

DRAFT

December 22, 2006

Charter for Shanghai Health Quality Assurance and Data Transfer Team

Purpose: The purpose of this team is to facilitate the successful completion of the Shanghai Health Study. This team will facilitate progress of this study by supplying further quality assurance of data collected as well as a rigorous quality assurance program for data transferred to other principal investigators. A multi-year study, the Shanghai Health Study has three principal investigators (PI), study databases in two countries, a clinical diagnostic laboratory delivering information to a hematologist, an investigative industrial hygiene team and an epidemiologist.

The team will be made up of the following members:

Members: Dr. Jerry Rice, Chairman, Chair of SRP
Dr. Richard Irons – Hematologist, PI
Dr. Otto Wong – Epidemiologist, PI
Dr. Judy Baldwin – Quality Assurance Expert
Dr. Helmut Greim – Industrial Hygienist, SRP
Dr. Rob Schnatter – Epidemiologist, Adjunct PI

******Others can be added as the team recognizes the need

Objectives: **This team will ensure processes are in place to provide oversight for data quality control in this complex multi-part study. These processes shall ensure the quality of the data is maintained, including during its transfer between principal investigators. The quality of the data will be assured by using fully reviewed and documented data quality and data transfer processes. Processes will be developed to further delineate roles and responsibilities. These procedures will result in enhanced communication and scientific excellence.**

Deliverables: The team will determine appropriate metrics for delivery to the team on the 15th of each month. Metrics considered reflective of the progress of the study might include:

- Regular, periodic review of data
- Documentation of data flow and data entry
- Cases accrued: AML and NHL
- Percent of consent forms and questionnaires signed
- Percent of consent forms/questionnaires entered into database
- Development of QA/QC program for final year
- Other metrics deemed necessary by the team

Timeline: First metrics report – March 15, 2007

The PI's will implement recommendations of the QA/QC team.

Note: Semi-annual, written progress reports as specified in original protocols will continue to be provided.

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