

	OnCore CTMS Standard Operating Procedure (SOP)	
	Title: Documenting Serious Adverse Events and Deviations	
Effective Date: September 11, 2022	Approval Date: September 11, 2022	
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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