1. **PURPOSE**

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

2. **SCOPE**

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

3. **CONSIDERATIONS**

   3.1. 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.

   3.2. 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.

4. **RESOURCES**

   Reportable Events Work Instructions

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**
1.2	**6.20.2023**	**Updated OnCore User Manual links post Confluence migration**