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FAQ: Can our nurse practitioners (NP), physician assistants (PA), or fellows who are listed as co-investigators on the protocol write orders for the investigational agents?

Answer: No

The FDA issuance on the subject says, “312.53 Selecting investigators. A sponsor shall select only investigators qualified by training and experience as appropriate experts to investigate the drug.”

Appendix X of CTEP's Investigator's Handbook defines investigator as, "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." Throughout the Handbook, “investigator” refers to a physician (from the definition of the term).

As far as writing orders is concerned, CTEP's stance is that the only people who should be writing orders for investigational agents are individuals who could receive a shipment of the agent from PMB. In order for PMB to ship the agent, the investigator (physician) must be registered, active, and (outside of Group protocols) listed on the face sheet of the protocol. An investigator may allow a resident/fellow to write orders, but the investigator must co-sign the order.

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