

## Record of unplanned deviation from an external source

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.***

**Please notify your local Supervisor immediately of any deviations.**

*Send the completed form to the Head of Quality and Standards at onCore UK (Tel: 020 8731 4592; Fax: 020 8731 4587).*

Process in which the unplanned deviation was found:
Nature of the deviation: <i>(Please give as much detail as possible)</i>
Deviation recorded by: Name (Print) : <span style="float: right;">Date:</span>
Organisation where deviation occurred:
Was work halted? Yes/No (please delete).  If yes,  Date work halted:  Date work resumed:  Resumption of work authorised by: (Print):  Signature:  Date:



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### Investigation

Investigation performed: *(Please give as much detail as possible)*

Assessment of impact of unplanned deviation (e.g. Donors or samples affected):

Severity of impact: *(Low, Medium, High, Critical)*

Root cause:

Proposed corrective actions: *(Please give as much detail as possible of the actions proposed to correct the deviation)*



Proposed preventive actions: *(Please give as much detail as possible of the proposed actions to be implemented to prevent a reoccurrence of the deviation)*

Investigation performed and corrective and preventive actions proposed by:

Name (Print):

Signature:

Date:

### Review and authorisation

Record reviewed and local corrective and preventive actions authorised by Supervisor:

Name (Print):

Signed:

Date:



**FOR ONCORE UK USE ONLY**

**Q-Pulse Record Data Entry**

Record raised by:

Name (Print):

Signature:

Date:

Person responsible for resolution of deviation at onCore UK (Owner)

Q-Pulse Record Number: