



# MEMORANDUM

OFFICE FOR PROTECTION OF RESEARCH SUBJECTS  
2107 Ueberroth Building  
169407

October 8, 2002

COPY

John Fahey, MD  
Department of Microbiology and Immunology  
12-262 Factor Building  
174718

**RE: Complaint About Human Research Collaboration on Malariotherapy**

Dear Dr. Fahey,

The Office for Protection of Research Subjects (OPRS) received an allegation of non-compliance with human research regulations regarding the above referenced research. The OPRS and the UCLA Institutional Review Boards (IRBs) collaborate with investigators and University administration to ensure the protection of the rights and welfare of human subjects in UCLA research as well as compliance with federal, State, and local laws and policies. To this end, the OPRS and IRBs are required through the University's federal assurance to address allegations regarding human subject research performed under the auspices of UCLA. Investigators are provided with an opportunity to respond to complaints prior to IRB review.

Enclosed please find the letter of complaint from "Dr. Bob Smith" and two referenced articles not available on the Heimlich Institute's website. Please respond in writing to the following issues by October 16, 2002.

1. The complainant indicates that you may be a co-author of "three scientific articles [that] have been submitted to international AIDS conferences describing research" related to malariotherapy in collaboration with Dr. Henry Heimlich. Please clarify whether you are acknowledged as co-author on any scientific papers, published or presented, regarding malariotherapy. If so, please provide the UCLA IRB with a copy of each article/paper for review.
2. The complainant indicates that the Heimlich Institute website promotes the "participation of UCLA and Dr. Fahey" regarding malaria experiments in China. The website indicates, "Our clinical studies in China continue to prove the benefits that malariotherapy has for HIV patients and to elucidate the interaction of malaria with HIV. To this end, the Heimlich Institute is working in conjunction with UCLA, gathering and analyzing data to show what immunological factors are responsible for the benefits derived from malariotherapy for HIV. It is our desire to analyze malaria parasites to determine how to duplicate their ability to

stimulate the immune system with synthetic products that cause the same effects in the immune system”.<sup>1</sup> Please clarify whether you are or have been “working in conjunction” with the Heimlich Institute. If so, please provide a detailed description of the work.

3. The complainant references an interview where Dr. Heimlich indicates, “We have an AIDS project now in China. We presented the results in 1996 at the National Institutes of Health and then at the AIDS Conference in Vancouver. As a matter of fact, UCLA has just joined with us on this project.... Now, with UCLA working with us doing viral loads, measuring the actual virus. Within the next five to six months we should know that answer. The patients are in China, the blood is being analyzed at UCLA. We want to treat the next 100 patients immediately. The patients are in China, the blood is being analyzed at UCLA.”<sup>2</sup> Please clarify whether you received human biological samples from Dr. Heimlich’s project. If so, please outline in detail the nature of the work you did with the samples.
  - a. Please clarify whether your work was acknowledged in scientific presentations, papers, or articles for the work Dr. Heimlich refers to in the interview.
4. The Heimlich Institute newsletter indicates in 1998, “The Heimlich Institute and our colleagues in China are working closely with John L. Fahey, MD, director for the Center for Interdisciplinary Research in Immunology and Disease at UCLA. Dr. Fahey’s laboratories are carrying out independent verification of the immunological results obtained in China, as well as providing technical support. Recently, Dr. Fahey visited Dr. Chen and found patients’ treatment progressing extremely well.”<sup>3</sup> Please clarify the nature of the work including “technical support” you and/or your laboratory conducted or supplied for the China research.
5. The Fall 1999 newsletter notes under the heading How You Can Save Lives, “Since 1994, Dr. Heimlich and his colleagues at the University of California at Los Angeles (UCLA) have been piloting the use of malariotherapy as a potential cure for HIV infection.... To date, 18 patients are in various stages of malariotherapy treatment. Follow-up data collected shows a substantial increase in CD-4 T-cell levels, and patients have remained asymptomatic for more than three years.... To validate and replicate these findings, Dr. Heimlich’s research team requires support that will enable them to offer this potentially invaluable treatment to additional patients. At \$10,000 per patient, \$1,200,000 would provide funds to test another 120 patients, and validate the use of malariotherapy to treat HIV....”<sup>4</sup> Please clarify whether

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<sup>1</sup> *Malaria and AIDS Epidemics in Africa*, <http://www.heimlichinstitute.org/aidsafrica.html>, accessed October 8, 2002.

<sup>2</sup> John McDougall, Interview with Henry Heimlich, MD, *The McDougall Newsletter*, July-August 1998, [http://www.drmcDougall.com/newsletter/july\\_aug1.html](http://www.drmcDougall.com/newsletter/july_aug1.html) accessed October 8, 2002.

<sup>3</sup> The Heimlich Institute, *Heimlich Institute Using Malariotherapy to treat HIV/AIDS Infection*, *Caring World*, v1, n1, Winter 1998, <http://www.heimlichinstitute.org/media/CaringWorldWinter98.pdf> accessed October 8, 2002.

