

Record of unplanned deviation

An unplanned deviation is a deviation that is discovered after a procedure has been carried out. Such deviations must be recorded, investigated and, whenever possible, corrective and preventive actions implemented.

NB: Do not record any data that will allow an individual donor to be identified.

Title and code of SOP for which an unplanned deviation was found:	
Nature of the unplanned deviation:	
<i>Please notify your local Supervisor and the Head of Quality and Standards at onCore UK (tel: 020 8731 4595).</i>	
Was work halted? Yes/No (please delete). If yes, date work halted:	
Unplanned deviation recorded by: Name:	Date:

Investigation

Investigation performed:
Root cause of the unplanned deviation:

Assessment of impact of unplanned deviation(eg Donors or samples affected, severity of impact):

Proposed corrective actions:

Proposed preventive actions:

Audit required? Yes/ No (please delete)

Investigation performed and corrective and preventive actions proposed by:

Name:

Date:

Signature:

Review and authorisation

Resumption of work authorised by HQS on (date):	
Record reviewed and corrective and preventive actions authorised by:	
Local Supervisor:	
Signed:	Date:
Head of Quality and Standards, onCore UK:	
Signed:	Date:

Please send form to the Head of Quality and Standards at onCore UK (Fax: 020 8731 4587).

For completion by HQS, onCore UK:

Annual review

Efficacy of corrective and preventive actions reviewed by Head of Quality and Standards, onCore UK:	
Signed:	Date:
Comments:	