 ATENEO DE MANILA UNIVERSITY	University Research Ethics Committee	SOP No: 3.3
	3.3 Review of Unanticipated Problems and Adverse Events	Version No: 02
		Approval Date: 08/01/16
		Effective Date: 08/01/16

1. Policy Statement ¹


In accordance with national and international ethics guidelines, the UREC has procedures for determining and reporting unanticipated problems and adverse events that transpire after the UREC had given the study ethics approval. The research proponent must promptly report any unanticipated problems involving risks to participants or others, and/or adverse events, to the University Research Ethics Committee, appropriate institutional officials, and other supporting department or agency head, in accordance with the guidelines stated herein.

The UREC has the authority to suspend or terminate approval of research that, among other things, has been associated with unanticipated serious harm to participants. In order for the UREC to exercise this important authority in a timely manner, they must be informed promptly of those adverse events that are unanticipated, related to or possibly related to participation in the research, and are serious in nature.

- 1.1 Unanticipated problems are generally defined as any incident, experience, or outcome that meets all of the following criteria:
- unexpected, in terms of nature, severity, or frequency, given a) the research procedures that are described in the UREC-approved research protocol and informed consent document; and b) the characteristics of the subject population being studied;
 - 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); and
 - suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

- 1.1.1 Any incident, experience, or outcome that meets all three criteria will warrant consideration of changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety,

¹ definitions of unanticipated problems and adverse events were taken from the U.S. Dept of Health & Human Services Office for Human Research Protections (OHRP) - <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/#Q1>

 ATENEO DE MANILA UNIVERSITY	University Research Ethics Committee	SOP No: 3.3
	3.3 Review of Unanticipated Problems and Adverse Events	Version No: 02
		Approval Date: 08/01/16
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welfare, and rights of the participants or others. Corrective actions that might need to be considered include:


- changes to the research protocol (may be necessary prior to official UREC notification and approval if it is to eliminate immediate hazards to participants)
- modification of inclusion or exclusion criteria to mitigate newly identified risks
- implementation of additional procedures for monitoring participants
- suspension of enrollment of new participants
- suspension of research procedures in currently enrolled participants
- modification of informed consent documents to include a description of newly recognized risks
- provision of additional information about newly recognized risks to previously enrolled participants

1.2 Adverse events include any event meeting the following definition: Any untoward or unfavorable medical occurrence in a human participant, including any abnormal sign (e.g. exam or lab findings), 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.

Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although they can occur in the context of social and behavioral research.

1.2.1 Serious adverse events are those temporally associated with the individual’s participation in the study that meets any of the following criteria:

- results in death;
- is life-threatening;
- requires inpatient hospitalization or prolongation of existing hospitalization;
- results in persistent or significant disability or incapacity;
- results in a congenital anomaly/birth defect; or
- any adverse event that, based on appropriate medical judgment, may jeopardize the participant’s health and may require medical or surgical intervention to prevent any of the aforementioned outcomes

 ATENEO DE MANILA UNIVERSITY	University Research Ethics Committee	SOP No: 3.3
	3.3 Review of Unanticipated Problems and Adverse Events	Version No: 02
		Approval Date: 08/01/16
		Effective Date: 08/01/16

1.3 All unanticipated problems should be reported to the UREC. Adverse events which are unanticipated (see policy 1.1; the adverse event should also meet all three criteria defining “unanticipated”) should likewise be reported to the UREC.

Risks and adverse events which are not unanticipated, i.e. have been included in the UREC-approved protocol, and where the proponents have delineated their plans of action to mitigate or address the potential adverse event, do not need to be reported to the UREC apart from their mandatory inclusion in the progress and/or final report, whichever was required by the UREC.

Unanticipated adverse events routinely warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of participants or others.


2. Objectives and Scope of the Activities in SOP 3.3

This SOP applies to the reporting and review of reports of unanticipated problems and unanticipated adverse events, as defined in the policy section in this document.

The guidelines indicated in this SOP help ensure that the review and reporting of unanticipated problems and adverse events occur in a timely, comprehensive, and efficient way so that human participants can be better and more immediately protected from avoidable harms.

3. Workflow of Reporting and Review of Unanticipated Problems and Persons Responsible

WORKFLOW OF REPORTING AND REVIEW OF UNANTICIPATED PROBLEMS AND ADVERSE EVENTS	RESPONSIBILITY	WORKING DAYS
Step 1: Receipt of report of unanticipated problem/s and/or unanticipated adverse event/s	UREO Secretariat	
Step 2: Recording of the report in the UREC database		


 ATENEO DE MANILA UNIVERSITY	University Research Ethics Committee	SOP No: 3.3
	3.3 Review of Unanticipated Problems and Adverse Events	Version No: 02
		Approval Date: 08/01/16
		Effective Date: 08/01/16

WORKFLOW OF REPORTING AND REVIEW OF UNANTICIPATED PROBLEMS AND ADVERSE EVENTS	RESPONSIBILITY	WORKING DAYS
Step 3: Retrieval of pertinent protocol file and forwarding of the report and the protocol file to the UREC Chair		0-3 days from acceptance (by UREC) of final report
Step 4A: UREC Chair convenes subcommittee to review and act on the report (for unanticipated serious adverse events) -or- Step 4B: UREC Chair includes the report in the agenda of the next plenary meeting, where action on the report is discussed	UREO Secretariat (includes report in agenda of plenary meeting)	
Step 5: Send UREC communication to PI		
Step 6: Document and file all reports, recommendations, decisions, and communications for the protocol		
Step 7: Present report and decision at UREC plenary meeting (if Step 4A was done)		

4. Description of Procedures

4.1 Receipt of report of unanticipated problem/s and/or unanticipated adverse event/s and recording of the report in the UREC database

4.1.1 Researchers are required to submit reports of unanticipated problems and unanticipated adverse events in soft copy as promptly as possible, as indicated in their ethics approval letter. Unanticipated problems that are serious adverse events (as defined in 1.2.1 of this SOP) should be reported to the UREO within one week of the investigator becoming aware of this event. Any other unanticipated problem should be reported to the UREO within two weeks of the investigator becoming aware of the problem.

 ATENEO DE MANILA UNIVERSITY	University Research Ethics Committee	SOP No: 3.3
	3.3 Review of Unanticipated Problems and Adverse Events	Version No: 02
		Approval Date: 08/01/16
		Effective Date: 08/01/16

4.1.2 A copy of the report of unanticipated serious adverse events should likewise be submitted to other appropriate institutional officials, namely the Department head of the proponent, and the Associate Dean for Research and Creative Work (for Loyola Schools faculty, students, or staff), or other appropriate official or office that oversees research activities in the unit.

4.1.3 Investigators should include the following information when reporting to the UREC an adverse event, or any other incident, experience, or outcome as an unanticipated problem:

- the protocol or study title and investigator’s name;
- a detailed description of the unanticipated problem/adverse event, experience, or outcome;
- an explanation of the basis for determining that the adverse event, experience, or outcome represents an unanticipated problem; and
- a description of any changes to the protocol or other corrective actions that have been taken (prior to reporting to UREC, in order to immediately mitigate the risk or harm to participants) or which are proposed in response to the unanticipated problem


4.1.4 The UREC Secretariat acknowledges receipt of the report via an email reply to the researcher and a stamped date of receipt on the receiving copy of the researcher.

4.2 Recording of the report in the UREC database and retrieval of pertinent protocol file

4.2.1 The UREC Secretariat files the report in the paper folder and the digital folder of the pertinent protocol.

4.2.2 File names of soft copies of documents and attachments pertaining to the report are tagged with the same ID code, e.g. AdMUREC_2015_017_UP (“UP” for unanticipated problem report of the 17th protocol submitted in school year 2015; “UAE” for unanticipated adverse event report).

4.2.3 The record is entered into a password-protected electronic database. Databases are updated and backed-up on a daily basis.

