



MEMORANDUM

DATE: March 13, 2020

TO: Principal Investigators and Operations/Statistics Offices of NCI CTEP-Supported Clinical Trials Networks & Consortia and DCP-Supported NCI Community Oncology Research Program (NCORP) Research Bases

FROM: Meg Mooney, MD, Associate Director, CTEP, DCTD, NCI
Worta McCaskill-Stevens, MD, Director, NCORP, DCP, NCI

SUBJECT: Interim Guidance for Patients on Clinical Trials Supported by the NCI Cancer Therapy Evaluation Program and the NCI Community Oncology Research Program (NCORP)

Due to concerns regarding the spread of the novel coronavirus and the impact it is having on hospitals, clinics, physician offices, and patients' ability to travel, the NCI Cancer Therapy Evaluation Program (CTEP) and the NCI Community Oncology Research Program (NCORP) are providing clarification on measures to address some of the current challenges in providing care to patients enrolled on clinical trials supported by CTEP and the NCORP in order to mitigate immediate hazards to the patients.

General Guidance for All Trials (Both IND and Non-IND Trials)

Transfer of Patient's Care 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 https://www.ctsuo.org/public/default_login.aspx.

- For NCTN and NCORP studies: Use the CTSU OPEN Website (<https://open.ctsuo.org/>) to access the *Transfer and Update Module (T&UM)*. Please review the *T&UM User Guide* located under *Training and Demonstration Materials* before logging into OPEN.

Alternatively, investigators can use the *Patient Transfer Form* located on the CTSU website (<https://www.ctsuo.org>) under the *Resources* tab → *CTSU Operations Information* → *CTSU Forms* (login required). This form can be completed online or by hand and uploaded to the *Regulatory Submission Portal*.

- For ETCTN and Other Consortia: Complete the *Patient Transfer Form* online or by hand and upload it to the *Regulatory Submission Portal*.
- Sites can contact the CTSU Help Desk with any questions or concerns regarding patient transfers and identifying active study sites at CTSUContact@westat.com or 1-888-823-5923.

Continuity of Care Provided by Non-Research Staff: The Responsible Investigator for a patient already enrolled on a clinical trial may make appropriate arrangements with a Local Healthcare Provider to provide certain study activities in order to provide continuity of care and follow-up study visits when the patient cannot travel to the site location of the Responsible Investigator. In this situation, the Local Healthcare Provider is providing intermittent/short-term care and the Responsible Investigator believes it is in the patient's best interest to continue study activities. The activities provided by the Local Healthcare Provider must be conducted under the oversight of the Responsible Investigator in accordance with the protocol and with assurances that processes are in place to report all required information to the Responsible Investigator who is responsible for ensuring that the data is entered into the data management system for the trial. These activities include the following:

- Protocol required physical exam(s) and assessment of the patient's vital signs, temperature, weight, performance status, and other standard assessments may be conducted by the Local Healthcare Provider. All clinical findings and information must be conveyed to the Responsible Investigator overseeing the patient's care in the trial. All decisions must continue to reside with the Responsible Investigator for the patient's care within the trial.
- Protocol specified clinical laboratory tests may be performed by the Local Healthcare Provider/Local Laboratory with results sent to the Responsible Investigator.
- Protocol required blood collections necessary for patient assessment within the clinical trial that require evaluation in a central research laboratory may also be collected by the Local Healthcare Provider and shipped to the designated central laboratory under the Responsible Investigator's oversight. The Responsible Investigator needs to ensure that the Local Healthcare Provider can make these collections depending on the protocol requirements.
- Protocol required standard parameters such as ECHO and radiologic imaging may be performed locally with results sent to the Responsible Investigator for review (report and image, if applicable).
- Drug therapy with non-investigational agents may be administered by the Local Healthcare Provider (this includes therapy on treatment arms that do not include investigational agents on IND trials) with appropriate reporting of study therapy administration data and adverse event information to the Responsible Investigator. Standard radiation therapy, surgery, and other interventions that do not require protocol-specified credentialing may also be performed by the Local Healthcare Provider with oversight by the Responsible Investigator. In such cases, for this activity, the Responsible Investigator must inform the IRB of record for the trial that a Local Healthcare Provider is providing study therapy under his/her oversight. For trials under the NCI CIRB, the Responsible Investigator can send a simple email notification to the NCI CIRB at ncicirbcontact@emmes.com. For trials not under the NCI CIRB, the Responsible Investigator should follow the appropriate local IRB notification policy.

