**Appendix 5
Sponsor SAE Email (Template)**

Dear Study Team

Thank you for providing the R&I office with the following SAE:

|  |  |
| --- | --- |
| Participant |  |
| Centre |  |
| Study Title |  |
| Sponsor Ref |  |
| Onset date |  |
| Title of Event |  |
| Type of Report |  |
| Date of Report |  |

<Delete as appropriate>

The SAE form you provided requires amendment/further information or signature as indicated below:

* Initial unsigned report received. **A signed copy of the either in the initial report of the final report is required within 7 days.**
* An initial signed report received. **A signed follow up report is required within 28 days.**
* Serious Criteria not completed. **Return within 7 days.**
* Causality assessment incomplete. **Return within 7 days.**
* Event expectedness incomplete. **Return within 7 days**
* Relationship to study procedure incomplete. **Return within 7 days.**
* Relationship to protocol violation incomplete. **Return within 7 days.**
* Study medication information incomplete. **Return within 7 days.**
* Action taken with regards to IMP incomplete. **Return within 7 days.**
* Was patient withdrawn as a result of this event incomplete. **Return within 7 days.**
* Outcome of the event incomplete. **Return within 7 days.**
* Other/comment. **Return within X days.**

Date of send to R&I …………………

Once completed, we would be grateful if you could please send the updated form to RIAdmin@uhl-tr.nhs.uk

Many thanks.