Rehabilitation Institute *of* Chicago

345 East Superior Street
Chicago, Illinois 60611-4496
312-238-1000 telephone
www.ric.org

October 22, 2010

Dear Dr. Kirkpatrick, Mr. Hoffman and Mr. Trachtman:

In accord with the letter directed to each of you dated September, 27, 2010, the Rehabilitation Institute of Chicago ("RIC") established a Preliminary Inquiry Committee to review the allegations you raised concerning Dr. Norman Harden and to determine if a formal investigation is required. The Preliminary Inquiry Committee has thoroughly reviewed your allegations and determined that the allegations do not warrant a formal investigation. The Preliminary Inquiry Committee's Report is attached.

RIC considers this matter closed.

Sincerely,

Nancy E. Paridy, Esq.
Senior Vice President, General Counsel & Government Affairs

CC: Leyla Erkan, Corporate Compliance Officer, Rehabilitation Institute of Chicago
Dr. Zev Rymer, Vice President for Research, Rehabilitation Institute of Chicago
Joseph Walsh, Vice President for Research, Northwestern University

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Ms. Nancy Paridy
Sr. Vice President, General Counsel & Government Affairs
Rehabilitation Institute of Chicago
345 East Superior
Chicago, IL 60611

October 22, 2010

Re: Preliminary Inquiry Report

Dear Ms. Paridy:

The Preliminary Inquiry Committee (the "Committee") has reviewed the allegations against Dr. Norman Harden raised in a September 2, 2010 email to Dr. Joseph Walsh, Vice President for Research at Northwestern University ("NU"). NU referred the complaint to the Rehabilitation Institute of Chicago ("RIC") since Dr. Harden is an RIC employee and the research in question was conducted through RIC and at RIC. The Committee reviewed the allegations raised by Dr. Anthony Kirkpatrick, Mr. Richard Hoffman and Mr. Jerry Trachtman (the "Complainants") in accordance with its policies and procedures for reviewing any allegations of research misconduct. Additionally, because the complaint was directed originally to NU, RIC has coordinated with NU throughout the Preliminary Inquiry process.

I. Allegations Regarding Research Misconduct

The following are the allegations reviewed by the Committee:

1. Dr. Harden did not have IRB approval for research conducted at RIC.
2. The integrity of Dr. Harden's research results relative to his 1999 publication in PAIN[1], the official publication of the International Association for the Study of Pain, is questionable due to different results in a Japanese study.
3. The integrity of Dr. Harden's research results relative to his publications in PAIN is questionable because Dr. Harden has refused to provide one of the Complainants with the data collection forms for his studies. The Complainants specifically note that Dr. Harden is trying to conceal information by not providing the data collection form for the initial validation study.
4. The integrity of Dr. Harden's research results relative to his 2010 publication in PAIN is questionable because Dr. Harden has refused to provide one of the Complainants with the instructional video referenced in the "Method" section of the publication.
5. Dr. Harden omitted data, namely Table 5, from the published version of the 2010 publication in PAIN, and used varying measurements for duration of pain (median vs. mean) which suggests manipulation of data to show a more favorable outcome.
6. Research in the 2010 publication in PAIN was biased because over half of the co-authors were part of the consensus group for the Budapest criteria and the study checklist used biased the study team.
7. Results of research in the 2010 publication in PAIN were manipulated by adding two subjects to subject data in the final publication.

[1] PAIN is the official publication of the International Association for the Study of Pain.

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II. Inquiry:

A thorough inquiry was conducted which included but was not limited to the following interviews and review of information:

a. Interviews

1) Dr. Norman Harden (Respondent)
2) Dr. Stephen Bruehl (Co-author on publications referenced in allegations)

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 requests for interviews or additional information relative to the allegations.