 ATENEO DE MANILA UNIVERSITY	University Research Ethics Committee	SOP No: 3.3
	3.3 Review of Unanticipated Problems and Adverse Events	Version No: 02
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		Effective Date: 08/01/16

4.3 Retrieval of pertinent protocol file and forwarding of the report and the protocol file to the UREC Chair

The report of the unanticipated problem or unanticipated adverse event, together with the relevant protocol file for reference, are forwarded to the UREC Chair via email. If the report pertains to a serious unanticipated adverse event, the UREC Chair is notified by phone and/or SMS for immediate attention.

4.4. UREC Chair convenes subcommittee to review and act on the report (for unanticipated serious adverse events), or the UREC Chair includes the report in the agenda of the next plenary meeting, where action on the report is discussed


In typical instances, the report will be reviewed and discussed at a UREC plenary meeting with a quorum of members, but if the matter is more urgent (i.e. a serious adverse event) and cannot be delayed until the next plenary meeting, then the UREC Chair may decide to convene a subcommittee. The UREC Chair may also call an emergency plenary meeting, but this would require a quorum of members for major decisions to pass. If convening a subcommittee, this may be composed of UREC reviewers and/or consultants who have particular knowledge or expertise on the nature of the unanticipated problem.

When reviewing a report of an unanticipated problem, the UREC plenary or subcommittee should consider whether the affected research protocol still satisfies the requirements for UREC ethics approval. In particular, the UREC should consider whether risks to subjects are still minimized and reasonable in relation to the anticipated benefits, if any, to the participants and the importance of the knowledge that may be reasonably be expected to result.

The proposed changes to the research study in response to the unanticipated problem must also be reviewed and approved by the UREC before being implemented, except when such changes were necessary to eliminate apparent immediate hazards to participants.

If the changes to be made or the recommendations are more than minor, the changes must be indicated in and submitted as a Protocol Amendment form (refer to SOP on Protocol Amendments). Such recommendations may require decision by consensus or voting at a UREC plenary meeting.

4.5 Send UREC communication to PI

 ATENELO DE MANILA UNIVERSITY	University Research Ethics Committee	SOP No: 3.3
	3.3 Review of Unanticipated Problems and Adverse Events	Version No: 02
		Approval Date: 08/01/16
		Effective Date: 08/01/16

The UREC sends official communication to the research proponent (refer to SOP on Communicating UREC Decisions). The communication includes any or all of the following points:

- recommendations for revisions in the protocol
- corrective or mitigating actions to address the unanticipated problem or unanticipated adverse event
- approving the planned revisions and corrective actions already proposed or conducted by the researcher
- suspension or termination of the ethics approval previously granted to the study, with accompanying justification

4.6 Document and file all reports, recommendations, decisions, and communications for the protocol

The UREC Secretariat files all relevant communications pertaining to the report and the protocol in the corresponding digital copy folders. See SOP 7.1 on Management of Protocol Files.

4.7 Present report and decision at UREC plenary meeting (if decision was made by convened subcommittee)


The UREC Chair presents the relevant aspects of the report of the unanticipated problem or adverse event at the next plenary meeting, and the corresponding decision/s and action point/s of the convened subcommittee.

5. Forms and Templates

AdMUREC Form 8 - Report of Unanticipated Problem or Unanticipated Adverse Event

6. History of SOP

Version No.	Date	Authors	Main Change
01	2017 Jan 30	Liane P Alampay (LPA)	

 ATENELO DE MANILA UNIVERSITY	University Research Ethics Committee	SOP No: 3.3
	3.3 Review of Unanticipated Problems and Adverse Events	Version No: 02
		Approval Date: 08/01/16
		Effective Date: 08/01/16

02	2022 May 11	Ronald Allan L. Cruz, Nico A. Canoy, Eduardo Valdez, Joseph Johnson, Alfred Pawlik	All references to hard copy submissions have been removed; hard copies of documents are no longer required for submission.
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