From: OC GCP Questions
To: [redacted]
Subject: DEA License Requirements
Date: Monday, June 19, 2017 11:06:00 AM
Attachments: [redacted]

Good morning -

We answered a similar question. Please see the information below.

According to the Controlled Substances Act (CSA), all persons who manufacture, distribute, dispense, import, or conduct research with a controlled substance must have a valid and current registration with the Drug Enforcement Administration (DEA). Generally, the dispersing and administration of the drug is carried out according to the drug's label unless the practitioner or primary investigator is conducting research under a FDA an NDA or IND that specifies otherwise. Furthermore, research can only be conduct to the extent determined under the authority of the state statute of that particular licensed practitioner, primary investigator or institution.

Under the supervision of an individually registered practitioner or investigator or an institutional primary investigator, only authorized personnel can dispense and administer a Schedule I -V drug to patients (21 CFR part 1301.22). Importantly, only a licensed practitioner, registered nurse, practical nurse under the direction of a DEA registered licensed practitioner can administer a Schedule II V drug to a patient for the indication of treatment of drug dependence, detoxification and withdrawal treatment (21 CFR part 1301.74(i)). Research with a Schedule I drug is much more rigorous since these substances have no approved or accepted medical use in the United States. A separate approval by the DEA is required for each individual protocol. This restriction applies to in vitro and preclinical studies, as well as human studies.

Dispensing and administration restrictions and exemptions of Schedule I V are based on business activities (i.e., practitioner/clinical facilities and hospital/testing hospitals; research institutions; narcotic treatment facilities (21 CFR part 1301.13):

-All Practitioners affiliated with clinical facilities and hospital/testing hospitals may dispense and prescribe a Schedule II V drug (also see 21 CFR part 1306.03).

-Exceptions are made for research institutions: for Schedule II V drugs, a prescription is not required. Note that the investigator is required to have all protocols approved by the institute's research committee and the Agency (FDA) (IND or NDA submissions). The institution and the Agency may require (due to type of drug; route of administration; potential adverse events) that a licensed practitioner or registered nurse administer drugs to human volunteers.

-Practitioners affiliated with narcotic treatment facilities not only need to be registered with the DEA but must be specially certified to dispense or prescribe Schedule II drugs that are approved by the FDA to manage drug dependence, detoxification and withdrawal. Individual practitioners are exempted from DEA registration, but must be specially certified for dispensing or prescribing Schedule III V drugs that are approved by the FDA to manage drug dependence, detoxification and withdrawal; however, a practitioner must still notify the Department of Heath and Human Services (HHS) (21 CFR part 1301.28).

-As it currently stands, under the Controlled Substance Act (CSA) Schedule I substances can only be dispensed and administered for research purposes by a DEA registered practitioner or primary investigator with an approved Schedule I protocol (21 CFR part 1301.18 & 1301.32). The registered practitioner or primary investigator is required to have all Schedule I protocols approved by their institute's research committee and the research, if it involves human testing, must be conducted under a NDA or with an accepted IND application.

If I have not adequately answered your question, please contact DEA directly.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Friday, June 16, 2017 11:48 AM
To: OC GCP Questions
Subject: DEA License Requirements

Dear GCP Questions,
For a study that involves a controlled substance, does the PI need to be the one with the DEA license or can he/she use a DEA license from one of the sub-I's?

I found the following from the DEA Practitioner's manual

https://www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html

Q Do all practitioners in a group practice need to be registered?

A An individual practitioner who is an agent or employee of another practitioner (other than a mid-level practitioner) registered to dispense controlled substances may, when acting in the normal course of business or employment, administer or dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he or she practices, under the registration of the employer or principal practitioner in lieu of being registered him/herself.

[redacted]

Kind Regards,

[redacted]