UNIVERSITY OF **LEICESTER**

**Development Safety Update Report (DSUR) Reporting Timeframe working instructions**

The following should be used in conjunction with the **Development Safety Update Report working illustration- Appendix 1**

- The Development Safety Update Report (DSUR) is due on the anniversary of the MHRA clinical trial authorisation. This is known as the **Data Lock Point**

- The Research Governance Office will send an email to the Principal Investigator **31 days PRIOR** to the **Data Lock Point**. Attached to this email will be:

  - DSUR Guidelines
  - Template DSUR form

  The email will include a date to return the completed DSUR to the Research Governance Office. This is the **Data Lock Point PLUS 21 days**. Investigators are welcome to submit the DSUR to the Research Governance Office for initial review prior to signing to ensure that they are completing the document to the required standards, providing the specified timeframes are adhered to

- If the completed DSUR is not returned to the Research Governance Office by this stipulated date the Principal Investigator will be emailed to offer a further 7 days for completion. If this extended deadline is not met the **UoL Procedure for non-compliance will be implemented as per SOP S-1016 UoL**

- Once the completed DSUR has been returned to the Research Governance Office, it will be reviewed and signed by the appropriate person/s.

- The Research Governance Office will submit the completed, signed and dated DSUR to the appropriate regulatory bodies by the final submission date which is the **Data Lock Point PLUS 60 days**

- The Research Governance Office will send an acknowledgement to the Principal Investigator along with a copy of the signed DSUR. This must be filed in the Trial Master File / Investigator Site File.

Development Safety Update Report (DSUR) Reporting Timeframe working instructions
Version 2 November 2016,     Appendix 3 to Sop S-1014 UoL
To be used in conjunction with the DSUR Reporting Timeframe working illustration (Appendix 2 to SOP S-1014 UoL)