

**Marc J. Levy, Esquire LLC**

2012 NOV 16 PM 4: 12

50 North Street, Suite 200  
P.O. Box 931  
Medfield, MA 02052  
Tel: (508) 359-8600 – Fax: (508) 359-0062 – Email: marclevy@marclevyesq.com

November 14, 2012

Ms. Johanna L. Oliver  
Attorney, Disclosure Unit  
U.S. Office of Special Counsel  
1730 M Street, N.W., Suite 218  
Washington, D.C. 20036-4505

Re: OSC File No. DI-12-1098

Dear Ms. Oliver:

Please be advised that this office represents Carolyn Bogal (the “whistleblower”) in regard to the above-referenced matter. Ms. Bogal is in receipt of your letter of November 1, 2012 which included a copy of a Report of Investigation and Supplemental Report received by OSC from the Department of Veterans Affairs along with copy of a Consent to Public Release form.

Kindly consider this correspondence to constitute Carolyn Bogal’s response to the Agency’s Report of Investigation and Supplemental Report. In addition, Ms. Bogal encloses herein the signed Consent to Public Release form authorizing OSC to include these written comments in its public file.

While Carolyn Bogal agrees with the VA Office of Research Oversight’s determinations that the VABHS and its researchers failed to comply with certain VA requirements for the conduct of research, for the reasons set forth below she, like OSC, disputes ORO’s failure to find a violation of any law, rule, or regulation, as well as its failure to identify a substantial and specific danger to public health. She, also like OSC, questions ORO’s findings, or lack thereof, with respect to the conduct of the PI, based on numerous inconsistencies identified by ORO during its investigation calling into question the credibility of the PI. Simply put, ORO had more than enough information in its possession to render a determination, by a preponderance of evidence, that the PI engaged in intentional falsification of data by inaccurately recording that she conducted research skin examinations when, in fact, she had instructed the whistleblower to do them. Despite being asked to do so a second time, ORO simply refuses to answer the question. This refusal is in contradiction to the VA’s obligation to conduct an investigation and submit a report setting forth the findings of the Agency head pursuant to 5 C.F.R. 1213(c) and (d).

As one of its major findings, ORO determined that its Focused For-Cause Review did not suggest that the scientific data or results obtained in CSP Protocol #562 at VABHS were inaccurately represented. As such, ORO determined that despite protocol irregularities having been found, there was no violation of any law, rule, or regulation, nor was there a substantial and specific danger to public health. OSC, in an email to the VA dated September 12, 2012, already pointed out that it considers any formally established and published agency-wide policy, such as those set forth in a VHA handbook, to be a law, rule or regulation. In response, the VA, on October 3, 2012, conceded that based on this definition such a violation was, in fact, identified.

By way of this submission, the whistleblower calls attention to ORO's dismissal of the notion that despite the irregularities identified it cannot be found that there is a substantial and specific danger to public health. The reason the whistleblower calls attention to this matter is because a review of ORO's report suggests that 1) either the "key personnel" identified by ORO were not completely forthright in sharing potentially relevant information with ORO during the course of their interviews or 2) ORO failed to properly address certain information, which if true, would be relevant to a determination that the PI's research could lead to improper approval or denial by the FDA of the drug studied. Put another way, a review of ORO's report reveals that certain information known to the PI and the Chief of Medicine and relevant to the question of whether or not the PI's actions could pose a substantial and specific danger to public health appears nowhere. The question then becomes whether the PI and Chief of Medicine withheld this information from ORO during its investigation or whether ORO withheld it from OSC in compiling its report.<sup>1</sup>

Specifically, the whistleblower alleges that the PI instructed her to conduct many of the initial skin assessments as provided for in the protocol.<sup>2</sup> The purpose of the initial skin exam is to determine participant eligibility. Specifically, a participant must be free of skin cancer at the time of randomization. The initial skin exam must also include an assessment of AKs (actinic keratoses) present on the face/ears. ORO has determined that the PI's actions in this matter did not result in an inaccurate representation of the scientific data or results obtained in CSP Protocol #562. In order for that to be an accurate statement, the determination must have been reached that had the PI done all the initial skin examinations herself the results would have been the same as those performed by the whistleblower. In other words, ORO, based on the information given to it by the key personnel interviewed, must have been fully satisfied with the clinical competence of the whistleblower.

Simply stated, the whistleblower would like to know whether or not the "key personnel" identified as being interviewed disclosed to ORO that the PI and Chief of Medicine have both raised concerns about the whistleblower's clinical competence, specifically, her ability to properly identify the presence of skin cancers during skin exams, during the same time period as this clinical study. Specifically, subsequent to the whistleblower's contacting the national coordinator of the study to report her concerns about protocol violations with respect to the

---

<sup>1</sup> The whistleblower has not been provided a copy of the actual interview or interview notes and therefore is unable to determine what the PI and/or Chief of Medicine said or did not say.

