**Adverse Events Form**

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| Research Study Title …………………………………………….. |
| PI …………………………………………….. |
| Protocol No |
| Approval Number  Phone ……………………………………………..  Email ………………………….…………………….. |

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| **Instructions** |
| Not all incidents which constitute adverse events need to be reported to the Bioethics Committee however still it is important to document them throughout the study. Please read the instructions as you move on to fill the adverse event form.  Adverse event (AE), Serious Adverse Event (SAE), unexpected Adverse Event (Unexpected AE)  Please answer the following before proceeding with the report:  Was the EA unexpected ?   * The event is considered unexpected from the perspective of participant or study team.   Yes No   * The event unforeseen in terms of severity, frequency, nature or other factors.   Yes No   * Was it included in the consent form   Yes No  If “NO” to all above, the event does not need to be reported to BEC.  If “ yes” to any of the above, proceed to next questions.  How would you describe the event in terms of relativity to the research?   * “related” means attributed to research nature and procedures and it would occur on any participant.   Yes No   * “possible” means that it is not qualify as unanticipated problem   Yes No   * “no enough information” means that it may be included on report format once information is provided.   Yes No  If “NO” to all above, the event does not need to be reported to BEC.  If “ yes” to any of the above, proceed to next questions.  Are participant placed at greater risk or harm as a result of the currently occurring incidents?   * It includes tangible risk on participants .   Yes No   * The consent form needs to be updated to include this form of risk.   Yes No  If “NO” to all above, the event does not need to be reported to BEC.  If “ yes” to any of the above, proceed to fill in the adverse event form.  Investigator must report the following incidents according to the listed time line.   |  |  | | --- | --- | | Deaths | with in 24 hours, if there is an approved protocol while the death incident occur. | | Any harm experienced by a participant which, in the opinion of the investigator is both unexpected and more likely than not cause by the research procedures. | 7 days | | Threats of harm to participants during their participation | immediately | | Change to any protocol with out prior BEC approval | immediately | | Identification of an unsafe research environment | immediately, if it severely affect the subject of interest or when there is a notable change than the approved protocol. | | Newly information that may affect the health, risks and benefits ratios for the participants | 7 days | | Breach of continentality | 3 days | | Any other adversely event, or serious or unexpected that the research team have not anticipated 7 days | 10 days maximum |   Note:   * Instructions are given in *Italic* font style. * Keep the font at 12 pt |
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| **Section 1: Submitted Report** | |
| **Report type** | *[indicate whether this report is routinely follow up report or if it is written as per incident occur]*  Follow-up Incident report  **Date :** *Click or tap here to enter text.* |
| **Type of adverse event (AE)** | *[indicate the type adverse event occurred throughout the study ]*  AE SAE Unexpected AE  Investigational new drug (IND) |
| **Date** | *[write down the exact dates of the following ]*  Report Date:  Incident Date:  Location :  Date Sponsor Notified (if applicable):  Adverse event resolving date :  Adverse event Stabilized date :  **Incident is on going**  Note: if the incident event reported is still ongoing, a follow up must be submitted after resolving the event or stabilizing. |
| **Subject Information** | *[fill down the indicated items ]*  Subject Name: *Click or tap here to enter text.*  Age: *Click or tap here to enter text.*  Gender: Male Female  Active participant still Yes No ,  If “No” what is stopping time : *Click or tap here to enter text.* |
| **Event Outcomes** | *[indicate the outcomes of the event according to the following]*  Death Hospitalization Life threatening  Congenital anomaly / Birth defect  Persistent or significant disability / incapacity  Required intervention to prevent outcome listed above:  Other, Please specify: *Click or tap here to enter text.* |
| **Section 2: PI Evaluation of the event** | |
| **Event outcome** | *[does the event being reported meet the following criteria ]*  Unexpected (in terms of nature, severity and implications), according to the approved research protocol, informed consent document and population characteristics  Yes No  Related – or possibly related to the research  Yes No  Participants at great risk (physical, psychological, economics or social harm) which was not recognized.  Yes No  Is the risk contained in the approved consent form  Yes No  Should the any portion of the study revised  Yes No  Will currently enrolled participants be notified of the event  Yes No  If “Yes”, how you are going to notify them  *Click or tap here to enter text.* |

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| **Section 3 : BEC USE only !** |  |
| **Communication** | **Member Name :**  *Click or tap here to enter text.*  Phone Number used:  Date of communication:  **Report received by :** |
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| **Committee Revision** | The reported event does not represent unanticipated problem or risk on inovled participants  The reported event is considered unanticipated problem and involving risks on participants  Immediate action is needed to protect the rights and welfare of currently enrolled participants  Immediate Action:  *Click or tap here to enter text.*  Action plan to mange the event :  *Click or tap here to enter text.* |
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| **Report Close-out** | The BEC considered the reported incidents is involving risks to participants and made the following determination :  *Click or tap here to enter text.*  Note, following the approval from BEC this report will be addressed to the national bioethics committee  Date :  Time : |