1. Objectives

This Guideline describes the obligation to report serious adverse events (SAEs). The purpose of this Guideline is to provide instructions on the review of initial and follow-up reports of SAEs occurring at clinical trial sites and offsite (non-USM site) for any study approved by JEPeM USM.

Information on how reportable serious adverse events will be defined, identified and what procedures for reviewing and reporting will be followed are outlined in this Guideline.

2. Reporting Requirements and Procedure

2.1 Although the JEPeM-USM only requires the PI to report adverse events as defined in the **Timeline Requirements**, he/she is responsible for assessing, documenting, and tracking all SAEs in the research study, including new physical symptoms, regardless of who observed or became aware of the event.

2.2 The PI is also responsible for reporting SAEs to the proper regulatory agency as defined by applicable laws (National Pharmaceutical Regulatory Agency], Kementerian Kesihatan Malaysia).

2.3 The reporting requirements of other organizations (e.g. Sponsor, FDA) also must be completed and are not satisfied or precluded by submitting SAE Report to the JEPeM-USM. Likewise, submitting SAE Reports to other organizations (e.g., Sponsor, FDA) does not satisfy the reporting requirement to the JEPeM-USM.

2.4 The observed SAEs must be submitted using **JEPeM USM FORM 3(G) 2019: SERIOUS ADVERSE EVENTS REPORT FORM**

3. Timeline Requirements

3.1. The Principal Investigator must report to the JEPeM USM Committee members all SAEs according to the following timelines:

3.1.1. Deaths MUST be reported to the JEPeM USM if they occur within thirty (30) days of study intervention.

3.1.2. If the suspected unexpected serious adverse event occurred onsite, it must be reported to the JEPeM USM panel promptly, within no more than one (1) week (7

calendar days) of recognition/notification of the event.

3.1.3. If a suspected unexpected serious adverse event occurred offsite as part of a multi-site research project, it must be reported to the JEPeM USM within fifteen (15) calendar days of recognition/notification of the event.

4. Summary of Timeline Requirements for Reporting of PI

Event type	**Onsite or Off-site**	**Expected or unexpected**	**Reporting requirements**
Serious adverse event	Onsite	Unexpected	Report within seven (7) calendar days using JEPeM USM Form 3(G)2019: Adverse Events Report Form.
Serious adverse event	Off-site	Unexpected	Report within fifteen (15) calendar days using JEPeM USM Form 3(G)2019: Adverse Events Report Form.
Serious adverse event	Onsite or off-site	Expected	Report with regular progress report and/or final report
Adverse event not serious	Onsite or offsite	Either	Report with regular progress report and/or final report

GLOSSARY

The following terminologies and definitions are to be used in the reporting of adverse events:

1. **Adverse event:** Any untoward or unfavorable 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. Adverse events may also be psychological in nature.

2. **Onsite adverse event**: From the perspective of one particular institution engaged in a multicenter clinical trial, *on-site adverse events* are those adverse events experienced by subjects enrolled by the investigator(s) at that institution. In the context of a single-center clinical trial, all adverse events would be considered *on-site adverse events.* It also includes adverse events occurring on all JEPeM USM approved clinical trials sites. If the PI is from USM and the study is JEPeM USM-approved, study site is considered onsite even if the site is outside any USM campus.

3. **Off-site adverse event**: From the perspective of one particular institution engaged in a multicenter clinical trial, *offsite adverse events* are those adverse events experienced by subjects enrolled by investigators at other institutions engaged in the clinical trial.

4. **Possibly related to the research**: There is a reasonable possibility that the problem, event, incident, experience or outcome may have been caused by the procedures involved in the research.

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

    5.1 results in death;
    5.2 is life-threatening (places the subject at immediate risk of death from the event as it occurred);
    5.3 requires inpatient hospitalization or prolongation of existing hospitalization;
    5.4 results in a persistent or significant disability/incapacity;
    5.5 results in a congenital anomaly/birth defect; or
    5.6 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 other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room

or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

6. **Suspected Unexpected Serious Adverse Reaction (SUSAR):** An adverse reaction, the nature and severity of which is not consistent with the applicable product information (e.g. as in Investigator's Brochure if product is unlicensed)

LIST OF ACRONYMS

AE	Adverse Events
AO	Administrative Order
CIOMS	Council for International Organizations of Medical Sciences
FDA	Food and Drug Administration
DOH	Department of Health
PI	Principal Investigator
SAE	Serious Adverse Event
SUSAR	Suspected Unexpected Serious Adverse Reaction
USM	Universiti Sains Malaysia
JEPeM	**J**awatankuasa **E**tika **Pe**nyelidikan **M**anusia