Serious Adverse Event – Cover Sheet

(For UoL sponsored clinical trials of investigational medicinal products)

**This form must be sent to** [**rgosponsor@le.ac.uk**](mailto:rgosponsor@le.ac.uk) **alongside its corresponding SAE reporting form A within 24 hours of the research team becoming aware of the Serious Adverse Event**

**<The table below may be adapted to suit the individual and additional reporting requirements of the trial based upon the requirements of the collaborating drug companies. The adapted report must be approved by the Sponsor prior to implementation. If any further changes are required the Sponsor should be notified.>**

| **Information Requested** | **Response** |
| --- | --- |
| Study title or Acronym |  |
| Sponsor reference number |  |
| Drug Company Reference |  |
| Country of Incidence |  |
| Participant Weight |  |
| Participant Height |  |
| Participant Gender | Male  Female |

<<Sponsor Ref\_Trial Title\_SAE Cover Sheet\_vX.X, DD/MM/YYYY>>