

Minutes
Benzene Consortium Conference Call
April 24, 2001

Participants:

Barach Brody	Stuart Cagen	Myron Harrison
Bill Maseth	Norm Zeiser	Tom Armstrong
Patrick Beatty	Chris Roythorn	Craig Parker
Lorraine Twerdok	Patsy Clegg	Rich Herold
Don Burnette	Otto Wong	Christy Quinn
John Depasquale	Rob Schnatter	George Woodall

Funding Status Summary (Lorraine Twerdok)

Available Funds

- It is unlikely that additional API Dues Budget funds would be provided without firm commitments from member companies. API has provided approximately \$700K in seed money for the project over the last 1.5 years (\$350K from specific Benzene Task Force projects, \$185K reprogrammed from other Benzene Task Force projects, and \$165K reprogrammed from H&PS).
- \$17K in company seed money contributions remain from the original \$85K promised (only \$60K was actually collected, another \$25K in outstanding commitments from 2 companies have not been paid)
- \$4,100 in API's Dues Budget monies remain uncommitted/unspent

Outstanding Commitments/Needs

- \$2,500 to Chinese bioethicist
- \$21K to EMBSI
- \$25K to Dr. Fu of Fudan University for laboratory renovations (part of the exit strategy commitments, see below)
- Reviewers to review final protocols, estimated cost of \$25K

Schedule for a Decision

- Funding in Irons lab for this work comes to an end on June 1, he needs a guarantee by May 15th or his staff positions will be terminated by the University.
- **ACTION ITEM/DECISION** (Member Companies): Letter of commitment from companies by May 1 (with contingencies) to Lorraine Twerdok. An e-mail followed up by a hard-copy letter is acceptable.

Lorraine Twerdok
American Petroleum Institute
1220 L Street, NW
Washington, DC 20005

Twerdokl@api.org

Points needed for the commitment letter:

- Co. is committed to participate in the consortium pending enough companies contribute to create a critical mass of funding (see note below).
- Any contingencies upon which participation is based, e.g., review process, non-industry stakeholder participation.
- Critical mass will be based upon number of shares represented by participating companies and will be determined by the consortium members on another conference call. **Next conference call on May 3, 3:30 PM EDT**

Ethics Summary (Baruch Brody - see handout)

Dr. Brody feels that the protocols are in very good shape and the areas have been identified that need to be finalized with the Chinese investigators (e.g., the consent forms, etc.)

Benefits

- Payments to individuals – may be in cash, and may need to be linked to completing the consent forms as a form of documentation
- There is a need to consider the mechanics/logistics of payments in the protocol

Protection of Confidentiality

- Four databases will be used, with limited access to each
- Only the final database will remain after the study is complete. It will be owned by the Chinese and will NOT contain any linkages to individuals.

The costs for ethics review were only ½ of those proposed due in large part to the substantial amount of work done by Otto Wong & Rich Irons to address the concerns raised by the ethics workgroup.

Consortium Formation Issues

Concern about Spy Plane Incident

- Dr. Fu is also concerned with this issue (The following is an excerpt of an e-mail from Dr. Fu to Otto after the call):
"I was really glad to hear the good progress of the project from you. I am concerning and worry about the relationship of Sino-US. In my side it would not affect our collaboration anymore. So I am waiting for the final decision..."
- Possibly discuss this with Chinese officials in DC
- Will be brought up and discussed on the May 3rd call.

Other Issues:

- Otto met Dr. Xu (the Chinese bio-ethicist) last month, who has been helping with review of the consent forms.

- Patrick received confirmation from Dr. Xu on his acceptance of the proposal for compensation (\$2,500).

