

From: Jerry H. Trachtman [jtrachtman@trachtman-law.com]

Sent: Monday, October 25, 2010 9:18 PM

To: Leyla Erkan

Cc: Jay Walsh PhD (research@northwestern.edu); Jay Walsh PhD; Julia Campbell, Nancy Paridy; Patricia

Sheahan; Dr. Anthony F. Kirkpatrick; Dr. Richard Hoffman PhD

Subject: R. Norman Harden, M.D.

Dear Ms. Erkan:

I am in receipt of the "Preliminary Inquiry Report" emailed to me by Ms. Julia M. Campbell.

By email dated October 8, 2010, I expressed to Dr. Walsh the concern of The International Research Foundation for RSD/CRPS, that RIC was not complying with the policies and procedures for reviewing alleged research misconduct, as established by Northwestern University for its research community, including RIC. I specifically asked Dr. Walsh, "If you believe that these policies and procedures do not apply to RIC, I would appreciate your furnishing me an explanation as to why not." Here is a copy of my October 8, 2010 email to Dr. Walsh:

From: Jerry H. Trachtman [jtrachtman@trachtman-law.com]

Sent: Friday, October 08, 2010 6:38 PM To: Jay Walsh PhD; Jay Walsh PhD Cc: Dr. Anthony F. Kirkpatrick Subject: R. Norman Harden, M.D.

Dear Dr. Walsh:

As legal counsel for the International Research Foundation for RSD/CRPS, Inc., the complainant in this matter, I have reviewed Ms. Leyla Erkan's September 27, 2010 email in response to the Foundation's inquiry regarding R. Norman Harden, M.D. Ms. Erkan has advised that, "RIC's Senior Vice President, General Counsel has established a Preliminary Inquiry Committee to review the substance of the allegations and determine if a formal investigation is necessary." She further has advised that the "Preliminary Inquiry Committee" is comprised of two people, Patricia Sheahan, Associate General Counsel and Julia Campbell, Associate Compliance Officer.

I have reviewed Northwestern University's published Policy for Reviewing Alleged Research Misconduct ("Policy document") and NU's published Procedures for Reviewing Alleged Research Misconduct ("Procedures document"). Both documents expressly provide they are applicable to all members of Northwestern University's research community, and NU's research community is expressly defined to include RIC in all NU publications where it is mentioned. I would respectfully suggest to you that the required procedures are not being followed in connection with the Foundation's inquiry into Dr. Harden's research.

There is no provision for a "Preliminary Inquiry Committee" in either the Policy document or the Procedures document. The Policy document provides for establishment of an Inquiry Committee, and further provides that, "The inquiry committee is responsible for conducting an initial review of the available evidence to determine whether or not to conduct an investigation." (See page 6 of the Policy document).

The Procedures document provides that:

"The Director ORI appoints full-time faculty members to serve on the inquiry committee, selected in consideration of Northwestern University's infrastructure. The inquiry committee includes at least three members meeting the following criteria:

-Have appropriate scientific expertise to evaluate the evidence and issues related to the allegations; and

-Have no personal, professional, or financial conflicts of interest with the complainant or respondent."

(See sec. 1.2 Procedures document, entitled Selection of Inquiry Committee)

The Policy document also provides that, "Neither Northwestern University nor the respondent may have legal counsel present at the meetings of the inquiry and investigation committees, except at the express invitation of the committees. Should legal counsel be invited, the invitation will be extended to both parties."

We are deeply concerned that failure to comply with Northwestern University's policies and procedures will invalidate any ultimate determination that is made. We are further concerned that the procedures being used are biased against the complainant. I would appreciate your assurance that this matter will be handled in compliance with the policies and procedures established by Northwestern University for its research community, including RIC. If you believe that these policies and procedures do not apply to RIC, I would appreciate your furnishing me an explanation as to why not.

Thank you for your time and consideration.

Jerry H. Trachtman Law Offices of Jerry H. Trachtman, P.A. 1735 West Hibiscus Boulevard Suite 300 Melbourne, FL 32901 Telephone (321) 723-8281 Facsimile (321) 394-4033 jtrachtman@trachtman-law.com

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In his response, Dr. Walsh requested that all further communication in this matter be directed to you. Here is a copy of Dr. Walsh's email response, dated October 14, 2010:

From: Jay Walsh [mailto:jwalsh@northwestern.edu]

Sent: Thursday, October 14, 2010 4:24 PM

To: itrachtman@trachtman-law.com

Cc: 'Dr. Anthony F. Kirkpatrick'; 'Patricia Sheahan'; 'Leyla Erkan'; 'Nancy Paridy'

Subject: RE: R. Norman Harden, M.D.

Dear Mr. Trachtman,

As the research in question occurred through RIC, this matter has been referred to at RIC.

Please direct all further correspondence regarding the your client's complaint to Ms. Erkan of RIC.

