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**