



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](mailto:aemd@tech-res.com)

Phone: (301) 897-7497

Fax Number: 301-897-7404

**Technical CTEP-AERS Questions/Help:**

Email: [ncictephhelp@ctep.nci.nih.gov](mailto:ncictephhelp@ctep.nci.nih.gov)

Phone: 1-888-283-7457