SWOG | CANCER RESEARCH NETWORK

June 15. 2020

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

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

RE: Guidance on Extension of Oral IND Agent Shipment Allowance

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MEMORANDUM

The purpose of this memorandum is to inform sites of the availability of NIH guidance on shipment of oral IND agents under CTEP-held INDs titled, "Updated (June 2, 2020) Interim Guidance for Patients on Clinical Trials Sponsored by the NCI Cancer Therapy Evaluation Program: Shipment of Oral IND Agents to Clinical Trial Subjects," which **extends the allowable shipment date of oral drugs under CTEP-held INDs through September 13, 2020**. The guidance memorandum is available on SWOG's COVID-19 Information Clearinghouse page available at https://www.swog.org/news-events/news/2020/06/02/covid-19-information-clearinghouse. The COVID-19 Information Clearinghouse page will continue to be updated as new information becomes available.

SWOG continues to mirror the NCI's processes for COVID-related guidance to the extent feasible; therefore, **the NCI-provided oral agent shipment guidance will also be applicable to oral agents under SWOG-held INDs**.

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

cc: PROTOCOL & INFORMATION OFFICES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

MEMORANDUM

Date: June 2, 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
Rodney Howells, R.Ph., Associate Branch Chief, PMB, CTEP, DCTD, NCI

Subject: **Updated (June 2, 2020)** Interim Guidance for Patients on Clinical Trials Sponsored by the NCI Cancer Therapy Evaluation Program: **Shipment of Oral IND Agents to Clinical Trial Subjects**

Due to continued concerns regarding the spread of the novel coronavirus and the ongoing impact it is having on hospitals, clinics, physician offices, and patients' ability to travel, the NCI Cancer Therapy Evaluation Program (CTEP) is providing updated information to extend the date for site shipment of oral IND agents on CTEP IND sponsored trials.

Ensuring the safety and continuity of care for clinical trial patients is paramount. During the current COVID-19 pandemic, the shipment of oral CTEP IND agents by sites to enrolled subjects on clinical trials will be performed under extenuating circumstances as determined by the physician Investigator in the best interest of continuing patient care.

For studies under CTEP IND with oral investigational agents, the Pharmaceutical Management Branch is extending the alteration of its standard operating procedures to allow the Dispensing Pharmacy to ship oral investigational agents directly to patients through **September 13, 2020**. Consideration can include possible shipment of multiple treatment cycles to study patients, if feasible, based on supply availability and protocol requirements.

Requests to ship CTEP IND oral investigational agents do not need to be submitted to the Pharmaceutical Management Branch, CTEP for authorization.

- The Dispensing Pharmacy must ensure shipment occurs in appropriately qualified shipping containers to maintain temperature control and product quality and integrity during transit.
    - CTEP can only recommend shipping of agents in qualified temperature-controlled shipping containers to maintain product integrity during transit. If the Dispensing Pharmacy is unable to obtain qualified containers, a decision as to what is in the best interest of the patient for

continuity of care will need to be made in consultation with the study investigator. Document the decision, the rationale and shipping method for future reference.

- Shipments will occur via overnight delivery service that allows for tracking and confirmation of delivery.

- Dispensing Pharmacy must ensure proper labeling of the drug product for patient use.

- 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).

- **Exception:** Agents considered Dangerous Goods must adhere to Department of Transportation and International Air Transportation Association regulation methods for shipment. CTEP does not authorize Dangerous Goods shipment unless shipments are performed in accordance with applicable regulations and by appropriately trained and certified individuals. If sites do not have someone trained and certified to oversee this process, consider possible dispensing of multiple cycles to the subject at the next visit or have another individual pick-up the prescription for the subject. The following is the current list of CTEP oral IND agents that must be shipped as Dangerous Goods:

  NSC 732517 Dasatinib
  NSC 767034 GSK2141795
  NSC 768435 MLN0128 (TAK-228)
  NSC 778795 GDC-0032 (taselisib)
  NSC 783668 LY3023414
  NSC 787289 Vistusertib (AZD2014)
  NSC 814100 CB-5339 tosylate

- **Other Agents with special considerations:**

  NSC 703813 Lenalidomide: This agent must be dispensed in accordance with the REMS dispensing requirements for the agent.
  NSC 767909 Pomalidomide: This agent must be dispensed in accordance with the REMS dispensing requirements for the agent.
  NSC 748727 Selumetinib: Temperatures below 25°C must be maintained during transit.
  NSC 763093 (Trametinib) and NSC 763760 (Dabrafenib): Trametinib tablets and dabrafenib capsules may be shipped together in a refrigerated temperature container.

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.

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. Sites will not be asked to submit Corrective Action Plans for shipments to subjects under these circumstances. PMB will re-assess this process before September 13, 2020 and extend or modify, as needed.

Submit any questions via email to PMBAfterHours@mail.nih.gov.