From:	George Woodall <Woodallg@api.org>
Sent:	Tuesday, August 6, 2002 5:53 PM (GMT)
To:	BenzConsort-TC@api.org
Cc:	Lorraine Twerdok <Twerdokl@api.org>; Paula Podhasky <Podhaskyp@api.org>; Matt Todd <ToddM@api.org>
Subject:	Meeting Minutes - Technical Committee (July30, 2002)
Attach:	Minutes-BHRC-TC-30July2002.doc

Technical Committee;

Attached are the draft meeting minutes of our meeting last week at API HQ in Washington, DC. This set of minutes have been reviewed and approved by legal counsel. As mentioned in the meeting, there will be a two-week review period after which the minutes will be made final. Please send comments and corrections to my attention or to the listserver (BenzConsort-TC@listserve.api.org) **before August 21, 2002**.

Thank you,

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DRAFT – August 5, 2002

Meeting Minutes
Technical Committee – Benzene Health Research Consortium
API Headquarters – Washington, DC
July 30, 2002

Participants:

Patrick Beatty (Chair), ChevronTexaco
Stuart Cagen (Vice Chair), Shell
Shan Tsai, Shell
Bill Broddle, Conoco
Michael Bird (by Phone), ExxonMobil
Don Burnett (by Phone), BP

Issues:

Committee Business

- Draft meeting minutes and conference call summaries
  - It was proposed and accepted by the committee that draft minutes will be sent out for review, and if no changes or corrections are sent that they will become final after a two-week period.
  - Previously drafted minutes will become final following review by legal counsel.

Governmental Organization Status Recommendation – requested by the Oversight Committee.

- Proposal for a "Competent Authorities Body" to include the governmental organizations and NGOs, with a dotted line relationship to the Technical Committee was discussed but not endorsed.
- Technical Committee's recommendation:
  - Expand the Technical Committee to include members with observer status.
  - Develop a list of regulatory/governmental bodies from throughout the world to invite to join (EPA, OSHA, Cal-EPA, NIOSH, WHO, Health Canada, NIH, EU, CDC/ATSDR, IARC, etc.)
  - Convene a meeting of the invitees to describe the study in detail and to define their role within the Technical Committee.
  - As a follow-up to that meeting, provide a list of activities that these organizations may be able to contribute to on an equity basis (types of analyses that might be performed – either in the current protocols or in addition to those in the protocols).
    - Proposed role:
    - Would participate in the Annual Meeting as a part of the Technical Committee.
    - Would participate in all Technical Committee meetings but not in discussion on financials – financial aspects would be covered during one-half of a full-day meeting with only the sponsor members, followed by the rest of the meeting open to the full membership.
- *Action Items*
  - TC Members: Provide a list of regulatory/advisory governmental organizations (worldwide) to invite. [See request for similar information from the Communications Committee, sent out July 31, 2002.]

Progress/Financial Reporting – the following is a summary of the main issues identified from the June 2002 progress and financial reports.

1. Calendars - API operates on a fiscal year that begins on January 1. UCHSC operates on a calendar that begins on July 1. In his progress report, Dr. Irons refers to a fiscal year that ends on August 31. Dr. Irons reports finances in his progress report up to May 30, which does not match the financial reporting period coming from the University that ends on June 30. The proposal accepted by the TC was to establish one set of dates for both progress reports and financial reports (semi-annual), with periods ending June 30 and December 31. Every other fiscal year and reporting date should be adjusted to coincide with those dates. The invoices to the consortium sponsors are scheduled to go out in August, and that should not be affected by this proposal.
2. Reporting Frequency - Otto Wong has suggested that all reports be on a semi-annual basis. Currently he has a requirement to report quarterly in his contract, and Dr. Irons is required to report semi-annually. The proposal to have all contract/grant reporting frequencies to be semi-annual, based on the dates proposed under item 1 above was accepted.
3. Travel Expenses - The UCHSC financial reports are showing travel-related charges and projections for continued charges. It was understood that all the travel expenses for the DP and ME Studies would be under Dr. Irons' separate contract. Enquiries will be made to see what are these charges and if they are appropriate.
4. UCSHC Financial Report Form - The format was changed by UCSHC from the original format agreed to for this reporting. A revised format has been proposed that can be used from this point forward (see attached) that will track both actual and budgeted values for the following: total previous expenditures, current expenditures, expenditures to date, and project totals. Some other discrepancies in the report will also be investigated in consult with UCHSC.
5. UCHSC Contract Addendum - In his June, 2002 Progress Report, Dr. Irons lists an issue with the current grant not including the revised project budget. The TC agrees that this should be remedied and proposes that a letter from the OC indicating the decision to increase the budget be sent to UCHSC, and that an amendment to the Grant Agreement be instituted to reflect those changes in budget.
6. Fudan Contact Issue - The first contract with Fudan University (covering the last 5 months of 2001) was signed late but without significant revisions. The second contract (covering 2002) has been delayed significantly due to numerous revision requests by Fudan and negotiations with API. Additional delays were due to a revised budget for the contract (see next point) and an expectation by the officials at Fudan that the revised budget would be accepted as submitted. The signed contract has been signed so this issue has been resolved.
7. Fudan Case-Control Study Budget Issue - The original estimated budget total for Fudan University was $191K; the revised budget total submitted by Fudan in June was $661K. The increase in budget was reflective (at least in part) of the

