

From: George Woodall <Woodallg@api.org>
Sent: Wednesday, January 30, 2002 8:39 PM (GMT)
To: 'BenzConsort-TC@listserve.api.org' <BenzConsort-TC@api.org>
Cc: Lorraine Twerdok <twerdokl@api.org>
Subject: Reply Requested: Mark-up of Irons 1st Progress report; 1st Travel Contract Expense Report
Attach: ProgressReport01-UCHSC-Dec2001GW_Mark-up.DOC;
IronsTravelExpense4Q2001.PDF

Technical Committee;

Attached are two documents related to the Benzene Health Research Project. Please review both and send your comments back by Noon this coming Friday (February 1, 2002).

The first is a mark-up I made of the first progress report submitted by Richard Irons for the UCHSC Grant. The document used the "track changes" option in Word and has some embedded comments I made. The progress report in essence should provide the details for activities associated with the project financial reports coming from UCHSC (note the revised spreadsheet I sent earlier today and copied you on). The purpose in sending you this file is to get your comment on the proposed format changes and to determine if you think they are appropriate, or if more/less detail is needed.

The second document is an accounting of the expenses for Richard Irons' Travel Contract for the 4th quarter of 2002. As you may recall, there were several categories of expenses where inclusion in the UCHSC grant was not advisable (onerous travel restrictions and high overhead costs); these were included in a separate "advanced payment" contract to Richard Irons. Since payment of funds takes place and no invoices are submitted prior to payment, Dr. Irons has been submitting this type of report along with a substantial volume of receipts as back-up (not included in this file). I have not provided mark-up on this file as I have with the UCHSC Grant Spreadsheet; however, I would propose that this report should include a similar set of columns providing "Current Expenses," "Budgeted Expenses," and "Projected Expenses" as shown in that spreadsheet. The purpose of sending this second file to you is two-fold: 1) this is an accounting of the expenses for this contract for 2002; and 2) for you to review the level of detail provided and determine if it is appropriate to use for the remainder of this contract.

I look forward to your responses. As an FYI, I will not be in the office tomorrow but will return on Friday AM.

Thank you,

George M. Woodall, Ph.D.
Senior Toxicologist
American Petroleum Institute
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RICHARD D. IRONS
4800 Baseline Rd.
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January 10, 2002

Dr. George Woodall
American Petroleum Institute
1220 L Street, NW
Washington, DC 20005

RE: China Project Contracts

Dear Dr. Woodall:

Herewith is a report of my expenses incurred in conjunction with contracts related to the Benzene Health Effects Project in China for the period, August – December, 2001. .

Credits:	Expenses:
\$52,000.00	\$39,646.91
<u>\$90,110.00</u>	<u>\$102,463.09*</u>
\$142,110.00	<u>\$142,110.00</u>
Balance:	0.00

Sincerely,



Richard D. Irons

*Receipts attached.

SHELL-MCCLURG-051915

Dr. Richard Irons
China Project
Expense Summary

MONTH	Sept. 01	Oct. 01	Nov 01	Dec 01	Total
EXPENSES					
Airfare	\$ 8,680.20	9,405.00	\$ 365.00	\$ 10,880.90	\$ 29,331.10
Lodging	\$ 6,841.16	6,841.16	\$ 6,873.11	6841.16	\$ 27,396.59
Computer/Telephone	\$ 112.98	310.91	\$ 1,345.98	\$ 21.06	\$ 1,790.93
Meals & Laundry	\$ 859.91	476.79	\$ 1,311.59		\$ 2,648.29
Ground Transportation	\$ 271.86	287.00	\$ 347.46		\$ 906.31
Office Equipment			\$ 452.29		\$ 452.29
Meetings			\$ 616.25		\$ 616.25
Miscellaneous	\$ 398.86	72.19	\$ 194.98	\$ 8.18	\$ 674.22
Advance Against Reserve				\$ 38,647.11	\$ 38,647.11
Monthly Totals	\$17,164.97	\$17,393.05	\$11,506.65	\$56,398.41	\$ 102,463.09

December 28, 2001

Herewith is my report on progress versus the budget as it relates to the expenditure of project funds in China for the period from August until December 31, 2001. In summary, although we are very early in start-up activities for the project, we are essentially "on budget" as we enter 2002.

Subcontracts: We have successfully negotiated contracts with Fudan University (FU), the Shanghai Municipal Center for Disease Control and Prevention (SMCDCP) and the Institute for Public Health Supervision (IPHS) (and ExxonMobil Biomedical Sciences Inc. which proved to be the most problematic!). This has not been an easy process, ultimately requiring the intervention of the Controller and Attorney General of the State of Colorado. These subcontracts provide for general descriptions of workscope and personnel as well as elaborate detail on the operating interrelationships between UCHSC and Chinese entities. In my opinion, the operating budgets agreed upon in these subcontracts are, in all likelihood, too lean. However, because we are intimately involved in the direction and management of field operations, we are in a position to monitor ongoing activities and supplement disbursement of funds to these entities as needed. This strategy is consistent with my extended budgetary authority in the UCHSC contract and I have already built these funds into our existing budget projections which require no further adjustments at this time or in the foreseeable future.

These agreements were concluded during the summer and early fall of 2001. As an act of good faith, each of the Chinese subcontractors has been expensing funds in support of project development over this time period in anticipation of contract approval and project funding. This has extended to equipment purchases as well as general operating expenses, but, unfortunately, according to Chinese custom, has not been extended to salary compensation. Consequently, I have authorized the immediate payment of invoices and salaries retroactive to their billing dates. Because the actual transfer of funds has only just taken place last week, I cannot provide any specific detail of the expenditures made by these entities at this time. However, it is my observation that we are generally on target with respect to progress and the budget. If anything, we have slightly under-expended relative to our expectations going into 2002.

Chinese Personnel: Senior faculty at Fudan University as well as faculty and staff at the IPHS and SMCDC were added to the payroll in July, September and October as provided for in the contracts with these respective organizations. In July, 2001 we hired Wang Xiao Chen as Associate Laboratory Director for Clinical Affairs. Professor Wang is a clinical hematologist at Hua Shan Hospital and a faculty member at Fudan University. She has been active in recruiting clinical coordinators from each of the participating hospitals and organizing training sessions. During the active phase of the study she will supervise clinical activities associated with the project, including case triage, and assist in managing laboratory hematology services. Also in July, we hired Ye Xibiao as Assistant Laboratory Director for Administration. He has played an important role in coordinating our interactions with Fudan University and in organizing our response to Chinese legal

and regulatory bureaucracy. In September we hired Jane Liu as senior laboratory secretary and personal assistant to me. She has a MS degree in English from University of British Columbia. Additional recruitments include Jane Yao, MD, Lu Hongfen, MD to the laboratory staff, and hires of other laboratory support staff are pending. Several of these individuals are scheduled to undergo training in the US during the first year of the project beginning in January. In the future I plan to provide less detail on personnel as it relates to the hire of less senior staff, but will continue to inform the Technical Committee with respect to senior personnel.

There is a historical expectation of Chinese applicants to be guaranteed employment for life that is only slowly changing in China. This tradition is especially strong within Universities. Fudan University has agreed to provide a small number of permanent positions for the Laboratory. However, we require a far greater number of highly qualified individuals. Independently, delays in the transfer of funds by API after completion of contract negotiations has resulted in many individuals already on the payroll not being paid salaries for several months. These issues have conspired to significantly delay our efforts to recruit sufficient numbers of qualified individuals for the laboratory. Funds have only recently been transferred to the Chinese entities for payment up to December 21, 2001. In the future it will be necessary to expedite the scheduling of payments to coincide more closely with our contractual obligations or we run the risk of not being able to maintain a satisfactory working relationship with our employees or our contracting institutions in China.

Laboratory Renovation: Laboratory space renovation in the School of Public Health was completed in early October and is ready for equipment installation. Office space has also been renovated for Dr. Bao, myself and a senior secretary which we occupied in October. The space we have available is small, relative to the projected activities of the laboratory once in operation. Consequently, we are negotiating with FU authorities for additional space slated to become available within the next two years. However, the space we have is exceedingly well prepared for our activities, and we are proceeding with equipment procurement.

