

**PROGRESS REPORT
ON THE BUDGET
July 2006**

Shanghai Health Study

- I. DISEASE PROGRESSION FOR APLASTIC ANEMIA,
MYELOYDYSPLASTIC SYNDROME, ACUTE MYELOGENOUS
LEUKEMIA AND BENZENE POISONING IN SHANGHAI, CHINA
- II. MOLECULAR EPIDEMIOLOGY OF BENZENE-EXPOSED WORKERS
IN SHANGHAI, CHINA
- III. EXPOSURE ASSESSMENT

Richard D. Irons

EXECUTIVE SUMMARY

A. Overall Status of Budget

Attached is an official summary of the overall budget for the period ending June 30, 2006.

Table 1 reflects actual expenditures for the period. For the first time these exceeded budgeted projections in all categories except for personnel (Table 1).

Table 1. Budget Summary (Reporting Period)

	Budgeted ¹	Expenditures	Variance
Personnel	\$236,350	\$227,105	\$9,245
Operating Expenses	\$235,580	\$265,524	(\$29,944)
Subcontracts	\$1,454,051	\$1,675,639	(\$221,588)
Travel	\$500	\$0	\$500
Equipment	\$0	\$0	\$0
Indirect	\$122,832	\$127,042	(\$4,210)
TOTALS	\$2,049,313	\$2,295,310	(\$245,997)

¹The budgeted amounts are the sum of each category from Jan-06 thru Jun-06.

Table 2. Budget Summary (Entire Project)

	Budgeted ²	Expenditures	Variance
Personnel	\$ 2,399,955	\$2,406,356	(\$6,401)
Operating Expenses	\$ 1,961,966	\$1,822,928	\$139,038
Subcontracts	\$ 8,652,639	\$ 8,297,249	\$355,390
Travel	\$ 10,493	\$9,098	\$1,395
Equipment	\$ 1,383,490	\$1,383,490	\$0
Indirect	\$ 1,166,418	\$1,129,385	\$37,033
TOTALS	\$ 15,574,962	\$15,048,506	\$526,455

²The budgeted amounts are the sum of each category from Dec-01 thru Jun-06.

Subcontract Summary (Entire Project)

Subcontracts	Expenditures (Dec 01-Jun 06)
Fudan University	\$ 5,121,580
IPHS	\$ 170,077
SMCDC	\$ 153,004
EMBSI	\$ 2,515,754
Children's Hospital Cincinnati	\$ 336,834
Total	\$ 8,297,249

B. Budget Analysis

The increased rate of expenditures experienced during this reporting period can be attributed to a combination of: 1) an increase in case load coinciding with increases in reagent costs; 2) the unexpected frequency of excluded cases which are approaching 30% in some categories (*i.e.* nutritional deficiencies); and 3) a large increase in efforts and expenditures in ME factory monitoring, exposure assessment and EA simulation exercises. However, as I discussed by telephone in April, the loss of critical personnel coupled with our inability to contract additional manpower has significantly slowed progress and has had a major impact on all of these initiatives by exacerbating inefficiencies and requiring “work-arounds” to complete tasks on the critical path. The increased rate of expenditures is not reflected in the overall budget summary (Table 2) because of the previous budgetary surplus. Projected costs for the remainder of the project are outlined in Table 3. Although projected expenditures are expected to stay within the overall budget through December 2006, we anticipate the possibility of a shortfall approaching as much as \$450,000 by June 2006. These projections assume case accrual ends December 31, 2006 independent of study case accrual target goals.

Table 3. Projected Budget (Remainder of Project) based on current projections

	July – Dec 2006	Jan - Jun 2007
Personnel	\$ 278,515	\$ 278,515
Operating Expenses	\$ 400,000	\$ 250,000
Subcontracts	\$ 1,311,864	\$ 894,935
Fudan	\$ 850,989	\$ 425,495
EMBSI	\$ 402,075	\$ 407,700
Cincinnati Children's	\$ 58,800	\$ 61,740
Travel	\$ 500	\$ -
Equipment	\$ -	\$ -
Indirect	\$ 176,544	\$ 137,414
TOTALS	\$ 2,167,423	\$ 1,560,864

