



Sean Kiernan <calbears72@gmail.com>

Re: Friendly Advice

1 message

Ryan Vandrey <rvandrey@jhmi.edu>
To: Sean Kiernan <calbears72@gmail.com>

Mon, Apr 17, 2017 at 10:56 PM

Sean, see below.

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On Apr 17, 2017, at 10:10 PM, Sean Kiernan <calbears72@gmail.com> wrote:

Ryan,

Thank you. You have said a lot and it is appreciated, with so many points, I am just going to number answers to your questions/points/or further questions. Feel free to answer in your way. I am truly trying to understand what went wrong and what could go wrong in the future. All I care about is getting the science out there.

1) I put you on the mailing list for our releases. Today was a letter to Sessions. I am happy to remove you if you wish.

Why did the cc address on this e-mail read "president@jhu.edu? Please tell me you did not send that to the president of JHU... If you did, please stop sending anything to him. This is not anything that you are going to get their public support for and I prefer to fly under the radar with the suits.

2) Can you explain to me what is the pragmatic difference between MAPS study and most other observational studies on cannabis. I believed it to be unique on many fronts but specifically in the fact it was using NIDA cannabis which is required for many of the approvals received and publication was differentiated from many of the studies conducted to include the ones you described below. I could be way off, any color would be appreciated.

Main difference is that a certain type of cannabis is randomly assigned to study participants in the MAPS study versus just trying to determine what folks are using on their own in the observational studies. That is a big deal in research. The NIDA cannabis gives us a consistent drug (all one homogenized batch), and we control who gets what and when. In the real world, people use all kinds of stuff, which introduces variability in the response from one day to the next and tracking and testing is very difficult.

3) What does Hopkins plan to do with the monies received? Are you giving full or partial monies back, or keeping said monies? Whose decision is this?

We invoiced as we went. We have no money to give back.

4) To answer one of your questions, multiple people told me upon Hopkins withdraw, the State of CO was prepared to yank the grant and forced much to be done within a very short amount of time to get the ok to proceed without JHU. Like your view, all I can say is that is their view.

5) I was unclear about your involvement in writing the protocol and CO grant writing. So to be clear, you believe your work on the protocol with Marcel was not only essential, that both of you did the work and without such, this study never would have received the grant from the State of CO nor approval necessary by the regulators.

Correct

6) When you say the previous work was effectively "bad science, can you identify what you mean? I ask because the University of Arizona's IRB and other seemed fine with most of the work done, although I must admit, I am no fan of the the UofA.

IRBs are tasked with human subjects safety, not scientific integrity. The original MAPS protocol had 10 different drug conditions (somewhat random THC/CBD concentrations) for a total of 50 planned participants. There is no way to draw any firm conclusions about the effects of a drug after only giving it to 5 people, but less to compare across subtle difference in concentration.

7) Were your major concerns with those in charge in credibility or protocol?

Yes

8) Why was no one enrolled at Johns Hopkins. What in your view was the major impediment?

We had several folks going through the screening process and actually had 3 people lined up to begin when we withdrew. It just so happened that I lost my patience before we enrolled anyone. I'm glad that it happened that way though because it was easier for us to make a clean break and not impact anyone's participation. I understand that it was disappointing for those who wanted to participate, but I called each of those people personally let them know that we were withdrawing.

May I state, your communication is appreciated.

STK

On Sun, Apr 16, 2017 at 7:39 PM, Ryan Vandrey <rvandrey@jhmi.edu> wrote:

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.