Sounds like you have touched all the bases, Rob. I'm comfortable. Myron

From Rob: As you know, we have found it very difficult to recruit factories and workers for phase 2 of the molecular epidemiology study in Shanghai. **We recently met with Chinese collegues from hospitals, cdc, and fudan, and they made a number of recommendations to our recruitment approaches, which were deemed as very western-oriented. One of the changes recommended was to not require each participant to sign a separate consent form.. it is viewed very suspiciously by Chinese employees, and often implies a forced indebtedness on the part of the individual. Rather, verbal, witnessed consent was recommended, with a collective list of participants and non-participants maintained.** At the recent SHS annual meeting, we discussed this with the ethics committee, and they agreed (see note below) that such an approach met international ethical standards. We hope that this will help somewhat in recruiting new factories and workers.

From Richard: I am forwarding the attached email from Dr. Idanpaan-Heikkila, Secretary General of the Council for International Organizations of Medical Sciences (WHO), concerning our request for approval of the ERP for the proposed changes in obtaining informed consent from workers as part of the ME Phase IIa study. We can now proceed to drafting changes to our IC's and study protocols. After final approval by the Fudan IRB and the Colorado COMIRB, we can update our IC methods and proceedures. It will be important communicate effectivey the proposed changes and why they are necessary to both IRB's and their members.

Dear Richard.

The Ethics Review Panel (ERP) of the Shanghai Health Project considered the proposal of the Chinese committee as introduced by you.

According to international ethical guidance documents such as the WMA Declaration of Helsinki (2004) and the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002), the following procedure should be applied in obtaining the informed consent.

After ensuring that the prospective research subject has understood the information regarding participation in the research, the physician should obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

In your special situation, the information regarding the participation in research is given when initial contact is made with a prospective subject and the oral agreement of the subject to participate in research will be properly witnessed. Instead of signing the individual informed consent form at that time, the subject will later on sign a list of consenting participants appended to the consent form.

The ERP reached a consensus that the proposed method described by the Chinese committee was in conformity with the international ethical documents listed above.

With best regards,

Juhana E. Idänpään-Heikkilä, MD, PhD

Secretary-General

Council for International Organizations of

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