**HUMAN RESEARCH SUBJECT ADVERSE EVENT REPORT**

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| Section 1. Research Information |
| **Responsible Research Principal Investigator (PI):** | : |  |
| **Title of Research:**  | : |  |
| **Ethics Approval Reference Number:** | : |  |
| Section 2. Description of Event |
| **Adverse events encountered during the study?****Specify any complications (medical, legal, practical, etc.) that have been encountered in this time interval of the study aside from adverse events.**  Yes (please summarize the complication (s)) No (proceed to 3) |

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| **Section 3. Impact on Study** |
| **Method Changes.** *In your judgment, is a change in the method is necessary to reduce or eliminate the risk?*  Yes (please attach method amendment). No  |
| **Informed Consent Document.** *Are there any changes required in the informed consent document(s) to better inform and protect the rights of subjects?*  Yes (please attach the revised consent form). No |
| **Did you experience any problems with the consent process?** Yes (please describe the problem(s) and how they were amended) No **Action taken by researcher.** |

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| **Section 4. Declaration** |
| I hereby declare that the information given is accurate and complete in all respects. Upon request, I agree to provide with any information or documents required in relation to the application, and ensure to inform any changes of information if applicable soon as possible.**( \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ) Date:**  **Research Principal Investigator**  |
| **Ethics Committee Approval** |
| **Comments:****Approved****Approved, with amendment****Not approved** **Reason:****( \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ) Date:**  **Chairman of Ethics Committee**   |