

the individual FileMaker databases will be user/password protected as well. The combination of these security features will prevent unauthorized access to clinical and/or study data.

25 RECRUITMENT AND TRAINING OF LABORATORY STAFF

25.1 Recruitment

Laboratory staff were recruited and selected from qualified applicants in Shanghai and elsewhere in China. Our goal is to select the best applicants that meet qualifications acceptable by US guidelines (CAP, ASCP, FDA- see CAP Guidelines Feb21-2000). For example, the Chinese Laboratory Director should be a certified clinical pathologist or a PhD with appropriate training and/or clinical specialty certification in one or more aspects of laboratory operation, ie. cytogenetics, hematology, and 3-5 years of clinical and/or research laboratory experience. Other supervisory positions (e.g. deputy director, clinical hematologist, cytogeneticist etc.) should be staffed by individuals with comparable training and experience, ie. clinical pathologists, or individuals with a terminal degree (MD, PhD) in the same or related field (hematology, cytogenetics, molecular genetics etc.) and two or more years of postdoctoral laboratory experience. Technical positions will be recruited from the best applicants possible.

25.2 Training

Training of Shanghai laboratory personnel at UCHSC fulfilled two purposes. First, training of staff is necessary in order to meet study obligations to leave a fully staffed functioning clinical and molecular laboratory in Shanghai by the end of the study. Second, training and staffing of the laboratory is crucial in order to maintain a functional laboratory and fulfill study outcomes.

Cytogenetics has not yet become part of the routine cancer diagnostic work-up in China. Therefore, recruitment of Chinese personnel with appropriate training and experience in clinical cancer cytogenetics is expected to be difficult. In order to facilitate standardization of clinical cytogenetic analyses as outlined in this proposal, it was necessary to train Chinese personnel at UCHSC. The training was intended to prepare Shanghai personnel with the knowledge and skills to perform all cytogenetic preparations and analyses, to develop and implement quality assurance and quality control programs and to transfer the latest technologies and information to the Shanghai laboratory. UCHSC and Cincinnati Children's Hospital Medical Center personnel will provide expert consultation and training for their Chinese counterparts throughout the study.