**Lancaster University**

**Adverse Event in Research**

**Report Form**

This report form is for use if and when an adverse event incident occurs in a research project being undertaken at the University by a member of staff or research student, unless a specific alternative is mandated by a regulatory body. It should also be used to record a ‘near miss’. It should be completed by the Principal Investigator of the project or the student’s supervisor and agreed with the Head of Department.

An adverse event in research is an unexpected event in the course of research activity that results in research participants being caused physical or psychological harm, unintentional release of information, breach of regulations or law, harm to the environment or any other event which may damage the reputation of the University. A near miss is an unplanned event which did not result in an adverse event, but had the potential to do so, i.e. a fortunate break in the chain of events prevented it. Adverse events may occur for any number of reasons beyond the control of the researcher as well as through errors or mistakes made in the course of research activity.

Adverse events and near misses should be reported to the Chair of the FREC and the Head of Department as soon as possible and within 24/48 hours of the event with as many details as known at the time. The report should be updated and resubmitted within 24/48 hours as more details become available and until the event is fully understood. A copy of the reports should also be forwarded to the Secretary of the FREC that approved the project originally. If the time of the initial report exceeds 48 hours, this should be covered in part 13. A copy of this report should be kept in the project’s site file for reference.

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| **1. Research Project/Student’s name and Thesis title:** |  |
| **2. pFACT/ACP number or student registration:** |  |
| **3. Principal/Chief Investigator or Supervisor:** |  |
| **4. Department** |  |
| **5. Who initially discovered the adverse event?** |  |
| **6. When was the adverse event reported to the Principal/Chief Investigator or Supervisor?** |  |
| **7. When was the adverse event reported to the Head of Department/School?** |  |
| **8. When did the adverse event actually occur (date and time)?** |  |
| **9. Where did it happen?** |  |

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| **10. What actually happened and what was the impact?** | |
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| **11. Why did it occur?** | |
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| **12. Describe what action(s) have been taken to address the impact of this specific event. Specify specifically whether the project has been stopped and cover any communications with other organisations involved or the funders.** | |
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| **13. Describe what action(s) have been taken or are planned to limit the risk of a similar event re-occurring (add any general notes here to qualify the information given elsewhere in the report).** | |
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| **Agreed and authorised by:** | |
| Principal/Chief Investigator:  *Name:*  Signature: | Date: |
| Head of Department:  Name:  Signature: | Date: |