



MEMORANDUM

OFFICE FOR PROTECTION OF RESEARCH SUBJECTS
2107 Ueberroth Building
169407

March 30, 2003

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

COPY

RE: Complaint About Human Research Collaboration on Malariotherapy

Dear Dr. Fahey,

The Medical Institutional Review Board (MIRB) thanks you for your cooperation in our review of the above referenced complaint. During the March 26, 2003 meeting the Board reviewed your March 21, 2003 response regarding your alleged participation in malariotherapy research. After extensive discussion the Board decided the following:

1. The MIRB notes that it appears from the available information that the samples brought to UCLA by Dr. Xiao Peng Chen from China for work in the Fogarty Program were coded with indirect links to personal identifiers. You indicated neither you nor "...any other UCLA contact was provided with any such individually identifiable information concerning Dr. X. P. Chen's malariotherapy research. The samples brought and the data provided to UCLA concerning Dr. X. P. Chen's research did not allow us to ascertain or to identify the particular individuals who were the source of the samples or data. We did not request or receive any individually identifiable information for any of the samples or data from Dr. X. P. Chen's research. (The only samples from that research brought to UCLA were samples brought by Dr. X. P. Chen to UCLA when he was here in 1997 for Fogarty grant purposes. Those samples came from a 1994 study previously completed without UCLA involvement.)"

While the Board acknowledges the above claim, your response also indicates, "In retrospect, it appears that Dr. X. P. Chen may have had links between the 1, 2, and 3 code and the patients in this study" and "Dr. Xiao Peng Chen, the investigator, may have had some means of linking data, but he did not share that with us." As previously documented, Dr. Chen worked on the samples in your laboratory as part of the Fogarty grant. Therefore, Dr. Chen's work was under your guidance and authority and he relied on your oversight regarding ethical and regulatory issues. Furthermore, though you may not have been the principal investigator for the research on the samples, you and the laboratory participated in the research by allowing the testing of the samples in the laboratory. As indicated in your December 30, 2002 response, it was your "understanding that [Dr.] Chen probably intended to use the analyses of his anonymized blood samples to contribute to a research publication on malariotherapy... Please be assured that I will require UCLA IRB approval or Certification of Exemption for any and all individuals who wish to work with human biological samples or data for research purposes and work in my laboratory or participate in scholarly programs under my supervision, such as the Fogarty International Center."

UCLA policies for human subjects research on existing human biological material or data related to human subjects were disseminated campuswide in 1996. Additionally, the UCLA Investigator's Manual for the Protection of Human Subjects was published and distributed in April 1997. The Manual contains explicit guidance regarding research with human biological material.

Part 1, Section III of the UCLA Multiple Project Assurance¹ (MPA) with the Department of Health and Human Services – Office for Human Research Protections (DHHS-OHRP) indicates UCLA will abide by and our IRBs will prospectively review “all research involving human subjects, and all other activities which even in part involve such research, regardless of sponsorship, if one or more of the following apply:

- the conduct or recruitment of the research involves institutional resources (property, facility or funding, including extramural funds administered by the institution), or
- the research is conducted by or under the direction of any employee, student or agent of this institution in connection with his or her institutional responsibilities, or
- the research is conducted by or under the direction of any employee, student or agent of this institution using any property or facility of this institution, or
- the research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.”

The DHHS-OHRP January 26, 1999 guidance, “Engagement of Institutions in Research²” indicates in Section A(5): an institution and by extension an investigator is engaged in human subjects research when, “Institutions whose employees or agents obtain, receive, or possess private information that is individually identifiable (either directly or indirectly through coding systems) for research purposes (e.g., obtaining private information from medical records in an individually identifiable form). (However, see Examples B(7) and B(8) for certain activities involving the release of information and/or specimens to investigators in non-identifiable form.)” Section B(7) of the same document states an institution is not engaged in human subjects research if “the data set contains no direct or indirect identifiers.” Section B(8) is not relevant to this issue.

Dr. Chen appears to have retained links between the codes and individual subjects, and tests were performed on the samples for research purposes at UCLA using campus resources, property, and facilities. Additionally, Dr. Chen’s work was performed as part of the Fogarty program under your supervision. Therefore, you as the faculty sponsor and UCLA were engaged in human subjects research.

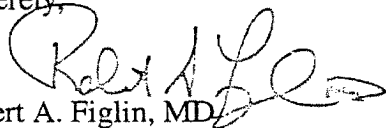
¹ UCLA. Multiple Project Assurance of Compliance with DHHS Regulations for Protection of Human Research Subjects, May 1, 1998: <http://www.oprs.ucla.edu/human/hspcmanual/MPA.htm>

² Director, Division of Human Subject Protections, OPRR. Engagement of Institutions in Research, January 26, 1999: <http://ohrp.osophs.dhhs.gov/humansubjects/assurance/engage.htm>

2. The Board reminds you that it was your responsibility to determine the nature of the samples that were being analyzed by Dr. Chen. It appears that your detailed letter to Dr. Heimlich regarding the data makes clear that you were personally involved in evaluating the data and that Dr. Chen's work at UCLA was done with your knowledge, approval, and intimate involvement. It, therefore, is inappropriate to shift the responsibility for the research done at UCLA to Dr. Chen. As the head of the laboratory and the faculty member in charge of the Fogarty Training Program it was your responsibility to ensure that activities done in your laboratory, using UCLA resources, were in accordance with UCLA policies and Federal regulations. Your responsibilities included making certain that Dr. Chen's work met all of the applicable Federal regulations and campus policies for human subjects research. In order to avoid future problems, please contact our Office for Protection of Research Subjects (OPRS) when questions arise regarding human subjects research.
3. The MIRB accepts your December 30, 2002 assurance that you will ensure that future Fogarty scholars and others under your direction have appropriate UCLA IRB approval or certification of exemption prior to initiating research activities at UCLA or using UCLA property, resources, material, or funding.
4. Your involvement in Dr. Chen's research will be reported to the DHHS-OHRP, the Fogarty International Program, and the Executive Vice Chancellor consistent with our MPA and the Federal regulations.

The Federal regulations and University policy provide investigators an opportunity to respond to all IRB decisions. If you have additional information relevant to this matter, please submit the information in writing in the next 30 days. Please contact Steven Peckman, Associate Director Human Subjects Research at 825-5344 or speckman@oprs.ucla.edu if you have any questions.

Sincerely,



Robert A. Figlin, MD

Chair

On behalf of the Medical Institutional Review Board

cc: Executive Vice Chancellor Daniel Neuman
Dean Gerald Levey, School of Medicine
Vice Chancellor Roberto Peccei
Chair Jeffrey Miller, Microbiology, Immunology & Molecular Genetics

Please forward all requested responses to:

Steven Peckman
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