

NCI DCP & DCCPS NCORP Guidelines

Advanced Practice Nurse Roles in DCP Trials & DCCPS Studies

Nurses are essential to the NCI clinical trial enterprise and fulfill a variety of roles on the research team including research nurse, clinical nurse, nurse administrator/manager and nurse scientist. Advanced practice provider (APP) nurses (those with master's and higher education levels) have a long history of improving patient outcomes and promoting care, health and wellness as well as playing lead roles in NCI funded symptom science, survivorship, quality of life and cancer care delivery research.^{1,2} Recognizing the important role of the APP the NCI Divisions of Cancer Prevention (DCP) and Cancer Control and Population Sciences (DCCPS) have developed a guideline to allow these individuals to have meaningful and enhanced roles in the development and implementation of NCORP Research Base funded research endeavors. Namely, for **NCORP protocols funded by NCI DCP and DCCPS** nurses with PhD, DNP or master's level preparation, training and NCTN/NCORP trial-related experience will be qualified to:

- a. serve as chairs (PhD),
- b. serve as co-chairs (PhD, DNP, or master's* level)
- c. serve as a local investigator to consent and enroll patients,
- d. prescribe/write orders for study agents.

* Masters level co-chair requirements: prior clinical trial research experience within NCTN/NCORP preferred; experience in the conduct of research as PI, Co-I, or Research Coordinator for investigator initiated, pharmaceutically sponsored, or quality assurance/improvement projects.

This guideline applies specifically to cancer prevention, symptom management and behavioral intervention trials funded by NCI Division of Cancer Prevention (DCP) and NCORP cancer care delivery research studies funded by NCI Division of Cancer Control and Population Sciences (DCCPS). This guideline does not apply to NCI CTEP funded trials.

Study Chair and Co-Chair

PhD prepared APPs will be allowed to serve as study chairs. Master's, DNP and PhD prepared APPs will be allowed to serve as co-chairs of NCI DCP and DCCPS funded NCORP trials.

Consenting and Enrolling Patients

Master's, DNP and PhD prepared APPs are permitted to serve as a local investigator to consent and enroll patients/participants to NCI DCP and DCCPS funded NCORP trials provided they are actively rostered as a non-physician investigator (NPIVR) in the NCI Registration and Credential Repository (RCR).

Prescribing Study Agents

Master's, DNP and PhD prepared APPs are permitted to write orders and prescribe study agents for NCI DCP and DCCPS funded NCORP trials provided they are actively rostered as a non-physician investigator (NPIVR) in the NCI Registration and Credential Repository (RCR). Note: State law specified prescriptive authority and/or institutional policy may supersede this NCI guideline.

References:

1. Good M, Castro K, Denicoff A, Finnigan S, Parreco L, St. Germain D. National Cancer Institute: Restructuring to Support the Clinical Trials of the Future. *Semin Oncol Nurs*. 2020 Apr;36(2):151003. doi: 10.1016/j.soncn.2020.151003. Epub 2020 Apr 5.
2. Castro, K., Bevans, M., Miller-Davis, C., Cusack, G., Loscalzo, F., Matlock, A. M., Mayberry, H., Tondreau, L., Walsh, D., & Hastings, C. (2011). Validating the clinical research nursing domain of practice. *Oncology nursing forum*, 38(2), E72–E80.