

The HALT Fentanyl Act: What Researchers Need to Know (FAQ)

February 9, 2026

In July 2025, President Trump signed the Halt All Lethal Trafficking of Fentanyl (“HALT Fentanyl”) Act into law. This law included significant reforms to the federal requirements for research involving controlled substances. The Frequently Asked Questions (“FAQs”) below are intended to help individual researchers and research institutions better understand the potential impact of the law. These FAQs are not a substitute for legal advice—if you have questions regarding the applicability of HALT Fentanyl to your research activities, you should contact your legal counsel and home institution.

Importantly, numerous questions regarding the implementation of the HALT Fentanyl Act have not yet been addressed by the Drug Enforcement Administration (“DEA”). BrainFutures will be advocating for DEA to issue appropriate regulations and guidance, and to establish appropriate processes in a timely manner so that researchers can reap the benefits of the HALT Fentanyl Act that Congress intended. If your organization is interested in collaborating with BrainFutures on these efforts, please contact Jazz Glastra (jjglastra@brainfutures.org) or Sarah Norman (snorman@brainfutures.org).

Q1. What are the key research-related reforms enacted as part of the HALT Fentanyl Act?

The HALT Fentanyl Act makes five important reforms to controlled substance research. The Act:

1. Expedites the process for initiating research with Schedule I controlled substances;
2. Permits agents and employees of the same institution to conduct research under a single DEA researcher registration;
3. Allows related research sites to conduct research under a single DEA researcher registration in certain circumstances;
4. Clarifies the manufacturing-related activities that are permitted under a DEA researcher registration; and
5. Enables research to continue if a substance is classified into Schedule I during the course of research.

Q2. How does the HALT Fentanyl Act expedite the process for initiating research with Schedule I controlled substances?

The HALT Fentanyl Act reduces administrative burdens for initiating research involving Schedule I controlled substances by establishing an expedited notice process with DEA in lieu of the existing Schedule I researcher registration process, which many researchers have viewed as onerous and, at times, unpredictable. Under the HALT Fentanyl Act, eligible research projects can proceed on a notice basis without DEA needing to review and approve individual research protocols.

To qualify, the research must either (1) be the subject of an active investigational new drug application (“IND”) or (2) be conducted by or funded in whole or in part by the Department of Health and Human Services, the Department of Defense, or the Department of Veterans Affairs. The notice to DEA must include:

1. The controlled substance to be studied;
2. The quantity needed;
3. Proof of eligibility (e.g., IND number and sponsor name or a federal grant number); and
4. Evidence of authorization to conduct the research under the applicable state law, as many states impose their own requirements (including obtaining permits) for controlled substances research.

If the investigator already holds an active DEA registration to conduct Schedule I or II research, the study may begin 30 days after DEA receives the notice—no additional DEA approval is required. If the investigator lacks such a registration, DEA must treat the notice as a complete application for registration and, within 45 days, either issue the registration or serve an order to show cause proposing denial.

Q3. How does the HALT Fentanyl Act alter registration requirements for researchers within the same institution?

The HALT Fentanyl Act allows agents or employees of the same institution as a DEA-registered researcher to conduct research under that researcher’s registration, rather than obtaining their own separate researcher registration, when specific conditions are met.

The DEA-registered researcher must notify DEA and provide the following information:

1. the name, title, and employer of each agent or employee working under the registration;
2. an explicit authorization from the DEA-registered researcher for the agent or employee to perform research under the registration; and
3. an affirmation that the registered researcher is responsible for the individual’s conduct with respect to the controlled substance.

Unless DEA objects within 30 days of receiving the notice, no separate DEA research registration is required for the agents or employees described in the notice.

Q4. How does the HALT Fentanyl Act impact registration requirements for research sites controlled by the same institution?

In the past, the DEA required a distinct researcher registration for every “principal place of business or professional practice,” even if several investigators at one institution were working together on the same study. Under the HALT Fentanyl Act, one researcher registration can cover multiple sites when those locations are in the same city or county and are under the control of the same institution or organization. This approach will cut down on duplicative registrations across labs and clinics within a single institution operating in the same city or county.

