**APPENDIX 2**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SERIOUS ADVERSE EVENT REPORT** | | | | | | | | | |
| Study Name : | | | | | | | | | |
| Protocol No. :  Ethics Ref. No. : | Protocol Version Date : | | | | | Principal Investigator : | | | |
| **Serious Adverse Event Report(s)** | | | | | | | | | |
| SAE Description | | Expected  Yes / No | UMMC  Yes / 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**