During and subsequent to the Committee's interview with Dr. Harden, Dr. Harden refuted each allegation. In summary, Dr. Harden stated that the Complainants do not agree with his opinion regarding diagnostic criteria for Complex Regional Pain Syndrome (CRPS). Dr. Harden stated that he, as well as the other study sites and study investigators, conducted all of the research in question under IRB approval and in accordance with the study aims and design. Dr. Harden stated that he did not fabricate or falsify any research data.

During the Committee's interview with Dr. Bruehl, Dr. Bruehl explained the methodology for the statistical analysis of the research data in question. In summary, Dr. Bruehl clarified the different application of median and mean in the data analyses in the publications. He explained that a determination was made to analyze the data by the measurement used in the publications and that this determination was based on sound scientific judgment. Dr. Bruehl stated that the research data was not fabricated or falsified.

The Committee also consulted with an independent third party who has extensive experience in biostatistics and peer review for journal publications. The independent third party provided the Committee with opinions based on his expertise in statistical methodology and analysis and insight into standard practices in the scientific community for the scientific publication process.

b. Documentation

The Committee obtained and reviewed the following documentation:

1) Copies of Institutional Review Board (IRB) documentation;
2) Copies of Dr. Harden et al. 1999, 2002 and 2010 publications in PAIN and a copy of the 2010 Japanese publication in PAIN;
3) Copies of e-mail correspondence, study design documents and study guidelines among Dr. Harden and other study site investigators for the research in question;
4) Copies of e-mail correspondence and draft publication versions among Dr. Harden and co-authors of Dr. Harden et al. 2010 publication in PAIN; and
5) Copies of correspondence between the PAIN peer review panel and Dr. Harden for the Dr. Harden et al. 2010 publication in PAIN.

III. Determinations:

Based on interviews and the review of documentation, the Committee has determined that the allegations noted in Section I of this report do not warrant an investigation. Instead, the evidence shows that Dr. Harden had and has IRB approval for the research in question. Additionally, there was adequate scientific basis and information related to the data analysis and data presentation for the research in question. The evidence shows that Dr. Harden shared the data collection form in question with other researchers, including researchers in the Japanese study, and has communicated the use of study guidelines and tools to study site investigators. Also, the Committee concluded that there was adequate scientific basis and information for the removal of certain data from a publication, and the peer review panel for the publication was fully appraised of the data submitted and omitted. Lastly, the Committee

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determined that the study subject data reported in the publications was consistent among publication drafts and the final publication.

IV. Allegations Outside of the Scope of Research Misconduct:

The Committee determined that the remaining allegations raised by the Complainants do not meet RIC's definition of research misconduct[2] and do not relate to the integrity of research conducted at RIC. Such allegations[3] fall outside of RIC's policies for reviewing allegations of research misconduct and are outside of the purview of the Committee. Notwithstanding, the remaining allegations were referred to Dr. Zev Rymer, Vice President for Research, to review.

Sincerely,

Patricia Sheahan, Associate General Counsel

Julia M. Campbell, Associate Compliance Officer

CC: Leyla Erkan, Corporate Compliance Officer, RIC
Zev Rymer, Vice President for Research, RIC
Dr. Norman Harden, Respondent
Anthony Kirkpatrick, Complainant
Jerry Trachtman, Complainant
Richard Hoffman, Complainant
Jay Walsh, Vice President for Research, Northwestern University

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[2] Fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretations or judgments of data. Research misconduct under the RIC policy also includes failure to comply with requirements for the protection of human or animal research subjects.

[3] The allegations that fall outside of RIC's definition of research misconduct are:
1) Dr. Harden should not have referenced his research and diagnostic criteria in a 2007 Florida civil lawsuit deposition because it was not widely accepted in the global scientific community at the time.
2) Dr. Harden falsely testified under oath that a group of physicians agreed that the Budapest criteria should be adopted as the criteria for making the clinical diagnosis of CRPS.
3) Not all co-authors saw the final draft of the 2010 publication in PAIN Dr. Harden did not disclose certain information to PAIN with his publication submissions.