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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Revision to the Department of Health and Human Services Guidance on Procedures for the Provision of Marijuana for Medical Research as Published on May 21, 1999.

AGENCY: Office of the Secretary, Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Announcement of the elimination of the Public Health Service (PHS) review of non-federally funded research protocols involving marijuana and the utilization of the existing Food and Drug Administration (FDA) Investigational New Drug (IND) process for drug development.

DATES: Effective June 2015.

ADDRESSES: Not applicable.

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SUPPLEMENTARY INFORMATION: On May 21, 1999, the PHS review process was established in response to enhanced interest by the biomedical research community in determining the potential therapeutic benefits of marijuana. The original notice of policy change

can be found at http://grants.nih.gov/grants/guide/notice-files/not99-091.html**.** The PHS review process, which includes a committee review of study protocols, helped create a pathway for non-federally funded researchers to conduct these studies. In order to further facilitate research, HHS recently re-evaluated the PHS review procedures to identify opportunities for increased efficiency. The Office of the Assistant Secretary for Health (OASH), in consultation with the National Institutes of Health (NIH) and FDA, determined that the PHS review overlaps in several important ways with FDA's IND process and is no longer necessary to support the conduct of scientifically-sound studies into the potential therapeutic uses of marijuana. The PHS review committee considers the following: research quality; incorporation of elements of good clinical and laboratory research practices; emphasis on adequate and well-controlled clinical studies; and development of dosage forms of marijuana that would be an alternative to smoked marijuana. The FDA's IND review process considers similar research characteristics: adherence to good clinical and laboratory practices; whether pivotal clinical trials to support the marketing of proposed drug products are adequate and well-controlled; and the therapeutic benefits and risks to study subjects, favoring dosage forms that would provide measured and consistent dosing to patients as well as reduced exposure to potentially harmful constituents. Therefore, while not identical, the two processes have similar goals (e.g., guiding research on drug development and assuring appropriate treatment of human subjects), share similar criteria for protocol reviews, and possess similar capacity to engage with federal experts for consultation. Based on these considerations, and in order to streamline the application and approval processes for cannabis research, the committee that conducts the PHS review shall be eliminated. Below are instructions for researchers interested in the acquisition of cannabis for medical research. Complete guidance can be found on the NIH/National Institute on Drug

Abuse (NIDA) website: (http://www.drugabuse.gov/researchers/research-resources/nida-drug-supply-program).

Background

Under the 1961 international Single Convention on Narcotic Drugs (amended in 1972), cannabis is designated a Schedule I substance, and participating countries are required to restrict production, manufacture, possession, and distribution of marijuana except for medical and scientific purposes. The Drug Enforcement Administration (DEA) regulates the cultivation of marijuana for research purposes through licensing requirements and establishment of annual aggregate production quotas under the authority of the 1970 Controlled Substances Act (CSA), which implements the Single Convention.

Marijuana for use in research can be obtained through the NIDA Drug Supply Program. All applicants must fulfill the following criteria:

For non-NIH funded human research projects:

1. Demonstrate scientific validity and ethical soundness through review by the FDA's IND process. Research protocols will undergo a scientific review which assures the safety and rights of subjects and the scientific quality of the clinical investigations, and assesses the likelihood that investigations will yield data capable of meeting the statutory standards for drug marketing approval; and
2. Possess a DEA registration for marijuana, a Schedule I controlled substance under the CSA.

For NIH-funded projects:

1. Demonstrate scientific validity and ethical soundness through the NIH grant review process which consists of three steps: (1) the NIH peer review system, which assesses the scientific and technical merit of all grant applications; (2) the National Advisory Council of the funding institute, comprising eminent scientists as well as public members; and (3) the funding institute's Director, who makes the final funding decision on the merit of an application, based on peer review, public health significance, and institute priorities. To find studies approved through the NIH review process go to: http://projectreporter.nih.gov/reporter.cfm;
2. Have an active-status IND application on file with the FDA (for human research only), which has been evaluated by FDA and found safe to proceed. For additional information go to: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm; and
3. Possess a DEA registration for marijuana, a Schedule I controlled substance under the CSA.

Once the above steps have been completed, investigators should contact the NIDA Drug Supply Program to place an order for marijuana with specific characteristics with regard to concentrations of delta-9-tetrahydro-cannabinol (THC), cannabidiol (CBD), and other cannabinoids. The program official will verify that the application is complete (with all the above-mentioned steps fulfilled), and forward the order on to the contractor responsible for shipping the marijuana. While not required in all cases, it is recommended that researchers contact the NIDA Drug Supply Program early in the planning of a study to obtain information on

specific strains of marijuana available so that this information can be included in the protocol and IND (http://www.drugabuse.gov/researchers/research-resources/nida-drug-supply-program).

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