

NWU-EMELTEN-REC

The Faculty of Health Sciences Ethics Office of the North-West University is acknowledged for the use of their document with minor adjustments made by the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC).

**INCIDENT REPORT FORM WHEN CONDUCTING RESERCH WITH HUMAN PARTICIPANTS**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***Note: An incident is seen as an unanticipated situation or issue that arises while conducting your research and that has no direct cause/effect due to an intervention.***  Please complete the form according to the following guidelines:   * Researchers need to complete Sections A to C. * The Chairperson of the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC) will complete Section D. | | | | | | | | | | | | | | | | |
| **SECTION A: GENERAL INFORMATION** | | | | | | | | | | | | | | | | |
| 1. **Project Leader/Principle Investigator/Study leader Details** | | | | | | | | | | | | | | | | |
| **Surname** |  | | | | | **Initials** |  | | | **Title** | | | |  | | |
| **School/**  **Research unit** |  | | | | | | | | | | | | | | | |
| **E-mail** |  | | | | | | | | | | | | | | | |
| **Telephone** | **Work** |  | | | | **Cell** |  | | | | **Fax** | | |  | | |
| 1. **Student Details (if applicable)** | | | | | | | | | | | | | | | | |
| **Surname** |  | | | | | **Initials** |  | | | **Title** | | | |  | | |
| **School/**  **Research unit** |  | | | | | | | | | | | | | | | |
| **E-mail** |  | | | | | | | | | | | | | | | |
| **Telephone** | **Work** |  | | | | **Cell** |  | | | | **Fax** | | |  | | |
| 1. **Details of approved research** | | | | | | | | | | | | | | | | |
| **Title** |  | | | | | | | | | | | | | | | |
| **Ethics Approval Number** | | | |  | | | | | | | | | | | | |
| **Approval date** |  | | | | | **Expiry date** | |  | | | | | | | | |
| **Last submission of a monitoring report** | | | | | | **Date:** | | | | | | | | | | |
| **SECTION B: INCIDENT REPORT** | | | | | | | | | | | | | | | | |
| **Please describe the progress to date of the project (not more than 500 words):** | | | | | | | | | | | | | | | | |
| **Please describe the incident that is being reported in detail (please ensure that you respond to what, where, who, how, when of the incident):** | | | | | | | | | | | | | | | | |
| **Please describe the action that has been taken to date in detail in order to contain the incident:** | | | | | | | | | | | | | | | | |
| **Please indicate a possible strategy/action plan for correcting the incident:** | | | | | | | | | | | | | | | | |
| **Please indicate a possible strategy/action plan for ensuring that it will not occur again:** | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | **Yes** | **No** | **NA** |
| **Will this incident require that the proposal will have to be changed?**  **If yes, please ensure that an amendment request is submitted to the Ethics Office as soon as possible.** | | | | | | | | | | | | | |  |  |  |
| **SECTION C: SIGNATURE** | | | | | | | | | | | | | | | | |
| **By signing this document, I certify that the information provided is accurate and complete.** | | | | | | | | | | | | | | | | |
| **Signature by the primary investigator** | | |  | | | | | | **Date** | | |  | | | | |
| **SECTION D (for office use only):** | | | | | | | | | | | | | | | | |
| 1. **Ethics Office report** | | | | | | | | | | | | | | **Yes** | **No** | **NA** |
| **Has the incident been satisfactorily reported?** | | | | | | | | | | | | | |  |  |  |
| **Has the incident been satisfactorily addressed?** | | | | | | | | | | | | | |  |  |  |
| **If yes, please explain the manner in which the incident was managed with the project leader/principle investigator/study leader and participant/s:** | | | | | | | | | | | | | | | | |
| **NWU-EMELTEN-REC Chairperson** | | | | | **Signature** | | | | | | | | **Date** | | | |
|  | | | | |  | | | | | | | |  | | | |

Original details: (22136630) G:\My Drive\9. Research and postgrad education\9.1.5 Ethics\9.1.5.5\_Research monitoring reports