Appendix A

	Dec-01	Jun-02	Dec-02	Jun-03	Dec-03	Jun-04	Dec-04	Jun-05	Dec-05	Jun-06	Dec-06	Jun-07	Total
Personnel													
Apr 05 Budget	\$ 172,140	\$ 224,883	\$ 317,665	\$ 314,703	\$ 230,328	\$ 211,016	\$ 229,260	\$ 227,260	\$ 236,350	\$ 236,350	\$ 278,515	\$ 278,515	\$ 2,956,985
Actual	\$ 172,140	\$ 224,883	\$ 317,665	\$ 314,703	\$ 230,328	\$ 211,016	\$ 229,263	\$ 235,437	\$ 243,816	\$ 227,105			\$ 2,406,356
Operating Expenses													
Apr 05 Budget	\$ 13,131	\$ 94,401	\$ 193,990	\$ 158,850	\$ 162,834	\$ 364,542	\$ 237,258	\$ 247,000	\$ 254,380	\$ 235,580	\$ 400,000	\$ 250,000	\$ 2,611,966
Actual	\$ 13,131	\$ 94,401	\$ 193,990	\$ 158,850	\$ 162,834	\$ 364,542	\$ 237,258	\$ 104,457	\$ 227,940	\$ 265,524			\$ 1,822,927
Subcontracts													
Apr 05 Budget	\$ 123,629	\$ 688,452	\$ 213,291	\$ 845,860	\$ 565,870	\$ 1,128,507	\$ 948,696	\$ 1,420,103	\$ 1,264,180	\$ 1,454,051	\$ 1,311,864	\$ 894,935	\$ 10,859,438
Actual	\$ 123,629	\$ 688,452	\$ 213,291	\$ 845,860	\$ 565,870	\$ 1,128,507	\$ 948,696	\$ 1,359,315	\$ 747,991	\$ 1,675,639			\$ 8,297,250
Travel													
Apr 05 Budget	\$ -	\$ 8,429	\$ 218	\$ 346	\$ -	\$ -	\$ -	\$ 500	\$ 500	\$ 500	\$ 500	\$ -	\$ 10,993
Actual	\$ -	\$ 8,429	\$ 218	\$ 346	\$ 105	\$ -	\$ -	\$ -	\$ -	\$ -			\$ 9,098
Equipment													
Apr 05 Budget	\$ 291,568	\$ 253,578	\$ 354,496	\$ 274,508	\$ 17,000	\$ 192,340	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 1,383,490
Actual	\$ 291,568	\$ 253,578	\$ 354,496	\$ 274,508	\$ 17,000	\$ 192,340	\$ -	\$ -	\$ -	\$ -			\$ 1,383,490
Indirect													
Apr 05 Budget	\$ 47,922	\$ 111,454	\$ 139,587	\$ 122,902	\$ 101,447	\$ 148,709	\$ 120,408	\$ 123,438	\$ 127,720	\$ 122,832	\$ 176,544	\$ 137,414	\$ 1,480,376
Actual	\$ 47,922	\$ 111,454	\$ 139,587	\$ 122,902	\$ 101,447	\$ 148,709	\$ 120,408	\$ 88,121	\$ 121,793	\$ 127,042			\$ 1,129,385
Travel & Expenses													
TOTALS													
Apr 05 Budget	\$ 648,390	\$ 1,381,197	\$ 1,219,247	\$ 1,717,169	\$ 1,077,479	\$ 2,045,114	\$ 1,535,622	\$ 2,018,301	\$ 1,883,130	\$ 2,049,313	\$ 2,167,423	\$ 1,560,864	\$ 19,303,248
Actual	\$ 648,390	\$ 1,381,197	\$ 1,219,247	\$ 1,717,169	\$ 1,077,584	\$ 2,045,114	\$ 1,535,625	\$ 1,787,330	\$ 1,341,540	\$ 2,295,310	\$ -	\$ -	\$ 15,048,506

Case Accrual

In the 12-month period ending May 1, 2006, there were 977 cases diagnosed at JCML, bringing total case contact to date to 2,313 for which 2,231 diagnoses have been reviewed. Diagnoses have been reviewed and entries verified in the database and strategies are being devised, implemented and tested for the retrieval of study data.

This includes all diseases included in the original case definitions, the expanded disease list that was suggested and approved by the SRP in 2004, nutritional, infectious or reactive diseases as well as other excluded conditions. In addition, we have diagnosed or supported case management of approximately 45 patients for humanitarian reasons that are not included in the case accrual.

Original CC goals for AML and NHL case accrual were predicated on power estimates derived from the ICD-9 classification of diseases but were scaled downward in response to the delay in laboratory start-up and other funding limitations. Case accrual for MDS, AA and BP were originally estimated based on existing diagnostic standards in place in Shanghai at the time the study was designed. Current and projected case accrual numbers are summarized in Table 4. During the last year, case accrual of NHL has increased significantly, exceeding accrual for the first two years of the study combined. However, we will be short of study accrual goals by 13% as of 12/31/06. The shortfall for AML case accrual is almost identical to that for NHL.

Table 4. Current and Projected Case Accrual

	Study goals ^a	Case Accrual ^b 5/1/2006	Case Accrual ^c (12/31/2006)	Time to Study goals ^c
AML:	600(500)	353	424	5/1/2007
NHL:	600(500)	336	433	5/1/2007
MDS ^b :	350	379	480	N/A
AA ^b :	250	112	137	N/A
BP ^b :	50	32	36	N/A

^aOriginal and scaled down () goals based on the ICD-9 classification of diseases.

^bCurrent case accrual for AA, MDS and BP reflect the influence of JCML on the frequency of these diseases diagnosed in Shanghai (e.g. routine use of bone marrow biopsies, application of WHO criteria, discovery of BID).

^cProjected case accrual based on ICD-9 criteria and current case rate. Numbers for AML, NHL and MDS based on WHO criteria employed in the laboratory are higher, reflecting the expanded disease categories included in the WHO classification that are not included in ICD-9. For example, lymphoid malignancies, including lymphocytic leukemias, total cases = 520. For AML, differences between ICD9 and WHO include MDS now diagnosed as leukemias, monocytic leukemias and other subtypes as well as differences in the diagnostic criteria employed (Irons et al (2006) *Leukemia Res.* 30: 769-775).

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Subject: Shanghai Health Study - Case accrual rates

I forgot to include this yesterday - sorry for the extra email.

Jerry Rice put together this table to document the rate of case accrual over the last three years using only WHO criteria. He is asking Dr. Irons to confirm the numbers.

Attachments:

SHS Cumulative WHO Case Accrual Figures JR Rev 3.doc