University of the Highlands and Islands

Adverse Events Policy

POL-136

Lead Officer (Post):	Deputy Principal
Responsible Office/ Department:	Academic Directorate
Responsible Committee:	Finance and General Purposes Committee
Review Officer (Post):	Deputy Principal
Date policy approved:	07/09/2017
Date policy last reviewed and updated:	01/09/2017
Date policy due for review:	07/09/2019
Date of Equality Impact Assessment:	To be completed
Date of Privacy Impact Assessment:	To be completed

Accessible versions of this policy are available upon request. Please contact the Governance and Policy Officer on 01463 279000.

Policy Summary

Overview	This policy identifies the responsibilities and accountabilities within the university for monitoring and reporting adverse events resulting from clinical studies the university is hosting or sponsoring.
Purpose	This purpose of this policy is to protect the safety of clinical patients/human subjects involved in studies conducted by the university, to outline the responsibilities and arrangements for assessing risk, monitoring, and reporting of adverse events, and to ensure legislative compliance.
Scope	This policy applies to all university staff involved in certain clinical research projects or studies involving human patients/subjects where the university is hosting or sponsoring the clinical study. The policy applies more specifically to projects or studies that involve particular types of procedures. These are set out in the policy.
Consultation	This policy had been created to form part of the university's research ethics framework. All parties named in this policy will be notified following committee approval.
Implementation and Monitoring	Responsibility for implementing this policy will be with clinical study principal investigators, with overall responsibility for monitoring being the Head of School of Health, accountable to the Vice-Principal Research and the Research Ethics Committee.
Risk Implications	Failure to comply with this policy may lead to ethical and legislative breaches, as well as failure to prevent or mitigate adverse events amongst study participants
Link with Strategy	Research ethics and legislative compliance.
Impact Assessment	Equality Impact Assessment: TBC
	Privacy Impact Assessment: TBC

1. Policy Statement

The university recognises that certain studies involving human patients/subjects carry a risk of adverse events occurring amongst study participants. 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. This policy identifies the responsibilities and accountabilities within the university for monitoring and reporting adverse events resulting from studies the university is hosting or sponsoring.

2. Definitions

2.1. Adverse Event

Any untoward medical occurrence in a clinical study participant.

2.2. Serious Adverse Event

Any adverse event or reaction in a clinical study participant that:

1. Results in death
2. Is life-threatening
3. Requires hospitalisation or prolongation of existing hospitalisation
4. Results in persistent or significant disability/ incapacity
5. Consists of a congenital anomaly or birth defect
6. Other important medical events

2.3. Clinical Study (for the purposes of this policy)

Research project involving human patients/subjects where:

1. Drugs, placebos or other substances (e.g. food substances, vitamins) are to be administered
2. Study involves intrusive interventions or data collection methods, for example, vigorous physical exercise, beyond the participants' everyday activity.
3. Blood or tissue samples are obtained from participants.
4. Physical pain or more than mild discomfort are likely to result from the study.
5. The study could induce psychological stress or anxiety, or cause harm or negative consequences beyond the risks encountered in everyday life.

2.4. Principal Investigator

The individual responsible for conduct of a clinical study. Sometimes known as the 'Chief' Investigator.

2.5. University

The University of the Highlands and Islands

3. Purpose

This purpose of this policy is to protect the safety of subjects involved in clinical studies conducted by the university, to outline the responsibilities and arrangements for assessing risk, monitoring, and reporting of adverse events as defined by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

The Medicines for Human Use (Clinical Trials) Regulations 2004 require that organisations leading clinical studies of investigational medicinal products have systems and processes in place to record and report adverse events resulting from these studies.

The Department of Health Research Governance Framework for Health and Social Care 2005 requires that the safety of study participants are given priority at all times, and requires organisations clarify responsibilities and accountabilities to prevent adverse events.

4. Scope

This policy applies to all university staff involved in clinical research projects or studies involving human patients/subjects where the university is hosting or sponsoring the clinical study.

5. Exceptions

This policy applies without exceptions, exclusions, or restrictions.

6. Notification

This policy will be made available on the university website and SharePoint, and provided to all principal investigators during project or funding application processes.

7. Roles and Responsibilities

7.1. Principal Investigator

The Principal Investigator is the named individual with responsibility for leading the clinical study. The Principal Investigator is responsible for:

7.1.1. Developing procedures to mitigate the risk of adverse events in clinical studies
7.1.2. Monitoring and enforcing risk mitigation plans during clinical studies
7.1.3. Assessing, investigating, notifying, and reporting adverse events during clinical studies as required by the Medicines for Human Use (Clinical Trials) Regulations 2004

7.2. Research team

All research staff members involved in a clinical study are responsible for ensuring that all adverse events are reported to the Principal Investigator, as well as implementing any mitigation plans to prevent the occurrence or severity of adverse events. This includes non-university staff on any university-led clinical study (where the university is hosting or sponsoring the clinical study).

7.3. Research Ethics Officer

The Research Ethics Officer is responsible for collecting reports on adverse events and reporting these to the Head of School, Chair of Research Ethics Committee and/ or the Vice-Principal of Research according to the procedures of this policy.

7.4. Head of School of Health

The individual responsible for overall management, mitigation and reporting of adverse events and serious adverse events, including:

7.4.1. Project development, assessment, and approval of clinical studies that involve human patients/subjects with a risk of adverse events.
7.4.2. Monitoring reports of adverse and serious adverse events and implementing appropriate investigations and action plans, up to and including suspension or termination of clinical studies.
7.4.3. Implementation of urgent safety measures and identification of action plan for responding to adverse and serious adverse events.
7.4.4. Notification of adverse and serious adverse events to project partners, funders, co-sponsors, and clinical study participants as appropriate and required.
7.4.5. Informing regulatory authorities of adverse event and serious adverse events.
7.4.6. Reporting of serious adverse events to the Vice-Principal of Research and other appropriate members of the university Senior Management Team.

7.5. Vice-Principal of Research

The Vice-Principal of Research is accountable for the implementation, monitoring and compliance with this policy at all stages of a clinical study, including pre- and post-approval.

7.6. Research Ethics Committee

7.6.1. Monitoring clinical study compliance with relevant legislation, project risk mitigation plans, policies, and procedures for adverse events.

7.6.2. Assessing suitability and performance of adverse event assessments, mitigation plans, investigations and action plan

8. Procedures

8.1. Process for reporting adverse events

All adverse events must be reported by the research team to the Principal Investigator, who will record the details of the event, as well as any investigations and actions taken or to be taken. The Principal Investigator will then report these events at the next research ethics committee meeting and/ or in the final project report.

8.2. Process for reporting serious adverse events

Any adverse event that is determined as serious by the Principal Investigator will be reported to the Head of School and Research Ethics Officer, who will notify the Chair of the Research Ethics Committee.

Expedited reporting to the Head of School and Research Ethics Committee will take place where necessary (i.e. to authorise suspension/ termination of a clinical study).

The format of external reporting of both adverse and serious adverse events should follow the statutory requirements outlined in Part 5 – Pharmacovigilance of the Medicines for Human Use (Clinical Trials) Regulations 2004.

9. Legislative Framework

Medicines for Human Use (Clinical Trials) Regulations 2004

10. Related Policies, Procedures, Guidelines and Other Resources

Department of Health Research Governance Framework 2005

ICH Guidelines for Clinical Safety Data Management 1994

World Medical Declaration of Helsinki

11. Version Control and Change History

Version	Date	Approved by	Amendment(s)	Author
0.9	21/08/17	C Lang	Development of new policy	N Oakley/ C Lang
1.0	07/09/17	FGPC	Final paper approved.	FGPC