# ANNEX 1

**AF/01-020/05** **Serious Adverse Event Report**

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| Principal Investigator:…………………………………….. | | Study Site: |
| Protocol Title: ……………………………………………. | | Protocol No.: |
| Sponsor (if applicable)…………………………… | | |
| Name of the study drug / medical device: | | |
| Report Type  ⬜ Initial ⬜ follow-up  ⬜ Final | Report Source:  ⬜ Investigator ⬜ Sponsor  ⬜ DSMB ⬜ REBH member  ⬜ Others, specify: | |

|  |  |  |
| --- | --- | --- |
| Subject’s initial/number: | Age: | **⬜** Male **⬜** Female |

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| Describe Reactions (onset date, signs, symptoms, including relevant tests/ lab data) |
| Medical treatment |
| Progression of the SAE |

|  |  |
| --- | --- |
| Seriousness:  ⬜ Death  ⬜ Life Threatening  ⬜ Hospitalization –⭘ initial ⭘ prolong  ⬜ Disability / Incapacity  ⬜ Congenital Anomaly  ⬜ Other………………………………… | Relation to ⭘ Drug ⭘ Device ⭘ study  ⬜ Not related  ⬜ Possibly  ⬜ Probably  ⬜ Definitely related  ⬜ Unknown |

|  |  |
| --- | --- |
| Changes to the protocol recommended? | ⬜ No ⬜ Yes , attach proposal |
| Changes to the informed consent form recommended? | ⬜ No ⬜ Yes , attach proposal |

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| Reported by: …………………………………………………  Report Date: |