

**BHRC Oversight Committee Meeting Minutes
August 16 – 19, 2004
San Francisco & Monterey**

Meeting Minutes Note:

The BHRC OC met on four consecutive days: August 16, 17, 18, and 19. Since many topics were discussed on several days, the minutes are organized by topic, rather than date. To avoid confusion, only the final disposition of topics is presented in the minutes. A list of attendees by date is presented at the end of the minutes.

L. Twerdok provided antitrust guidance and established that a quorum of voting members was present at all meetings.

Consortium Agreement Amendment #2

Discussions were initiated on 8/16/04 and final approval on the amendment #2 language was given on 8/19/04. It was decided that members should have the signed amendment(s) returned to API by September 15, 2004.

ACTION: J. Wagner will make all approved changes to the amendment and will obtain API signatures. Two copies of the API signed amendment will then be sent to OC members for signature. Additionally, for those companies that did not sign amendment #1 (which changed the payment schedule for payment in 2003/early 2004 of all initially committed funds), amendment #1 will be sent along with amendment #2 for signature.

Technical Committee Update (P. Beatty on 8/16)

- For information – NCI is updating their previous case-cohort study in Beijing; the contact, per federal register notice, is Richard Hayes
- SRP/ERP pre-annual meeting conference call went well
 - No new substantive issues
 - Discussions tended to be follow-ups from the 2003 Annual Meeting (SRP- urinary biomarkers) or revisiting issues (ERP – patient/control compensation)
- Study Progress
 - Case-control study issue with controls resolved by only using inpatients as controls for NHL
 - Exposure assessments behind schedule
 - AML case accrual is faster than expected; NHL accrual numbers are lower than estimated but not expected to adversely impact study
 - Laboratory turnover/transition to Fudan University may come sooner than expected – see more detailed discussion below under PI/sponsor discussions

Outreach Update

- Outreach contact matrix updated, see attached file, which will also be posted to the website
- Communications Committee is developing process for individual company outreach – discussions are still in committee

ACTIONS: L. Twerdok will (1) follow up with H. Feldman to see if there will be a slot on the October 19 HESGC agenda for a SHS update, (2) seek opportunity for a SHS

update to the newly formed General Committee on Special Programs (GCSP), and (3) circulate roster for GCSP.

Review of Action Item Table and 2004 yearly plan

- Action item table was updated, see attached file, which will also be posted to the website
- Action item table & yearly plan to be updated on calls and at meetings. Both documents will be posted to the website

ACTIONS:

- **L. Twerdok** will update update OC action item table, and coordinate posting to website
- **M. Todd** will tabulate list of additional professional organizations for potential outreach for OC discussion at the Nov. 3-4, 2004 meeting in Houston
- **M. Johnston** will work with **J. Wagner** to further investigate cost recovery potentials for the JCML; this activity could be a good way to initiate transition of laboratory to Fudan University
- **M. Todd and B. Jarnot** to fill in 2004 Plan for Communications, Technical and Budget committees
- **M. Todd, B. Jarnot and L. Twerdok**, in consultation with respective committees, will update yearly plan, and post updates to website

New Funding Sponsor Privileges

Agreed privileges are summarized in table below

ACTIONS:

- **L. Twerdok** to communicate privileges to Marathon
- **M. Todd** to give Craig Parker of Marathon Ashland full access to website (with the exception of the SRP/ERP areas, which no sponsor has access to)
- **OC members** should use this chart in any updates presented at API, and other presentations as appropriate

Approved Sponsorship Privileges for New Funding Sponsors		
Privileges	\$200,000	\$500,000
Oversight Committee	X	1 share Participant
Technical Committee	Observer	Participant
Budget Committee	X	Participant
Communications Committee	Invite to participate	Participant
SRP/ERP	X	X
Study Updates	√	√
Website access	√	√
Financial Reports	√	√
Identified as sponsor on publications, posters and meeting presentations	Second tier acknowledgement: "With additional funding by . . ."	Full
Annual Meeting	Observer	Participant

2Q04 Financial Report

- 2Q04 report reviewed and approved 8/17/04, pending (1) receipt of UCHSC financial report and insertion of UCHSC subcontractor cost breakout, and (2) updating of case accrual worksheet
- OC approved leaving contingency expense projection in 2005
- Sponsor invoicing of remaining committed funds to be done on an as needed basis

ACTIONS:

- **B. Jarnot** to update/verify case accrual numbers for 2Q04, and add case referral numbers (total number of diagnosis performed at JCML) to 3Q04 financial report
- **Technical Budget Committee** to develop recommendations to OC for sponsor invoicing as funds are required
- **L. Twerdok** to add invoice dates to yearly plan as they are adopted
- **L. Twerdok and B. Jarnot** to adjust UCHSC EMBSI subcontractor projected expenses to first half of calendar year. EMBSI is paid once per year, rather than the current biannual projections o

Discussions between OC and PIs

Clinical laboratory transition and turnover after the SHS is completed (8/16 & 18)

- It is not too soon to begin developing plan, with the goal of initiating discussion in 1Q05 and presenting formal plan to Chinese at the 2005 Annual Meeting in Shanghai
- Brainstorming ideas:
 - Commercialization of lab to make it self-supporting/profitable could be a part of the transition plan
 - Identification of a Chinese Clinical Director to manage the transition
 - Joint venture opportunities with Chinese & biotech industry to conduct fee-for-service, while maintaining diagnostic and research functions of the lab
- R. Irons informed OC on 8/18 that Fudan University is already having internal discussions on the disposition of the laboratory once the SHS is complete.

ACTIONS:

- **M. Johnston** to take lead on lab transition/turnover plan development. M. Johnston to work with **S. Tsai** and **J. Wagner** on issue
- **OC members** to research in-house experience on sustainability transitions, e.g. health clinics in E&P areas
- **R. Irons** to keep OC informed of progress/decisions by Fudan University on disposition of laboratory

Outreach & Publications

- L. Russo explained BHRC plans for outreach to a broader circle of stakeholders (in addition to PI traditional outreach via scientific publications and presentations)
- Investigators concurred with sharing with Technical Committee pre-submission publications for suggestions to improve quality of manuscripts (as with the SRP/ERP, acceptance/rejection of comments totally at discretion of PIs)
- BHRC may enlist PI aid and knowledge of Chinese cultural differences for outreach in China

ACTION

Investigators will keep SRP, ERP, Technical Committee and OC updated on upcoming scientific meeting presentations and papers, and circulate draft manuscripts to SRP/ERP and Technical Committee prior to submission to journals

Exposure Assessment Issues

- Exposure assessment behind case accrual

ACTIONS

P. Clegg work with R. Irons to explore use to Shell's access to Shanghai Mayor's Office to request that IPHS devote more experienced IH resources to the study

QA/QC Issues for Case Control study and Exposure Assessment

ACTION: Technical Committee to evaluate existing QA/QC resources to see if they can be deployed to address IH and QA/QC issues.

Program Budget:

- Exposure assessment and QA/QC issues will have budgetary impact

ACTIONS:

- **R. Irons and O. Wong** will develop revised study proposals to align funding to address exposure assessment and QA/AC issues.
- **Technical Committee** will work with the investigators in development of proposals, and appropriate review by OC and SRP/ERP.
- **Technical Committee** will update OC on investigators' proposals at the November OC meeting in Houston.
- **M. Bird** will explore funding opportunities with American Leukemia Society, Health Effects Institute (HEI), and International Life Sciences Institute/Health Effects Sciences Institute (ILSI/HESI), and report back on progress at the November OC meeting.

2005 Annual Meeting Planning (discussions on 8/16, 8/18 with PIs, and 8/19)

- Possible Shanghai venues suggested by PIs
 - Ritz Carlton
 - Four Seasons
 - Hilton
 - Howard Johnson
- P. Clegg contacted first three hotels via internet for preliminary information/rates. It appears to be feasible to arrange meeting by phone and email.
- API to take lead on meeting planning; do not want to divert laboratory resources for meeting planning purposes
- Should plan one hour rest period after lunch, in the Chinese custom
- Dr. Irons volunteered his assistant to arrange the banquet
- Laboratory tours in small groups (6-8); should be able to move guests through in 1.5-2 hrs, reserve a half day on the agenda for tours
- Need to reserve time on agenda for Q&A during plenary sessions
- Attendees to include PIs, SRP/ERP, sponsors, API staff (as directed by OC), and invite sponsor in-country representative attendance (first day plenary)
- Preliminary 2005 agenda:

Day 1	Full Day Plenary Include time for Q&A Close with panel discussion	Evening banquet
Day 2 – AM PM	Laboratory tour Closed SRP/ERP meetings	
Day 3 – AM	SRP/ERP/PI meetings	

PM	Closing Plenary	
Logistics: • Begin meetings at 9 AM • noon – 1 PM Lunch provided at meeting • 1 – 2 PM rest period, in the Chinese custom • TBD – provide group breakfasts		

ACTION:

- **L. Russo and C. Roythorne** to check if they have corporate discounts with any of the potential hotels for the meeting
- **M. Sellouk** to research hotel options for 2005 Annual Meeting in Shanghai and report to OC at November OC meeting
- **O. Wong to provide L. Twerdok** detailed map of Shanghai, noting locations of hotels and Fudan University

8/20/04 "Lessons Learned" debrief of 2004 Annual Meeting

- Include attendee roster with full contact information in meeting packages next year.
- Reserve plenty of time for Q&A during opening plenary session
- Pls should be invited to give closing remarks, in addition to SRP/ERP Chairs and Sponsors
- OC/PI informal discussion session worked well, repeat in 2005

Next Meeting:

Wednesday/Thursday November 3-4, 2004

November 3; 1 – 5 PM

November 4; 8 – noon

ConocoPhillips to host in Houston

ACTION: M. Johnston to provide logistical information to L. Twerdok for distribution to OC

Agenda to include:

- Review professional organizations identified for outreach by L. Russo and M. Todd
- Update on International Benzene Symposium
- Lab transition – OC members to report out on company experience with similar sustainability transitions (e.g. health clinics)
- Update action item table and 2004 Plan
- Update on 2005 Annual Meeting hotel options (M. Sellouk)
- Contract status review
- M. Bird update on funding solicitation progress
- Technical Committee report on PI proposals
- Technical Budget Committee recommendation for timing of 2005 sponsor invoicing

- **BHRC Oversight Committee Meeting Attendees by Date**

Monday, August 16, 2004:

<i>In person:</i>	<i>By phone:</i>
Patrick Beatty, ChevronTexaco	Mark Fitzsimmons, Steptoe & Johnson (P/T)
Don Burnett, BP	John Wagner, API
Patsy Clegg, Shell	
Brian Doll, ExxonMobil	
Mike Johnston, ConocoPhillips	
Lynn Russo, ExxonMobil	
Lorraine Twerdok, API	

Tuesday, August 17, 2004:

<i>In person:</i>	<i>By phone:</i>
Patrick Beatty, ChevronTexaco	Mark Fitzsimmons, Steptoe & Johnson (P/T)
Don Burnett, BP	John Wagner, API
Stuart Cagen, Shell	
Patsy Clegg, Shell	
Brian Doll, ExxonMobil	
Mike Johnston, ConocoPhillips	
Lynn Russo, ExxonMobil	
Lorraine Twerdok, API	

Wednesday, August 18, 2004:

	<i>Guests:</i>
Patrick Beatty, ChevronTexaco	Richard Irons, UCHSC
Michael Bird, ExxonMobil	Robert Schnatter, EMBSI
Don Burnett, BP	Otto Wong, Applied Health Sciences
Patsy Clegg, Shell	
Brian Doll, ExxonMobil	
Mike Johnston, ConocoPhillips	
Chris Roythorne, BP	
Lynn Russo, ExxonMobil	
Lorraine Twerdok, API	

Thursday, August 19, 2004:

	<i>Guest</i>
Patrick Beatty, ChevronTexaco	Michael Bird, ExxonMobil (P/T)
Don Burnett, BP	
Stuart Cagen, Shell (P/T)	
Patsy Clegg, Shell	
Brian Doll, ExxonMobil	
Lorraine Twerdok, API	