



MEMORANDUM

Date: March 24, 2020
To: SWOG Cancer Research Network Members
From: Charles D. Blanke, MD, Group Chair
Re: SWOG Trials and COVID19

Many of our members – physicians, nurses, clinical research associates, and other health care providers – are on the frontlines of this public health emergency. I am grateful to each of you working to ensure the very best care for patients.

Here is what I can report/recommend regarding our clinical trial enterprise:

- **Please follow guidance from your institution on clinical trial conduct and enrollment.** SWOG and National Cancer Institute (NCI) leadership understand that every site has unique recommendations and requirements for managing its resources and priorities.
- **All SWOG currently active trials remain open for patient enrollment.** You may accrue to activated SWOG trials at this time, provided that treating investigators feel it is appropriate for the patient to be enrolled and enrollment is allowed under institutional rules. We're working with study chairs to determine whether any study-specific protocol changes are needed, or if there are ways to streamline protocols to reduce workload for site staff. **Should specific protocol changes occur, SWOG will notify sites.**
- **SWOG Biospecimen Bank, located at Nationwide Children's Hospital, is continuing essential activities without significant interruption of services at this time.** If you have any bank-related questions, please use these contacts:
 - All cancer types, except leukemia:
 - BPC Bank 800-347-2486
 - BPCBank@nationwidechildrens.org
 - Leukemia:
 - BPC MGL 614-722-2866
 - BPCMGL@nationwidechildrens.org

- **We are gathering information about other protocol specific labs and biobanks and their ability to accept and process SWOG specimens.** We'll soon post this information to our [COVID-19 clearinghouse](#).
- **SWOG and NCI recognize that enrollment for trials may slow due to the pandemic.** However, some studies are paradoxically still accruing very well.
- Per NCI, **activation of new NCTN or NCORP trials will be at the discretion of the Cancer Therapy Evaluation Program (CTEP) and the Division of Cancer Prevention (DCP).** Decisions will be made on a case-by-case basis. Trials that may benefit individual patients will likely receive higher priority than those advancing scientific/societal knowledge over the long term.
- **To reduce the burden on sites, we are relaxing the SWOG Institution Performance Review Policy (Policy #33), which covers data and specimen submission.** Institution Performance Review reports will continue to be run and sent to the head clinical research associate and site principal investigator on the 2nd of the month, but SWOG will not issue warnings or suspensions. **Please continue to collect and submit study data and specimens to the best of your ability.** We will continue to monitor data and specimen submissions and expect data to be submitted when you are able.
- **CTEP is allowing sites to reschedule audits as necessary. NCI is allowing remote audits.** SWOG is exploring options for remote audits and will offer options on a site-specific basis. Continue to track any protocol deviations, as audits will eventually occur. **SWOG Statistics and Data Management Center staff are developing a case report form for Rave and pre-Rave studies that must be used to document protocol deviations.** Further instructions will be posted to our [COVID clearinghouse](#) as soon as possible.
- **Timely data entry of serious adverse events in Rave and CTEP-AERS is still required.**
- **CTEP has announced that patient care may be transferred to a different participating study site.** If it becomes necessary to transfer a patient's care to a different study site, this can be accomplished on-line using standard operating procedures available on the Cancer Trials Support Unit (CTSU) OPEN website. Active study sites can be found on the [CTSU members site](#).
- **CTEP is allowing local physicians to administer standard therapies, conduct exams, and run the standard laboratory tests called for on its treatment trials, as long as they follow protocol rules and get agreement from a treating physician approved to participate in the trial.** All data resulting from this care, including adverse events, must be sent to the study physician(s). Similarly, **standard radiation and surgery, which do not require protocol-specified credentialing, may also be performed by the local healthcare provider with oversight by the responsible investigator.**

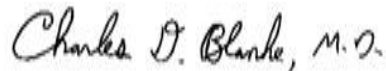
- **Oral investigational agents under an NCI-held IND or a SWOG-held IND can be shipped from the dispensing pharmacy directly to patients. Drugs must be shipped using a trackable method, such as FedEx, and must be documented in the patient record.**
- **Intravenous investigational medications, however, must be administered at NCI-approved treatment sites only.**
- **NCI has approved the use of telemedicine.** Study visits conducted by phone or videoconferencing technology (i.e., “virtual” or “telemedicine” visits), including adverse event assessments for patients, may be substituted for protocol-required in-person visits, if the responsible investigator determines that the phone/virtual visit is adequate to achieve the central purpose of the visit and to assure the safety of the patient.
- **Study visits may be delayed or missed** if, in the judgment of the responsible investigator, the benefit of delay/omission of a visit outweighs the risks of exposure of the patient to the virus by coming in for an in-person visit and an alternative method is not possible. Likewise, scheduled data collections for secondary objectives, such as optional quality of life or other sub-studies embedded in a cancer treatment trial, could be delayed or missed. **These approaches would be considered minor deviations by NCI, and would need to be reported to SWOG or any organization managing the trial.**
- **NCI reports there are no cancer drug shortages or supply issues now.**

SWOG will continue to send updated guidance directly to sites, and post these updates to our [COVID-19 clearinghouse](#). This clearinghouse includes guidance, information, and news from NCI, the National Institutes of Health, the U.S. Food & Drug Administration, ASCO, major news outlets and more, and is updated daily Monday-Friday.

If you have questions about a SWOG trial, please contact the study chair or protocols@swog.org. If you have **any** concerns, questions, or suggestions for me, contact me at blankek@ohsu.edu.

Please stay safe and be well. At this extraordinary time, thank for your service.

All my best,



Charles D. Blanke, MD
Group Chair
SWOG Cancer Research Network