

Payment to Participants: A case study

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History

- ▶ Following an article in the Philadelphia Inquirer published on July 27, 2019, documenting financial ties between Jefferson's Lambert Center for the Study of Medicinal Cannabis and Hemp, and Ananda Hemp, a subsidiary company that produces CBD products and is owned by a major donor to the Center, the Office of Human Research determined a need to conduct due diligence by auditing all studies involving medical marijuana and CBD.
- ▶ Quality Improvement team identified 9 studies and performed review of each study file.
- ▶ From the audit, the only issues of note were found with Dr. Ari Greis' study, "The use of cannabis vs. non-use in patients with low back and leg pain caused by degenerative lumbar spinal stenosis: an observational study."

Study summary

- ▶ Primary objective of study is to determine the effect of use of cannabis, hemp oil ,or neither, on pain and other quality of life factors in patients with back and leg pain.
- ▶ Study is observational, and as such, does not prescribe medical cannabis or hemp oil. Rather, it follows the autonomous use (or non-use) of these products by the participants.
- ▶ Participants are assessed at monthly intervals with a set of questionnaires for 5 months.
- ▶ Subjects are paid \$25 for completing first set of questionnaires. Subjects are provided coupon for free hemp oil gel caps upon completion of each subsequent set of questionnaires.

IRB Review

- ▶ As the study intervention was comprised exclusively of questionnaires, it was deemed to be minimal risk and was given expedited review.
- ▶ Study was approved with inclusion of the coupons for free hemp oil gel caps.

Ethical concerns

- ▶ The QI team's primary finding identified the provision to participants of coupons for free hemp oil as presenting several ethical concerns:
- ▶ 1) Study design is observational, which stipulates **no intervention or influence** of researchers on the behavior of the participants while in the study. The provision of a coupon to the participants for one of the treatment modalities under study could skew results by promoting use of that modality and thereby compromising the observational design of the study.

Ethical concerns

- ▶ 2) Provision of coupons for a specific brand of product under study is bad optics. Looks like blatant product promotion and does not align with the academic pursuit of science.
- ▶ 3) Coupons were for hemp oil gel caps produced by Ananda Hemp, a company with financial ties to Jefferson. Use of the coupons could be construed as promotion of a product and leading to potential emolument of agents of Jefferson. Again, bad optics.
- ▶ Appearance of a conflict of interest can, in its own way, be just as damaging as an actual COI. (e.g., negative media coverage, compromised trust of community, tarnished reputation of researcher, consequences on future funding)

Remediation

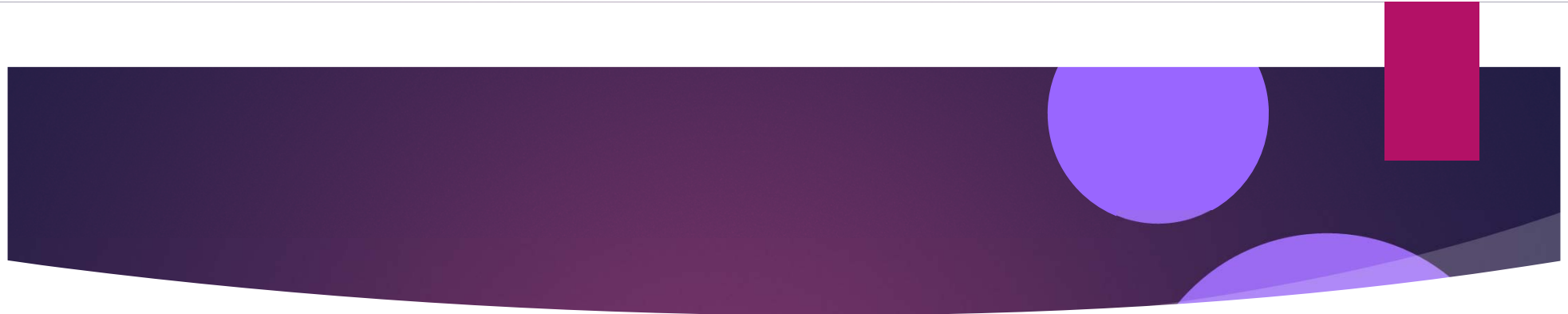
- ▶ To address these concerns, OHR leadership took the following steps:
- ▶ 1) Following audit of the study file, QI team posed several clarifying questions to the Director of Research at Rothman, as Dr. Greis is a Rothman employee
 - ▶ Of note, the response from Rothman indicated that study was closed to enrollment and 5 subjects remaining in the study had one final questionnaire to be completed in November 2019.
- ▶ 2) Ass't Director of Compliance drafted a letter to PI and circulated to Director and Assoc. Director for review. Letter addressed OHR's concern with provision of coupons and determined that it would have been more appropriate to provide \$ payments.

Remediation

- ▶ 3) However, given that study was nearing completion and that provision of the coupons does not affect subject safety, it was decided that study should be allowed to continue.
- ▶ 4) No further action was required of the PI, as the audit findings did not indicate non-compliance.
- ▶ 5) As Director of Research at Rothman was already aware of OHR's concerns and their resolution, OHR decided that letter would not be sent to PI, but rather memo would be retained with audit findings in OHR.

Lessons

- ▶ Provision of coupons to research participants for a product under study, whether brand-specific or not, is not appropriate and creates bad optics.
- ▶ OHR will consider modifying IRB policy on payment to address coupons.



THANKS