



MEMORANDUM

DATE: March 13, 2020

TO: Principal Investigators and Operations Staff of DCP-Supported Phase 0-2 Cancer Prevention Clinical Trials Program (“Consortia”) and CP-CTNet

FROM: Eva Szabo, MD, Director, CP-CTNet, DCP, NCI

SUBJECT: Interim Guidance for Patients on Clinical Trials Supported by the NCI DCP Phase 0-2 Cancer Prevention Clinical Trials Program

Due to concerns regarding the spread of COVID-19 and the impact it is having on hospitals, clinics, physician offices, and clinical trial participants’ ability to travel, the NCI, DCP is providing clarification on measures to address some of the current challenges in providing care to participants enrolled on clinical trials supported by NCI DCP Phase 0-2 Cancer Prevention Clinical Trials Program in order to mitigate immediate hazards to the patients.

The risk-benefit for each individual participant must be considered in determining whether participants already enrolled on trials are to be asked to return for scheduled appointments and whether new participants are enrolled. Separate guidance has been sent to all Consortia sites by the CIRB.

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

Participants Enrolled on DCP Consortia Clinical Trials:

If a participant at a site is unable to complete a required study related activity per the CIRB approved protocol or if a study visit needs to be delayed, this is a protocol deviation and should be evaluated for Serious and/or Continuing Noncompliance (SNCN). This event should be reported to the DCP Medical Monitor and the CIRB by the site investigator per standard process. The Principal Investigator (PI) should assess the impact of the missed or delayed study activity on the safety of the subject and the scientific validity of the trial. If in the PI’s determination, neither of these are meaningfully impacted by the deviation, the subject may stay on study.

If, in the opinion of the PI, the missed visit or intervention poses a risk to the safety of the subject, the investigator should develop a plan to minimize the impact of the deviation. For example, if the subject is scheduled to return to the study site for safety lab work, the investigator may arrange for labs to be drawn either at a location closer to the participant’s home, such as a commercial lab or physician’s office. The Study Chair may consider modifying the protocol to replace in-person visits with remote options or implement other measures to limit exposure to COVID-19 if these are feasible and do not negatively impact participant safety; this modification to the protocol is not permitted at local sites and would be submitted and approved at the protocol level. All changes to previously approved research

must be made by the Study Chair at the trial-wide level and reviewed and approved by the CIRB in the form of an official amendment prior to implementation.

The regulations allow for modifications to be implemented prior to IRB approval only when it is necessary to eliminate apparent immediate hazards to the subject (§46.108 (a)(3)(iii) and 21 CFR 56.108(a)(4)). If this occurs, the event is considered a deviation from the CIRB approved protocol and should be evaluated and submitted for SCNC. The study should then be evaluated and formally amended if appropriate via standard processes.

New Participants Being Screened for Enrollment on DCP Consortia Clinical Trials:

New participants should only be enrolled on open clinical trials if the benefit of the intervention outweighs the risk of participation (including the added risks associated with travel, being in a healthcare setting, etc. during the COVID-19 pandemic). In most situations, participation in early phase cancer prevention clinical trials does not provide direct benefit to the individual participant. For instance, the health and safety of a healthy volunteer would not be adversely affected by inability to enroll onto a phase I trial and thus such a person should not be enrolled during the current COVID-19 pandemic.

DCP will continue to closely monitor the conduct of the trials being conducted in the Consortia program and, if the current challenging situation continues longer than expected, in the CP-CTNet program, to see if there are additional accommodations that can be made to help maintain continuity of care of participants in clinical trials. Principal Investigators and Site Staff should contact the appropriate Medical and Scientific Monitors for their respective trials with any issues that may arise during this outbreak of COVID-19.