From: OC GCP Questions
To: [redacted]
Subject: FDA regulations
Date: Thursday, January 25, 2018 11:26:00 AM

Hi [redacted] –

The full list of the FDA regulations can be found below.

Clinical Trials and Human Subject Protection > Regulations

The drug regulations can be found below.

CFR - Code of Federal Regulations Title 21

Please see 312.58(b) –

Controlled substances. If an investigational new drug is a substance listed in any schedule of the Controlled Substances Act (21 U.S.C. 801; 21 CFR part 1308), records concerning shipment, delivery, receipt, and disposition of the drug, which are required to be kept under this part or other applicable parts of this chapter shall, upon the request of a properly authorized employee of the Drug Enforcement Administration of the U.S. Department of Justice, be made available by the investigator or sponsor to whom the request is made, for inspection and copying. In addition, the sponsor shall assure that adequate precautions are taken, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

Please see 312.61 –

Control of the investigational drug.

An investigator shall administer the drug only to subjects under the investigator's personal supervision or under the supervision of a subinvestigator responsible to the investigator. The investigator shall not supply the investigational drug to any person not authorized under this part to receive it.

The Center for Drugs (CDER) at drunginfo@fda.hhs.gov can help you with your specific drug questions.

Kind regards,

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