<sup>4</sup> The Heimlich Institute, *Malariotherapy Research to Treat HIV/AIDS (\$1.2 million)*, *Caring World*, v1, n3, Fall 1999, <http://www.heimlichinstitute.org/media/CaringWorldFall99.pdf>, accessed October 8, 2002.

you collaborated in the pilot malariotherapy research as indicated in the article. If so, please outline the timeline of your participation and the work performed.

- a. Please clarify whether you participated in fund raising for the Heimlich Institute's malariotherapy research. If so, please outline the nature of your participation.
  - b. The same article also indicates, "In 1996, Professor John Fahey, of UCLA, asked to join the Heimlich Institute in this research project. UCLA is currently conducting our laboratory studies. Having recently returned from visiting our colleagues in China, Dr. Fahey is very positive about the results of these three-year clinical studies.... The Heimlich Institute plans to extend malariotherapy to the treatment of cancer and other diseases that may be curable by strengthening the immune system." Please clarify whether you asked to join the Heimlich Institute research project in 1996 and whether you did join the project. If so, please outline the nature of your participation since that time.
  - c. Additionally, the complainant provides Dr. Heimlich's response to the Food and Drug Administration [please see attached] that may refer to your participation in the research as indicated in the newsletter: "...In 1996, following presentations at the NIH (Bethesda, MD) and the 12<sup>th</sup> World AIDS Conference (Vancouver), a leading AIDS authority, a professor from a major U.S. university's immunology department, asked to join in this effort. Their doctors also made regular trips to the research site in [x] to provide independent evaluation of the quality of the research being done by our colleagues in [x]. They also provided independent corroboration of the results from [x]."<sup>5</sup> Please clarify whether the statements refer to you or individuals affiliated in your laboratory.
    - (i) If so, please outline in detail whether you or individuals from your laboratory or Center "made regular trips to the research site in [x] to provide independent evaluation of the quality of the research" or provided "independent corroboration of the results."
    - (ii) Additionally, please comment on whether your examination of the results was in a professional capacity resulting in co-authorship on scientific articles, papers, or presentations.
6. An article by Xiaoping Chen, et.al., *Phase-1 Studies of Malariotherapy for HIV Infection*, acknowledges you "for providing a part of the financial support, suggestions, and comments...."<sup>6</sup> Please clarify whether you provided financial support for the referenced research.

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<sup>5</sup> Letter from Henry Heimlich to Jane Henney, FDA, May 4, 2000: [http://research-watch.web1000.com/Heimlich\\_FDA1.html](http://research-watch.web1000.com/Heimlich_FDA1.html)


<sup>6</sup> Xiaoping Chen, Phase-1 Studies of Malariotherapy for HIV Infection, *Chinese Medical Sciences Journal*, December 1999, provided by complainant.

- a. If so, please clarify whether UCLA funds were provided for the research.
  - b. If so, please provide a detailed outline of the UCLA funds provided for the research.
7. The complainant references a presentation at the 6<sup>th</sup> International Annual Conference on AIDS in Asia and the Pacific by Xiao Ping Chen, et.al., that acknowledges your help in research design and work on the research, *Impact of Acute Vivax Malaria on the Immune System of HIV-positive Subjects* [please see attached article].<sup>7</sup> Please clarify whether you assisted in the research design of the clinical trial.
- a. Please clarify whether you “donated reagents for flow cytometry and cytokine quality measurement” or whether you performed laboratory tests for this research or any other malariotherapy research.
8. If you received any research materials obtained from subjects in malariotherapy research, such as biological samples, please clarify whether the materials included direct or indirect identifiers that could be linked back to the subjects/donors. If so, please describe the direct or indirect identifiers.
9. Please outline any other information provided to you with the samples.
10. If you or members of your laboratory visited China in order to provide services, information, or guidance related to the malariotherapy research, please clarify whether any UCLA funds were expended. If so, please outline the fund sources.
11. The complainant indicates that Dr. Xiao Ping Chen is a former UCLA post-doctoral student. Please clarify whether Dr. Chen worked in your laboratory or was your student.
- a. If so, please clarify when he was at UCLA.
  - b. Please clarify whether he worked with the Heimlich Institute and/or on malariotherapy while under your supervision.
  - c. Please describe in detail the nature of his work with the Heimlich Institute while at UCLA.
12. Please provide any other information you think is pertinent to the review of the allegations.

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<sup>7</sup> Xiao Ping Chen, et.al., *Impact of Acute Viva Malaria on the Immune System of HIV-positive Subjects*, <http://www.aidsvaccine2001.org/Posters/149.1.a.pdf>, accessed October 8, 2002.

I look forward to receiving your response. Please contact me at 825-5344 or [speckman@oprs.ucla.edu](mailto:speckman@oprs.ucla.edu) if you have any questions.

Sincerely,  


Steven Peckman  
Associate Director-Human Subjects Research

- Enclosures:
1. October 2, 2002 letter from "Dr. Bob Smith".
  2. Henry Heimlich May 4, 2000 correspondence to Jane Henney, FDA, supplied by "Dr. Bob Smith".
  3. Xiao Ping Chen, et.al., Impact of Acute Vivax Malaria on the Immune System of *HIV-positive Subjects*, supplied by "Dr. Bob Smith".

**Please forward all requested responses to:**

Steven Peckman  
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