

BLOOD SERIOUS ADVERSE EVENT (SAE) REPORT FORM

ALL CONSUMER/PATIENT AND REPORTER INFORMATION WILL REMAIN CONFIDENTIAL

Please complete as much information as possible. Do not be put off reporting if some details are not known.

REPORT IDENTIFICATION NUMBER OF REPORTING ESTABLISHMENT:

DETAILS OF SERIOUS ADVERSE EVENT (SAE)

Date of SAE (DD/MM/YYYY):

| Serious Adverse Event (SAE) which may affect quality and safety of blood component due to a deviation in: | Specification | | | |
|---|----------------|-------------------|-------------|------------------------|
| | Product defect | Equipment failure | Human Error | Other (please specify) |
| Whole blood collection | | | | |
| Apheresis collection | | | | |
| Testing of donations | | | | |
| Processing | | | | |
| Storage | | | | |
| Distribution | | | | |
| Materials | | | | |
| Others | | | | |

REPORTING ESTABLISHMENT

Type (please circle): blood establishment, hospital blood bank

Name:

Address:

Telephone/Mobile:

E-mail address:

Signature _____ Date of Report _____