Protocol Review

- Good agreement that the protocols are being reviewed over again outside the development process
- It was proposed to get NCI, EPA and/or other regulatory agencies involved in the review; it will give the studies more weight with agencies
- **ACTION ITEM** (George Woodall): Need to get written comments from reviewers, response to comments etc. from 1st round. The previous reviewers were: Dick Albertini (Genetic Toxicologist, U. of Vermont); Nancy Mueller (Epidemiologist, Harvard); Richard Larson (Hematologist/Oncologist, U. Chicago); Elizabeth DelZel (Epidemiologist U. of Alabama, Epidemiologist)
- **ACTION ITEM** (George Woodall): Need to make sure to document this 2nd set of reviews and provide a proposed timeline for completion.
 - Initial plan for 2nd round is to have 4 original reviewers (world class scientists, removed from the process) to do a review prior to IRB review by the Principal Investigator's organizations
 - Six weeks anticipated for review
- Issue of getting gov't agency to also review
 - Raises the issue of proper level of participation for NGOs & agencies (The model of having a stakeholder group as well as the oversight committee was discussed.)
 - How to approach the issue? They could participate as a formal member of the committee, or provide them with a more informal review of the protocols prior to an IRB review.
 - Depends on proper discipline represented by agency personnel and on how the organization will participate.
 - It was suggested to approach EPA & WHO for possible participants; IARC may also be a consideration (Patricia Buffler, Dean of the School of Public Health, UC Berkeley)
 - Need to determine how this review process will be constructed (parameters) prior to deciding on who to ask. Shell would rather have adverse comments early rather than late in the game.
- Responses to comments need to be handled by the PI's, but an issue of who has "final say." PI's need to take the comments into consideration, but do not need to accept all comments.
- **ACTION ITEM** (George Woodall/Patrick Beatty): Draft a proposed outline for the process steps for scientific review
 - This outline should also be reviewed by the Ethics Review Workgroup
 - Guidelines for reviewers: What is expected, how it will be processed, how it impacts the project

Contract Issues

- **ACTION ITEM** (Member Companies): All companies should send comments on the draft contract to George Woodall by May 1

Consortium Administration

- What is API's role in Adminstrating the project?, concerns with document management and segregation of documents (not necessarily only attorney/client privilege)
- All documents should go through API's OGC or other counsel prior to release
- The cost for outside counsel would be part of the \$1M communications budget.
- All funding management, invoicing, budgets, legal review of documents (by API counsel), tracking and archiving documents, oversight and administrating, etc. would be covered in the 5% administrative charge in the proposed budget
- Question on having API as administrator and also as a member of the consortium is a non-issue since two separate parts of API (Subscription Research and Benzene Task Force, respectively) will perform these functions.
- Legal review – lawyer should not change a document but needs to understand the document control process

Cost Control

- Basic concern of costs escalating in the future
- The reason they did escalate between the initial estimate and the final was that a lot of up front costs have been included. Inflation has been built into the estimate
- PI's needs to be are aware that costs are fixed
- Put a "true ceiling" on expenditures in the contract. It was suggested to put a "not to exceed" percentage where a member can exit "without prejudice" if it is exceeded.
- It was mentioned that a proposal for NIH-type funding could be used for other issues as they come up. Having an on-going flow of data may be looked upon favorably by the granting institution.
- PI's have been very thorough in looking at the details of the costs

Availability of Data

- The issue was sparked by Bill Moyers Special and concern that "burying information" not be a perception with this project
- "We expect open flows of information" which also works well with having agencies and NGO's as members on the oversight or a stakeholder committee
- Opposite side of coin is not to release data as they are being collected (interim findings), issues of confidentiality, incomplete data, etc.
- Paragraph 6 of draft contract (TSCA reporting) was seen as very appropriate

Consortium Structure

- Draft document not on the web site
- Only those having a full share will have a vote
- **ACTION ITEM** (George Woodall): Provide the detailed draft document on the web site

Exit Strategy

- Need to meet all financial obligations, including the 25K to Fudan University (see discussion above)
- The individual companies also need to honor their commitments to seed money contributions
- There is a communication issue on providing a reason "why the consortium did not go forward", if that is the case (done by the communication workgroup)

Next conference call on May 3, 3:30 PM EDT

DRAFT