Notification Letter of Institutional Review Board of Sichuan University West China Hospital

2011 Shenzi Number(121)

Department: Hematology		PI of the project (name and title): Xu Caigang, Vice Chief Physician
Title of project	A multi-center international hospital-based case-control study of lymphoma in Asia (AsiaLymph)	
Study Protocol	Version #: NA	Version Date: Nov. 29, 2011
Consent form	Version #: NA	Version Date: Nov. 29, 2011

Review Decision:

1. The investigators are qualified the requirement by IRB;
2. Research protocol and consent forms basically meet the requirement of IRB;
3. Please provide the following additional documents to the IRB for documentation:
    a. Approval from Chinese DNA export office for shipment of bio-specimen
    b. SOP of bio-specimen shipment

    The IRB agrees to conduct the clinical study after the submission of the above complementary documents

Review result: ■Agree ☐Agree after revised ☐Review after revised ☐Disagree ☐Terminated or paused

Please conduct the study and protect the health and rights of the respondents in accordance with Chinese laws, regulations, and agreements: SFDA “Good clinical practice” (2003), “Provisions for clinical trials of medical devices” (2004), WMA “Declaration of Helsinki”, and CIOMS “International ethical guidelines for biomedical research involving human subjects”, MOH “Ethical review of biomedical research involving human subjects”, approved protocol and consent forms by IRB.

In the progress of the study, any changes of the main investigators, protocol, and consent forms need to be submitted to IRB for reviewing the amendment.
If any serious adverse events happened, the applicants need to submit a report to the IRB; After the urgent event, provide detailed follow up report on the adverse event as soon as possible.
Annual and regular reports need to be submitted to the IRB. A written report need to be submitted to the IRB in case of any possible situation which may have significant impact on the progress of the study or increase the risk to the respondents.
A violation report should be submitted to the IRB in the events that the clinical trial (or study) enrolled subjects who are not qualify, remained subjects who should be quit due to meet the criteria of termination, provided wrong treatment or dosage, provided combined medicine which the protocol forbids to do so; and the possibility of having impact on subjects’ health/rights, and any situation of impacting the science of the study and violating the ethnic principal or regulations.
If the applicants pause or terminate the clinical trial (or study), please provide a report to the IRB. When the clinical trial (or study) is completed, a completion report should be submitted by the applicant to the IRB.

Institute (Seal of Sichuan University West China Hospital)
Chairman of the IRB:
Dec. 9, 2011