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| UNC HEALTH | Procedure Name | **Investigational Drug Services Authorized Prescribers** |
| | SOP # | **IDS SOP-14** |
| | Date this Version Effective | **01 Jul 2020** |
| | Responsible for Content | **IDS System Clinical Manager** |

## I. Description

This SOP describes the control processes undertaken by IDS to ensure that only orders entered by authorized prescribers are verified and dispensed.

## II. Rationale

Per regulations governing investigational medical practice, only authorized prescribers may submit orders for a given investigational protocol. To ensure that only orders from authorized prescribers are dispensed, up-to-date information regarding prescriber status will be given to IDS on a periodic basis.

## III. Procedure

### A. Authorized Prescriber Verification

1. The FDA 1572 form, also called the 'statement of investigator', delineates which providers, coordinators, and others involved in research activity for a given protocol are authorized by the PI as sub-investigators. Whenever the FDA 1572 is updated, IDS shall be notified and given the updated form.
2. If the study does not require a 1572, then all authorized prescribers must be listed on the IRB document for the study.
3. To write valid orders for a study protocol, a provider must be licensed by the state as a provider with applicable prescribing privileges *and* be listed on the 1572 or IRB document.
4. All authorized prescribers must complete good clinical practice and human subjects protections training and keep these trainings up to date per current IRB guidelines.

### B. CTEP ID Verification for Oncology Studies

1. NCI & Alliance policy requires pharmacy to ensure orders are received from providers with an active Cancer Therapy Evaluation Program (CTEP) ID when prescribing on cooperative group trials independent of a centralized clinical trials office. CTEP IDs are updated annually.
2. Study coordinators will provide IDS with information regarding CTEP IDs and expirations on a periodic basis and at any time that IDs or expirations change between periodic updates to IDS.
3. IDS staff will enter CTEP IDs and expirations into the electronic accountability system, which will notify IDS staff at the time of dispense if CTEP IDs are expired.
4. IDS staff will update CTEP IDs and expirations in the electronic accountability system within two business days of notification by study coordinators.
5. If a provider with expired CTEP ID enters an order, IDS will contact the study coordinator to discuss appropriate resolution of the problem.

## IV. Original Procedure Date and Revisions

12 Oct 2018 – Initial, partial release

01 Jul 2019 – SOP live

15 Jun 2020 – Revised to further clarify qualifications and documentation of authorized prescribers