Reporting of Adverse Events on studies approved by Wrexham University Research Ethics Committee

Context

The University acknowledges that certain studies involving human participants or personal data carry a risk of adverse events occurring. Legislation and governance frameworks exist to ensure that assessment, monitoring, and reporting of adverse events are clearly defined in order to prevent and mitigate adverse events and promote and protect participant safety. Safety reporting is historically based on studies involving clinical intervention, full details of the HRA requirements can be found on the HRA webpages. Nonetheless, an adverse event can include all types of physical harm, psychological, social, legal or economic as a result of participating in a research study. NHS definitions of the differing safety reporting types have been broadened to reflect Wrexham University based research.

This procedure identifies the responsibilities and accountabilities within the University for monitoring and reporting adverse events resulting from studies the university is hosting or sponsoring.

Adverse events

The University defines an adverse event (AE) as an untoward occurrence during a research study that led to or could have led to an unintended or unexpected harm, loss, or damage. The Principal Investigator or Supervisor should inform the University's Research Ethics Sub-Committee within 10 days of an adverse incident occurring. Examples that may constitute a non-serious adverse event include the unintended deviation of the study protocol, a physical event such as rash or fall, or a confidentiality breach.

Serious adverse events

A serious adverse event (SAE) can include an untoward occurrence that:

i. results in death
ii. is life threatening
iii. requires hospitalisation or prolongation of existing hospitalisation
iv. results in persistent or significant disability or incapacity
v. consists of a congenital anomaly or birth defect
vi. results in physical or psychological harm to a participant
vii. involves a breach of the confidentiality of personal data without the participant's consent

Serious adverse events occurring during or as a consequence of a research project involving human participants, their tissues, or their data which has been ethically approved by a Research Ethics Sub-Committee must be reported by the Principal Investigator or Supervisor to the University's Research Ethics Sub-Committee within 24 hours of the discovery of the event.

Examples provided are not an exhaustive list. The Principal Investigator or Supervisor should assess the adverse event in the context of the study and population being investigated.

Procedure of Reporting

AEs and SAEs should be reported to Research Ethics Sub-Committee (rescadmic@glyndwr.ac.uk) in the time stipulated above. The following should be included when notifying the committee.

- Research Ethics Approval ID
- Study Title
- Principal Investigator / Supervisor and Student Investigator details
- Participant's details
- Date and time of the adverse event
- Details of the adverse event
- Assessment of adverse event; Mild, Moderate, Severe
- Assessment of adverse event; related or unrelated/ expected or unexpected
- Confirmation of whether the study has been halted and proposed future action

The Research Office will then inform the Chair Research Ethics Sub-Committee of receipt of the report within a further 24 hours. Depending on the severity of the event, the Research Ethics Sub-Committee (RESC) Chair may take the decision to suspend or revoke ethical approval of research on behalf of the Committee, or recommend modifications to the protocol or study design if it is considered to be in contravention of the University's policies and procedures on research ethics

Contacts

This procedure will be regularly reviewed in the light of experience and revisions to codes of practice laid down by any relevant professional or learned society. Any comments should be sent to rescadmin@glyndwr.ac.uk