increased exposure assessment activities required after the SRP review. My understanding, based on the January 2001 presentation given by Dr. Irons, was that the additional costs for staff involvement and other costs associated with the increases in the exposure assessment would be born by the UCHSC grant and was reflected in the increased budget (see attached spreadsheet IronsPost-SRP-Budget.XLS). In subsequent communications between Dr. Irons and Dr. Fu, it seems that there is some split among the costs being covered by UCHSC and the separate contract between Fudan University and API (see attached e-mail from Dr. Fu that includes an e-mail from Dr. Irons to Dr. Fu). At present, there is no clear indication what that split should be, and this is hampering the ability of API to modify the contract values for Fudan. A communication has been sent to Dr. Irons requesting clarification of the details for what is covered in the contract between Fudan and UCHSC, so that API will better be able to determine the outstanding need for resources on the contract with Fudan.

8. Ongoing IRB Fees - COMIRB has changed their policy and instead of charging a fee only when they review a protocol, they are also asking for funds on an annual basis (see attached e-mail "COMIRB Fees"). In addition to that information, G. Woodall was informed in a conversation with Wayne Stillman that this project has three protocols that were submitted for review (not two). The third protocol is for the Metabolism Feasibility Study (attached in e-mail titled "Documents").

- *Action Items*
  - G. Woodall: Investigate the nature of the travel budget in the grant. Understanding was that all travel would be through the separate contract with Dr. Irons.
  - G. Woodall: Send revised financial report format and other questions regarding the financial report to UCHSC for clarification. [Completed. See attached e-mail.]
  - Oversight/Technical Committee: Send a letter to UCHSC indicating that the approved budget has been increased as of January 2002, and that a revised grant agreement is forthcoming.
  - G. Woodall/L. Twerdok: Revise the grant agreement as indicated in the point above.
  - G. Woodall: Set-up a conference call with both Dr. Wong and Dr. Irons on-line to discuss the split in contract coverage for the Fudan University portion of the expanded exposure assessment. Both the OC and TC will be invited to have a representative join the call.
  - G. Woodall: Contact Dr. Irons and get clarification about the nature of the 3rd protocol (Metabolism Feasibility Study) and the review process that was undertaken on that protocol.

Milestones – Many of these for the DP and ME Studies have been taken from the list suggested by Dr. Irons in his progress report.

- Publication milestones should be added to all studies.
- Case-Control Study

  - Milestones will be based on case accrual by disease (NHL/AML - 500 total cases or 125/year for 4 years)
- Disease Progression Study
  - Missing from the list are decision points along the way that would help determine if continuation along a line of research is warranted:
    - Determination of unique identifiers/markers for benzene-induced leukemia.
    - Assessments of whether certain assays/analyses are useful/feasible.
  - Case accrual – need to break out by number of cases for each diseases and not as an aggregate alone (based on expected incidence)
    - The protocol mentions annual disease rates as follows: 50 cases AA/yr; 60 cases MDS/yr; 120 cases AML/yr.
    - Major Issue: Determine the number of cases needed to acquire adequate statistical power and the length of time that will be needed to accrue that number of cases (potential that it may take longer than the five year project length).
  - Include reporting obligations in milestones
  - Include expected/actual/deviation in the number of cases in the progress reports.
  - Dr. Irons list has exposure assessment done prior to identifying cases – check on that detail.
- Molecular Epidemiology Study
  - Need clarification on timing of the phases
    - Is the plan to identify all 200 highly exposed individuals first then look at feasibility of doing later phases, or
    - Do the factory-by-factory approach as shown in the draft milestones. If the latter, what are the costs for each factory and when do you reach a decision point on when the study will yield results.
- *Action Items*
  - G. Woodall: Contact Dr. Irons to get clarification on his list of milestones on a number of issues related to case accrual rates, timing for phases within each of the studies, overall length of study, etc.
  - G. Woodall: Set-up a conference call between the TC, and Drs. Irons and/or Schnatter to discuss the timing of phases within the ME study.
  - Drs. Irons and Wong: Add publication milestones on all studies.

