Graphical user interface, text, application

Description automatically generated

Adverse Event Reporting Form

*The completed form must be submitted via the Research Ethics Application Management System (REAMS).*

Section 1: Project Details

REAMS Reference Number:

Project Title:

Principal Investigator (or Academic Supervisor, if applicable):

Email address of Principal Investigator (or Academic Supervisor, if applicable):

School/Department:

Trinity College Dublin Research Ethics Committee (REC) that granted approval for the project:

Date of approval:

Ethical Approval also granted by an external organisation

|  |  |  |
| --- | --- | --- |
| Yes | No | If Yes, provide details of organization, Ethics Reference number and date. |
|  |  |  |

Section 2: Details of the Adverse Event or Unanticipated Problem

Date and time of occurrence:

Location of occurrence:

Who was affected?

|  |  |  |  |
| --- | --- | --- | --- |
| Party affected? | Yes | No | If Yes, provide details |
| Research Participants |  |  | How many: |
| Researchers |  |  | Provide name, affiliation, role in the study: |
| Research Records, Property or Other |  |  |  |

Describe the incident using lay language. Include details of any negative consequences, harm or damage that occurred as a consequence of the incident.:

If the cause of the incident has been identified, provide details:

Describe the steps that have been taken in response to this incident. You should describe any immediate actions that were taken at the time of the incident or its discovery:

Does this incident have wider implications for the project, the researcher, or the institution?

Describe the steps that have been taken to ensure such incidents can be averted in the future. Include details of any mitigation strategies:

Section 3: Reporting

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes | No | N/A |
| Has this incident been reported to the Head of School/Department? |  |  |  |
| Has this incident been reported to the relevant REC? |  |  |  |
| Has this incident been reported to a sponsor of the study? |  |  |  |
| Other |  |  |  |

If “Other”, please specify:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes | No | N/A |
| Has a similar incident occurred previously during this project? |  |  |  |
| Does this incident have ethical implications? |  |  |  |
| Is the incident related to the study design and / or procedure? |  |  |  |
| Was the adverse event anticipated in the original research protocol? |  |  |  |
| Was the possibility of this adverse event described in the Participant Information Leaflet and / or Consent Form? |  |  |  |
| Will the adverse event raise additional safety concerns for participants in this research? |  |  |  |
| Will prior knowledge of the adverse event affect the willingness of individuals to participate in the research? |  |  |  |

If you have answered “Yes” to any of the questions above, please provide details:

Section 4: Participant Considerations

If you are reporting a Serious Adverse Event, please indicate the consequences:

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Death: |  |  |
| A threat to life: |  |  |
| Requiring in-patient hospitalization or prolongation of existing hospitalization: |  |  |
| Persistent or significant disability or incapacity: |  |  |
| Congenital malformation/birth defect: |  |  |
| The jeopardising of the health (physical, psychological, economic, or social) of the research participant or researcher, requiring medical or other intervention to prevent one of the outcomes listed above: |  |  |

If you have answered “Yes” to any of the questions above, please provide details:

In total, how many participants have been recruited to the study?

If applicable, indicate the number of participants affected by this incident:

Section 5: Actions

In light of the information that has been provided above, what actions would you recommend?

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Termination of the study: |  |  |
| A temporary cessation of the study: |  |  |
| Changes to the study design/procedures: |  |  |
| Changes to the Participant Information Leaflet and / or Consent Form: |  |  |
| That participants previously enrolled are notified: |  |  |
| Other actions: |  |  |

If you have answered “Yes” to any of the questions above, please provide details:

Section 6: Certification

Signature of Principal Investigator (or Academic Supervisor, if applicable):

Date: