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Sent: Tuesday, December 18, 2001 7:03 PM (GMT)
To: 'BenzConsort-OC@listserve.api.org' <BenzConsort-OC@api.org>; 'BenzConsort-TC@listserve.api.org' <BenzConsort-TC@api.org>
Cc: Richard Irons (E-mail) <richard.iron@uchsc.edu>; Otto Wong (E-mail) <OttoWong@aol.com>; Thomas Armstrong (E-mail) <twarmst@erenj.com>; Robert Schnatter Ph. D. (E-mail) <arschna@fpe.erenj.com>
Subject: IMPORTANT Call Reminder - (Revised Agenda and Meeting Materials)
Attach: ProjectCostEstimate.xls; EpiStudyAdditionalBudget.xls; IronsPost-SRP-Budget.XLS; EMBSI-AdditionalExpense.xls

Oversight and Technical Committee Members;

The Agenda for the conference call for tomorrow has been revised and is shown below. This call will be a joint call of both the Oversight and Technical Committees due to the need for input from both sets of members on the important issue of authorizing the researchers to go forward with IRB review, and the path forward on authorizing the additional costs associated with the protocol review process. Details for the call are also shown below. Four spreadsheets are attached for the first main item on the agenda (Project Budget) which will involve both the Oversight and Technical Committees.

- ProjectCostEstimate.xls - shows the overall revised budget estimate for the project.
- EpiStudyAdditionalCosts.xls - shows the additional costs that are specific to the Case-Control Study; refer to the Consortium Web page for the original cost estimate for this work. The line item for the Case-Control Study costs in the overall budget (first spreadsheet) includes both the original estimate (adjusted for inflations) and the additional costs.
- IronsPost-SRP-Budget.xls - shows the additional costs associated with the Disease Progression (DP) and Molecular Epidemiology (ME) Studies, with details indicating which costs have increased and decreased. This has been added to the original estimates provided in the overall budget (1st spreadsheet).
- EMBSI-AdditionalCosts.xls - shows the exposure assessment work being done by EMBSI that is reflected in the estimates from Dr. Irons as a separate line item in his spreadsheet (3rd spreadsheet).

Conference Call

Oversight and Technical Committees - Benzene Health Research Consortium

Date/Time: Wednesday, December 19, 2001, 11:00 AM - 1:00 PM EST

Call-in Number: (703)736-7274

Moderator: George Woodall, API

Confirmation Number: 573 4738

Call Title: Milestones

Agenda

- Discussion of protocol changes and budgetary impacts from the SRP review.
 - Need for approval of the Disease Progression and Molecular Epidemiology Protocols to go the University of Colorado IRB for review ASAP (Irons/Beatty)
 - Need for approval of increases in costs to be adopted by the Oversight Committee and definition of the path forward (Burnett/Twerdok)
 - Need for approval of funds based on increased costs prior to authorizing contracts for 2002 (Woodall/Wong)

- Establishment of Milestones for tracking progress on the research project and other Technical Committee activities - please see the Gantt Chart of Project Timeline (<http://www.api.org/benzene-consortium/Project%20Progress/TimelineBenzeneHealthResearchNov2001.pdf>) on the Consortium Web Page (Username = ; Password =).
- Discuss need for follow-on meeting or conference call (All).