These activities performed locally are part of usual oncology care and are being provided only on an intermittent/short-term basis with direct oversight by the Responsible Investigator with respect to protocol requirements. All decisions on care within the clinical trial are made by the Responsible Investigator. In this situation, these activities are not considered protocol deviations simply because they are being performed locally and not directly by the Responsible Investigator. The Responsible Investigator is still required to report any protocol deviations and unanticipated problems that occurs (e.g., non-compliance with protocol therapy) per standard procedures.

New Patient Enrollment: Patients can only be enrolled on a clinical trial at an active site that is participating in the study. The active participating sites for a trial can be found on the members side of the CTSU website at: https://www.ctsu.org/public/default_login.aspx.

Special Guidance for IND Trials

Administration of Oral Investigational Agents: For studies under CTEP IND with oral investigational agents, the Pharmaceutical Management Branch is altering its standard operating procedures for the next 90-day period (March 16, 2020 to June 14, 2020) as described below to allow the Dispensing Pharmacy to ship oral investigational agents directly to patients. For studies under IND by another regulatory sponsor (e.g., NCTN Group), participating site investigators should contact the lead organization conducting the trial to see if similar arrangements are possible for oral investigational agents for those studies.

On a protocol-by-protocol basis, the CTEP Pharmaceutical Management Branch (PMB) will consider requests from Responsible Investigators at participating sites to allow shipment of oral IND agents on NCI/CTEP sponsored trials directly to patients enrolled on a clinical trial. Consideration can include possible shipment of multiple treatment cycles to study patients or possible dispensing of multiple treatment cycles (for patients that are able to initially return to the treatment site), if feasible, based on supply availability and protocol requirements.

- The Dispensing Pharmacy must ensure shipment occurs in appropriately qualified shipping containers to maintain temperature control and product quality and integrity during transit
- Dispensing Pharmacy must ensure proper labeling of the drug product for patient use
- Agents requiring specialized shipping (e.g., Dangerous Goods) must be performed in accordance with applicable regulations and by appropriately trained and certified individuals
- Adequate records of treatment administration must be maintained and reviewed by the site at the time of the next scheduled visit (i.e., Diary Cards)
- Protocol Site Principal Investigators may submit requests and any questions via email to PMBAfterHours@mail.nih.gov.

Since this is an alteration in the standard operating procedures of the CTEP PMB (not part of the protocol), this is a not a protocol deviation and it does not need to be reported to the IRB of record for

the trial. PMB will re-assess this process before the end of the 90-day period and extend or modify, as needed.

Injectable Investigational Agents & Other Investigational Interventions: For studies under CTEP IND with injectable/IV investigational agents, the investigational agents are required to be administered at a registered participating site for the trial. If a patient cannot travel to the site location of the Responsible Investigator, transfer of the patient's care to a different participating site located closer to the patient can be investigated. The process for transferring a patient is described on the first page of this memo.

Active study sites for particular trials can be found on the member side of the CTSU website at: https://www.ctsu.org/public/default_login.aspx. Sites can contact the CTSU Help Desk with any questions or concerns regarding patient transfers and active study sites at CTSUContact@westat.com or 1-888-823-5923. In some cases, for Network programs (e.g., NCTN, NCORP, ETCTN), a registered site located close to a patient may also be able to open the trial.

For studies with injectable/IV agents under IND by another regulatory sponsor (e.g., NCTN Group), participating site investigators should contact the lead organization conducting the trial to see if other arrangements are possible.

For other investigational interventions requiring special protocol requirements or special credentialing (e.g., experimental/investigational radiotherapy protocols), those interventions can only be conducted at specific sites that have met the protocol requirements. Transfer of a patient's care to one of those sites is also an option.

CTEP and the NCORP will continue to monitor closely the studies being conducted across all its clinical trials network programs to see if there are additional accommodations that can be made to help maintain continuity of care of patients on the trials as much as possible in this challenging situation. Principal Investigators and Operations Centers for the CTEP and NCORP clinical trial Networks and Consortia should contact the appropriate Program Director for their respective trials program with any issues that may arise during this outbreak of the novel coronavirus.