

Key Responsibilities of the Principal Investigator following Research Ethics Approval by the University

June 2017

Following approval the Principal Investigator **MUST**:

- protect the rights and welfare of human research participants and be knowledgeable about the requirements of the University's policies and procedures for the protection of human participants.
- ensure that each participant understands the nature of the research and his/her participation in it and takes whatever steps are necessary to gain that comprehension.
- ensure that each research/member of staff who will have access to children (ie., anyone under 18 years of age) or vulnerable adults has undergone a satisfactory criminal records check.
- provide a copy of the approved **informed consent** document to each participant at the time of consent, unless this requirement has been waived by the University Research Ethics Committee.
- ensure that the research is **compliant with the Data Protection Act 1998**.
- report any *PROPOSED CHANGES* in previously approved research to the University Research Ethics Committee through completion and submission of the **Amendment Request Form (RE7)**. The changes may not be initiated without prior review and approval, except where necessary to eliminate apparent immediate hazards to the participants.
- report *PROMPTLY* any *ADVERSE EVENTS* involving risk to participants or others to the University Research Ethics Committee in the form of a full written report that should include any amendments to the participant information sheet and study protocol. Both non-serious and serious adverse events must be reported.

Reporting Non-Serious Adverse Events.

The Principal Investigator should inform the Secretary of the University Research Ethics Committee within ten days of an adverse incident occurring and provide a full written report that should include any amendments to the volunteer information sheet and study protocol. The Chair or Deputy Chair of the University Research Ethics Committee will confirm that the incident is non-serious and report to the Committee at the next meeting. The final view of the Committee will be communicated to the Principal Investigator.

Reporting Serious Adverse Events

The Committee should be notified of all serious adverse events. The sponsor of the research project should be informed in accordance with the researcher's contractual obligations. The Principal Investigator should inform the University Research Ethics Committee immediately the incident occurs. Where the adverse incident is unexpected and serious, the Chair or Deputy Chair will decide whether the study should be terminated pending the opinion of an independent expert. The adverse event will be considered at the next Committee meeting and a decision will be made on the need to change the information leaflet and/or study protocol.