**APPENDIX 2**

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| --- |
| **SERIOUS ADVERSE EVENT REPORT** |
| Study Name :  |
| Protocol No. : Ethics Ref. No. :  | Protocol Version Date :  | Principal Investigator :  |
| **Serious Adverse Event Report(s)** |
| SAE Description | ExpectedYes / No | UMMCYes / No | Relationship to study drug | Event date | Report No. | Country |
|  |  |  |  |  |  |  |
| Subject ID : | Patient Age : |  | Patient Gender (M/F) : |
| Comment by Investigator (pertaining to the risk of our research subjects) :Is there any ethical concern or other matter to be highlighted to MEC?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature : Date :  |

 **BK-MIS-1118-E01**