

SUBJECT: Research Misconduct Complaint
RESEARCH: Ecological Momentary Analysis (EMA)
ALLEGED AGAINST: Daniel Gillen
Pathik Wadhwa
Elizabeth Ward aka “Ben”
Annamarie Stehli
Karen Lindsay
FILED WITH: Research Integrity Officer, UCI
FILED BY: Robert J. Baron
DATE: August 23, 2017

This Follow Up Complaint is a continuation of the Whistleblower Complaint lodged on June 12, 2017 by the Complainant with UCI Research Integrity Officer (RIO) Dr. Craig Walsh and Jill Kay.

At that meeting, the Complainant was discouraged from pursuing his Complaint due to concerns by RIO that the Complaint could be a “career ender” for Pathik Wadhwa, Daniel Gillen, Elizabeth Ward, Annamrie Stehli and Karen Lindsay. He was further advised that RIO will not even talk to anyone regarding the Complaint or do any investigation whatsoever unless the Complainant brings a “smoking gun” to RIO or “someone actually confesses” to the misconduct.

The Complainant was disheartened by RIO’s response to his whistleblower complaint at the meeting but decided to start gathering evidence of research misconduct to provide to RIO regardless. Complainant started providing RIO with initial supporting evidence and was in the process of providing extensive evidence when he was terminated on June 20, 2017. This Follow

Up Complaint contains evidence that Complainant was unable to provide to RIO due to his termination.

Background

This research study (EMA) by Wadhwa and Gillen was to be conducted on pregnant women to study the effects of various stress factors during each pregnancy trimester and gestational age. The project description in the grant document for this research specifically states the importance of gestational age to the study:

“Our specific aims are: 1) To estimate the magnitude of the effect of maternal psychosocial stress on *a*) maternal-placental-fetal (MPF) hormonal parameters, and *b*) birth outcomes; 2) To estimate the magnitude of the effect of maternal biological stress reactivity on *a*) MPF hormonal parameters, and *b*) birth outcomes; and 3) To determine whether the magnitude of the effect of maternal stress is modulated by the stage in gestation of occurrence of stress. Complete prospective data will be collected in a sample of at least 120 pregnant women over three 4-day assessments in **early, mid and late gestation.**” (Exhibit A, Abstract).

Furthermore, the “Specific Aims” of the study in the grant document state the importance of gestational age and trimesters to the accuracy of this study and the purpose behind it:

“AIM 1: To estimate the magnitude of the effect of maternal psychosocial stress using EMA measures on *a*) maternal-placental -fetal endocrine factors, and *b*) birth outcomes (**length of gestation, and birth weight adjusted for gestational length**).” (Exhibit A, Specific Aims)

“AIM 2: To estimate the magnitude of the effect of maternal biological stress reactivity using EMA measures on *a*) maternal-placental-fetal hormonal parameters, and *b*) birth outcomes (**length of gestation, and birth weight adjusted for gestational length**).” (Exhibit A, Specific Aims)

“AIM 3: To determine whether the magnitude of the effect of maternal psychosocial stress and biological stress reactivity on *a*) maternal-placental-fetal hormonal parameters and *b*) **birth outcomes varies as a function of the stage/time in gestation of occurrence of stress.**” (Exhibit A, Specific Aims)

The grant document specifically states that the trimesters and gestational age were to be calculated in this study by measuring time since LMP, confirmed by ultrasound scans:

Timing of Stress in Gestation			
Stage of Pregnancy	Trimester of pregnancy, gestational age	Time since LMP, confirmed by ultrasound	Ultrasound/ medical record
Outcomes			
Length of Gestation	Gestational age	Time since LMP, confirmed by ultrasound	Ultrasound/ medical record

(Exhibit A, Appendix H).

The Issues

Complainant found that:

1. The study data contained no ultrasound scans or time measured since LMP to calculate trimesters and gestational age per the grant document.
2. Gillen, Wadhwa, Ward, and Stehli intentionally fabricated and manufactured false data including baseless trimesters and gestational ages of study participants.
3. Gillen, Wadhwa, Ward, Stehli and Lindsay took intentional and deliberate steps to cover-up the data fabrication and research misconduct.

Supporting Evidence

In March 2017, Complainant found that the research data had no trimesters or gestational age listed for the study participants but had a column labeled “visit” that contained values of G1, G2 or G3 without any record of ultrasound scans and LMP calculation regarding how pregnant women in the study were assigned one of these G values (Exhibit B).

There were also no fields or columns assigned in the RedCap data sheets to store any ultrasound scans or any other basis for the trimester and gestational age calculation values assigned to the pregnant women in the study (Exhibit C).

During a weekly meeting of the research group in March, Complainant raised this issue and asked Pathik Wadhwa regarding the missing ultrasound scans and LMP calculations but received no answer. Complainant also asked Wadhwa if the G values in the data were for the three trimester values in the data and how were they calculated without any ultrasound scans and LMP measurements in the data. Wadhwa again said nothing but Elizabeth Ward aka “Ben” and Annamarie Stehli stated that they just “guessed” the trimester for each pregnant woman in the

study and the “G” prefix in G1, G2 and G3 values in the “visit” column stood for “guessed” trimester value for trimester 1, trimester 2 or trimester 3.