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	A	B	C
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5	DP Study Design and Control Changes		
6		Remove AML controls from DP Study	
7			Subject/history costs
8		Addition of controls for AA and MDS	
9		Elimination of "mild cases"	
10			Increase AA and MDS by 10%
11		Changes in testing protocol	
12			AA/MDS/AML
13			
14			
15			
16			NHL
17			
18			
19			
20		Subtotal SRP changes	
21		Exposure assessment	
22			China personnel
23			IH supplies
24			EMBSI cost increases
25		Subtotal exposure assessment	
26			
27		Total DP Study	
28			
29	ME Study Design Changes		
30		Phase 1	
31			Increase subjects to 1,600
32		Phase 2a	
33			Increase subjects to 2,000
34			
35			Cost of making/storing cell pellets
36			Remove FISH and banded analysis
37		Phase 2b	
38			Increase subject compensation
39			Fit3
40			Eliminate GST-T1 and CYP2E1
41		Exposure assessment	
42			China personnel
43			IH supplies
44		Total ME Study	
45			
46	Glycophorin A Mutation Assay Costs		
47			
48	Total All Changes		
49			
50	Notes:		
51			1
52			2
53			3
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55			4
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59			6
60			7
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	D	E
1	Incremental Changes in DP and ME Study Budgets	
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9		
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11		
12		
13	Flt3	
14	Special stains	
15	Presentation system	
16		
17	Eliminate HBV	
18	HHV8	
19	LDH	
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34	Test costs	
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51	Provides for potential increased accrual of AA/MDS cases from 23 Central District Hospitals	
52	SRP recommended removal of HBV assays and addition of HHV8 and HHV6. We have added only HHV8.	
53	Provides additional Shanghai staffing to a) cover 2:1 controls for DP and b) follow the	
54		same EA design for the AML/ NHL study.
55	Expanded to cover AML/NHL with the same sampling and assessment design, resulting in	
56		approximately 2 x the number of subjects to evaluate compared to the original DP study plan.
57	Provides for additional field time for Shanghai staff development and oversight, in order to follow same	
58		exposure assessment design for the AML/NHL study, and additional sites in ME study.
59	Increases in study group size recommended by Chinese and SRP.	
60	FISH and banded cytogenetic analysis of peripheral blood in Phase 2a eliminated as cost savings.	
61		DNA pellets will be prepared and stored for selective retrospective FISH analysis based on 2b results.

	F	G	H
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4	Incremental cost		
5	Total 5 years	per year	
6			
7	\$ (40,000)	\$ (8,000)	
8	\$ 44,000	\$ 8,800	
9	\$ (77,000)	\$ (15,400)	
10	\$ 56,000	\$ 11,200	Note 1.
11			
12			
13	\$ 85,000	\$ 17,000	
14	\$ 67,000	\$ 13,400	
15	\$ 20,000	\$ 4,000	
16			
17	\$ (10,000)	\$ (2,000)	
18	\$ 90,000	\$ 18,000	Note 2.
19	\$ 10,000	\$ 2,000	
20	\$ 245,000	\$ 49,000	
21			
22	\$ 342,000	\$ 68,400	Note 3.
23	\$ 210,000	\$ 42,000	Note 4.
24	\$ 556,000	\$ 111,200	Note 5.
25	\$ 1,108,000	\$ 221,600	
26			
27	\$ 1,353,000	\$ 49,000	
28			
29			
30			
31	\$ 53,000	Over two yrs	Note 6.
32			
33	\$ 86,000	\$ 17,200	
34	\$ 25,000	\$ 5,000	
35	\$ 21,000	\$ 4,200	Note 7a.
36	\$ (592,000)	\$ (118,400)	Note 7b.
37			
38	\$ 40,000	\$ 8,000	
39	\$ 27,000	\$ 5,400	
40	\$ (19,000)	\$ (3,800)	
41			
42	\$ 171,000	\$ 34,200	Note 8.
43	\$ 51,000	\$ 10,200	Note 9.
44	\$ (137,000)	\$ (27,400)	
45			
46	\$ 377,000	\$ 75,400	
47			
48	\$ 1,593,000	\$ 318,600	
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62		If these studies are performed they will be funded through independent sources.
63	Revised to cover more facilities to provide the expanded numbers needed for power, and	
64		additional logistics issues due to the probability of sites outside of Shanghai.
65	Includes additional sites to meet size projections, and thus additional supplies for the additional survey work.	
66		
67	Dose-response analysis of banded cytogenetics and FISH to Phase 2a: Add \$3,200,000	
68	Dose-response analysis of clonal cytogenetic lesions only to Phase 2a: Add \$1,500,000	

ANLL and NHL Case-control Studies
Additioanl Budget Estimate for Exposure Assessment
Applied Health Sciences, Inc.

