocol and/or consent document
* notification of current participants of the adverse event and requiring that current (active) participants re-consent to participate
* modification of the continuing review schedule
* suspension of the protocol pending IRB approval of appropriate modifications of the protocol
* termination of the protocol
* other actions deemed appropriate by the IRB
* reporting to the sponsoring agency, dean, department head or other appropriate persons

**Adverse Event Report**

Protocol title:

Principal investigator(s):

Phone:

Email:

Date of discovery of the adverse event:

Date of the adverse event if known:

Where the adverse event occurred:

Research personnel present during the adverse event:

Description of the adverse event including the cause (if known), the severity, the action taken and the outcome:

Have other similar events occurred? If so, how many and when?

Was the adverse event anticipated or unanticipated?

Was the adverse event severe or not?

Was the adverse event related to the research protocol or not?

If applicable, what steps will you follow to ensure that this type of adverse event will not occur in the future? If appropriate, submit a request for modification of an approved protocol form that includes those steps and a revised consent form.

Has the principal investigator reported this adverse event to the sponsor?

If applicable, has the principal investigator reported this adverse event to all co-PIs?

Signature of principal investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of principal investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_