**Accountability (drug accountability):** The process of tracking investigational medications through the medication use process, including receipt, storage, picking, labeling, and dispensing. Most traditionally, ‘accountability’ applies specifically to the tracking and counting tasks throughout the process.

**Accountability, double:** When accountability is performed and documented by two individuals. Standard practice is that only one individual perform accountability.

**Ancillary staff:** Staff not specifically part of UNC Investigational Drug Services (IDS), but who may work with IDS to complete the work of research dispensing under the oversight of IDS. Ancillary staff can include but is not limited to pharmacists, pharmacy technicians, pharmacy residents, and pharmacy interns.

**Audit:** The act of deep review of records and practice. This information may be obtained through records review, interviews, discussions, or recorded data.

**Central IDS:** The team at UNC Health referred to as UNC Investigational Drug Services. This group is composed of those who work full-time in IDS-related activities.

**Central IDS liaison pharmacist (liaison pharmacist):** A full-time IDS pharmacist from the Central IDS team that acts as the liaison to an IDS satellite.

**CITI:** Collaborative Institutional Training Initiative. This organization provides educational courses in responsible conduct of research and other pertinent topics to conducting clinical trials.

**Continuous temperature monitoring:** Temperature data with data points every 15 minutes or more frequent will be considered to be continuous monitoring.

**Controlled access:** Access to an area with controlled access must be granted through a security system and entry is identifiable and measurable. A simple locked door, cabinet, or lockbox will not be considered controlled access.

**Double accountability:** See Accountability, Double.

**Electronic accountability system:** See ‘Vestigo’.

**EDC:** Electronic data capture.

**EMR:** Electronic medical record.

**Encapsulation:** The act of placing tablets or other materials into capsules. This is typically done for blinding purposes and opaque capsules are used.

**Epic:** The electronic medical record in use at UNC Health facilities.

**Hazardous medication:** Any medication that is deemed to pose a risk to healthcare workers who may handle it. For the purposes of investigational medications, hazardous status is often not certain and in these cases, a determination will be made by the assigned IDS pharmacist for a given protocol whether the medication will be considered hazardous.

**IDS satellite:** A UNC Health pharmacy location that has been evaluated by Central IDS and assists to provide research pharmacy services under the oversight of Central IDS.

**IDS satellite staff:** See ancillary staff.

**IDS satellite primary pharmacist (primary pharmacist):** A pharmacist on staff at an IDS satellite location who is the primary point of contact for IDS-related items at that satellite. This person works closely with the Central IDS Liaison pharmacist on decisions and ongoing studies at the applicable satellite.

**Interactive response technology (IRT):** Technologies that study teams or IDS interact with to receive information, often related to medication assignments for patients. Includes interactive web response systems (IWRS) and interactive voice response systems (IVRS).

**Investigational medication:** Any medication or supplement, whether previously FDA approved or not, being studied for efficacy or safety in the context of a clinical trial. If the medication or supplement is the intervention being studied, it is likely to be considered an investigational medication.

**Investigational product (IP):** See ‘investigational medication’. IP may include non-medication items (devices, etc.) but for the purposes of UNC IDS SOPs, IP and investigational medication are synonymous.

**Oversight:** In the context of these documents, oversight of one entity over another for pharmacy practice implies that the entity providing oversight oversees the activity and ensures proper practice. This does not mean that the overseeing staff/person/entity is continually present during activities or that the staff/person/entity practicing under their oversight is doing so under the auspices of the license of the staff/person/entity providing the oversight.

**Par level:** An inventory management term that refers to the inventory level targeted for stock on hand to purchase up to when the re-order level has been reached. In other words, when re-ordering, enough is ordered so that the par level is reached.

**Re-order level:** An inventory management term that refers to the inventory level where, once reached, more stock is purchased to ensure that the pharmacy does not stock out of the relevant inventory item.

**Research pharmacy:** Pharmacy activity specifically for clinical trials.

**Returns:** Investigational medications or associated items that have been dispensed and are returned to UNC IDS.

**SOP:** Standard operating procedure.

**Vestigo:** A web-based platform for study product accountability, record keeping, document storage, and billing. Also referred to as the ‘electronic accountability system.’ UNC IDS is endeavoring to store increasing amounts of documents electronically in order to make these documents more accessible. Vestigo servers are backed up in triplicate, meaning the risk of data or file loss is minimal.