SWOG
COVID-19 DIAGNOSIS AND PROTOCOL DEVIATIONS

Participant Identifier | | | | | | | **Study Identifier** | S | | | | |

Participant Initials _____ (L, F M)

Page: COVID-19 Diagnosis and Protocol Deviations

Instructions: Complete this form if the participant has tested positive for the COVID-19 virus or has any protocol deviations due to a COVID-19 diagnosis or other pandemic-related reasons. Submit this form within 15 days of knowledge of a positive COVID-19 diagnosis or protocol deviation. Amend the existing form if this participant has an initial COVID-19 diagnosis or additional COVID-19 related protocol deviations not previously reported.

- Report any ***major*** deviations following the guidance of the IRB of record for the study. If unsure if an event is minor or major, contact SWOG Quality Assurance at qa@swog.org.

Instructions for documenting COVID-19 pandemic impact on other study forms:

- All minor and major deviations should also be documented on the appropriate study form(s) (**Treatment**, **Disease Assessment**, **Adverse Event**, etc.)
  - Clearly specify in the Comments section of the study form that the deviation is due to "COVID-19 pandemic related" or "COVID-19 diagnosis."
- A positive diagnosis is considered an adverse event and must also be reported on the **Adverse Event** form as "Infections and Infestations – Other, Specify" (Specify = COVID-19) as appropriate.
- If a participant goes off protocol treatment or study intervention due to a COVID-19 diagnosis or other pandemic-related reason, submit the **Off Treatment/Protocol Notice** and include the text "COVID-19" in the Other, specify field.
- If a participant permanently withdraws consent for further follow-up due to a COVID-19 diagnosis or other pandemic-related reason, submit the **Consent Withdrawal** form if applicable.
  - The **Consent Withdrawal** form must be requested through the SWOG Data Operations Center.
  - Document the COVID-19 details in the Comments and include the text "COVID-19".

COVID-19 Diagnosis

Continue to update this section until the participant's first positive test result. Do not update for subsequent tests after that.

Was a COVID-19 test performed? ◯ Yes ◯ No ◯ Unknown

If yes, did the participant test positive for the COVID-19 virus? ◯ Yes ◯ No

If yes, what was the date of the first positive test? | | | | | | | | | | |

COVID-19 Protocol Deviations

Note: *Per NCI guidance released on March 13, 2020, activities performed locally that are part of usual oncology care with direct oversight by the Responsible Investigator on an interim basis are not considered protocol deviations.*

Were there any protocol deviations? ◯ Yes ◯ No

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Page: COVID-19 Diagnosis and Protocol Deviations, continued

If yes, complete the table below. Enter each protocol deviation on a separate logline in Rave as needed. Submit this form even if the deviation was reported on study-specific forms.

Protocol Deviation Category	Protocol Deviation*	Reason for Deviation	Date *(Date of planned treatment, procedure, test/scans, assessments, follow-up, etc. that deviated)*	Comments *(Specify justification on why it is considered major/minor; e.g. routine follow -up on patient no longer on therapy.)*
◯ Major ◯ Minor	____________	◯ COVID-19 Pandemic Related ◯ COVID-19 Diagnosis ◯ Other	☐☐ ☐☐☐ ☐☐☐☐	____________
◯ Major ◯ Minor	____________	◯ COVID-19 Pandemic Related ◯ COVID-19 Diagnosis ◯ Other	☐☐ ☐☐☐ ☐☐☐☐	____________
◯ Major ◯ Minor	____________	◯ COVID-19 Pandemic Related ◯ COVID-19 Diagnosis ◯ Other	☐☐ ☐☐☐ ☐☐☐☐	____________
◯ Major ◯ Minor	____________	◯ COVID-19 Pandemic Related ◯ COVID-19 Diagnosis ◯ Other	☐☐ ☐☐☐ ☐☐☐☐	____________
◯ Major ◯ Minor	____________	◯ COVID-19 Pandemic Related ◯ COVID-19 Diagnosis ◯ Other	☐☐ ☐☐☐ ☐☐☐☐	____________

***Protocol Deviations**

- Cycle Treatment Given Early or Late
- Cycle Treatment Missed
- Phone or Virtual Visit
- Late or Missed Study Visit
- Late or Missed Study Procedure
- Late or Missed Study Lab
- Late or Missed Imaging Procedure
- Late or Missed QOL/PRO
- Late or Missed Study Specimen Collection
- Changes to Specimen Shipment Schedule
- Other