

CONFIDENTIAL DRAFT – FOR INTERNAL USE ONLY – NOT FOR DISTRIBUTION

Max Benavidez (maxb@support.ucla.edu)
(310) 794-6868

For Immediate Use:
April 2, 2003

**UCLA MEDICAL INSTITUTIONAL REVIEW BOARD (MIRB) ISSUES ITS
DETERMINATION IN THE FAHEY CASE REGARDING CLAIMS ABOUT
MALARIOOTHERAPY STUDIES FOR HIV**

On March 30, 2003, the UCLA Medical Institutional Review Board (MIRB) issued its determination regarding a complaint about Dr. John Fahey and allegations that he participated in malariotherapy research.

The MIRB determined that Dr. Fahey was personally involved in evaluating data brought to UCLA from China by Dr. Xiao Peng Chen under the Fogarty International Program. Since Dr. Chen's work was performed as part of the Fogarty Program under Dr. Fahey's supervision, the MIRB determined that Dr. Fahey was engaged in human subjects research.

According to the MIRB, Dr. Fahey violated Federal regulations as well as UCLA policy for the protection of human research subjects by allowing Dr. Chen to conduct research at UCLA in a UCLA program without prior UCLA approval. At the same time, based on a review of the information in this case, Dr. Fahey did not directly participate in clinical trials where malariotherapy was administered to Chinese subjects. The Board also determined that Dr. Fahey and his laboratory participated indirectly in the research by allowing the testing of Dr. Chen's samples. This indirect participation in the research occurred by assisting and overseeing the subsequent analysis of biological material for research purposes with indirect subject identifiers brought from China as part of the Fogarty training program.

The MIRB accepts Dr. Fahey's assurances made on December 30, 2002, that he will ensure that future Fogarty scholars and others under his direction will have appropriate UCLA approval prior to conducting any research activities at UCLA or using UCLA property, resources, material, or funding.

Dr. Fahey's involvement in Dr. Chen's research will be reported to the U.S. Department of Health and Human Services – Office for Human Research Protections (DHHS-OHRP), to the Fogarty International Program, and to UCLA's Executive Vice Chancellor. This reporting is consistent with UCLA's Multiple Project Assurance (MPA) and with Federal regulations.

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4/6/03

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According to the MIRB, Dr. Fahey violated Federal regulations as well as UCLA policy for the protection of human research subjects by allowing Dr. Chen to conduct research at UCLA in a UCLA program without prior UCLA approval. At the same time, based on a review of the information in this case, Dr. Fahey did not directly participate in clinical trials where malariotherapy was administered to Chinese subjects. The Board also determined that Dr. Fahey and his laboratory participated indirectly in the research by allowing the testing of Dr. Chen's samples. This indirect participation in the research occurred by assisting and overseeing the subsequent analysis of biological material for research purposes with indirect subject identifiers brought from China as part of the Fogarty training program.

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**UCLA MEDICAL INSTITUTIONAL REVIEW BOARD (MIRB) ISSUES ITS
DETERMINATION IN THE FAHEY CASE REGARDING CLAIMS ABOUT
MALARIOOTHERAPY STUDIES FOR HIV**

On March 30, 2003, the UCLA Medical Institutional Review Board (MIRB) issued its determination regarding a complaint about Dr. John Fahey and allegations that he participated in malariotherapy research. *(obj incl. AZZ)*

The MIRB determined that Dr. Fahey while not personally involved in the clinical trials, was involved in evaluating data and biological samples brought to UCLA from China by Dr. Xiao Peng Chen under the Fogarty International Program. Since Dr. Chen's work was performed as part of the Fogarty Program at UCLA and was under Dr. Fahey's supervision, the MIRB determined that Dr. Fahey was engaged in human subjects research. *laboratory*

According to the MIRB, Dr. Fahey violated Federal regulations as well as UCLA policy for the protection of human research subjects by allowing Dr. Chen to conduct research at UCLA in a program funded to UCLA without prior UCLA approval. At the same time, based on a review of the information in this case, Dr. Fahey did not directly participate in clinical trials where malariotherapy was administered to Chinese subjects. The Board determined that Dr. Fahey and his laboratory participated indirectly in the research by allowing the testing of Dr. Chen's samples. This indirect participation in the research occurred by assisting and overseeing the subsequent analysis for research purposes of biological material with indirect subject identifiers brought from China as part of the Fogarty training program.

The MIRB accepted Dr. Fahey's assurances made on December 30, 2002 *MS* (IS THIS THE RIGHT DATE?), that he will ensure that future Fogarty scholars and others under his direction will have appropriate UCLA approval prior to conducting any research activities at UCLA or using UCLA property, resources, material, or funding.

Dr. Fahey's involvement in Dr. Chen's research will be reported to the U.S. Department of Health and Human Services – Office for Human Research Protections (DHHS-OHRP), to the Fogarty International Program, and to UCLA's Executive Vice Chancellor. This reporting is consistent with UCLA's Multiple Project Assurance (MPA) and with Federal regulations.

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For Immediate Use:
April 7, 2003

**UCLA MEDICAL INSTITUTIONAL REVIEW BOARD (MIRB) ISSUES ITS
DETERMINATION IN THE FAHEY CASE REGARDING CLAIMS ABOUT
MALARIOOTHERAPY STUDIES FOR HIV**

On March 30, 2003, the UCLA Medical Institutional Review Board (MIRB) issued its determination regarding a complaint about Dr. John Fahey and allegations that he participated in malariotherapy research at UCLA

The MIRB determined that Dr. Fahey while not personally involved in the clinical trials, he was involved in evaluating data and biological samples brought to UCLA from China by Dr. Xiao Peng Chen under the Fogarty International Program. Since Dr. Chen's work was performed as part of the Fogarty Program at UCLA and was under Dr. Fahey's supervision, the MIRB determined that Dr. Fahey was engaged in human subjects research.

According to the MIRB, in not getting prior approval from UCLA, Dr. Fahey violated Federal regulations as well as UCLA policy for the protection of human research subjects by allowing Dr. Chen to conduct research at UCLA in a program funded to UCLA. Dr. Fahey did not, however, directly participate in clinical trials where malariotherapy was administered to Chinese subjects. The Board determined that Dr. Fahey and his laboratory participated only indirectly in the research by allowing the testing of Dr. Chen's samples.

The MIRB accepted Dr. Fahey's assurances made on December 30, 2002, that he will ensure that future Fogarty scholars and others under his direction will have appropriate UCLA IRB approval prior to conducting any research activities at UCLA or using UCLA property, resources, material, or funding.

Dr. Fahey's involvement in Dr. Chen's research will be reported to the U.S. Department of Health and Human Services – Office for Human Research Protections (DHHS-OHRP), to the Fogarty International Program, and to UCLA's Executive Vice Chancellor. This reporting is consistent with UCLA's Multiple Project Assurance (MPA) and with Federal regulations.

UCLA has never approved any research pertaining to malariotherapy studies for HIV.

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