Advanced Practice Providers (APPs) & Investigational Agent Orders:

Update on CTEP Policy and Implementation

September 7, 2021

NIH NATIONAL CANCER INSTITUTE

Advanced Practice Providers (APPs)
Update on Policy Plan & Tentative Implementation Date

- Wide support for respecting individual institution & state policies as implemented and per site's compliance monitoring
- Short policy change document for CTEP-supported trials reviewed by NCI, ETCTN, and NCTN and NCORP Group Leadership
- CTEP performed IT changes within the infrastructure systems to support update
- CTEP Implementation set for September 7th, 2021

NCI CTEP Updated Policy on APPs Writing Orders

Before Sept. 7th 2021:

- CTEP's Investigator Handbook (2014 version 1.2) states:

  In Section: 14.2 Writing a Patient-specific Orders

  - Patient-specific orders for study agents should be written by NCI-registered investigators participating on the specific trial. If other licensed prescribers write orders, the registered investigator who is officially participating on the trial must cosign the order.
  - In Appendix VI: INVESTIGATOR: Any physician who assumes full responsibility for the treatment and evaluation of patients on research protocols as well as the integrity of the research data.

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 <u>without</u> a physician cosignature**.
- 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.

NCI CTEP Updated Policy on APPs Writing Orders (continued)

- **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 and the ETCTN, NCTN, and other DCTD and CTEP-sponsored networks, consortia and studies.

APP Policy Implementation at Clinical Trial Sites

- Sites must have an institution policy that qualifies APPs, including:
  - Credentialing processes for APPs to write study agent orders that are consistent with their local and state laws and regulations including requirements as mandated for international sites.
  - Statement that a qualified physician investigator is responsible for all trial-related medical decisions, including providing oversight of APPs in their capacity of writing study agent orders (GCP requirement).
  - Institution policies can be stored in the site's regulatory files and be available for review.
- Sites will need to ensure that APPs qualified to write study agent orders as NPIVRs are registered in NCI's RCR and renew and maintain their registration and qualifications annually. RCR verifies professional licenses, including APPs, during the annual registration process.
- Site CIs will identify APPs qualified to write study agent orders on site DTLs, where required. Site DTL Administrators or CI will need to add the "IND Prescribing" task for the NPIVR and the CI must sign this task.

Questions about the new APP Policy Implementation:

Contact the CTSU Help Desk:

E-mail: ctsucontact@westat.com

Phone:1-888-823-5923

Policy on the CTEP website:
https://ctep.cancer.gov/investigatorresources/investigators_handbook.htm