	OnCore CTMS Standard Operating Procedure (SOP)	
Washington University in St. Louis School of Medicine	Title: Documenting S	Serious Adverse Events and Deviations
Effective Date: June 20, 2023		Approval Date: June 20, 2023
Version: 1.2		Page 1 of 1

## 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 <u>oncore@wustl.edu</u> 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	