



To: Members of the State Board of Health

From: Ken Gershman, MD, MPH, Manager, Medical Marijuana Research Grant Program

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Date: November 20, 2015

Subject: Interim Progress Report of the Medical Marijuana Research Grant Program

This report represents the initial progress report to the State Board of Health (BOH) required by § 25-1.5-106.5, C.R.S. for the Medical Marijuana Research Grant Program. This new grant program was created effective July 1, 2014 after the Governor signed SB 14-155.

A Request for Applications (RFA) was released on September 3, 2014. In response, 47 grant applications were submitted that met technical requirements for scientific review. Initially, the Scientific Advisory Council (SAC) recommended eight grants to the BOH for funding. These recommendations were approved by the BOH in December 2014. However, the total funding approved (which included up to 10% contingency funds per grantee if needed during the contract negotiation process) was less than the \$9 million authorized to fund the grants. The Department identified, and the SAC approved, a ninth grant to be recommended to the BOH for funding, along with proposed increases (above the 10% contingency funding) which were identified during contract negotiations and considered appropriate, for three of the grants. The BOH approved these recommendations at the February 2015 meeting, bringing the total approved funding to \$9 million for the support of nine studies, each of 3 years duration.

Six of the research grants are for observational studies which only require approval by human subjects review boards (i.e., IRBs), and no federal approvals. The other three research grants are for randomized clinical trials (RCTs) which require both IRB approvals and multiple federal agency approvals (i.e., FDA, NIDA, and DEA). The three RCTs are, therefore, expected to require more time to obtain all necessary approvals than the observational studies.

All six observational studies have obtained IRB approval and contracts were executed by October 1, 2015. The first three contracts were executed in April, June and August, and the remaining three were executed on October 1 (see table below).

The three RCTs are at various stages of submission/preparation and review at the federal agencies and local IRBs (see table). Based on current assessments of the principal investigators, all three RCTs are projected to receive required approvals and be contract ready by spring 2016, which would allow for adequate time to complete these projects within the authorized timeline. The Department will continue to monitor progress closely, and as necessary begin contingency planning in early 2016.

The following table summarizes contract execution dates and implementation progress of the six observational studies, along with submission and approval progress of the three pending RCTs.

Medical Marijuana Research Grants - Progress Updates Through 10/1/2015*

Grant – Short Title & [PI]	Contract Start Date	Progress
Observational study of high CBD oils for pediatric epilepsy: [Dr. Kelly Knupp]	April 10	<ul style="list-style-type: none"> • Database developed • Study promoted to neurologists • Piloting of study flow to prepare for “ramp-up” • <u>5 study subjects enrolled</u>
Observational study of marijuana use and quality of life in children with CNS tumors: [Dr. Nicholas Foreman]	June 30	<ul style="list-style-type: none"> • Purchased study supplies • Developed subcontract between UCD and Children’s Hospital (execution pending) • <u>Enrollment pending</u>
Observational study of marijuana for sleep disorders: [Dr. Russell Bowler]	August 1	<ul style="list-style-type: none"> • Hired clinical research coordinator • Purchased study equipment & supplies • NJH Sleep Clinic agreed to help recruit subjects • <u>1 study subject enrolled</u>
Observational study of marijuana for Inflammatory Bowel Disease in adolescents & young adults: [Dr. Edward Hoffenberg]	October 1	[Study implementation underway]
Observational study of marijuana for PTSD: [Marcel Bonn-Miller, Ph.D.]	October 1	[Study implementation underway]
Observational-pharmacokinetic study of high CBD oils for pediatric epilepsy: [Dr. George Sam Wang]	October 1	[Study implementation underway]

Grant – Short Title & [PI]	Contract Start Date	* Progress [through October 26]
RCT of marijuana for PTSD in veterans: [Marcel Bonn-Miller, Ph.D.]	TBD	Construction (building renovation) pending at Arizona study site with completion estimated in early December, then DEA can approve this site. Submission of protocol for DEA review will take place by end of October. All other approvals have been obtained (or provisionally obtained).
RCT of cannabidiol (CBD) for Parkinson’s Disease tremor: [Dr. Maureen Leehey]	TBD	Final agreement with pharmaceutical company regarding supply of study drug (cannabidiol - CBD) pending. UCD scientific review committee and FDA submissions to follow.
RCT of marijuana versus oxycodone for chronic spine pain: [Emily Lindley, Ph.D.]	TBD	Submitted to UCD scientific review committee on 10/19; once approved will submit to FDA and then local IRB