Upon hearing this, Complainant advised Wadhwa, Ward, and Stehli of his concerns with them having “guessed” the trimester values instead of calculating the trimester values based on gestational age of a pregnant study participant measured by LMP and ultrasound scans as specified by the grant document.

Complainant also asked Wadhwa, Ward and Stehli if they could provide him with accurate trimester values for the study participants based on gestational age and LMP calculations. Although these individuals stated that they would provide the Complainant with the requested information, no such information was provided to the Complainant despite his repeated requests.

On May 18, during a meeting with Gillen, Ward, and Stehli, Complainant again asked to be provided with true trimester values for the study participants in the data. Gillen asked Ward and Stehli to “identify trimester” for each participant in the data and “identify day” that the measurements were taken (Exhibit D).

On May 24, after still not receiving the trimester values for the data, Complainant sent another email to Stehli, Ward, Gillen and Wadhwa requesting the information (Exhibit E). In response, Complainant was sent two files (Exhibit G, Exhibit H). Complainant was asked to make the database based on the two files sent to him (Exhibit F).

Upon analysis of the two files, Complaint found that the files contained a column labeled “Trimester” but did not contain any basis or calculation regarding the trimester values contained in that column.

Upon further analysis, Complainant found that the “supposed” trimester values in the “Trimester” column in the files were the same values as the “guessed” and fabricated G values previously labeled as G1, G2 and G3 in Exhibit B provided to the Complainant in March. The only difference was that in the new files’ “Trimester” column, a “0” correlated to G1 in Exhibit B, “1” to G2 and “2” to G3 respectively.

Ward, Stehli, Gillen and Wadhwa had simply copied the “guessed” visit values G1, G2, and G3 from the data in Exhibit B, renamed them 0, 1, and 2, and inserted them in the new files in a column labeled “Trimester”. There was no record of any ultrasound scans, LMP measurements or any other clinical documentation regarding the study participants’ actual trimesters and gestational ages.

On May 26, 2017, Complainant advised Gillen and Wadhwa of his concerns regarding research misconduct involving trimester values (Exhibit I). In response, Gillen again attempted to cover up the issue by stating that trimester values in the data were really visit day values and he had asked that gestational age be added to the data (Exhibit J). This statement by Gillen was false because the pregnancy trimester and visit days of a study participant for data collection are two completely separate and distinct entities and Gillen himself had asked Ward and Stehli to provide the Complainant with trimester as well as visit days (Exhibit D). Furthermore, by his own admission, Gillen had asked that gestational age to be added to the data when there was no clinical basis in the data to calculate the gestational age without any ultrasound scans and LMP measurements. There was absolutely nothing in the data to base accurate trimester and gestational age values upon.

Gillen, Wadhwa, Ward and Stehli further attempted to cover-up their data fabrication and research misconduct by even claiming that trimester values are “not calculated” (Exhibit K). This

claim is patently false and directly contradicted the grant document (Exhibit A) where they specifically stated that trimesters and gestational age values were to be calculated based on ultrasound scans and LMP measurements.

On June 1, 2017, Complainant invited Wadhwa to Complainant's office and showed him the fabricated trimester values in the data on his computer. Wadhwa offered no possible explanation. On the same day, during the weekly meeting, Complainant again pointed out the trimester values issue and asked Ward and Stehli where the trimester values came from. Ward responded that "you will just have to believe me on that". Wadhwa immediately told Ward to not say that and instead say that they came from some documents. Complainant asked what these "documents" were and where were they located. Wadhwa had no answer and just stared at the Complainant in anger.

On June 2, Complainant emailed his concerns about the previous day's meeting to the Wadhwa-Gillen group and what had transpired at that meeting. It was obvious that Ward's evasive response was coached and tailored by Wadhwa and Gillen even though Gillen was not even present at the meeting. In this response, Ward (and Wadhwa and Gillen) continue to cover-up the trimester fabrication by stating that "The variable called "Trimester" is not "calculated" in any way", "as we explained to you, and as it is recorded in the data dictionary, "Trimester" indicates study visit number" (Exhibit L). The majority of this response from Ward (and Wadhwa and Gillen) consisted of false statements and attempts to confuse the trimester issue with improbable and inaccurate explanations and cover-up the trimester fabrication.

On June 13, Complainant asked Wadhwa to provide him with a clinical formula regarding how gestational age is calculated for a pregnant female. Wadhwa provided the formula

in a series of confusing, self-contradictory and rude emails to the Complainant (Exhibit M).

Wadhwa's emails were an additional attempt to confuse and cover-up the trimester issue.

On June 15, during the weekly meeting, Wadhwa subjected the Complainant to extreme verbal abuse for asking questions about the trimester values.

On June 19, Complainant discovered that Wadhwa and Lindsay had removed Complainant's access to the RedCap data containing all EMA data (data containing the fabrication and misconduct) while leaving his access intact to non-EMA data. When Complainant asked why his access to EMA data was removed, he received no response (Exhibit N).

On June 20, Complainant was fired in retaliation.

Conclusion

Gillen, Wadhwa, Ward, Stehli and Lindsay intentionally and knowingly fabricated the trimesters and gestational ages of study participants without any clinical basis (ultrasound scans, LMP), then took intentional and deliberate steps to cover-up their research misconduct.