11/28/2001

	A	B	C	D	E	F	G	H	I	J	K	L
1	Labor by category											
2		Hourly rate	Year 1		Year 2		Year 3		Year 4		Year 5	
3	Category	in 2001 \$	Hours	Amount	Hours	Amount	Hours	Amount	Hours	Amount	Hours	Amount
4	Chief Epidemiologist (PI)	\$280	80	\$22,400	40	\$11,200	40	\$11,200	40	\$11,200	40	\$11,200
5	Statistical programmer	\$120	20	\$2,400	20	\$2,400	20	\$2,400	20	\$2,400	20	\$2,400
6	Research assistant	\$90	20	\$1,800	20	\$1,800	20	\$1,800	20	\$1,800	20	\$1,800
7	Consulting industrial hygienist	\$200	120	\$24,000	120	\$24,000	100	\$20,000	100	\$20,000	100	\$20,000
8	Total labor for regular activities (2001 \$)			\$50,600		\$39,400		\$35,400		\$35,400		\$35,400
9												
10												
11	Meetings/working trips (time & expenses)											
12		Unit cost	Year 1		Year 2		Year 3		Year 4		Year 5	
13		in 2001 \$	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount
14	Meetings in China (8 days @)	\$26,000	1	\$26,000	2	\$52,000	1	\$26,000	1	\$26,000		
15	Meetings in USA (3 days @)	\$12,000	1	\$12,000	1	\$12,000	1	\$12,000	1	\$12,000	1	\$12,000
16	Total for meetings/working trips (2001 \$)			\$38,000		\$64,000		\$38,000		\$38,000		\$12,000
17												
18	Total in 2001 \$ (labor and trips)			\$88,600		\$103,400		\$73,400		\$73,400		\$47,400
19												
20												
21												
22	Yearly budget estimates with a 5% annual adjustment											
23												
24	Budget by calendar year			Year 2002		Year 2003		Year 2004		Year 2005		Year 2006
25	Total (with 5% annual adjustment)			\$93,030		\$113,999		\$84,970		\$89,218		\$60,496

ANLL and NHL Case-control Studies
 Additiona Budget Estimate for Exposure Assessment
 Applied Health Sciences, Inc.

11/28/2001

	M	N
1		
2	Total	
3	Hours	Amount
4	240	\$67,200
5	100	\$12,000
6	100	\$9,000
7	540	\$108,000
8	\$980	\$196,200
9		
10		
11		
12	Total	
13	No.	Amount
14	5	\$130,000
15	5	\$60,000
16	10	\$190,000
17		
18		\$386,200
19		
20		
21		
22		
23		
24	Total	
25	\$441,712	

Project Total Cost Estimate

	A	B	C	D
1	Updated:	December 18, 2001		
2				
3	Item		Original Cost Estimate (Jan. 2001)	Revised Cost Estimate (Dec. 2001)
4	Case-Control Study		\$1,761,000	\$2,283,094
5	DP & ME Studies		\$15,109,000	\$16,702,000
6	Total Research Costs		\$16,870,000	\$18,985,094
7	Scientific Review Panel			\$648,000
8	Ethics Review Panel			\$216,000
9	External Pathology Workgroup			\$66,000
10	Total Panel Costs		\$450,000	\$930,000
11	API Seed Monies		\$500,000	
12	Outside Counsel			\$500,000
13	Public Affairs			\$1,000,000
14	Miscellaneous Costs		\$500,000	\$1,500,000
15	Subtotal		\$17,820,000	\$21,415,094
16	API Overhead (5%)		\$891,000	\$1,070,755
17	GRAND TOTAL		\$18,711,000	\$22,485,849
18				
19	Notes/Assumptions:			
20	- The total research costs have changed as a result of the protocol review			
21	- Panel costs assume that there will be only one face-to-face meeting for each			
22	- Miscellaneous costs for outside counsel and media relations are based solely			