April 1, 2020

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

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

RE: NIH   Guidance for Collection of Adverse Events Related to COVID-19 Infection

MEMORANDUM

The purpose of this memorandum is to inform sites of the availability of NIH guidance for collection and reporting of adverse events related to COVID-19 infection. The current NIH guidance is attached and available on SWOG's COVID-19 Information Clearinghouse page available at https://www.swog.org/news-events/news/2020/03/26/covid-19-information-clearinghouse. The COVID-19 Clearinghouse page will continue to be updated as new information becomes available.

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

cc: PROTOCOL & INFORMATION OFFICE

4201 Medical Drive, Suite 250 | San Antonio, TX 78229 | OFFICE 210-614-8808 | FAX 210-614-0006

In partnership with KNIGHT CANCER Institute OHSU | NCI National Clinical Trials Network | NCI Community Oncology Research Program

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

MEMORANDUM

DATE: March 25, 2020

FROM: Meg Mooney, MD, Associate Director, CTEP, DCTD, NCI
Jeff Moscow, MD, Chief, IDB, CTEP, DCTD, NCI
S. Percy Ivy, MD, Program Director-ETCTN, Assoc. Chief, IDB, CTEP, DCTD, NCI
Worta McCaskill-Stevens, MD, Director, NCORP, DCP, NCI

TO: Principal Investigators and Site Staff Conducting NCI CTEP, CIP, and NCORP-Supported Clinical Trials

SUBJECT: Guidance for Collection of Adverse Events Related to COVID-19 Infection

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Infections occurring in subjects on clinical trials are considered adverse events and should be reported per protocol guidelines via normal procedures (on CRFs/Rave and via CTEP-AERS if serious).

Please document COVID-19 related adverse events as follows:

> **Infections and infestations - Other, specify**
> **Specify = COVID-19**

Additionally, please record (and if applicable, report via CTEP-AERS) any other Adverse Events the subject experiences such as Dyspnea, Acute respiratory distress syndrome, etc.

CTEP-AERS specific instructions:
- **Narrative**: Identify all pertinent facts related to the COVID-19 infection including, but not limited to the following:
  - Presumptive vs confirmed diagnosis. If presumptive, please update your narrative if/when diagnosis is confirmed, including timelines.
  - Treatment information
  - Recovery information, including timelines
  - Outcome information/status
- **Supporting documentation**: Please fax supporting documentation including admission notes, progress notes, clinical visits, and discharge summary if/when available.
  - Fax Number: 301-897-7404, include protocol number, ticket number and subject ID on the fax cover sheet and each page faxed.

Queries:

Medical Questions/Help:
Email: aemd@tech-res.com
Phone: (301) 897-7497
Fax Number: 301-897-7404

Technical CTEP-AERS Questions/Help:
Email: ncictephelp@ctep.nci.nih.gov
Phone: 1-888-283-7457