DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute

9609 Medical Center Drive
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# MEMORANDUM

**DATE:** September 7, 2021

**TO:** Principal Investigators and Operations/Statistics Offices of NCI CTEP-Supported Clinical Trials Networks & Consortia and DCP-Supported NCI Community OncologyResearch Program (NCORP) Research Bases

**FROM:** Meg Mooney, MD, Associate Director, CTEP, DCTD, NCI
Worta McCaskill-Stevens, MD, Director, NCORP, DCP, NCI

**SUBJECT:** Guidance and Update on Advanced Practice Providers Writing Study Agent Orders on Clinical Trials Supported by the NCI Cancer TherapyEvaluation Program and the NCI Community Oncology Research Program (NCORP)

The NCI Cancer Therapy Evaluation Program (CTEP) and the NCI Community Oncology Research Program (NCORP) received inquiries from clinical trial sites about the CTEP policy in the Investigator Handbook (2014 version 1.2 in section 14.2) that states if Advanced Practice Providers (APPs) write study agent orders in NCI CTEP-supported treatment trials, a qualified physician investigator must co-sign their orders. Some sites expressed concerns that this policy was a barrier to their conducting trials at their sites and reported other trial sponsors, including many industry trials, do not have this co-signature requirement. A survey of NCI sites was conducted across the country to assess if this policy represented a barrier to the conduct of NCI CTEP-supported clinical treatment trials. The results revealed this policy is a barrier for some sites and overall, there is wide support for allowing APPs to practice within their full licensure as determined by their local and state regulations and institution policies. Based on all the input, a short policy change document for CTEP-supported trials has been developed and will go into effect on September 7, 2021.

On Sept. 7th, 2021 and going forward:

- Patient orders for study agents, including IND agents and standard of care agents, may be written by qualified APPs without a physician co-signature. Qualified APPs must be registered in NCI's Registration and Credentialing Roster (RCR) as Non-Physician Investigators (NPIVRs) and be added to site Delegation of Tasks Logs (DTLs) to the task of "IND Prescribing", where required. Site Clinical Investigators (CIs) must sign the DTL for the qualified NPIVR to conduct this new task.

Qualified APPs may include:

- Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, Advanced Degree Nurses, and Pharmacists who are licensed and qualified per institutional policy, local and state laws and regulations including requirements as mandated for international sites.
    - Definition from the Advanced Practitioner Society for Hematology and Oncology (APSHO) www.apsho.org

NCI trials covered under this policy include those in the DCP NCORP program, the NCI's Experimental Therapeutics Clinical Trials Network (ETCTN), the NCI's National Clinical Trials Network (NCTN) and other DCTD and CTEP-sponsored networks, consortia and studies.

Please review the complete policy document and slides on the CTEP website at:
https://ctep.cancer.gov/investigatorResources/investigators_handbook.htm

- https://ctep.cancer.gov/investigatorResources/docs/Advanced_Practice_Providers_Policy.pdf
- https://ctep.cancer.gov/investigatorResources/docs/Slide_Set_on_Advanced_Practice_Providers_Policy.pdf