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Subject: Shanghai Health Study - Case Control Progress Report - YE 03

Attached is the latest progress report from Otto Wong on the Shanghai Health Study Case Control project. This is not for further distribution.

Regards,
Patsy

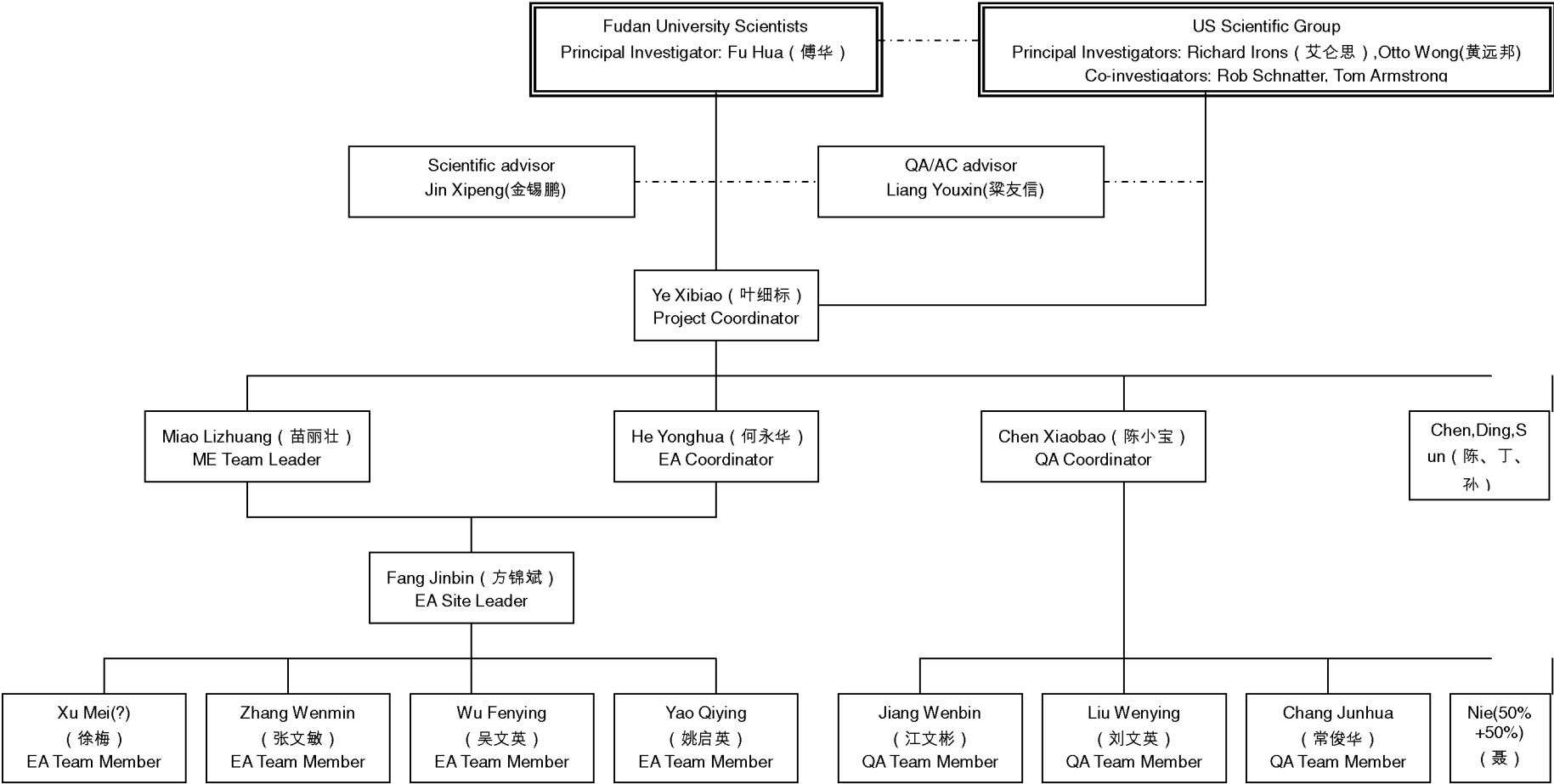
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Attachments:

