

**Minutes
Oversight Committee
Benzene Health Research Consortium
July 26, 2001**

Participants:

Patrick Beatty (Chevron)
Patsy Clegg (Shell)
Carol Fairbrother (ExxonMobil)
Lynn Russo (ExxonMobil)
Tom Bond (BP) – via phone
Don Burnett (BP) – via phone
George Woodall (API)
Lorraine Twerdok (API)

Issues

Finances and Scheduling

- Rich Irons has secured a \$150K advance from the University of Colorado to begin work on the project.
- Need to find out when the IRB at the University of Colorado meets
- Some payments on invoices sent out last year and earlier this year are still outstanding.

Selection of a Chair for the Committee

- It was decided to rotate the chair among the companies on an annual basis, and that a vice-chair would also be selected and would serve as chair in the following year.
- BP will hold the chair, with Shell serving as vice-chair for the first year.

Contract Issues

- Issue of contracting with the Consortium (incorporating the consortium and having a separate contract with API to manage the project) versus companies contracting with API
- Need for a more explicit statement that the Oversight Committee would negotiate contracts with other types of organizations.
- Remove references to China, throughout.
- Do not include any of the individual researchers in the contract, this also pertains to the Shanghai Medical University and/or Fudan University.
- New title should be: AGREEMENT FOR THE CONDUCT AND FUNDING OF A RESEARCH PROGRAM ON HEALTH RISK FROM BENZENE EXPOSURE
- Section 1 – BP has comments on re-writing this section
- Section 2 – Membership needs to be broader in scope
- Section 3 – Definition of company also needs to be broadened and re-worked for other types of organizations.

- Section 5 - API Policies and Procedures will be used in administering the contract. Copies of the table of contents and selected policies relevant to the business of the consortium will be sent to the Oversight Committee members for review.
- Section 6 – Delete paragraphs (i) and (ii), then rework (iii) to not specify TSCA.
- Section 7 - Share Formula
 - May need some mechanism to negotiate variances to the funding structure (either for separate instances or for the overall structure)
 - Reimbursement language/mechanism
 - Weight of votes on funding issues (Section 7)
 - Need a cap written into the contract.
 - Potential for companies negotiating a “lower than share” contribution and having such companies given “associate” status with lower privileges, especially voting.
- Section 9 – **Action Item:** Scope statement will be developed by Patrick Beatty and George Woodall for inclusion as Section 9.
- Consortium Structure
 - Some statement on structure will need to be included as part of Section 7.
 - All protocol changes will be documented by API and posted to the consortium web page.
 - Ethics Review Panel will need a direct line of communication with the Scientific Review Panel

API Responsibilities

- Documentation – need to accurately summarize activities and meetings but should not create a permanent transcription of proceedings.
- API will facilitate setting up meetings and agendas, and may serve to support each committee, if requested to do so.
 - The independent review panels (both ethics and scientific) may be given the option of hiring their own support.

Panel Organization and Responsibilities

- The intent of each of the panels will need to be defined in some statement.
- The Oversight Committee will need to decide on the size of the Scientific Review panel, and 12 was discussed as a reasonable maximum number of members. Otherwise, the SRP will have complete control over their structure (number of members in each discipline and disciplines to be included). The Oversight Committee was given the recommendation of the Technical Committee on the initial composition of the SRP (discussed below).
- A process for developing an amendment to the protocol was discussed. Attachment A shows a draft document used to track a proposal to change the protocol and document approvals.

Technical Committee Update (Refer to the Minutes of the July 23 Conference Call)

- The Communications Committee stated a desire to have the Technical Committee available as a source of expert opinion and to serve as a spokesman when necessary.

- The decisions will be made by the Oversight Committee with advice from the Technical Committee
- The division of labor will be such that API will track the financial auditing of the project with the Technical Committee developing milestones with the investigators to track reasonable progress relative to the resources spent. This will be tracked by reports from each to the Oversight Committee.
- QA/QC concerns
 - How are they to be guaranteed?
 - Lab is to be FDA Certified
 - In 2-3 years the lab will be certified by the College of American Pathologists
- Issues with communications between committees, the investigators, and the independent panels
 - The roles and expectations of each of the panels should be specified and communicated to them
 - One role of the Ethics Review Panel – all complaints or problems should be communicated to them (e.g., issues between the Scientific Review Panel and the Investigators).
 - One official observer from the Technical Committee will be allowed to attend the Scientific Review Panel meetings. Others may be allowed to attend (not necessarily participate) based on the discretion of the SRP.

Membership

- An ad hoc committee should be formed to solicit additional membership, identify targets for this solicitation effort, and work within their respective companies to muster resources to assist in the effort (including contacts involved with philanthropic contributions).
- Bill Frick was suggested as the API person to spearhead this effort.
- **Action Item:** Distribute the list of targets identified from the internet (GW).
- **Action Item:** Provide nominations for this committee to Lorraine Twerdok by August 3 (all)

Action Items

ALL ACTION ITEMS ARE DUE FRIDAY, AUGUST 3, unless otherwise indicated.

Consortium Agreement Issues:

1. JOHN WAGNER will write & distribute a one-pager listing the pros and cons for an agreement between companies and API vs incorporation of the consortium to include a contractual agreement between companies.
2. JOHN WAGNER will edit the exiting contract agreement based on comments from today's meeting. John will also list sections to be reworked by the consortium agreement workgroup.
3. OVERSIGHT COMMITTEE (OC) MEMBERS will send Lorraine and Paula nominations (minimum = 1 per company) for a consortium agreement workgroup to be staffed by JOHN WAGNER.
4. PATRICK BEATTY and the Technical Committee will develop a 1-page scope of research work, referencing study protocols, to be added to consortium agreement.

5. LORRAINE TWERDOK will circulate relevant API Policies and Procedures to OC for review.

Technical Committee, Scientific and Ethics Review Panels and Protocol Issues:

1. LORRAINE TWERDOK will transcribe and circulate template for technical issue review and flow of information, e.g. protocol amendments.
2. TECHNICAL COMMITTEE will evaluate QA/QC measures for study conduct and report back to OC (due date to be determined).
3. TECHNICAL COMMITTEE will develop milestones for study progress assessment from study protocols (due date to be determined).
4. The following contacts will be made to seek recommendations for international participants on the Scientific Review Panel (SRP):

Myron Harrison - LYNN RUSSO

Chris Roythorne - DON BURNETT & PATRICK BEATTY

Shan Shai - PATSY CLEGG

Otto Wong - PATRICK BEATTY & GEORGE WOODALL

Chinese Investigators - PATRICK BEATTY & GEORGE WOODALL

Jerry Rice - PATRICK BEATTY & GEORGE WOODALL

concawe - LORRAINE TWERDOK

5. The TECHNICAL COMMITTEE will contact existing list of proposed SRP nominations (due date to be determined).
6. PATRICK BEATTY will contact Rich Irons to find out dates for upcoming U. of CO and Chinese IRB reviews, and also seek advice from Rich on how much "up front" work (purchase lab equipment; train technicians, etc.) is appropriate & advisable before IRB approval is in place.

Communications Committee Issues:

1. SUSAN HAHN of API will contract PR firm with CC guidance (mid-late September timeline).
2. JOHN WAGNER will contract outside council for consortium needs (due date to be determined).

Ad Hoc Consortium Membership Committee - BILL FRICK will spearhead:

1. OVERSIGHT COMMITTEE MEMBERS will submit committee nominations (1/company) to Lorraine Twerdok.
2. GEORGE WOODALL will circulate to OC a list of NGOs & foundations for potential consortium membership.
3. MEMBERSHIP COMMITTEE will develop a list of companies (refining, chemical, other business sectors), associations, NGOs, Foundations, Agencies, etc, to target for membership "drive." Strategies for contacting the various organizations will be developed. (will be a continuing effort over at least the next few months).

From: Lorraine Twerdok [twerdokl@api.org]
Sent: Tuesday, October 02, 2001 8:34 AM
To: 'Benzene OC listserve'
Cc: Bill Frick; 'Irons, Richard'
Subject: WE HAVE A BENZENE CONSORTIUM

Importance: High

Want you all to be the FIRST to know that we have now received all five consortium agreement signatures, satisfying the conditions for consortium formation.

Thanks to everyone for making this happen!

Regards,
Lorraine

Lorraine E. Twerdok, Ph.D., DABT
Manager, Health Sciences
American Petroleum Institute
1220 L Street, N.W.
Washington, DC 20005

tel: 202-682-8344
fax: 202-682-8270
email: twerdokl@api.org