5. **We have the following comments regarding the GLCCM web site's description of the IRB.** The web site contains the following statement: "The IRB has met National Institutes of Health guidelines." This statement is misleading in that as of March 9, 2000, your IRB has not been granted a Multiple Projects Assurance, a Single Project Assurance, or a Cooperative Project Assurance by the Office for Protection From Research Risks. →→ Please remove this statement from your web site.

6. **We have the following comments and questions regarding the February 25, 2000, meeting minutes that were submitted with the IRB's response dated March 17, 2000:**

   A. Regarding study M022, the minutes state "this study was approved 9/20/97 and was placed on hold for over one year." Meeting minutes should provide sufficient background to explain the history in such situations. →→ Please explain why the approved study was placed on hold, and describe the circumstances that have since changed to allow the study to proceed.

   B. The IRB's uses of the term "significant risk" in reference to studies that do not involve a medical device. Please refer to the discussion in item 1 above regarding the written procedures *Section VI.B.2.*

7. **We have the following comments regarding the IRB's review and approval of the study entitled "Induced Malaria as Therapy for HIV Infection."**

   We strongly disagree that the IRB properly considered the scientific merit of the study and that the protocol minimized risks to subjects concerning this study, as expressed in you response letter dated March 17, 2000, for the following reasons:

   A. The protocol is inadequate in that it does not describe what testing is done to screen the malarial parasite donors. The direct injection of blood from a malaria parasite donor into a study subject would not be permitted in the U.S. because cultured malaria parasites are available. The IRB did not review information about how subjects and malaria parasite donors are recruited and screened.

   B. The statement in the response letter that "the IRB's approach [to this study] was no different than if the research was conducted in the U.S." demonstrates that the IRB appears to lack the expertise or experience to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

C. We reject your position that the IRB was able to consider the community attitudes of the Chinese population in which the research was to be conducted. Given the great differences between Chinese and American cultures, we do not accept that the GLCCM was capable of understanding Chinese attitudes about the research. This is one reason, among many, that the academic institution in China that was associated with the research, as referenced in your response letter, should have obtained governmental and approval from a local IRB (or equivalent body).

D. Although Dr. Heimlich's Foundation is apparently underwriting this research study, he has no responsibilities for subject screening, study procedures, or evaluation of the subjects, and appears to have no direct supervisory role over the study. Dr. Heimlich is not obligated to obtain IRB approval for his limited involvement in this study, and, indeed, in this case, it was inappropriate for him to do so.

E. The IRB file for this study did not contain the Chinese translation of the protocol or consent form. In general, when study subjects are non-English speakers, the IRB must assure that the consent form translation is accurate.

F. Please describe the IRB's efforts to determine that this study had been approved by the appropriate office in the Ministry of Health and by the local institution(s) where the research was conducted.

The IRB should rescind approval of this study and defer the human subject protection responsibilities to the responsible Chinese authorities. →→ Please provide documentation that the IRB has informed the Chinese clinical investigator of his responsibility to obtain the appropriate Chinese government and local institutional approval for the research.

The IRB remains under the following restrictions imposed on March 9, 2000, in accordance with 21 CFR 56.120(b)(1) and (2):

- *no new studies that are subject to Parts 50 and 56 of the FDA regulations are to be approved by your IRB, and*
- *no new subjects are to be admitted to ongoing studies that are subject to 21 CFR Parts 50 and 56 until you have received notification from this office that adequate corrections have been made.*

These restrictions do not relieve the IRB of its responsibility for receiving and reacting to reports of unexpected and serious reactions and routine progress reports from ongoing studies.