**Drug accountability Language:**

The Principal Investigator is responsible for the management and accountability of the Investigational Product in a clinical trial at the site. For devices, the MICHR website has a device accountability log for the study teams to help manage these products. For investigational drug and biologic products (vaccines, allergenics, blood and blood products, and cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions, or injury, etc.), it is expected that you will use the University of Michigan Research Pharmacy (RP).

For investigational drug studies, the principal investigator can delegate the tasks for investigational drug management and accountability to the University of Michigan Research Pharmacy to assure compliance with local, state, and federal laws. When the RP is used, the RP will maintain drug accountability records using standard forms that are maintained per the regulations. However, the ultimate responsibility of investigational product accountability lies with the PI. In addition, we have provided a “Chain of Custody” form on the MICHR website that will help study teams track where the study drugs go after being picked up from the RP. If you have an Investigational New Drug study, you must use these or comparable documentation for drug accountability.

If the Principal Investigator obtains a waiver from using the RP for the study, the PI will be responsible for complying with all the regulations, including Michigan Public Health Code related to dispensing physicians, as well as the relevant University of Michigan policies. The drug accountability forms required for maintaining these records are not provided in these study templates. If you wish to obtain examples of these, you can contact the RP.

 Per eResearch section 15.2:

Per pharmacy Policy, investigational drugs used in humans in the UMHHC must be stored and dispensed by IDS pharmacy. Exceptions (waiver of IDS involvement) may be allowed in situations where it can be shown that storage or dispensing of the drug by IDS presents a hardship to the investigator, to study subjects or to the conduct of the study. In these cases, IDS (Research Pharmacy) shall assure storage, dispensing and inventory control criteria are met by auditing these processes. A "Drug" is defined as an article that meets any of the following criteria (as specified by state and federal regulations or standards set by national performance improvement organizations): criteria are met by auditing these processes.

For more information see the Research Pharmacy information

@: [Research - Home (umich.edu)](https://pharmwebsp.med.umich.edu/Research/SitePages/Home.aspx)