# 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 |

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| --- | --- |
| 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: |