Recruitment and Organization of the Shanghai Professional Community : We have held several organizational meetings with the Shanghai Hematology and Pathology Societies. Both societies have agreed to participate as official collaborators in the project, lending great weight to the intellectual and clinical importance of the project. This is a virtual requirement for the broad-based professional involvement necessary for the successful conduct of these studies. We have also obtained written commitments from 14 out of 15 major referral hospitals as well as 2 of the largest Central District Hospitals to participate in the project and refer qualified subjects to our studies. We have identified clinical coordinators from each of these hospitals who are senior staff or faculty hematologists. Two training sessions already have been conducted to orient and train clinical coordinators, and others are planned.

Shanghai Governmental Liason: Early on we incurred some difficulties in organizing Central District Hospitals and encountered some bureaucratic resistance to our efforts to obtain permits and obtain the necessary permission to operate the laboratory. We

subsequently determined that this was the result of a lack of official support at higher levels of the Chinese and Municipal Shanghai governments. Accordingly, we have met with and established a formal relationship with the Head of the Shanghai Public Health Bureau who has extended official support and recognition to our laboratory and project. This should ensure participation by all Central District Hospitals as well as facilitate other activities, such as obtaining visas and resident permits, as well as aiding in obtaining the necessary import/export authorizations and licenses.

University Administrative Liason: Some of our early difficulties appear to have been the result of a lack of understanding as to the nature and scope of our project within the Fudan University Administration. Accordingly, we have established a close working relationship with Professor Chen xiao man who is director of research for Fudan University.

Exposure Assessment: The SMCDP and IPHS will play major roles in exposure assessment activities. In order to achieve this we have developed the concept of exposure assessment teams that will be made up of individuals from FU, CDC and IPHS. These teams will be responsible for historical review and current assessment of benzene exposures for all three studies, including performance of industrial hygiene and analytical chemistry procedures. In the Molecular Epidemiology Study, these teams will be responsible for factory selection, inspection and subject recruitment. In October, Gail Jorgenson of ExxonMobil Biomedical Sciences, Inc consulted with IPHS staff on upgrading the Shanghai benzene poisoning and benzene exposure databases. With her help and advice, IPHS purchased a computer to serve as a platform for the upgrade. We also initiated discussions with SAS consultants in Shanghai to begin the upgrading process which will shortly involve software leasing.

Differential Diagnosis of Hematopoietic and Lymphoid Neoplasms: According to custom, Chinese hematologists and pathologists use separate methods, evaluate different materials and utilize different data sets in reaching independent diagnoses. Traditionally, there is little dialogue between the two disciplines. In order to utilize the WHO criteria for Diagnosis of Hematopoietic and Lymphoid Tumours, we require that all of these modalities be combined into an integrated diagnosis. In order to achieve this, an expert diagnostic working group has been recruited and organized. This group, which consists of the foremost experts in hematopathology, morphologic hematology and immunopathology in Shanghai, will be moderated by Dr. Irons and will meet on a biweekly basis to review diagnoses for both clinical and research purposes.

Ethical Issues: The harmonization of ethical and culture issues associated with this project has been ongoing over the last 6 months. This has been largely an interactive process involving Professors Baruch Brody, Xu Zong Liang and project staff. In November, the Fudan University IRB approved the project after conducting a full evaluation of the project. This amounted to a second level review of ethical issues and clinical procedures.

Equipment and Supply Issues: Contracts with international companies have been concluded for the purchase of major clinical laboratory equipment at a total value of approximately \$650,000. In addition, purchasing agreements have been established with both US and Shanghai distributors for the importation of reagents and supplies. These negotiations invariably involve import/export rules, currency exchange, tariffs and shipping. At present, we are slightly ahead of our initial budget projections for these activities. However, we underestimated the complexity of the bureaucratic process and, consequently, time-effort requirements. These are complex and laborious issues that promise to occupy about 3 FTE (roughly evenly split between China and UCHSC) for many months to come. Equipment and supply procurement, along with training activities have a high priority because of their potential impact on study start dates.

Projections:

- Needs
- Activities
- Etc.

Conclusion

RDI