The HALT Fentanyl Act requires that researchers give DEA advance notice before using a site for research or for storing or administering controlled substances. That notice may be included in the initial registration application or submitted separately, but it must be provided before the site is used for research, storage, or administration.

Sites located in different cities or counties, or sites not under the institution’s control, will still require separate DEA researcher registrations.

Q5. How does the HALT Fentanyl Act impact manufacturing of controlled substances used in research?

Existing DEA regulations permit researchers to conduct certain manufacturing activities for research purposes without having to obtain separate manufacturing registrations. The HALT Fentanyl Act modifies existing requirements by permitting authorized researchers to manufacture small quantities of the controlled substance that is the subject of the research if they notify DEA of the activities and amounts by either (i) an expedited Schedule I notice (as described in Q2 above), (ii) a traditional researcher registration application, or (iii) a standalone submission identifying the registrant and attesting that the work fits within the scope of the registration. The HALT Fentanyl Act does not define “small quantity” – DEA may further explain this term and the parameters under which manufacturing incidental to research will be permitted through rulemaking. The Act also permits dosage-form development for Schedules II–V controlled substances under a researcher registration when done to prepare an IND for FDA. These reforms do not apply to marijuana cultivation.

Q6. What happens if the controlled substance used in research is moved to Schedule I in the middle of a study?

If a drug is reclassified to Schedule I while research is underway, the HALT Fentanyl Act provides a way to keep the work going. A researcher who already holds a Schedule I research registration may submit an application to add the newly scheduled substance to their research activities. Once that application is filed, the study may continue—including receiving material from manufacturers and distributors—unless and until the researcher withdraws the application or DEA issues a proposal to deny it. This provision does not apply to researchers without Schedule I research registrations – such researchers must apply for and obtain Schedule I research registrations. The expedited avenue described under Q2 is available for these researchers.

Q7. Does the HALT Fentanyl Act affect the applicability of any state laws regulating controlled substance research?

No, the HALT Fentanyl Act does not preempt or affect the applicability of state laws that apply to controlled substance research. Researchers must be mindful of any state registrations, permits, or licenses that may be needed for their research.

Q8. How is DEA implementing the HALT Fentanyl Act?

The HALT Fentanyl Act authorizes DEA to publish regulations implementing the law as interim final rules, meaning they become effective upon publication. After publication, stakeholders will have an opportunity to submit comments, and DEA can then revise and finalize the rules in light of that feedback. The HALT Fentanyl Act requires that DEA issue these implementing regulations within six months of enactment (i.e., by January 16, 2026). However, the DEA did not meet this deadline, and it is not apparent when these regulations will be published.

Although the HALT Fentanyl Act became effective immediately upon enactment, DEA has not published any rules (proposed or final), guidance, or other policy statements explaining how interested researchers may take advantage of the research reforms provided under the law. This leaves open many practical questions for researchers, including how and where to provide notice to DEA for the various processes specified in the law (e.g., notice of Schedule I research via the expedited registration process, notice of employees or agents operating under the same researcher registration, or notice of related research sites controlled by the same institution). BrainFutures will encourage DEA to issue appropriate regulations and guidance, and to establish appropriate processes in a timely manner so that researchers can reap the benefits of the HALT Fentanyl Act that Congress intended.

BrainFutures is grateful to the following people for providing feedback on this document:

- **Albert Garcia-Romeu, PhD**, Associate Director, Johns Hopkins Center for Psychedelic and Consciousness Research
- **Charles L. Raison, MD**, Professor of Human Ecology and Psychiatry, School of Medicine and Public Health, University of Wisconsin-Madison
- **Frederick Barrett, PhD**, Director, Johns Hopkins Center for Psychedelic and Consciousness Research
- **Shane A Pennington, JD**, Partner, Blank Rome LLP

Participation as a reviewer does not imply endorsement of this document.