<sup>2</sup> While the PI denies this allegation, as set forth below in detail, based on the evidence of record and the credibility issues pertaining to the PI and SC, a determination should be made that the whistleblower did, in fact, conduct many of the initial skin exams in violation of the protocol.

initial skin exams, both the PI and Chief of Medicine questioned her clinical competence. This included allegations that the whistleblower had failed to properly identify the presence of skin cancers during skin exams performed in her clinical practice (i.e. outside the study). The VA threatened to report this alleged clinical incompetence to the state licensing board.<sup>3</sup> While the whistleblower vehemently denies allegations that she was clinically incompetent at any time, based on the allegations raised by the PI and the Chief of Medicine in those communications from 2011, the whistleblower wonders whether the PI and Chief of Medicine disclosed these concerns to ORO during their interviews. Certainly this information would be relevant to a determination of whether or not the actions of the PI in allowing the whistleblower to perform initial skin examinations in violation of the protocol had any impact on the accurate representation of scientific data or results obtained.

ORO's report contains no information that the PI or Chief of Medicine offered up information about their concerns (or lack thereof) with respect to the whistleblower's clinical competence. Was this information purposely withheld from ORO by the PI and Chief of Medicine in order to bring about a determination that there was no impact on results? Was this information provided to ORO but for some reason held out of ORO's report? Did the PI and/or Chief of Medicine inform ORO that they had no concerns about the whistleblower's clinical competence? Was the question even asked? It would appear that at a minimum further inquiry into what the PI and Chief of Medicine shared with ORO on this topic would be appropriate.

This issue with respect to the potential lack of candor of certain key personnel interviewed is a common theme running throughout ORO's investigation. Not only is there a question as to whether or not the PI and/or Chief of Medicine disclosed to ORO their concerns about the whistleblower's alleged clinical incompetence, but a review of ORO's findings reveals the following with respect to credibility of the key personnel in regard to the issue of whether it was known that the whistleblower was conducting many of the initial skin exams:

1. In an email to the CSP dated May 23, 2010, the PI denied knowledge that the whistleblower was conducting initial skin exams and stated she only first learned about it on July 1, 2010. This denial was in direct contradiction to a March 25, 2010 Source Document Worksheet for Form 25 signed by the PI.
2. In an email from the SC to the whistleblower dated June 3, 2010, the SC clearly stated that it was the whistleblower's job to do the "skin exams" and "orders" because basically it is "just YOU and ME." Yet, in a statement from the SC to ORO, he denied that the whistleblower was doing the skin exams and claimed that the PI did them all, and that in most instances he was actually present when they were done. These two statements are in direct contradiction and also contradict the PI's claim that she was unaware that the whistleblower was doing many of the initial skin exams. In fact, the whistleblower had numerous conversations with the SC regarding this issue in which she expressed her concerns that the protocol was not being

---

<sup>3</sup> The whistleblower received a series of communications from the VA in late 2011 alleging clinical incompetence and potential reporting of the matter to the state licensing board. The last such communication was dated December 7, 2011, to which the whistleblower responded on January 13, 2012. She has received no similar communications since that time and has no knowledge that a report to the state licensing board was ever actually made.

followed. When the SC continued to respond by passing along the message from the PI that the whistleblower was to continue with the initial exams, this in turn led to the whistleblower's email to the PI dated July 1, 2010.

3. Documentary review done by ORO reveals that the PI signed a Source Document Worksheet form Form 13 indicating that she had performed an initial skin exam for a subject on November 4, 2009 despite time and attendance records indicating that the PI was on sick leave that day. The PI failed to provide any evidence to support her contention that she worked half a day that day (even though she claimed a full day of sick leave). While this certainly evidences one specific date on which the PI's claim that she did, or was present for all, the initial skin exams, was proven to be untrue, it also serves to call into question her credibility with respect to her overall denial of the allegation, especially when placed into context of the other evidence of record.
4. The PI signed a Source Document Worksheet form Form 13 on December 14, 2009 for a patient enrolled in the study on December 11, 2009 indicating that she had done the initial skin exam despite the Progress Note for December 11, 2009 indicating that the whistleblower has performed that exam. Again, while this certainly evidences a second specific date on which the PI's claim that she did, or was present for all, the initial skin exams, was proven to be untrue, it also serves to call into question her credibility with respect to her overall denial of the allegation, especially when placed into context of the other evidence of record.

As pointed out by OSC in its email request for supplemental information dated September 12, 2012, ORO's report revealed at least three patients whose records initially indicated the whistleblower conducted research skin exams but were subsequently modified. Despite being asked this second time to fulfill its obligation to conduct an investigation and render specific determination on this critical issue, ORO refused to answer the question. The whistleblower claims she was instructed to conduct, and did conduct, many of the initial skin exams, in violation of the protocol, by the PI. The record contains an abundance of evidence suggesting that this in fact was the case. It also contains an abundance of evidence calling into question the credibility of both the PI and the SC with respect to their responses to the question of how and by whom these initial exams were conducted. Add in the PI's and Chief of Medicine's apparent failure to disclose potentially relevant information on the issue of whether the PI's actions could pose a substantial and specific danger to public health, and it would appear that ORO's report is incomplete at best and, at worst, potentially complicit in a larger conspiracy to protect certain key personnel and the VA as a whole.

Very truly yours,

A handwritten signature in black ink, appearing to read 'M. J. Levy', with a long, sweeping horizontal stroke at the end.

Marc J. Levy

MJL/mjl