



MEMORANDUM

OFFICE FOR PROTECTION OF RESEARCH SUBJECTS
2107 Ueberroth Building
169407

February 14, 2003

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 Medical Institutional Review Board (MIRB) received additional information regarding your alleged participation in malariotherapy research and your letters of January 9 & 10, 2003. The Board was sorry to hear of your scheduled surgery and wishes you the best for a speedy recovery.

The MIRB reviewed the material during the meeting of January 29, 2003. The MIRB noted that the new information may indicate you were "engaged" in human subjects research as defined by the Federal regulations, 45 CFR 46, and the Department of Health and Human Services-Office of Human Research Protections (DHHS-OHRP) guidelines. Please note: the MIRB did not consider your assessments of the malariotherapy research as subject to its inquiry.

The Board requests your response to the following issues related to the conduct of human subjects research by March 14, 2003.

1. The MIRB previously noted that you do not appear to be engaged in human subjects research related to the allegations from "Dr. Bob Smith". The IRB's determination was based in part on your October 17, 2002 statement, "I have not been 'working in conjunction' with the Heimlich Institute" and similar statements in response to our October 2002 inquiry. As a result of the Board's determination, Campus Counsel Patricia Jasper sent a letter to Dr. Henry Heimlich. The MIRB, therefore, was surprised to receive Dr. Heimlich's documentation indicating your possible involvement in malariotherapy research.
 - a. For example, your August 8, 1996 letter to Dr. Heimlich offers assistance in measuring cytokine levels "in selected patients treated with malariotherapy." Your January 9, 2003 letter to Ms. Jasper indicates the August 8, 1996 correspondence "...is an initial exploratory letter without commitments. It enabled us to get the address, etc., of the lead Chinese investigator, Dr. Xiao Ping Chen." Yet, the August 8, 1996 letter outlines a dual intent. The first intent or in your words, "context", offers your laboratory's assistance, as

noted above. The second “context” offers to “...develop a means of helping [Dr. Heimlich’s] Chinese colleagues in carrying out their studies. Assistance with reagents and quality control samples for CD4 measurements as well as for other parameters of HIV infection.” Please clarify whether Dr. Chen was encouraged to bring biological samples from the malariotherapy research to UCLA as a result of your August 8, 1996 letter and your subsequent recruitment of him for participation in the Fogarty training grant.

- b. Your August 6, 1997 letter to Dr. Heimlich included “tables of the data obtained on the samples provided by Chen Xiao Ping.” The letter indicates tests performed at UCLA on samples 4001, 4002, 4003, 4004, 4005, 4006, 4007, and 4008. The letter informs Dr. Heimlich to “please feel free to use this data in reports and publications. We would appreciate an acknowledgement and credit to the support provided by NIH grants TW 00003 and AI 36086.” Your October 17, 2002 letter to the MIRB, however, indicates samples “...independently brought by Dr. X.P. Chen to UCLA and tested by Dr. X.P. Chen were identified only by serial numbers (1,2,3, etc.) and could not be linked to the subjects.” Furthermore, your November 6, 1998 letter to Dr. Chen acknowledges the difficulty of performing clinical research and appears to indicate the samples are not anonymous or anonymized but rather coded with direct or indirect codes that could be linked to direct subject identifiers [“... to maintain continued follow-up contact, obtaining blood samples, seeing that appropriate analyses are done and that the data is collected is an enormous task.”]. Please clarify whether the above referenced biological samples analyzed in UCLA facilities were coded, unlinked, or unidentified. If the samples were coded, please provide a detailed description of the code, e.g., the information from donors linked to the code, and identify the individuals who held or hold the links to the code.

Please use the following National Bioethics Advisory Commission (NBAC) definitions¹ to guide your response to the request:

Coded Samples: Sometimes termed “linked” or “identifiable,” these samples are supplied by repositories to investigators from identified specimens with a code rather than with personally identifying information, such as a name or a Social Security number. The code could be used to link personal identifying information with the sample.

Unlinked samples: Sometimes termed “anonymized,” these samples lack identifiers or codes that can link a particular sample to an identified specimen or a particular human being.

