Steve trubow

To: trubow1@gmail.com

Subject: FW: MMAS NCT01884545 DUKE UNIVERSITY

Attachments: Health Coaching and Genomics, Potential Avenues etc..pdf; Untitled attachment 01012.html

From: Allison Vorderstrasse <av92@nyu.edu> Sent: Thursday, January 31, 2019 8:33 AM

To: trubow1@gmail.com

Cc: Wolever, Ruth Quillian <ruth.wolever@vumc.org>; Tejinder Rakhra-Burris <teji.rb@duke.edu>; Donald Morisky

<dmorisky@g.ucla.edu>; qing Yang <qing.yang@duke.edu>
Subject: Re: MMAS NCT01884545 DUKE UNIVERSITY

Dear Steve and Don

We did not have a renewal license, and we see in the fine print now that we should have asked about this on an annual basis, but did not realize that. We also can not find from you any requests for us to renew.

Thus far, we have only published the original protocol. Let me also point out that we ended up making a few changes to the published protocol. In terms of the data you are interested in, we had originally planned to use the Morisky-4, as noted in the protocol paper, but changed it to the Moriksy -8 after learning more about the 8 item tool in email communications with Dr. Morisky. We also did not collect data at as many time points as originally planned because the subject burden was too great to have 5 assessment points in a single year. The protocol paper is attached so that you do not need to try and find it.

In terms of scheduling a meeting, Dr. Wolever, Yang and I are open to an initial conversation to get clarity as to what the issues are. Of course our legal team can communicate with yours if we all determine that is the right next step. Can you provide us with some potential times for the web meeting - next week perhaps?

Best, Allison

> From: Allison Vorderstrasse <a wpg@nyu.edu Sent: Tuesday, January 29, 2019 8:58 AM To: Steve Trubow <<u>trubow1@gmail.com</u>>

Cc: Wolever, Ruth Quillian <<u>ruth.wolever@vumc.org</u>>; Tejinder Rakhra-Burris <<u>teji.rb@duke.edu</u>>; Donald Morisky <<u>dmorisky@g.ucla.edu</u>>; <u>mmas@bersteinlaw.com</u>; JR Dimuzio <<u>JR@bersteinlaw.com</u>>

Subject: Re: MMAS NCT01884545 DUKE UNIVERSITY

Dear Steven, David, and JR,

Please find below the responses to your questions regarding our use of the MMAS in our study. Please find attached the license agreement we executed with Dr. Morisky in August 2013.

Let us know if you have any further questions.

Best,

Allison Vorderstrasse Allison A. Vorderstrasse, DNSc, APRN, FAAN Associate Professor Director, Florence S. Downs PhD Program in Nursing Research and Theory

NYU Rory Meyers College of Nursing

433 First Avenue, Room 606 New York, NY 10010 P: 212 998 5786 F: 212 995 5143 allisonvorderstrasse@nyu.edu nursing.nyu.edu

1. Name and address of the Principal Investigator or Licensee.

Allison Vorderstrasse, DNSc, APRN, FAAN

Associate Professor New York University 433 First Ave New York, NY 10010

(Formerly Associate Professor at Duke University when this study was conducted (see Institution in #2).

2. Name and address of the Sponsoring Institution.

Duke University, 2200 W Main Street, Durham NC 27708

3. Name of the study for the MMAS license.

Genetic Risk Testing and Health Coaching for T2D and CHD

4. Please attach a PDF copy of the MMAS-8 scale administered to patients

Attached PDF.

5. Name of any MMAS translation(s) used for the study. Where did you obtain the MMAS-8 translations?

No MMAS translations were used for this study

6. The date that data collection (MMAS Tests) began and ended.

Began 12/20/13, Ended 2/28/17.

7. The number of patients given MMAS tests.

Total sample of study participants =200 (only completed MMAS if taking medications). See number completed at each timepoint in #8.

8. The total number of MMAS tests given

Participants were asked to complete this at baseline, 6 weeks, 6 months and 12 months.

Completion rates were:

Baseline - 169 6 weeks - 121 6 months - 119 12 months - 112

9. How were the MMAS tests given, electronically or paper and pencil?

Electronically via Redcap

10. List all locations where the MMAS tests were administered, scored, and reported, and by whom.

David Grant USAF Medical Center, Travis AF Base (administered). Duke University (scoring and reporting).

Tests were administered electronically via Redcap. Data were scored and reported at Duke by Qing Yang (statistician), Allison Vorderstrasse (MPI), Ruth Wolever (MPI).

11. Please show the MMAS-8 scoring and coding criteria that was used to score and code patient MMAS-8 tests.

You will need to reverse the code response in a positive direction for item number 5 and standardize the code for item 8 (0-4), resulting in a scale from low adherence to high adherence. Item 8 is divided by 4 when calculating a summated score. This procedure standardizes the 5-point Likert scale. The total scale has a range of 0 to 8.0.

Re-coding performed:

If Item5 = 0 Item5r = 1 (high adherence)

If Item8=4 Item8r = 1 (highest adherence)

If Item8=3 Item8r = .75 (high adherence)

If Item8=2 Item8r = .50 (moderate adherence)

If Item8=1 Item8r = .25 (low adherence)

If Item8=0 Item8r = 0 (lowest adherence)

12. Who has the MMAS results from this study?

Dr. Qing Yang, Duke University; Dr Ruth Wolever; Dr Allison Vorderstrasse

13. Please list all publications and presentations which contained MMAS-8 results. Please send PDFs of any poster presentations, abstracts, or articles.

