

*To be added to the CEP guidelines as an addendum*

### **Handling adverse events in the context of studies that are *NOT* subject to Medical Research Involving Human Subjects Act (WMO)**

Definition of an adverse event (AE; following U.S. Food and Drug Administration): In general, an AE observed during the conduct of a study is defined as an unanticipated problem involving risk or actual harm to human participants. They must be reported to the Institutional Review Board (i.e., the ethics committee). AE are unexpected and serious events that could have implications for the conduct of the study (e.g., requiring a significant, and usually safety-related, change in the protocol such as revising inclusion/exclusion criteria or including a new monitoring requirement, informed consent, or investigator's brochure). **\*Note that events may be considered as an AE even if this only becomes apparent after the experimental session (e.g. unexpected and unusual after effects of an intervention). In case of doubt whether or not a situation concerns an AE, always discuss this with the CEP and SOLO.**

#### *Handling adverse events during an experimental session: acute phase*

For all studies performed in the lab, there is a calamity protocol to deal with emergencies. This protocol can be found in the labs and/or are available via the research portal, the lab coordinators, and SOLO. As AE and emergencies directly concern people's safety, it is crucial that all experimenters running the study in the lab as well as their direct supervisors (senior/junior researchers, assistants, as well as students running the study) are acquainted with this protocol and should feel confident in dealing with an emergency situation (e.g. participant fainting). If the experimenter feels uncomfortable with this protocol or feels unsure what actions should be taken in an emergency situation, please consult the supervisor, lab coordinator and/or SOLO before running an experiment.

#### *Procedure on how to handle an adverse events afterwards:*

The ultimate goal of this procedure is to primarily ensure safety of the participant/future participants and for the CEP, SOLO, and investigators to receive meaningful information about the AE. As detailed below, different parties play a role in ensuring the safety of (future) participants in research conducted within the institute.

1. The *first researcher* who is involved in/observes the AE (i.e., the experimenter) is responsible to notify the responsible PI and other involved senior researchers (who holds a PhD), CEP, and SOLO.
  - In case First Aid (EHBO) was given by the experimenter during the acute phase of the AE, the experimenter reports these details to SOLO. SOLO and the experimenter report details of the event to the ARBO department via the [Incident notification form](#).
2. Immediate action is required from the *responsible PI or other senior researcher* (who holds a PhD) of the study:
  - Appropriate after care should be provided to the participant. The PI or other senior researcher should be directly involved in the communication with the participant, even if communication is initiated by more junior researchers/students. Appropriate care should also be given to the experimenter – especially if this person is a student or junior researcher.

- CEP and SOLO should be notified immediately about the AE. The involved researchers provide detailed information about the event to CEP and SOLO.
  - The responsible PI /senior researcher submits a report about the case (description from start of procedure to end of after care; and other details based on evaluations) to the CEP and SOLO as soon as possible, but in no event later than 10 working days after the investigator first learns of the event. All communication about the case needs to be documented.
3. *SOLO* is responsible for initiating contact with *CEP, lab coordinators, ARBO*, the management team, and scientific director.
- CEP and SOLO decide whether or not to stop/pause testing until it is clear that continuation of the study is safe. If applicable, the lab coordinators facilitate SOLO in the communication to all investigators using the same experimental procedure/device involved in the AE to (temporarily) stop testing.
  - Depending on the nature of the AE, CEP and SOLO evaluate the experimental procedures and protocols with the experimenter and responsible PI/senior researcher.
  - Depending on the nature of the AE (e.g., an unanticipated adverse device effect), SOLO takes the responsibility to conduct an evaluation/let the evaluation be done by an expert about the device. SOLO reports the results of this evaluation to the CEP, lab coordinators, ARBO, and participating investigators as soon as possible and within 10 working days after SOLO first receives notice of the effect.
  - Testing can only be resumed once safety is guaranteed, and when the CEP and SOLO have approved any necessary amendments made to the study protocol.
  - Details of the event are reported to the ARBO department via the [Incident notification form](#). This form has to be filled out directly after the event by the *responsible BHV or EHBO person*. If necessary, a health and safety coordinator will contact SOLO for a further investigation.
  - SOLO shares all reports (their own and from the investigator) with ARBO for monitoring purposes.

**Handling (serious) adverse events (S)(AE), serious adverse reactions (SAR), or suspected unexpected serious adverse reaction (SUSAR) in the context of FSW studies that are subject to Medical Research Involving Human Subjects Act (WMO)**

All studies that are subject to WMO should follow the procedures as defined by the Central Committee on Research Involving Human Subjects (CCMO). To learn about the definitions of the different type of adverse events and to determine what is the right procedure to follow in case of adverse events, please consult the [CCMO website](#). .

For all (S)AE that happen in FSW studies that are subject to WMO, particularly if these studies are conducted in the laboratories of FSW and/or the research methods are supported by SOLO, the procedures as described under '*Handling adverse events in the context of studies that are NOT subject to Medical Research Involving Human Subjects Act (WMO)*' apply in addition to the CCMO procedures. In case of doubt if this FSW specific procedure applies, always consult the CEP and SOLO.