



Monday Morning Practice Pearls #21

Who can write an order for IND agents (i.e., drugs & biologics)?

Pharma-held IND agents, CCR-held IND agents, & Investigator-held IND agents

Only licensed prescribers (MDs, NPs, or PAs) who are listed as an investigator on the FDA Form 1572 are allowed to order IND agents for a clinical trial. Note that there is ONE Form 1572 per site, per study. The Form is updated as needed.

ALL other licensed prescribers, must get the order co-signed by a Form 1572 MD Investigator. In CRIS, this means orders are entered *as an agent for*.

CTEP/DCTD IND agents

The following requirements are needed to be in place before licensed prescribers (MDs, NPs, or PAs) may write an order for a CTEP IND agent:

1. Have an [Identity and Access Management \(IAM\)](#) account for one the 2 roles below:
 - a. [Investigator \(IVR\)](#) — MD, DO, or international equivalent
 - b. [Non-Physician Investigator \(NPIVR\)](#) — advanced practice providers (e.g., NP or PA)
2. Once the IAMs account is established, register with NCI via the [Registration and Credential Repository \(RCR\)](#)
3. Listed on the site Delegation of Tasks Log (DLT) for the task “IND Prescribing” and have the site PI sign the DTL for the qualified NPIVR to conduct the task

At no time is a Registered Nurse allowed to order an IND agent regardless of who is the sponsor even if that nurse is listed on the Form 1572 as this is a licensing issue.