

To: Clegg, Patsy M SCC-DCS/22 <patsy.clegg@shell.com>; Tsai, Shan P SHLOIL-SHS
<Shan.Tsai@shell.com>
From: Cagen, Stuart Z SHLOIL-SHOIL-SHS
</O=SHELL/OU=MSXSCC/CN=RECIPIENTS/CN=SC724012>
Cc:
Bcc:
Received Date: 2006-12-08 14:28:20 GMT
Subject: FW: SHS. please revise / resubmit the newest AHS budget

Stuart Cagen, Ph.D.

Senior Toxicologist
Shell Health Services
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-----Original Message-----

From: OttoWong@aol.com [mailto:OttoWong@aol.com]
Sent: Friday, December 08, 2006 2:07 AM
To: jarnotb@api.org
Cc: whiter@api.org; Cagen, Stuart Z SHLOIL-SHOIL-SHS
Subject: Re: SHS. please revise / resubmit the newest AHS budget

Dear Bruce:

After talking to you about the increased airfares to Shanghai, I looked up the airfares on United Airline's website again. On the average, I underestimated my estimate for airfares in my previous budget proposal by about \$1,500 per trip. I have revised my budget proposal accordingly (attached, dated 2006-12-8). Although the total increase (\$11,418) over the previously estimated budget is relatively minor, I agree with your advice that it is far better to request an adequate budget upfront than to ask for supplemental funds later.

In my revised cover letter (attached, dated 2006-12-8), I have added a couple of sentences (in the second paragraph) emphasizing the importance of an adequate study sample size. Specifically, I added the following sentences. "An adequate sample size of both AML and NHL cases is important for analyses stratified by exposure level, occupation/industry, diagnostic subtype, etc. Recent studies suggest that different subtypes of AML and NHL are associated with different risk factors." Please make sure that the sponsors understand this point.

If you have any questions or need additional information, please let me know.

Regards,

Otto

Otto Wong, Sc.D., F.A.C.E.

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--- Original message ---

Subj: Shanghai Health Study... please revise / resubmit the newest AHS budget
Date: 12/4/2006 9:27:11 AM Pacific Standard Time
From: jarnotb@api.org
To: OttoWong@aol.com
CC: whiter@api.org
Sent from the Internet (Details)

Dear Otto –

Repeating my rambling voicemail message...

- 1) At your earliest convenience, please revise and resubmit the most recent AHS budget, which you developed in response to the revised NHL case collection timeline;
- 2) Also, I would like to pick your brain for potential metrics of study progress that can be easily checked on a regular (monthly?) basis, and that will – in total – provide reasonable assurance that “all systems are go”

Best Regards – Bruce (202/682-8473)

Attachments:

Letter to Bruce Jarnot 2006-12-8.ZIP

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December 8, 2006

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 case-control study for 2007 & 2008

Dear Bruce:

I am writing to follow-up my recent discussions with both you and Dr. Stuart Cagen regarding our request for revising both the timeline and budget estimate for the case-control study of AML and NHL.

As reported at the August meeting in Houston, the number of patients in the case-control study will not reach the target sample of 500 by December 2006, the original end date for case accrual. An adequate sample size of both AML and NHL cases is important for analyses stratified by exposure level, occupation/industry, diagnostic subtype, etc. Recent studies suggest that different subtypes of AML or NHL are associated with different risk factors. To reach the target sample size, it becomes necessary to extend case accrual into 2007. As a result, 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 case accrual will end by December 2007.

As you well know, the timeline of the case-control study depends heavily on the timing when diagnostic and exposure data (both test data samples and final complete data sets) are provided to us. The delay of any one event in the timeline will likely affect the others. The revised timeline below for the case-control study is based on our current understanding and assumptions.

Tasks	Date
Test data sets to AHS*	June 2007
QA/QC of test data sets	July-September 2007
Development of analytical programs/plans	October 2007-March 2008
End of patient accrual*	December 2007
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*	June 2008
Final QA/QC and data editing	July-August 2008
Statistical/epidemiological analysis	August-September 2008
Preparation of draft report	September-October 2008
Presentation of study results	October 2008
Discussion with SRP	October-November 2008
Preparation of final report	October-December 2008

*activities not under our 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. We will begin analysis and draft report preparation in the third quarter of 2008. 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.)

Obviously, we need additional funds to complete the case-control study. Based on the newly estimated timeline above, I have prepared an additional budget that will allow us to complete the case-control study by the end of 2008. The additional budget (dated 2006/12-8) is attached. Additional amounts by year (2007 and 2008) are itemized and justified in the attached budget. We are requesting the following additional amounts by year:

Year 2007	\$157,395
Year 2008	\$640,883
Total	\$798,278

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

If you have questions, please let me know.

Sincerely yours,



Otto Wong, Sc.D.
Chief Epidemiologist

Enclosure: AHS additional budget for 2007 & 2008
cc: Dr. Stuart Cagen