



Sean Kiernan <calbears72@gmail.com>

Re: Friendly Advice

1 message

Ryan Vandrey <rvandrey@jhmi.edu>
To: "skiernan@wfwproject.org" <skiernan@wfwproject.org>

Sun, Apr 16, 2017 at 7:39 PM

Sean,

I can't really point you to anywhere that provides details about the other studies, but I can give you brief descriptions.

Marcel's observational study involves recruiting individuals with PTSD who are and are not using cannabis and following them over time. We are not administering cannabis, but are getting study participants to tell us what they are using and then we get samples of those products and send them for testing to determine cannabinoid content. Anyone who lives in CO and is interested can contact Megan Brunstetter at megan.brunstetter@va.gov or 303-399-8020 ext. 4009 for more info.

The Realm of Caring research I am running can be found here: <https://www.theroc.us/orr> Anyone is welcome to participate and we have survey content built specifically for folks with PTSD as an additional component. If you could spread the word, it would help us a lot. These are just internet surveys, but we again follow people over time (survey every 3 months) and ask details about cannabis and other medication use as well as assessments of quality of life, pain, mood, sleep, etc.

If you have additional questions about these studies, just let me know.

Regarding the MAPS protocol, nothing heroic had to happen for them to continue. When I decided to withdraw from the study, I notified the state of Colorado that I was withdrawing from the study and wanted to give back the money. Period. They said that they valued my participation in the study and asked me if I wanted half the money to keep doing the study independently from MAPS, as a direct subcontract from the State. I told them that half of the study would not be enough to draw any conclusions, it would be a waste of that money, and my intention was not to sink the study. After some deliberation I offered to give them a proposal for a new study on PTSD that I could complete, in entirety, with half the money. In that scenario MAPS could run as much as they could with the other half of the CO money and use MAPS money for any remaining need (they were initially going to fund this study themselves entirely). CO said that would not work on their end because the money was specific to the protocol that was submitted. Thus, it was actually very simple and that whole discussion happened within 24 hours. Not sure who told you that heroic efforts were undertaken, but that seems completely out of place from my vantage point in all of this. I will also mention that the only reason MAPS ever got to this point is because Marcel and I completely redesigned their original protocol and wrote the grant to the state of CO. They like to complain about how the feds wouldn't approve their study because they don't want to approve a study on the health benefits of cannabis. The real truth is that MAPS couldn't get approval because they had a horrible protocol that wouldn't pass review at the federal level because it was bad science, and because none of the people involved had any credible research experience. Neither Rick or Sue are trained in the conduct of clinical research, they misunderstand a lot of important nuances to doing good clinical research, and I would have to argue on every phone call to get them to agree to very fundamental protocol decisions. Rick has good scientists on his team at MAPS, but he often ignores their feedback and insists on doing things the way he wants, which created big problems.

That leads to your last point... why don't we go public with our reasons for dropping out? If I do that, I think it will sink the study. I have major concerns with how Rick and Sue are running the study, I have major problems with them compromising the integrity of the protocol by using it as a basis for leveraging their own political and personal agendas, and I lost all trust and a lot of respect for them with the PBS piece and how the testing of the NIDA product was handled. That said, I may be wrong about what I believe are major issues with their ability to complete this study the right way. I truly hope that they are able to push forward and get a good study done, and I want them to succeed or fail on their own merits, not based on my beliefs. However, I reached a point where I couldn't trust that the study was going to be conducted in accordance with the standards of science that I hold for myself, and I no longer wanted my name or the Johns Hopkins name associated with the study. The JHU PR group never said that NIDA cannabis was a reason for our decision to withdraw. I worked with them through the whole thing and was copied on all correspondence. Many things that came out in the media reports were things that were either pulled from your letter, things that came from MAPS, or were speculation on the part of the reporters. I can appreciate that folks want more answers, but in this case I think it is better for all involved that some people get worried about what a carefully crafted media relations post is hiding than to know the whole story.

Again, the decision to withdraw came from me. When that happened, I brought my concerns to the JHU leadership and my study team. I told them that because of my concerns, I wanted to give back the money and withdraw from the study. Everyone I talked to agreed that it was the right decision to make. We also all agreed, that it would be best to do so quietly and not raise a big public issue about it. I also helped write the media release and stand by what it said. To reiterate, I am not aware that MAPS has done anything that is in violation of any regulatory rules or against the study protocol, so there is no need for me to publicly point fingers. However, my staff was frustrated working with them, I was frustrated working with them, and in the end it was no longer worth it to remain involved. I am glad that both Marcel and Paula Riggs remain involved with the study. They have the requisite experience to guide it. We will see how things unfold over the next 2 years... In the meantime, I feel like I have plenty to offer through other research projects that I am truly excited about and happy to be a part of.

I have gone into much more detail here that I ever intended to disclose, and I again ask that you respect this and keep this to yourself and not share.

Regards,

-Ryan

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On Apr 16, 2017, at 3:02 PM, skiernan@wfwproject.org wrote:

Ryan,

Thanks for the reply

We are not going to agree at all on the phone call issue. I can assure you, I personally called, other veteran testimonials state they called both the numbers listed on the advertisement and yours personally. In fact, I am in receipt of audio recordings of veterans leaving messages on multiple lines at Johns Hopkins to include yours. However as you state, we are just going to disagree on this issue obviously and honestly, it isn't the issue I care to push.

I would love to learn more about your PTSD treatment study with Marcel, a scientist we are very familiar with. Can you point me in a direction where I can read more about this study.

I am also very familiar with the Realm of Caring Foundation started by the Stanley Brothers. Can you point me in the direction of more information. I have read about Stanford's involvement with the Realm of Caring but as of yet, didn't know JHU was involved.

Also, can you explain to me how the above studies are similar and different to MAPS study using full plant cannabis with FDA, DEA, and the myriad of approvals gained?

Regarding MAPS continuation of that study, it is my understanding the study almost failed due to Johns Hopkins withdraw. If not for the heroic work of many individuals involved, MAPS study would be DOA. Would you agree or disagree with that characterization and was that risk discussed before withdrawing.

Once again, I appreciate the conversation and I hope you can understand, the intentions of your withdraw are completely unknown to most of the world. I think it would be wonderful if Hopkins publicly responded on why they withdrew in much greater detail then to state it was simply over a disagreement and that was after your media relations department accused the NIDA supply of cannabis as the sole reason. Of course, only to change their story later.

I also hope you can understand why the veteran demographic isn't the most trusting of promises, pledges or carefully crafted responses by media relations that seem more intended to deflect then to honestly address the problem at hand.