Research Subcommittee Meeting Minutes

Date: May 18, 2018

Time: 2:00 pm – 4:00 pm

Location: Portland State Office Building, 800 NE Oregon St., Portland, Oregon

Attendees:

OCC Attendees: Esther Choo, Thomas Jeanne (standing in for Katrina Hedberg)
Subcommittee Members:
Subcommittee Members On phone: Peter Barr-Gillespie, Jane Ishmael
Guests: Collin Roberts
OMMP/OHA Staff: Carole Yann and Shannon McFadden
Members of the Public as listed on the Sign in sheet: Michael Rochlin, Melissa Egan, Aaron Ford, and Sunnie Sanchez

Subgroups	Responsible Party
Research	Esther Choo and Katrina Hedberg (leads)

Welcome and Introductions by the Oregon Cannabis Commission

Topic	Key Discussion	Responsible

Review of first Draft of proposal for Cannabis Research Center	Outline of legislative proposal for research: There is a need for research that expands our understanding of the health effects of cannabis with greater specificity of products. The state of Oregon will establish a Cannabis Research Center (CRC) devoted to advancing science related to the health effects of cannabis consumption. According to the Senate Bill 844 Task Force report, such a body "will be capable of driving forward critical research at a much faster pace than other similar attempts have been able to…No other single initiative could do as much to strengthen the Oregon cannabis industry and to support the needs of Oregon medical marijuana patients." 1. **Goals**. The CRC will develop lines of inquiry within three general priority areas defined by the state (in HB 2198): cannabis-related public health policy and public safety policy; agricultural and horticultural best practices; and medical and pharmaceutical best practices. Within those areas, priority topics may include (as outlined within SB 844): a. Basic plant and agricultural research. Studies on the cannabis plant to fully understand the medicinal properties of the plant. b. Public health research. Research projects designed to assess impacts of policies (such as those relating to time, place and manner of sale) on use, attitudes, and health effects critical to	Esther Choo/Katrina Hedberg

	developing policies and procedures for cannabis retail and medical distribution systems, as well as to inform interventions to mitigate potential negative impacts of cannabis legalization; public health questions around cannabis involving toxicology and contamination issues relating to cannabis grown in Oregon. c. Observational studies related to the medical benefits of cannabis, which will provide evidence of the likely medical and public health benefits of cannabis and preliminary information for the development of clinical research studies. d. Pre-clinical research. Research establishing the safety and efficacy of cannabis and its components necessary to obtain FDA approval to conduct clinical (human) research. e. Clinical research (meeting FDA standards). Rigorous clinical trials meeting FDA standards necessary to develop the evidence base for use of cannabis use in Oregon and lead to products FDA approved for medical use. 2. **Structure**. The CRC is conceived as a collaboration across academic institutions, housed within Oregon Health & Science University (OHSU), given its focus on health effects, and with potential co-leadership by OHSU and Oregon State University (OSU). Member investigators will have	

	established experience in cannabis research relevant to public health and medical care. 3. **Funding**. Oregon legislature will allocate cannabis excise tax receipts (?) and OMMP fees to support the CRC, to a total of $10 million over 3 years. A portion of the funds will provide administrative support for the Center. The remainder of the funds would establish a grants program. Although Center investigators will pursue federal and other sources of support, a foundation of sustained support from the state will ensure the long-term success and effectiveness of such a program. 4. **Grant administration.** The CRC grants program could support both internal grants, which would be awarded to Center investigators, and external grants, which would be awarded to investigators from public and private entities outside the Center. Both programs would be administered through a competitive process with a rigorous external peer review process, similar to an NIH grant program, and with input from the Oregon Health Authority. This process will be designed to maximize support for research that will be of the highest possible impact in the scientific community; that will answer critical questions necessary to promote the health and safety of Oregonians; and that will support	

	best practices and policies for the Oregon Medical Marijuana Program (OMMP). Additionally, the peer review process will be designed to guard against funding research that is biased in favor of or against particular outcomes, or that brings up potential conflicts of interest. Grants would focus on innovative early stage research that will generate the data necessary to obtain external federal grant funding. The funds could also be used to support critical areas of cannabis research that are not likely to be funded by NIH or other federal agencies. 5. **Other functions:** With sustained funding, the Center has great potential to develop a workforce for innovative, dynamic, state-of-the-art research related to cannabis. Resources and activities may include: a. A centralized, secure, web-based research participant registry for OMMP members or other citizens who want to learn about getting involved in IRB-approved research studies involving medical cannabis. b. Creation of partnerships and data-sharing arrangements with other institutions and relevant state agencies in order to assemble, organize, and make available as much collected data as possible on the use of cannabis in the state of Oregon.	

	c. Standardized administrative, educational, training, and structural support for university-based researchers in Oregon working on cannabis-related issues in order to expedite the process of obtaining federal approvals for research. d. In-depth institutional understanding of policy and other barriers to cannabis research, establishment of appropriate recommendations to state agencies in addressing those barriers, and creation of internal or collaborative routes toward completing research that is hindered by such barriers e. Partnerships, collaborations, or contractual relationships with public and/or private entities within the U.S. and other countries in furtherance of the Institute's objectives	
Discussion with Peter Barr-Gillespie, Cindy Sagers about creation of joint center	Peter Barr-Gillespie • A new center would have to be approved by the president and Dr. Robertson who will be stepping down and turning over his role to Dr. Danny Jacobs on August 1st. Nothing will get approved until Dr. Jacobs gets there and it would be his call. So, this creates a timing problem because Dr. Jacobs won't be able to approve anything such as this on day one.	Peter Barr-Gillespie

