

Human Ethics Adverse Event Report

For reporting of incidents involving human research participants

This form should be submitted to the sponsor and/or WSU HREC: [humanethics@westernsydney.edu.au](mailto:humanethics@westernsydney.edu.au)

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| **Guidance for Using the Adverse Event Report Form**  This form is for reporting any **unintended, unexpected, or ethically significant events** involving research participants.  Use this form to report:   * Physical, psychological, or emotional harm * Breaches of confidentiality or privacy * Serious complaints or distress raised by participants * Any other event that may impact participant welfare or ethical conduct   This form will assist the Human Research Ethics Committee (HREC) to assess participant risk, monitor compliance, and provide guidance or follow-up where required.  If the event was caused by a **protocol deviation or procedural issue**, a Correction and Preventive Action (CAPA) form may also be required: [https://www.westernsydney.edu.au/research/forms#](https://www.westernsydney.edu.au/research/forms)  **Definitions** | |
| 1. **Study Details** | |
| Study Title: | Click or tap here to enter text. |
| Ethics ID: | Click or tap here to enter text. |
| Site Number / Location: | Click or tap here to enter text. |
| Chief Investigator (CI): | Click or tap here to enter text. |
| Chief Student (if applicable): | Click or tap here to enter text. |

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| 1. **Event Details** | | |
| **Date of Event:** | | Click or tap here to enter text. |
| **Date identified by research team:** | | Click or tap here to enter text. |
| **Location (if relevant):** | | Click or tap here to enter text. |
| **Event Severity** | | |
|  | Adverse Event (AE) – Minor or non-serious event  *Minor AE’s do not need to be reported to the HREC immediately. Instead, submit this form with the annual progress report.* | |
|  | Serious Adverse Event (SAE) – Resulted in death, hospitalisation, significant harm, or serious ethical concern  *SAE’s must be reported to the HREC and/or sponsor immediately as per reporting obligations.* | |
| **Event Classification (select all that apply):** | | |
|  | Unintended Event An occurrence during the research that was not planned or deliberately caused, even if it is related to the approved study procedures. Usually due to human error, oversight or miscommunication. *Examples:*   * *A participant did not sign the consent form prior to data collection starting* * *A participant was given the wrong study medication* * *A researcher sent identifiable participant data to the wrong person* | |
|  | Unexpected Event An event that was not anticipated based on the approved protocol, risk assessment, or prior experience with the study. These may or may not be related to the research activities. Usually signals a gap in risk planning or an unanticipated outcome from standard procedures *Examples:*   * *A participant was harmed during a routine medical procedure related to the study* * *A technology failure resulted in data loss or accidental recording of participants* * *A research device malfunctioned in a way not previously reported* | |
|  | Ethically Significant Event Any situation that may raise ethical concerns or compromise participant rights, safety, dignity, or well-being—even if no physical harm occurred. *Examples:*   * *A major privacy breach (eg sharing information publicly)* * *A participant made a serious complaint involving distress, coercion or discrimination* * *A procedure deviated from the protocol in a way that affected consent, risk or recruitment* | |
| **Type of Event:** | | ☐ Physical injury  ☐ Psychological distress  ☐ Breach of confidentiality  ☐ Complaint about conduct of the research  ☐ Protocol deviation  ☐ Other (please describe):  Click or tap here to enter text. |
| **Was a participant directly affected?** | | ☐ Yes ☐ No  If yes, how many participants were affected?  Click or tap here to enter text. |
| **Is the event related to the research procedures?** | | ☐ Yes ☐ No ☐ Unclear |

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| 1. **Description of Event**   Provide a factual, objective description of what occurred. Avoid speculation.  Example: A participant experienced acute anxiety during a survey discussing traumatic experiences. The survey was immediately stopped, and support was offered.  Click or tap here to enter text. |

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| 1. **Immediate Actions Taken and Follow-up Plan**   Describe any immediate steps taken to manage or resolve the issue, as well as your plan for any necessary follow-up.  Example: The participant was offered psychological support on the same day and was withdrawn from the study without penalty. The research team discussed the incident, and a follow-up welfare check was scheduled for the following week. Relevant documentation was reviewed to determine if protocol adjustments were needed.  Click or tap here to enter text. |
| Who undertook these actions or follow-up?  *Example: a research team member, an external person/body (eg health professional).*  Click or tap here to enter text. |

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| 1. **Impact Assessment** | | | |
| Risk to Participant Welfare: | ☐ Low | ☐ Moderate | ☐ High |
| Impact on Data Integrity or Study Validity: | ☐ None | ☐ Minor | ☐ Significant |
| Have other participants been notified or withdrawn? | ☐ Yes | ☐ No | ☐ Not applicable |
| Please explain how you assessed the level of risk to participants and the impact on study integrity. What factors informed your assessment?  *You are encouraged to reflect on:*   * *Severity and duration of harm or distress (if any)* * *Likelihood of recurrence* * *Whether the data remains valid and usable* * *Whether the deviation or event compromises the study’s scientific or ethical integrity*   Click or tap here to enter text. | | | |

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| 1. **Preventative or Corrective Actions**   Explain how future occurrences will be prevented, and whether any changes to the protocol, consent process, or procedures are proposed. |
| Click or tap here to enter text. |

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| 1. **Non-HREC or External Reporting**   Has the event been reported to any organisation/professional body/higher education institute/ WSU academic unit other than the WSU HREC? | |
| Check all that apply: | Provide details including name of individual/organisation, when contacted etc. |
| ☐ Sponsor | Click or tap here to enter text. |
| ☐ Internal WSU unit | Click or tap here to enter text. |
| ☐ WSU Privacy Officer | Click or tap here to enter text. |
| ☐ Research partner/ funding org’n | Click or tap here to enter text. |
| ☐ Another organisation | Click or tap here to enter text. |
| ☐ Other reporting not required | Click or tap here to enter text. |

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| 1. **Attachments** | | |
| Please list any documents/study materials that have been updated or developed as a result of the adverse event.  *Example: protocol, participant information sheets, consent forms, data management plan etc.* | | |
| **Document Title:** | **New Version Number** | **Updated or new document?** |
| Click or tap here to enter text. | Enter text. | Enter text. |
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| 1. **CI Sign Off** | |
| Name: | Click or tap here to enter text. |
| Signature: |  |
| Date: | Click or tap here to enter text. |

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