Serious Adverse Event [SAE] / Unanticipated Problem [UAP] Source Document Coversheet

Study ID:

☐ **SAE** ☐ **UAP**

SAE / UAP *Description (e.g., pneumonia*)

Site Name: SELECT SITE

☐ **Initial submission** ☐ **Follow-up submission**

Date (MM/DD/YYYY):

Number of pages (including coversheet):

Records included: (check)

☐ **Laboratory reports:**

☐ **Office records, specify:**

☐ **Hospital records, specify:**

☐ **Other, specify:**

Name of person submitting records:

Phone: **E-mail:**

Note: the study ID must be recorded on every source document page.

All identifying information must be concealed.