REPORTING OF ADVERSE EVENTS ON STUDIES APPROVED BY THE UNIVEIRTSY RESEARCH ETHICS SUB-COMMITTEE

## **Project Details:**

|  |  |  |  |
| --- | --- | --- | --- |
| Research Ethics ID number \*this can be found on your approval letter  |  | Principal Investigator/ Supervisor Name: |  |
|  |  | Other researchers involved, including student researchers:  |  |
| Full title of research project:  |  |
| Date of reporting:  |  | Date of event:  |  |
| Does your project have a sponsor, data monitoring committee or a collaborating partner? | Y/N | If yes, please provide details of what reporting requirement are in place:  |  |

\*Please note if your study involves a clinical trial or medical intervention and safety reporting processes are already in place, please complete and send through the relevant forms.

## **Type of Event:**

|  |  |  |  |
| --- | --- | --- | --- |
| Reporting Type: | Initial report □ | Follow up □ |  |
| Type of event: | Adverse Event □ | Serious Adverse Event □ |  |
| Severity: | Mild □ | Moderate □ | Severe □ |
| Assessment:  | Related □ | Unrelated □ |  |

## **Serious Adverse Event**

If you have noted the type of incident as a serious adverse event, please select.

□ results in death

□ is life threatening

□ requires hospitalisation or prolongation of existing hospitalisation

□ results in persistent or significant disability or incapacity

□ consists of a congenital anomaly or birth defect

□ results in physical or psychological harm to a participant

□ involves a breach of the confidentiality of personal data without the participant’s consent

## **Narrative:**

|  |
| --- |
| Please provide a summary of the event and what steps have been taken following the incident:  |
|  |

## **Participant Details:**

|  |  |  |  |
| --- | --- | --- | --- |
| Participant Initials:  |  | Participant ID number: |  |
|  |  |  |  |
| Outcome:  | Withdrawn from study □ | Continued with study □ | Follow up □ |

## **Next Steps:**

|  |
| --- |
| Has the study been halted? |
| Yes □ | No □ |

|  |
| --- |
| Have any changes been made to the research protocol or risk assessment following the event?  |
|  |

## **Sign Off:**

|  |  |
| --- | --- |
| Principle Investigator  |  |
| Signature |  | Date |  |

**Please return completed forms to the University Research Ethics Committee-** **rescadmin@glyndwr.ac.uk**