<u>Prioritization</u> – requested by the Oversight Committee to determine the options if additional sources of funds are not found.

- Regrets Analysis – based on the presentation in January 2001 by Dr. Irons.
  - Incremental cuts suggested by Dr. Irons would get $1.6M in cuts if all were adopted – would be accompanied by major regrets.
  - However, this was based on the budget at that time of $16.5M and does not include the budget increases due to the Scientific Review Panel (SRP) recommendations.
  - Any changes would require approval by the SRP and the IRBs, which could call for a close to the project due to decreased scientific benefit from the pared-down study.

- Only way to get to $3-4M in savings would be to cut out one of the studies (Case-Control; Disease Progression; or Molecular Epidemiology) which would effectively stop the project.
  - Cutting any one of the studies would entail major regrets including the withdrawal of support for the project from the Chinese, thus ending the project.
- Recommendation from the Technical Committee (in order of preference):
  - Get additional sponsors using a new marketing focus that emphasizes:
    - New studies such as HealthWatch raise additional questions that the Shanghai Study may help to answer.
    - That this is a unique opportunity to couple high exposure levels with modern analytical techniques when compared to previous studies.
    - Need to identify more potential sponsors with more active follow-up (e.g., Dow)
    - Need to act ASAP on additional funding efforts.
  - Investigate potential for an API Safety Net.
    - API would only cover costs not covered by additional funding.
    - Need to find a "champion" among one of the sponsor company CEOs to plead the case to the other CEOs within API
  - Investigate potential for other "partners" to help fund pieces of the project (e.g., EPA pay for one type of analysis to be performed in the ME Study).
    - May also include applying for grants.
  - Pursue additional funding from the existing sponsors
    - All other potential funding avenues should be pursued first (those listed above as well as the options for cutting back) in order for this proposal to even be considered.
- September 11th effect
  - Delays have resulted in increased costs
  - More difficult to get visas for Chinese nationals to come to US for training.
  - More difficult to get equipment into China.
- Funds from the Petroleum Product Stewardship Council
  - $300K in unspent funds
  - Can this be used in BHRC? Who at API can answer that question?
- Timelines
  - Annual API Meeting in October – need to identify any potential CEO champions and brief them prior to that meeting
  - Follow-up with Dow in the next two weeks.
- *Action Items*
  - Marketing Group: Needs to become more aggressive in attaining new sponsors. Need to revitalize marketing materials and change the marketing focus (adding governmental bodies as part of and expanded TC may be a positive aspect; answering the questions raised by HealthWatch may also be a useful inducement).
  - TC Members: Identify a CEO Champion within the API member companies to encourage the "API Safety Net" as a consideration to secure the project if the marketing approach fails. Annual Meeting scheduled to occur October 14-15, 2002.

- M. Bird/L. Twerdok: Follow-up with Dow to determine interest level and chance to add them as a sponsor.
- G. Woodall: Get input from Dr. Irons on a revised "Regrets Analysis" based on the new budget and protocols; similar to his analysis presented at the January 2001 meeting.

2002 Invoice Recommendation – Request for a recommendation on whether the August 2002 invoice should be based on 25% of $16.5M or $22.8M

- Recommendation to send an invoice for the previously expected amount and then send an invoice in January for any adjusted funding needs.
- *Action Item*
  - G. Woodall/P. Podhasky: Need to get total invoice requests for 2003 to the sponsor companies ASAP so they can plan appropriately. This should include any amounts that may be included in a January 2003 Invoice.