Best regards,

Jav

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Joseph T. Walsh, Jr. Vice President for Research Professor, Biomedical Engineering Northwestern University Rebecca Crown Center 633 Clark St. Evanston, Il 60208 phone 847-491-3485 fax 847-467-4620

jwalsh@northwestern.edu

As of this date, no one at RIC has responded to the concerns and questions I raised in my email to Dr. Walsh. The "Preliminary Inquiry Report" which has been issued should be an embarrassment to RIC. It is lacking in many

respects, including but not limited to:

- 1. There is no provision for a "Preliminary Inquiry Committee" in either the NU research misconduct Policy document or the NU research misconduct Procedures document. The Policy document provides for establishment of an Inquiry Committee, and further provides that, "The inquiry committee is responsible for conducting an initial review of the available evidence to determine whether or not to conduct an investigation." (See page 6 of the Policy document).
- 2. The NU Procedures document provides that:

"The Director ORI appoints full-time faculty members to serve on the inquiry committee, selected in consideration of Northwestern University's infrastructure. The inquiry committee includes at least three members meeting the following criteria:

-Have appropriate scientific expertise to evaluate the evidence and issues related to the allegations; and -Have no personal, professional, or financial conflicts of interest with the complainant or respondent." (See sec. 1.2 Procedures document, entitled Selection of Inquiry Committee)

Here, the "preliminary inquiry" was conducted by Patricia Sheahan, Associate General Counsel and Julia Campbell, Associate Compliance Officer, both having been appointed by RIC's Senior Vice President/General Counsel. Neither Ms. Sheahan nor Ms. Campbell has any scientific expertise whatsoever to understand and evaluate the evidence and issues related to the allegations. Additionally, both have a clear professional conflict of interest, since they are employed by RIC which also employs Dr. Harden. Their lack of understanding of the evidence and issues set forth in the Foundation's complaint is reflected in the list of "Allegations Regarding Research Misconduct" contained in the Report. While this list of allegations repeats some of the evidence presented in the Foundation's complaint in support of the allegations of research misconduct, it completely fails to recognize or state the substance of the scientific allegations which should have been investigated. This is clearly due to the investigators' lack of any appropriate scientific expertise.

3. The NU Policy document provides that, "Neither Northwestern University nor the respondent may have legal counsel present at the meetings of the inquiry and investigation committees, except at the express invitation of the committees. Should legal counsel be invited, the invitation will be extended to both parties."

Here, RIC not only had legal counsel present, but legal counsel conducted the inquiry.

This "preliminary inquiry" consisted of asking the respondent and the respondent's research co-author whether or not they agreed with the Foundation's allegations, and a "review" of the research in question by two unqualified reviewers. There is nothing in the "preliminary inquiry" which addresses the scientific basis of Dr. Harden's research in light of the science issues raised by the Foundation, yet the Report concludes that there was "adequate scientific basis and information" in Dr. Harden's research.

I take issue with the statement in the Report that, "The Committee also contacted the Complainants for interviews. The Complainants' lawyer, Mr. Jerry Trachtman, responded on behalf of the Complainants and was not responsive to the requests for interviews or additional information relative to the allegations." By email to Dr. Kirkpatrick dated October 13, 2010, Ms. Campbell acknowledged being told by Dr. Kirkpatrick's assistant that his availability for a 30 minute conference was limited until November. Nevertheless, she requested the conference "this week or early next week." Here is a copy of her email:

From: Julia Campbell [mailto:jcampbell@ric.org] **Sent:** Wednesday, October 13, 2010 10:35 AM

To: akirkpat@tampabay.rr.com

Cc: Patricia Sheahan; Jean Holewa; Leyla Erkan

Subject: Request for conference call regarding your allegations [no ephi]

Dr. Kirkpatrick,

Jean Holewa has been in contact with your assistant to schedule 30 minutes to speak with Patti Sheahan and myself regarding your allegations against Dr. Harden. We understand from your assistant that you have limited availability until November. If at all possible, we would appreciate your taking 30 minutes of time to speak with us this week or early next week.

I look forward to hearing from you.

Sincerely, Julia

Julia M. Campbell
Associate Compliance Officer
Rehabilitation Institute of Chicago
345 East Superior Street
Chicago, Illinois 60611
312.238.2805
312.238.2716 (facsimile)

jcampbell@ric.org

Dr. Kirkpatrick has been out of Florida, and out of the country, for almost 2 weeks, and is not reachable by phone or email. He is not expected back until mid-November. Ms. Campbell was told he would be available in November. No one was advised that the Committee would not wait until he returned to speak with him, and that the Report would be issued in his absence.

Further, by email dated October 14, 2010 I acknowledged Ms. Campbell's request, and I expressed our concern to Ms. Campbell about the handling of the complaint by RIC. I also furnished her a copy of my October 8 email to Dr. Walsh, and I specifically requested, "Before you proceed further in this matter, I would appreciate a response to the concerns we have raised." Instead of answers to our questions, a week later I received a "Preliminary Inquiry Report." If anyone has been non-responsive, it is RIC. Here is a copy of my October 14, 2010 email to Ms. Campbell:

Ms. Campbell – As legal counsel for the International Research Foundation for RSD/CRPS, Inc., Dr. Kirkpatrick has furnished me a copy of your email request to speak with him regarding Dr. Harden. On October 8, 2010 I emailed Dr. Jay Walsh and expressed our concerns regarding RIC's handling of the complaint in this matter. As of this date, I have not received a response. I am furnishing you a copy of my email correspondence to Dr. Walsh below. Before you proceed further in this matter, I would appreciate a response to the concerns we have raised.

Jerry H. Trachtman

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Ms. Erkan, I would appreciate your providing me answers to the following questions:

- If you believe that the research misconduct policies and procedures established by NU for its research community do not apply to RIC, please furnish me an explanation as to why not. On their face, they apply to RIC. Dr. Walsh referred me to you for an answer.
- If RIC has its own research misconduct policies and procedures which were complied with in this matter, please furnish me a copy or direct me to a source where I can obtain a copy.
- If RIC has a procedure in place to formally challenge the findings in the "Preliminary Inquiry Report", please consider this correspondence as such a challenge and furnish me a copy of that procedure.

Based upon the foregoing, it appears that this "Preliminary Inquiry" is a sham, it should be set aside, and a proper investigation into the Foundation's allegations of research misconduct should be conducted in accordance with NU's published research misconduct policies and procedures.

I look forward to your prompt reply.

Jerry H. Trachtman

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