Unidentified Samples: Sometimes termed “anonymous,” those specimens for which identifiable personal information was not collected or, if collected, was not maintained and cannot be retrieved by the repository.

¹ National Bioethics Advisory Commission, Research Involving Human Biological Materials: Ethical Issues and Policy Guidance, Rockville: August 1999.

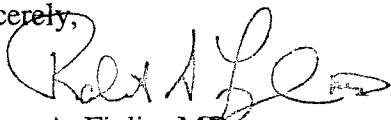
2. Your September 18, 1998 email to Dr. Chen notes, "However, it would be interesting to review your preliminary data with both HIV- and HIV+ populations in Guanzhou. We do not expect that the data would be the same in both locations, but a look at the initial data might be advantageous at this time, particularly if more reagents will be needed. Separately, of course, there is the interest in the clinical and laboratory status of the participants in your study of malarial therapy. It would be interesting to know how many febrile episodes each of the recipients had and any other clinical manifestations of the malarial infection or of HIV induced AIDS. Also, the CD4 T-cell levels and other laboratory parameters that you have been able to measure should be quite interesting. I do hope that you will be willing to share that with me." The email also seems to suggest there were identifiers linked to the coded samples that would enable connecting outcome to possibly identifiable clinical information.
 - a. Please clarify whether you or other UCLA personnel were provided with any such data described in your September 18, 1998 email during or after the visit to China. If so, please explain the nature of the data and describe the method of coding using the NBAC definitions outlined above.
 - b. The same email indicates, "We can discuss the shipment of samples for viral load determination. It would be reasonable to wait until I have visited Guangzhou before sending any samples here." Please clarify whether such samples were sent to UCLA or any other facility in the USA.
3. A September 25, 1998 email from "Eric" through Dr. Chen's email account to Dr. Heimlich indicates in part, "This foundation has told [sic] that we will not be able to get any funding for additional patients until Dr. Heimlich and Dr. Fahey present the results on the current patients, especially the viral loads." Your January 9, 2003 letter to Ms. Jasper indicates the email is "Misleading." Please explain why the email is "misleading."
 - a. Please identify "Eric" and describe his relationship to the Fogarty grant, the malariotherapy research, or UCLA.
 - b. Additionally, please describe the nature of the presentation referred to in the email and whether you participated in such a presentation.
4. Your November 10, 1998 email to Dr. Chen requests the exclusion of Dr. Najib Aziz and you as co-authors on "the 2nd study." Rather, you suggest "it is more appropriate if you simply acknowledge assistance.... we should not be among manuscript authors at this time." Please explain why you and Dr. Aziz declined co-authorship "at this time."
 - a. The email also indicates "...it will certainly facilitate making judgments about tests where the results appeared to changed [sic] substantially during the malarial period as well as subsequently. We hope to be of assistance in this data analyses. The data for the CD4 and CD8 measurements obtained at the 1 month and 3 month time points after the

end of malarial infection will also be interesting to see.” Please clarify if you or Dr. Aziz were provided with such information.

- b. If so, please outline the coding system applied to the data, using the NBAC definitions described above.
5. Please provide the full title and IRB number, if applicable, for the grant referenced as AI 36086.
6. The MIRB acknowledges your December 30, 2002 response wherein you provided assurance that UCLA IRB approval or Certification of Exemption would be required “...for any and all individuals who wish to work with human biological materials or data for research purposes and work in my laboratory or participate in scholarly programs under my supervision, such as the grant from the Fogarty International Center.”
7. Please provide the Board with any other information you think is pertinent to the review of the allegations.

On behalf of the MIRB, I thank you for your commitment to the protection of the rights and welfare of human research subjects. Please contact Steven Peckman, Associate Director Human Subjects Research at 825-5344 or speckman@opr.ucla.edu if you have any questions.

Sincerely,



Robert A. Figlin, MD

Chair

On behalf of the Medical Institutional Review Board

Please forward all requested responses to:

Steven Peckman
Office for Protection of Research Subjects
2107 PVUB
169407