CC Org Chart 01-26-2004.doc
CC Progress Rpt 01-26-2004.doc

SHANGHAI PROJECT TEAM ORGANIZATIONAL CHART



Progress Report
AML and NHL Case-control Study
Activities through December 2003

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Hospital Participation and Patient Enrollment:

- Patient enrollment was delayed for several months because most of the hospital resources were diverted to the diagnosis, treatment and control of the SARS epidemic from April to August 2003.
- There are now 26 hospitals participating in the study; including 15 municipal hospitals, 9 district hospitals and 2 occupational hospitals. Of particular interest is the new participant Ruijin Hospital [瑞金医院]. Ruijin is the major teaching hospital of Shanghai Number 2 Medical University (Fudan University Medical School was formerly Shanghai Number 1 Medical University before the merger). We expect Ruijin will contribute a substantial number of cancer patients to the study.
- Patient enrollment in the study began in late July 2003. As of December 2003, the Joint Sino-US Clinical & Molecular Laboratory had diagnosed 66 cases of NHL and 42 cases of AML. Please note that these numbers might change slightly because hospital involvement was somewhat sporadic in the initial weeks of operation (July and August). The accrual rates of NHL and AML cases are within the estimated range. Since some hospitals, including Ruijin Hospital, joined the study late in 2003, we anticipate that the number of cases may go up in the future.

Selection of Controls

- Several meetings with hospital Clinical Coordinators (who are responsible for case enrollment and control selection) were held. The Clinical Coordinators were provided with the study protocol, case definitions, and instructions for selecting controls. Two individually matched controls are to be selected for each case. The matching variables are: same hospital, same gender, no disease of the lymphatic and hematopoietic system, age within 5 years, closest admission date, and same inpatient/outpatient status. So far, the Clinical Coordinators have been able to provide two matched controls for each case.
- We are in the process of developing several measures to monitor the selection of controls at each hospital to ensure that the instructions are being followed. We are working closely with Dr. WANG Xiaoqin [王小钦医师] of Huashan Hospital [华山医院], who is our primary contact with all the Clinical Coordinators.

Patient Interviews:

- At most hospitals, interviews took place at the patients' bedside. It was not possible to blind the interviewers completely with regard to the case/control status of the patient. We, however, do not consider this a serious problem, since interviewers do not participate in exposure classification of the patients.

Exposure assessment:

- The Exposure Assessment Committee met every Friday for exposure assignment of study subjects. Professor LIANG Youxin [梁友信 教授] chaired these meetings. Committee members were blinded as to the case/control status of the study subjects.
- We continue to work with the Shanghai Institute of Public Health Supervision (IPHS) to expedite the process of retrieving relevant information from its database of benzene monitoring data at factories.
- Another major source of information for exposure assessment is the occupational medicine literature in China. Reports of benzene poisoning cases in Chinese medical journals often provide a description of the work environment and industrial hygiene measurements. A systematic search (both online and manual) of both national and regional journals has been completed. Copies of articles are being retrieved and are being organized for review.

Project Organization:

- To make the best use of available resources, the Shanghai project team was re-organized recently. Attached is the new organizational chart. Communication

seemed to have improved between various groups of the Shanghai project team as well as between the latter and US investigators.

Social Event:

- A banquet to celebrate the inauguration of the laboratory and the study was held on December 9, 2003 in Shanghai. More than 160 individuals attended, including project staff members, representatives of collaborating agencies and hospitals, and representatives of sponsors. Professor WANG Shenghong [王生洪 教授], the President of Fudan University, and Dr. Douglas Spelman, the US Consul General, were among the guests of honor. (Dr. Spelman delivered his speech in both English and Chinese.) The event was a great success and was broadcast on several television channels.