

From: Elsie Barbaza [Barbaza@api.org]
Sent: Tuesday, May 15, 2001 7:37 AM
To: 'pmclegg@shellus.com'
Subject: Shell Chem Check/Benzen Health Research Consortium

Importance: High

Lorraine Twerdok wishes to inform you that she received the check \$15,000 for Benzene Health Research Consortium.

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Shanghai Health Study - Ethics

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Assuring that medical, social and cultural ethical issues are addressed appropriately is a challenge for the Shanghai Health Study. The consortium has addressed ethical issues. The attached document provides a summary of the issues and the processes for addressing.

Successfully managing ethical issues in China during the study will result in

Individuals

- Good medical treatment for participants
- Participants compensated appropriately
- Participants understand and consent to be a part of the study
- Confidentiality for participants is maintained

Workplace

- Benzene exposures are reduced in the workplace
- Monitoring technology is shared

Community

- Laboratory is gifted to Fudon University
- Trained technicians remain
- Diagnostic tools

For Shell, we will have

- Honored our commitment to HSE and Product Stewardship
- Proactively investigated the potential health effects of exposure to benzene
- Participated in a joint US-China project

- **Consortium Ethics Issue Paper**

Issue	Resolution
Scientific Validity of the Study	• Multiple review of protocols by an independent Scientific Review Panel • Approval of protocols by US and Chinese Universities' Institutional Review Boards • Future protocol changes to be approved by Scientific Review Panel
Benefits to Participants	• Uniform, general understood diagnostic standards for hematopoietic disease • Regular, defined follow-up after treatment • Technology transfer for workplace monitoring • Ensure patients with benzene toxicity have been removed from workplace as required by law • Compensation for study participation
Appropriateness of Compensation to Participants	• Compensation for participation based on level of participation and standard practice in China for similar procedures.
Informed Consent	• Consent forms tailored to type of participation in the study and disease status, e.g., case or control. • Forms were developed with Chinese clinicians and bioethicist.
Confidentiality	• Separate password controlled databases for clinical and study-specific research data. Transfer of data between databases requires consent of participant.
Results	• The investigators will have final control over content and interpretation of published or presented study data.
Benefits to the General Worker Population Exposed to Benzene	• Investigators are cooperating with government efforts to lower benzene occupational exposures. • Identification of more sensitive biological indicators of exposure to benzene • Laboratory provides increased diagnostic capabilities
Community Benefits	• State of the art diagnostic laboratory with trained laboratory technicians is available to medical community and will remain in Shanghai. • Technology transfer from training of local laboratory technicians • Possible increase in standards for diagnosis and follow-up care for hematopoietic disease • Technology transfer of industrial hygiene monitoring technology & practices

