**APPENDIX 4**

**Template email text to request Annual SAE Line Listing for UHL Hosted studies**

Dear (add name of PI)

According to our records, the anniversary for HRA approval or Clinical trials Authorisation (MHRA Approval) (delete as appropriate) for your study is soon due:

EDGE ID XXXXXX

Study Title xxxxxxxx

UHL R&I will require a line listing of all Serious Adverse Events that have occurred at this site in the past 12 months. The Sponsor will need to submit an annual report to the regulatory authorities and part of this will include a complete listing of all SAEs. Please would you liaise with them to extract the UHL SAEs in advance of the due date of XX/XX/XX.

Further detail is available in the [SOP C-2002 UHL](http://www.leicestersresearch.nhs.uk/wp-content/uploads/2019/05/SOP-C-2002-Safety-Reporting-signed-V5-Feb-2019.pdf)

Kind Regards