

--- A special DEA license is required to work with any controlled substance ---

The current list of controlled substances first originated with the Controlled Substances Act (“CSA”) passed by Congress in 1970 [1]. This legislation categorized regulated drugs into ‘Schedules’, weighing a drug’s medical benefits against its potential for being abused.

There are five schedules of controlled substances, I to V, with schedule I considered the most restricted and potentially dangerous. The list of substances provided in the schedules is updated annually. Approximately 160 compounds are currently included. Organizations that handle controlled substances (including practitioners, manufacturers, hospitals, drug treatment programs, laboratories and research institutions) must register and apply with the US Drug Enforcement Administration (“DEA”) for certification to handle specific restricted substances [2]. Depending on the business activity, a particular clearance category is specified during the application process. For a research and early development organization like Tioga Research, the application process comprises the following:

- The entity must first determine the schedule within which substances to be handled fall (a complete list is provided under the [DEA website](#));
- New registrations can be made by mail or completed online. Approved licenses are effective for 1 year, and renewals can be completed [online](#);
- For Schedules II through V a ‘blanket’ license provides for work on any one or more of the controlled substances in that Schedule;
- For Schedule I substances, a license is granted only for a specific compound or class of compounds²;
- For Schedule I substances, an organization can apply only by mail and must include the supplemental information detailed within [21 CFR 1301.18](#) along with their application;
- To work with Schedule I substances may also require state approval (in California such approval is provided by the [Research and Advisory Panel of California](#)).

With any licensed use, it is important to know which certification an organization carries if any controlled substance is to be transferred, for example between research facilities, as it is the responsibility of the sponsor organization to adhere to protocol in any such transfer.

Tioga Research maintains an active license to work with substances within Schedules I-V, has worked with select Schedule I substances, and is equipped to apply for additional Schedule I drug codes if necessary.

References:

[1] **Controlled Substance Law: Controlled Substances Act (CSA)** <www.hg.org/control.html> November 2015.

[2] **Controlled Substance Schedules**, <www.deadiversion.usdoj.gov/schedules/index.html> November 2015.

¹ This brief overview of the requirement to consider when working with any controlled substance is not intended to be definitive.

For formal guidelines the reader is referred to the [official DEA website](#) [2]

² For example, a license might be applied for and granted for work with tetrahydrocannabinols, or with gamma hydroxybutyric acid