Final report to Air Force Medical Sciences (funding agency).

On Fri, Jan 11, 2019 at 5:28 PM < trubow1@gmail.com> wrote:

Dear Ruth, Allison and Teji,

We have not received a response to our inquiry.

We have turned this matter over to our lawyer for legal action.

Please forward all future correspondence in this matter to David Berstein or JR Dimuzio.

They will be in touch with you shortly.

Sincerely

Steven Trubow

Donald Morisky

MMAS Research LLC

Coronado California

www.morisky.org

From: trubow1@gmail.com <trubow1@gmail.com>

Sent: Wednesday, January 2, 2019 8:35 AM

To: 'Wolever, Ruth Quillian' < ruth.wolever@vumc.org >; teji.rb@duke.edu

Cc: 'Allison Vorderstrasse' <av92@nyu.edu>; dmorisky@g.ucla.edu; mmas@bersteinlaw.com; 'JR

Dimuzio' <<u>JR@bersteinlaw.com</u>> **Subject:** RE: MMAS NCT01884545

Hi Ruth, Allison, and Teji,

Thank you for your response.

While we are waiting for a copy of your signed MMAS license, could you please answer the 13 questions below and return the requested PDF documentation.?

Best

Steve

Steve Trubow

Donald Morisky

MMAS Research LLC

Coronado California

360-824-0701

www.morisky.org

- 1. Name and address of the Principal Investigator or Licensee.
- 2. Name and address of the Sponsoring Institution.

Ex. C

- 3. Name of the study for the MMAS license.
- 4. Please attach a PDF copy of the MMAS-8 scale administered to patients
- 5. Name of any MMAS translation(s) used for the study. Where did you obtain the MMAS-8 translations?
- 6. The date that data collection (MMAS Tests) began and ended.
- 7. The number of patients given MMAS tests.
- 8. The total number of MMAS tests given.
- 9. How were the MMAS tests given, electronically or paper and pencil?
- 10. List all locations where the MMAS tests were administered, scored, and reported, and by whom.
- 11. Please show the MMAS-8 scoring and coding criteria that was used to score and code patient MMAS-8 tests.
- 12. Who has the MMAS results from this study?
- 13. Please list all publications and presentations which contained MMAS-8 results. Please send PDFs of any poster presentations, abstracts, or articles.

From: Wolever, Ruth Quillian < ruth.wolever@vumc.org >

Sent: Wednesday, January 2, 2019 8:08 AM

To: Steve Trubow < teji.rb@duke.edu

Cc: Allison Vorderstrasse

<av92@nyu.edu>; dmorisky@g.ucla.edu; mmas@bersteinlaw.co

<u>m</u>

Subject: Re: MMAS NCT01884545

Hi Steve and Donald - Both Allison and I have moved to other Universities over 3 years ago, and as you know original grant files stay with the primary university awarded the grant. The person who was our Project Leader has also moved to another job. I am including someone who is still at the prior Institute at Duke, but don't know if she can access the records....

Teji - Can you access the Sharepoint files for the Genetic Risk and Health Coaching trial? The originator of the Morisky 8 item questionnaire that we used is asking for a copy of the license we purchased. Allison may have already asked you, and if so, my apologies. Perhaps Gladwell could help to locate it if she is still there as well?

THANK YOU, Ruth

Ruth Q. Wolever, PhD

Director of Vanderbilt Health Coaching: Practice, Research & Education,

Osher Center for Integrative Medicine

Associate Professor, Physical Medicine & Rehabilitation and Dept of Psychiatry

Vanderbilt Schools of Medicine and Nursing

Onsite: 3401 West End Ave. Suite 380

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Durham, NC 27705

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ruth.wolever@vanderbilt.edu

ruth.wolever@vumc.org

Co-author <u>The Mindful Diet</u> published by Scribner/Simon & Schuster in 2015

Program Coordinator: Lindsay Dickson Phone: 615-343-8994 lindsay.dickson@vanderbilt.edu

Check out the Vanderbilt Health Coaching Certificate Program: VanderbiltHealth.com/healthcoach

On Jan 2, 2019, at 9:47 AM, Steve Trubow trubow1@gmail.com> wrote:

MMAS Research LLC

On Dec 9, 2018, at 11:35 PM, < trubow1@gmail.com wrote:

Dear Dr. Vorderstrasse, and Dr. Wolever

My name is Steven Trubow. I am the Chief Investigator for the registered copyright and trademark protected MMAS-8. We have some questions regarding the use of the MMAS-8 at Duke University when you were the Chief Investigators for the Genetic Risk and Health Coaching for Type 2 Diabetes and Coronary Heart Disease study. Can you please send us your signed MMAS license and copyright agreement for use of the MMAS-8 in the NCT01884545 study.

Thank you in advance for your soonest response.

Sincerely yours, Steven Trubow Donald Morisky MMAS Research LLC Coronado California USA 360-824-0701

www.morisky.org

The Morisky Widget MMAS are evidence based diagnostic assessments of medication taking behaviors that improve and reduce the cost of care for Americans with chronic diseases, with improved outcomes via increased medication adherence, reduced medical complications, and decreased emergency department visits and hospital readmissions.

Steven Trubow Donald Morisky MMAS Research LLC Coronado California USA 360-824-0701

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