



MEMORANDUM

DATE: March 25, 2020

FROM: Meg Mooney, MD, Associate Director, CTEP, DCTD, NCI
Jeff Moscow, MD, Chief, IDB, CTEP, DCTD, NCI
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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

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: ncictephhelp@ctep.nci.nih.gov

Phone: 1-888-283-7457