

Incident and Deviation Reporting Form

Site Name _____

Principal Investigator: _____

Participant Study Number (if applicable):

Participant day and month of date of birth (if applicable): DD / MM

Incident number: *(to be completed by NPEU CTU)*

Date incident occurred (started): DD / MM / YY

Detail of incident:

Resolution: *(include actual and planned corrective and preventative action at site)*

If this information is not available at the time the incident is first reported, please send without this information and send this information later.

Details of Reporter:

Name: _____

Role: _____

Signature: _____ Date: / /

List any relevant documentation included with this form:

Please complete and send immediately after becoming aware of the incident.

One copy to NPEU CTU, along with relevant documentation, and one to be filed in the Investigator Site File.

Please email form to:

TOAST Study Team

Email: toast@npeu.ox.ac.uk

NPEU CTU Receipt:

Received at NPEU CTU by:

Name: _____

Role: _____

Signature: _____ Date: / /

NPEU CTU comments to reporting site:

Name: _____

Role: _____

Signature: _____ Date: / /