University of the Witwatersrand, Johannesburg

Human Research Ethics Committee (Non-Medical) Guidelines for the Reporting and Management of Serious Adverse Events (SAEs)

Introduction and Definitions

Serious Adverse Events (SAEs) are serious negative outcomes that arise unexpectedly during the research data collection process. SAEs may arise where (1) the researcher or research participant do something wrong, something unauthorized, risky or inappropriate. In this instance, the action itself represents the SAE, irrespective of whether it leads to negative outcomes or not; or (2) where any action by the researcher or research participant (whether this action is authorized or unauthorized) leads to an unexpected negative outcome. This then describes the outcome of the action, not the action itself. In case of (1), if the researcher displays negligent or reckless behaviour then this may result in disciplinary action being taken against the researcher. In case (2), it may be that the outcome is simply an unforeseen accident and that no one is to blame.

The outcomes of a SAE may include:

- Physical harm or injury taking place to a person;
- Significant mental or psychological harm or trauma taking place to a person; or
- Any other serious outcome to human society, animals or to the environment as a consequence of the processes or outcomes of research data collection.

In all cases, the person affected may be a research participant, the researcher themselves, any other person (a bystander, member of the public, etc.), or the environment (i.e. by environmental damage or pollution caused by the research activity).

Any potential risk involved in research data collection activities is evaluated by the Research Ethics Committee before the research study takes place using the *Risk Categories Table*, when a project is initially designed (through the research proposal), and when ethics clearance is being obtained (through providing information sheets, consent forms and (where appropriate) distress protocols). This procedure of risk management is undertaken throughout the research and ethics application process, and deals with risks that <u>are anticipated</u> by the researcher. SAEs however arise where events or outcomes take place that <u>are not anticipated</u> by the researcher. They can therefore be considered as extreme, one-off events that lead to negative or undesired outcomes to research participants, researchers, or any other persons or the environment.

Definitions

An **Adverse Event** can be any unfavourable or unintended change in the structure (signs) or function (symptoms) of a person after an intervention (an activity or intervention for research purposes), including occurrences which are not necessarily caused by or related to that activity.
A **Serious Adverse Event** is where an adverse event leads to a serious or significant negative outcome to a person(s), as listed above.

An **Adverse Reaction** can be all unwanted and unintended responses to any activities related to the research actions. This may include participants experiencing distress, for example.
A **Protocol Violation** is intentional or unintentional divergence from the protocol (i.e. the agreed data collection methodologies or procedures) that materially reduces the quality or completeness of the data. Non-compliance with the agreed procedures may in some cases result in disciplinary action against the researcher.
Research Impropriety is non-compliance with laws, regulations or policies regarding the safety or wellbeing of research participants or any other people, animals or the environment. This may also include Covid-19 Guidelines Non-Compliance.
Research Misconduct includes but is not limited to plagiarism, fabrication or falsification of performing, reviewing or reporting research results. This is described in the *Wits Research Integrity Policy, Guidelines and Procedures Document*.

Relationships of SAEs to Other Events During Data Collection

A SAE is not the same as something in your research just not going very well, or someone (a research participant or another person) complaining about something. Therefore it is important to distinguish between these different types of queries or reporting, and the actions that are required in each case (Table 1).

Table 1. The different categories of events, queries or reporting procedures that may take place in any research project.

Nature of the event	**What happened now**	**Who reports it**	**Guideline document for this action**
Nothing goes wrong but someone has a question or query.	A query is made by phone or email to the researcher and/or supervisor, using the information provided on the *Information Sheet.*	A research participant or any other concerned person (such as a member of the general public).	The *Information Sheet* for the research activity.
Something minor goes wrong or just does not go to plan.	A query or complaint is made to the Legal Advisor (Research Office) according to the line of reporting given on the *Ethics Complaints Structure.* Please note that if something does not go to plan in the research, students should inform their supervisor as soon as possible and get advice on what to do.	A research participant or any other concerned person (such as a member of the general public). A student should inform their supervisor. If needed, supervisors or researchers are welcome to contact the HREC:NM for advice.	The *Ethics Complaints Structure* should be followed.

Something major goes wrong (a SAE).	The event must be reported to the Legal Advisor (Research Office) within 24 hours, according to the *Standard Operating Procedures* of the HREC:N-M, and according to the guidelines given in *this document.*	A research participant or any other concerned person (such as a member of the general public), or the researcher and/or the supervisor.	The *Ethics Complaints Structure* should be followed.

In all cases it is very important that the researcher is responsive to the queries or needs of participants and to maintain communication with participants, supervisors and the HREC:N-M. Effective and timely communication can prevent situations getting out of hand.

Human Research Ethics Committee (Non-Medical) Guidelines for Managing SAEs

The *Standard Operating Procedures* (SOP) of the Research Ethics Committee (Non-Medical) gives details of how SAEs should be reported and managed (on p33). We now describe how a SAE (item 3 in Table 1) is reported and dealt with, in this order of actions:

1. If an event takes place, that has negative impacts on people or the environment, you need to report it immediately (no later than within 24 hours of the occurrence). If you are not sure whether something is a SAE or not, please just report it anyway. The person this must be reported to is: Ms Eleni Flack-Davison, Eleni.Flack-Davison@wits.ac.za, tel 011 717-1328 (Research Office: Legal Advisor and Research Compliance Manager), or emergency out-of-hours contact number 011 717-4444 or 011 717-6666. Based on the nature of the incident, we may ask you to provide certain things:
    1.1 If it is decided that this is not a SAE you may be advised to just carry on with your research or to discuss what happened with your supervisor;
    1.2 If this is indeed a SAE you should complete and submit the *SAE Reporting Form* (see point 3 below). You may also be advised that the research is temporarily suspended or paused until things are resolved.
2. The first step undertaken by the University, upon being informed of the incident, is to ensure the safety and wellbeing of the affected person(s). If a SAE is declared, the University may take a number of steps immediately to safeguard human health and wellbeing. This may include liaising with or informing hospitals/psychologists/the police, communicating with the affected person(s)/their familty, and providing psychological support to the researcher; and communicating with the supervisor/Head of School, as appropriate. The relevant HREC: N-M chairs will also be informed.
3. If requested to do so, the *SAE Reporting Form* must be completed by the person reporting the incident within 72 hours of the incident occurring, and the form submitted by email to Ms Eleni Flack-Davison, Eleni.Flack-Davison@wits.ac.za. The purpose behind this form is to give a considered written account of the incident. This report will then be discussed in a meeting chaired by the Research Office: Legal Advisor and Research Compliance Manager and comprising the HREC: N-M chairs, Director: Research Development and if so, required where appropriate the Dean of the specific Faculty, Assistant Dean: Research of the specific faculty and / or the Head of School of where the research is located, and any other relevant experts or stakeholders as

required. The researcher may also be contacted for any clarification required. The committee will respond to the *SAE reporting form* in writing to the researcher and/or the supervisor.

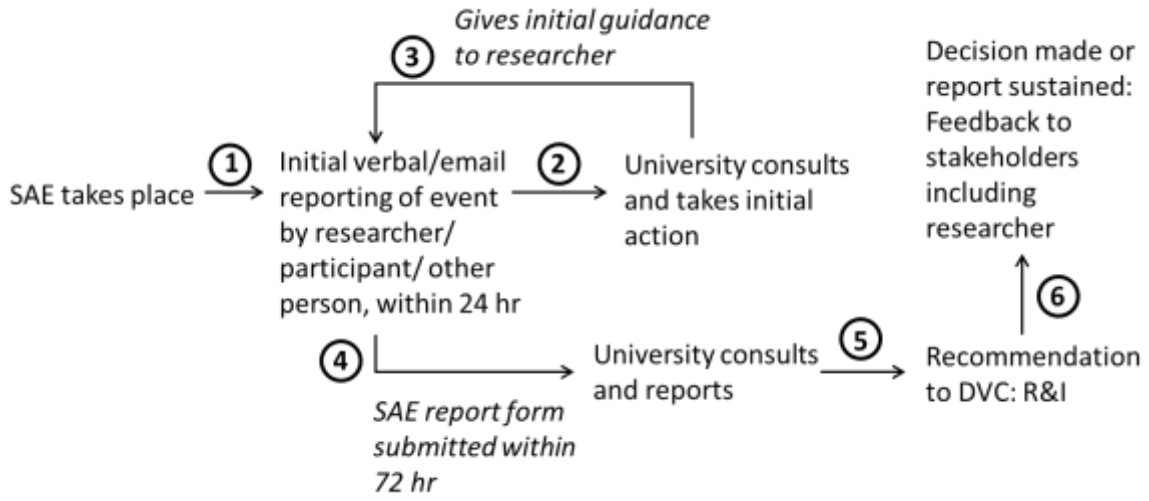
4. After the event, a full enquiry of the SAE will be undertaken by the Research Office: Legal Advisor and Research Compliance Manager who will collect relevant information from the researcher, any affected person(s), supervisor / Head of School (where appropriate), and HREC Chairs. This report will be submitted to the Deputy Vice-Chancellor: Research and Innovation (DVC: R&I) who will make the final decision regarding any actions to be taken.

4.1 If it is deemed that the SAE was just an accident that was unavoidable and not foreseen through the research proposal and ethics application process, relevant support will be offered if required, and it may be recommended that no further action should be taken.

4.2 If it is deemed that the incident arose because of negligence or inappropriate behaviour on behalf of the researcher, it may be recommended that further legal action may be taken by the University.

5. Following the decision made by the DVC: R&I, the report and its key outcomes will be shared with relevant stakeholders including the HREC: N-M, Head of School, Dean of the Faculty and supervisor/researcher.

A flow chart illustrating these steps is shown below:



How to minimise the likelihood of a SAE

Good study design is critical from the outset because this can reduce the risks associated with any study and can therefore reduce the likelihood of a SAE occurring. For studies with vulnerable participants, providing counselling and support services can reduce risk. A distress protocol should be considered by the researcher if there is a likelihood of an adverse reaction and distress amongst participants.

For more information:

The Ethics Office is located in the Research Office, Solomon Mahlangu House (East Campus), 10th floor, room 10004.

Secretariat:
Main University HREC and for all initial queries, including using the online form:
Shaun Schoeman, Shaun.Schoeman@wits.ac.za (tel 011 717-1408)
Reporting and management of School committees:
Charmaine Khumalo, Charmaine.khumalo@wits.ac.za (tel 011 717-1788)

Main University HREC Non-Medical Chair and Co-Chairs:
Prof Jennifer Watermeyer (Chair), Jennifer.watermeyer@wits.ac.za (tel 011 717-4578)
Prof Jasper Knight (Co-Chair), jasper.knight@wits.ac.za (tel 011 717-6508)
Prof Edmarie Pretorius (Co-Chair), edmarie.pretorius@wits.ac.za (tel 011 717-4476)

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