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12 May 2007

Bruce M. Jarrot, Ph.D., DABT
Senior Toxicologist
Regulatory and Scientific Affairs
American Petroleum Institute
1220 L Street, NW
Washington, DC 20005

Re: Revised timeline and additional budget for the completion of the case-control study

Dear Bruce:

I am writing to follow-up our recent discussions of revising the timeline and budget estimate for the completion of the case-control study of AML and NHL.

As a result of the new timeline of deliverables from Cinpathogen, both the timeline and the budget for the case-control study will be significantly affected, and both need to be revised. I have been asked, for the purpose of projecting a new timeline and estimating additional budget for the case-control study, to assume that AML case accrual will end by June 2007 and that for NHL patients by December 2007. Your email dated 10 May 2007 further indicates that we will receive from Cinpathogen a comprehensive test dataset by the end of September 2007 and the final dataset with complete diagnostic, exposure and questionnaire information ready for analysis by the end of August 2008.

Based on these newly projected dates of deliverables, I have revised the timeline for the completion of the case-control study (see below). I am being slightly optimistic and project that we may be able to complete our analysis and report within four months after we receive the final dataset. However, I must emphasize that I am being optimistic. The actual date of completion of the case-control study will depend heavily on the date of delivery and the status of the final dataset, but for planning purposes I will set the end of 2008 as our goal.

Revised timeline for the case-control study

Tasks	Date
Test dataset to AHS*	September 2007
Exploration of test dataset	October-November 2007
QA/QC of test dataset	November-December 2007
End of patient accrual*	December 2007
Development of analytical programs/plans	December 2007-May 2008
Final diagnoses of all patients completed*	March 2008
Interviews of all patients completed*	March/April 2008
Questionnaire data entry completed*	May 2008
Exposure assessment completed*	July 2008
Final dataset ready for analysis to AHS*	August 2008
Final QA/QC and data editing	September-October 2008
Statistical/epidemiological analysis	September-November 2008
Preparation of draft report	September-November 2008
Consultations with SRP members	September-December 2008
Preparation of final report	December 2008

* activities not under AHS control.

As indicated in the timeline above, some of our most important tasks can be carried out in 2008 only after patient accrual has been completed, diagnoses have been finalized and exposure classifications have been assigned. In projecting the above timeline, we assume that we will receive a final dataset with complete information ready for analysis by August 2008. Any delay in receiving the final dataset or any unanticipated additional preparation or processing of the final dataset will have an impact on the projected timeline.

At this moment, there is no budget for the case-control study at all for 2008. (Please refer to the contract amendment signed between American Petroleum Institute and Applied Health Sciences in November 2006, Contract No. 2004-101153, Amendment No. 1.) Additional funding will be needed. Attached is a spreadsheet detailing the additional budget needed to complete the case-control study. Again, the budget estimate is based on the assumptions and timeline outlined above. Any changes in our assumptions will likely affect the budget.

Additional amounts needed by year (2007 and 2008) are itemized and justified in the attached budget (dated 2007-05-12). We are requesting the following additional amounts by year:

Year 2007	\$184,695
Year 2008	\$703,505
Total	\$888,200

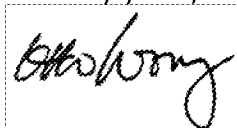
These amounts are needed in addition to those already approved in the November 2006 amendment (Contract No. 2004-101153, Amendment No. 1.).

I am assuming that I will continue to be assisted by Professor Fu's group in connection with the case-control study, particularly with my QA/QC activities in Shanghai. Professor Fu's graduate assistants are also assisting me in a literature review of occupational and non-occupational risk factors of subtypes of AML and NHL. I anticipate that Professor Fu's group will also participate in analysis and report preparation. For the past years, Professor Fu had a separate contract with API to assist me in these activities. If Professor Fu's contract is not renewed, then we need to explore other appropriate alternatives.

Please note that I have reserved both time and budget for interacting with members of the SRP in the last quarter of 2008. I anticipate that I will seek advice and suggestions in both analysis and report preparation from SRP members in the final months of the study. By the same token, API should budget separately some time for the SRP members to interact with me.

If you have questions, please let me know.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Otto Wong", enclosed within a dashed rectangular box.

Otto Wong, Sc.D.
Chief Epidemiologist

Enclosure: AHS additional budget for 2007 & 2008

2007-05-12

We will receive a comprehensive test dataset by the end of September 2007 and the final dataset ready for analysis by the end of August 2008. We will perform the following tasks in September–December 2008: final QA/QC, data editing, statistical analysis, presentations, discussion with SRP and report writing.

In addition, based on our recent experience, we need to increase our efforts of QA/QC, database testing and auditing, and monitoring of patient interviews in 2007. For 2007, we have also added two additional trips to Shanghai (to the three already approved, with a new total of five trips).

Category	Approved 2006	Year 2007		Year 2008		Total
	hourly rates	Hours	Amount	Hours	Amount	Amount
Chief Epidemiologist (PI)	\$355	160	\$56,800	700	\$248,500	\$305,300
Biostatistician	\$175	100	\$17,500	400	\$70,000	\$87,500
Statistical programmer	\$150	80	\$12,000	400	\$60,000	\$72,000
Research/Administration assistant	\$115	40	\$4,600	160	\$18,400	\$23,000
Consulting industrial hygienist	\$250	20	\$5,000	80	\$20,000	\$25,000
Total labor in 2006 dollars			\$95,900		\$416,900	\$512,800

	Approved 2006 unit costs	No.	Year 2007 Amount	No.	Year 2008 Amount	No.	Total Amount
Trips to Shanghai (10 days each)	\$39,000	2	\$78,000	5	\$195,000	7	\$273,000
Trips in USA (3 days each)	\$11,600	0	\$0	2	\$23,200	2	\$23,200
Total for meetings/working trips in 2006 dollars			\$78,000		\$218,200		\$296,200

Miscellaneous expenses (copying, domestic & international calls, mail) in 2006 dollars	\$2,000	\$3,000	\$5,000
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Total additional budget in 2006 dollars (labor, trips & miscellaneous expenses)	\$175,900	\$638,100	\$814,000
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<u>Yearly budget estimates with a 5% annual adjustment</u>	Year 2007	Year 2008	Total
Total additional budget by year (with 5% annual adjustment)	\$184,695	\$703,505	\$888,200
Budget already approved (Contract No. 2004-101153, Amendment No. 1)	\$456,475	\$0	\$456,475
TOTAL REVISED BUDGET	\$641,170	\$703,505	\$1,344,675