	It is encouraged however to get a proposal into Dr. Robertson now even though he won't be making the decision. Also, Centers do need to be self-sufficient. • Peter Barr-Gillespie's department can put forth a small amount of money to get the center off the ground which would help administratively. Having a web presents early on will be important and that will be something that can be built off with. • Doesn't think it will hit a significant pushback for the study of a schedule 1 drug. Dr. Collin Roberts – Associate professor of pediatrics and neurology-Child Epilepsy Specialist-Direct the Epilepsy center for children's Doernbecher • Many of parents are enthusiastic to get their children in this study – using a pure form of cannabidiol. These children's disease is quite severe so we'd be able to notice a change in the study than using someone that had more of a milder form. Two companies to choose the cannabidiol from and they could verify what it was, how much of it was there, how stable it was. The things you'd need to know to be comfortable using it in a clinical trial, especially one with children. There is no shortage of people who are interested in using it in a clinical study.	Collin Roberts

	We are in a very exciting point in the epilepsy community which we could help a large number of children and adults who are not getting the benefits of our current therapies.	
Public Comment	Michael Rochlin-independent cannabis nurse/advocate I have a couple questions in reference to current treatment like what Dr. Roberts was saying, in terms of standardizing information, facts, templates sheets whatever for practicing medical folks, practitioners/clinicians and seems to me that some of this falls in that category where under goals you have, Plant agricultural research which is significant. You need to understand medicinal properties although there is a lot of literature out there and a really good solid literature review from OSU would be awesome. Public Health Research which is significant that's where we not only get into health but into safety. There are concerns about the supply chain. The current supply chain from what I understand talking to some of the expert lab professionals in the state wouldn't be suitable in some cases for medicinal use because immunosuppressed or sensitive individuals might be susceptible to low level pesticides or whatever's in there that we haven't regulated so this is beyond regulation. We are talking about certainly research public health interventions and that's what I am excited about and	Public

	I think that is really a high priority because we already got legalization folks are using this in a massive scale of course we didn't have the testing standards we have now but still I think we need to take a step forward when I see this the one maybe two issues I don't see on here specifically although there is pharmaceutical which is important and has to do with the chemical constituents as well as the testing but also the biomarkers the things that go along with that. So, to me the question that I would have in having the academic medical center being the focus of the study would be could we have any kind of services count towards the grants and all that doesn't necessarily cut costs incremental so whether the state public health, state public health lab maybe that. What I am saying is there are some other methods to the gender sum cost effective things that could do short term and long term which might set the stage for further research center so we don't have to a lot of cash flow up front, external money. Cost some money but it's not the same as paying a third-party lab outside of our existing resources, there personal budgets and things. But for clinical issues I think what you had here with toxicology and contamination are significant. I think it's what we don't know that would hurt us more than what we do already know. We have some data and so the laboratory issues toxicology	

	as well as it kind of covers both. It covers the agricultural part and it covers the medicinal part/clinical part and needs to be combined in some way and it's a hybrid so when we do, not so much the clinical research if you will but we can just do this observationally you know we can do observational research with biomarkers and retesting or doing some objective testing with constituents in there and that way we'll know for sure what we're giving or getting being delivered to them rather than just CBD and THC because that's what's going on now pretty much those two make major constituent cannabinoids and some basic contaminate testing and so as a c, d, and e on the goals if they are really good in that order because I think we can do a lot of observational studies at fairly low cost compared to return for some of this information as well as developing some of the medical benefits that can help the providers that's what I am looking for, the clinicians are practicing have. In the training subcommittee talked about this, standardizing nomenclature trying to come up with some facts and there was a wonderful idea about a clearing house for the experts to develop this expertise because that's what we are doing now. We are amercing ourselves in developing some expertise and we'd sure like to centralize it to have it in a house setting so we can collaborate and certainly more than just here in	

	Oregon but starting here and then moving to California because they've been around a long time and certainly going forward I am hoping that the state, I know we have a governor who is very proactive in this event that would want to help see our way to getting some funding but it's our legislature that has to do that so with OHSU which I think has the reputation and the credentials and the pathway already and need to establish a certain pathway to get there with industry collaboration. I see that also being available that current industry that's there that is providing product in the state made promises three years ago that they were going to contribute to this not necessarily with money but at least products but some said money too and without that they are not going to get the health plans that they needed and I think that is the collaboration that I am looking for in here and I don't see that directly, I know that you intended it to happen but the patients and the growers especially that have done a lot, that have information and maybe it may sound antidotal but there are some people that have been for years collecting information on their patients and would be valuable as a baseline so I think this is really well laid out and not really	

	adding much to it except that I really endorse the concept and I am hoping that we can get some movement on this before the end of the year.	