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| UNC HEALTH | Procedure Name | **Investigational Drug Services Training** |
| | SOP # | **UNC IDS SOP-04** |
| | Date this Version Effective | **15 Jun 2020** |
| | Responsible for Content | **IDS Manager** |

## I. Description

This SOP describes the process and documentation of trainings performed by Central IDS and IDS Satellite pharmacy staffs.

## II. Rationale

Proper training is important and must be documented, whether this training is for general practices, CITI training, or study-specific trainings.

The goal of this SOP is to produce consistent practice to ensure compliance.

## III. Procedures

### A. CITI Training

1. All Central IDS staff will keep current and active good clinical practice and human subjects protection through the Collaborative Institutional Training Initiative (CITI) program.
2. CITI training must be renewed every three years.
3. IDS primary pharmacists at IDS satellite locations will also keep current and active good clinical practice and human subjects protection trainings through the CITI program.
4. Ancillary staff at IDS satellite locations are not required to perform CITI training as they practice under the oversight and supervision of the IDS primary pharmacist at their IDS satellite location. The IDS primary pharmacist, in turn, practices under the oversight and supervision of the Central IDS.
5. Certificates of training are retained and may be made available upon request.

### B. General IDS Practices Training

1. Central IDS maintains oversight of all training of staff at IDS satellites per UNC IDS SOP-02.
2. Central IDS staff are trained in all relevant aspects of IDS workflows and responsibilities under the supervision and direction of the IDS system clinical manager.

### C. Study-Specific Training

1. For each study, the lead pharmacist creates an information sheet and any other instructional documents as needed to meet the needs of the given study.
2. The lead pharmacist will distribute all applicable materials to all Central IDS staff and IDS primary pharmacists at satellites where dispensing on the relevant study will occur. Once Central IDS staff and any IDS primary pharmacists at applicable satellites have reviewed the materials, they will document their training. Training documentation may be made available upon request.
3. Training documentation will be done according to the standard process as designated by the IDS manager. Central IDS staff and IDS primary pharmacists will not document training on

sponsor-provided logs. Staff will also not document training in interactive response technology (IRT) systems, with the exceptions listed below under section D.

4. Trainings may include, but not be limited to: protocol review, investigational product (IP) receipt and storage, IP dispensing, IP preparation, returns and destruction of IP, accountability, documentation, IRT, and unblinding.
5. Updates and amendments will be reviewed by the lead pharmacist who will make a determination if there are substantive changes to the pharmacy practice that require re-training or any changes in practice. If the lead pharmacist determines that substantive changes are included in the update or amendment, the lead pharmacist will decide what form is best to do any re-training or updating of pharmacy staff and whether documentation of the re-training or update is required. If the update or amendment does not make substantive changes to pharmacy processes, no training will be performed or documented.

### D. IRT Training

1. If a study requires the use of an IRT system, a sufficient number of pharmacists as designated by the IDS manager will perform trainings to gain access to the IRT.
2. IDS staff will not perform trainings designated as required by the sponsor that do not pertain to pharmacist activity. It is the responsibility of the lead pharmacist to identify those trainings that are not applicable and to notify the sponsor. The lead pharmacist may coordinate this process with the IDS system clinical manager as needed. If the sponsor will not waive trainings designated as required and identified by IDS as not applicable to pharmacist activity, then a sufficient number of IDS pharmacists will perform these trainings and the sponsor will be invoiced a one-time training fee of an amount at the discretion of the IDS system clinical manager to cover the labor costs of the additional training.
3. IDS primary pharmacists at IDS satellites may or may not be required to perform trainings to gain IRT access. The determination of this requirement will be made for each study by the lead pharmacist, with the assistance of the IDS manager as needed.

### E. Online Study Management Systems

1. IDS staff will perform no trainings specifically for sponsor online study management systems.
2. Study documents, amendments, pharmacy manuals, etc. are provided to IDS through the IRB or by study teams, thus negating any need for IDS staff to have access to such systems.

### F. Delegation of Authority Logs

1. For details on delegation of authority logs, please see UNC IDS SOP-01.

## IV. Original Procedure Date and Revisions

01 Jul 2019 – SOP live

15 Jun 2020 – Revision to clarify when trainings for updates and amendments will or will not be documented. DOA details moved to SOP-01.