

SWOG COVID-19 PROTOCOL DEVIATIONS (DRAFT)

Participant Identifier <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>	Study Identifier S <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 40px; height: 20px; border: 1px solid black;" type="text"/>	Registration Step <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>
Participant Initials _____ (L, F M)		

Page: COVID-19 Protocol Deviations

Instructions: Please complete this form for all protocol deviations with the same start date. Add more loglines in Rave as needed. For major deviations, please complete the CIRB and local IRB notification questions. Date is in **DD MON YYYY** format.

Were there any protocol deviations? Yes No

If yes, what is the category of the protocol deviation? COVID-19

If yes, what is the start date of the deviation?

Protocol Deviation Subcategory	Protocol Deviation*	Was CIRB notified?	If yes, date	Was the local IRB notified?	If yes, date	Comments
<input type="radio"/> Major <input type="radio"/> Minor	_____	<input type="radio"/> Yes <input type="radio"/> No	<input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>	<input type="radio"/> Yes <input type="radio"/> No	<input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>	_____
<input type="radio"/> Major <input type="radio"/> Minor	_____	<input type="radio"/> Yes <input type="radio"/> No	<input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>	<input type="radio"/> Yes <input type="radio"/> No	<input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>	_____
<input type="radio"/> Major <input type="radio"/> Minor	_____	<input type="radio"/> Yes <input type="radio"/> No	<input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>	<input type="radio"/> Yes <input type="radio"/> No	<input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>	_____
<input type="radio"/> Major <input type="radio"/> Minor	_____	<input type="radio"/> Yes <input type="radio"/> No	<input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>	<input type="radio"/> Yes <input type="radio"/> No	<input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>	_____

***Protocol Deviations**

Missed Study Visit	Cycle treatment Given Early or Late	Late or Missed Study Specimen
Phone or Virtual Visit	Late or Missed Imaging Procedure	Late or Missed QOL/PRO
Late or Missed Study Lab	Late or Missed Other Study Procedure	Other