Shanghai Benzene Epidemiology Study
Consortium Conference Call
April 24, 2001

Shell Notes

1. Budget

- Not all companies have paid $15K seed money
- Expenses to be paid:
  - Chinese bioethicist
  - Reconvening protocol review panel
- 3 research assistants working for Irons funding ends May 31. Must notify b y May 15 as to continuation of position. Consortium commitment would be enough to continue. Monies to cover 3 are included in the study budget

2. Commitments

- May 15 commitment date
- May 1
  - Firm letter to API indicating commitment with conditions
    - Shell conditions include (1) critical mass, (2) Government/NGO representation on review panel, (3) a voice in overseeing the project, (4) assurance of cost control.
  - Comments on draft contract
- May 3
  - Conference call to determine if critical mass (enough shares are committed) meets company needs

3. Ethical Issues Review

See notes on Ethics Paper dated April 24, 2001

4. Protocol Review

There was a lot of discussion around the first review in 2000 and the role of the review panel in reviewing protocols as the study progresses.

Original review panel:

R. Larsen, Hematologist, University of Chicago Medical School
E. Delsell, epidemiologist, University of Alabama
N. Mueller, epidemiologist, Harvard
D. Albertini, genetic toxicologist, University of Vermont

Written comments from original review cannot be found (highlights need for document control)

Second Review

Shell expressed requirement to have non-industry representation. Possible candidates include: Richard Hayes, Nathaniel Rothman, EPA, WHO, IARC (Pat Butler)

Next protocol will happen in about 6 weeks. Proposal was to have original 4 review protocols and then spend 1 day with PIs.

Concern was expressed that a NGO/government review might derail project. Response was that it is better to address critics now, rather than later. Also, it will be the responsibility of the PIs to address the comments, not the consortia. This is an extension of the ethics opinion that PIs ;have control of study.

Suggestion: Develop a written role description and procedures for the Review Group. Document would be a scope/charter for the scientific review.
- Get ethics review
- Need an exposure assessment expert (S Tsai)

2 approaches suggested:
- Government scientist on review panel
- Larger stakeholder group not on panel to include NGO/ government

Scientific re view for the life of the project
- Expectations of reviewers
- Describe reviewers work product

- **Shell will clarify review process condition in our letter of commi**tment

5. Contract

Shell will send comments to API by May 1 – Christi

6. Consortium Administration

Shell concerns: Legal review; document management; scope of APIs administrative service

- Legal Review
  - Need a more structured approach
  - Need legal representation that understands consortium company concerns
  - Documents need legal review before release
  - Suggestion to put legal review with PR function

- Document Management

- Repository
- Controls
- Accountability
- Classification

- API Administrative Serviced
  - Funding management
  - Legal review
  - Document management
  - Meeting organization
  - Possible API membership in consortium

7. Concern about spy plane incident

Dr. Wong reported that Dr. Fu, Fudon University had expressed concern. Dr. Wong agreed to contact Dr. Fu to get details of his concern

Dr. Xu, bioethicist Fudon University, is very supportive of project.

Patsy will contact Shell DC office who may have contact with Chinese embassy

8. Consortium structure

Monetary sponsors have vote

9. Exit strategy

Need a statement if critical mass is not achieved and study is not done – Referred to Lynn Russo and Communication team

Question of reimbursing API seed money (Shell's position is that those who made the commitment are responsible for money.)

10. Cost escalation

Believe that budgets are well constructed and include inflation factors.

Put language in contract to protect consortium members from escalating costs with consent.

Believe that there is an opportunity for government grants after study is under way.

11. Data Availability

Focus is on transfer of information to the outside

Data will be made available via the final report

TSCA reporting will be done as required

Communication committee is responsible

Concern about release of data during the study

Have to protect the confidentiality of the study participants