

Shanghai Health Study

Charter: *Data and Process Quality Assurance Team*

Purpose: The role of this team is to facilitate successful completion of the Shanghai Health Study through development, implementation and management of an independent data and process quality assurance and control program; to set definable milestones for study completion; and to assure timely transfer of information among investigators. The focus of the Team is to be on the Shanghai Health Study as a whole, rather than on specific protocols, and the team is not expected to duplicate or replace existing QA/QC measures that have already been established by individual principal investigators for individual protocols or other SHS elements.

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. Therefore, this complex study needs a well understood process for the transfer of data from one investigator to another.

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 – Toxicologist, SRP
 Dr. Rob Schnatter – Epidemiologist, Adjunct PI

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

Team and PI Responsibilities:

- Ensure that a rigorous system for data and process quality assurance and control is in place and functioning (defined processes, roles and responsibilities, process reviews, project timeline with goals & milestones, and key metrics) to provide oversight and assurance addressing the following:
 - (1) data and process quality control are robust and sustained;
 - (2) data capture, analyses and transfers are done in a timely, accurate, complete, consistent and secure manner;
 - (3) data tracking and progress reporting is on-time and accurate;
 - (4) effective communications and collaboration among investigators occurs in a way that facilitates study completion;
 - (5) processes clearly define roles and responsibilities;
 - (6) QA/QC procedures will result in enhanced communication and scientific excellence;
 - (7) The PI's will implement recommendations of the QA/QC team.