

September 15, 2020

TO: ALL NATIONAL CLINICAL TRIALS NETWORK (NCTN) MEMBERS AND NCORP AFFILIATES AND SUB-AFFILIATES

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

RE: Updated COVID-19 Guidance for Shipment of Oral IND Agents

MEMORANDUM – Updated COVID-19 Guidance for Shipment of Oral IND Agents

The purpose of this memorandum is to notify sites that per the [August 28, 2020 Updated NCI guidance memorandum for shipment of Oral IND Agents to Clinical Trial Subjects](#), the NCI Pharmaceutical Management Branch (PMB) extended the allowable timeframe for the alteration of its standard operating procedures, which allows the Dispensing Pharmacy at participating sites to ship oral IND agents directly to patients, **until May 31, 2021**.

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 May 31, 2021 and extend or modify, as needed.

For investigational oral agent shipping questions related to protocols conducted under a CTEP-held IND, questions should be directed to PMB at PMBAfterHours@mail.nih.gov.

SWOG will follow NCI's guidance for timeframe for allowing shipment of oral agents with IND's held by SWOG. For investigational oral agent shipping questions related to protocols conducted under a SWOG-held IND, questions should be directed to protocols@swog.org.

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

cc: PROTOCOL & INFORMATION OFFICE