**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** |