1. **PURPOSE**

Outlines the considerations for documenting serious adverse events, deviations and violations.

1. **SCOPE**

For all studies, documentation in OnCore is at the discretion of the department.

1. **Considerations**
	1. SAEs tracked in the Subject Console appear on the Invoiceable Items tab of the Financials Console. Contact OnCore Support Team oncore@wustl.edu for more information.
	2. Protocol deviations will automatically display a list of visits for which the entered Visit Date is outside of the tolerance defined for that visit. For more information on Subject Deviations, contact OnCore Support Team.
2. **RESOURCES**

[Reportable Events Work Instructions](https://confluence.wustl.edu/x/RqSADQ)

|  |
| --- |
| **Revision History** |
| **Version** | **Effective Date** | **Description** |
| 1.0 | 2/24/2020 | Initial Version |
| 1.1 | 9.11.2022 | Updated OnCore User Manual links post Confluence migration |