SWOG CANCER RESEARCH NETWORK

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TO: ALL NATIONAL CANCER CLINICAL TRIALS NETWORK (NCTN) MEMBERS AND NATIONAL COMMUNITY ONCOLOGY RESEARCH PROGRAM (NCORP) COMPONENTS AND SUBCOMPONENTS

FROM: SWOG Operations Office (protocols@swog.org)

RE: SWOG COVID-19 Deviation Guidance

MEMORANDUM- SWOG COVID-19 Deviation Guidance

SWOG COVID-19 Data Collection
SWOG will collect pandemic-related data via Rave for trials which use this Medidata Rave and via the CRA Workbench for all pre-Rave trials. Both pandemic-related deviations and positive COVID-19 diagnoses for patients followed on SWOG-coordinated trials will be collected by SWOG. We anticipate these data collection tools will be ready mid-May 2020. To proactively track deviations, a COVID-19 Protocol Deviation log is attached to this memorandum.

COVID-19 Protocol Deviation Log:
Current guidelines from the NCI NCTN and NCORP programs require that protocol deviations must be documented and reported at the time of continuing review to the NCI CIRB. The attached log should be used by all sites to document deviations related to the coronavirus pandemic. It is designed to collect deviations by SWOG study (one deviation log per study). This log will help a site track the deviations that will be reported in the electronic data capture (EDC) system (Rave or CRA Workbench) once they are available and will also be sufficient source documentation for future audits.

Some of the key instructions for the upcoming form(s) include:

- All major and minor deviations must also be documented on the appropriate study form(s) (Treatment, Disease Assessment, Adverse Event, etc.) as well as the SWOG COVID-19 Protocol Deviation form. Major deviations must also be reported according to the guidelines of the IRB of record. Only those deviations that indicate research participants may be at greater risk of harm (physical or otherwise) than previously anticipated should be reported to SWOG.
- If the participant has a positive diagnosis of COVID-19 the new COVID-19 Diagnosis form must be submitted. An Adverse Event also must to be reported on the Adverse Event or Late Effects form as “Infections and Infestations – Other, Specify” using the text “COVID-19” in the specify field.
- 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 document the COVID-19 details in the Comments including the text “COVID-19” in the text.
- If a participant permanently withdraws consent for further follow-up due to a COVID-19 diagnosis or other pandemic reason submit the Consent Withdrawal form.

Additional communications will be available when the EDC systems have been updated to capture COVID-19 protocol deviations and diagnoses data.

This memorandum serves to notify the NCI, CIRB, and SWOG Statistics and Data Management Center.

cc: PROTOCOL & INFORMATION OFFICE

SWOG COVID-19 Deviation Log

Study: _____ Site Name / CTEP ID: _____ Site Primary Investigator: _____

Investigator/Designate Signature (*at time of data entry into Rave/CRA Workbench*): _____ Date_____

SWOG Patient ID	Date (*Date of planned treatment procedure, test/scan, etc. that deviated)*	Brief Summary of Deviation *(Specify the detail of the protocol deviation and justification on why it is considered major/minor)*	Deviation Code*	Reason for Deviation (*COVID Outbreak vs COVID Infection)*	Major/Minor	If Major Deviation	
						Notified SWOG? If Yes, Date	Notified IRB? If Yes, Date

* Deviation Codes:

1. Cycle treatment Given Early or Late
2. Cycle of Treatment Missed
3. Phone or Virtual/Video Visit
4. Late or Missed Study Visit
5. Late or Missed Study Procedure
6. Late or Missed Study Lab
7. Late or Missed Imaging Procedure
8. Late or Missed QOL/PRO
9. Late or Missed Study Specimen
10. Changes to Specimen Shipment Schedule
11. Other