CLINICAL RESEARCH PROTOCOL
**INITIAL** REVIEW APPLICATION

PRINCIPAL INVESTIGATOR (Name of NIH Employee, Institute/Branch, Address, Telephone and email):
Qing Lan, NCI/OEEB, 6120 Executive Blvd, EPS 8010, 3014354706,qingl@mail.nih.gov

PROTOCOL TITLE: A multi-center international hospital-based case-control study of lymphoma in Asia (AsiaLymph)

ABBREVIATED TITLE (30 characters or less): lymphoma in Asia (AsiaLymph)

PROPOSED START DATE: 9/1/11 END DATE: 9/1/15 TOTAL SUBJECTS TO BE ACCRUED (Attach target table for Phase 3-4): 6600

MULTI-SITE COLLABORATION:
Is this a multi-site collaboration? ☒ Yes (complete this section) ☐ No
Will subjects participate on the protocol at the NIH CC? ☐ Yes ☒ No
Will subjects participate on the protocol at other sites? ☒ Yes ☐ No
If yes, are the sites ☐ Domestic ☒ Foreign ☐ Both
Is NIH the coordinating site?
☐ Yes. For each participating site, provide: Institution name, address, investigator(s), indicate if subjects will be recruited and if they are, include a contact name on attached sheet/protocol face sheet.
☒ No. Coordinating Site is University of Hong Kong

REQUESTED ACCRUAL EXCLUSION (Check all that apply):
☐ None ☐ Asian
☐ Male ☒ Black or African American
☐ Female ☒ White
☒ Children <18 ☒ Hispanic or Latino
☒ American Indian/ Alaskan Native ☒ Native Hawaiian or Pacific Islander

SUBJECT ACCRUAL CHARACTERISTICS:
Minimum Age Permitted 18
Maximum Age Permitted 79
Pediatric ☒ None ☐ <2 Yr. ☐ 2-6 Yrs. ☐ 7-17 Yrs.
Protocol involves healthy volunteers? ☐ Yes ☒ No
Are Healthy Volunteers NIH Employees? ☐ Yes ☒ No
Does the protocol permit self referral? ☐ Yes ☒ No
Will the protocol involve adults unable to give informed consent? ☐ Yes ☒ No

PROTOCOL TYPE: (Check one):
☐ Screening
☐ Training
☐ Natural History – Disease Progression/ Physiology
☒ Natural History – Sample/Data Collection or Analysis (Recruiting Patients)
☐ Natural History – Sample/Data Collection or Analysis (Not Recruiting Patients)
☐ Pharmacokinetics/Dynamics
☐ Clinical Trial: Identify Phase (Check one)
☐ Phase 0 ☐ Phase 1 ☐ Phase 1-2
☐ Phase 2 ☐ Phase 3 ☐ Phase 4

If a Phase 3 Clinical Trial, is analysis for sex, racial/ethnic subgroups required according to the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research? ☐ Yes ☐ No ☐ N/A

KEY WORDS (Words or phrase that describe the protocol.)
1. lymphoma
2. hospital-based case-control study
3. occupational epidemiology
4. molecular epidemiology
5. genetic polymorphisms

IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET; etc.): check all that apply
☒ None ☐ Medically indicated ☐ Research indicated*
*Complete NIH-88-23a, and attach to this application. Send a copy of entire protocol and NIH-88-23a to Chair, Radiation Safety for concurrent review).

INVESTIGATIONAL NEW DRUG/DEVICE: ☒ None ☐ IND ☐ IDE
*If reporting more than one IND/IDE, list on attached sheet.
FDA No. _____
IND/IDE Name: _____
Sponsor: _____
Who is the manufacturer of the above entity: _____

Does the protocol involve a Tech Transfer Agreement? ☐ Yes ☒ No

Does the protocol involve a drug/device/product that may lead to you or the NIH receiving payment and/or royalties?
☐ Yes (Append a statement of disclosure)
☒ No

Has the NIH IRP COI Guide been distributed to NIH Investigators?
☒ Yes ☐ No

Has the NIH IRP COI Guide been distributed to Non-NIH Investigators?
☐ Yes ☐ No ☒ N/A

CONFLICTS OF INTEREST REVIEW:
Date submitted to IC DEC: _____ Date cleared by IC DEC: _____

Is an Extramural Investigator an ADJUNCT PRINCIPAL INVESTIGATOR? ☐Yes ☒No
Name of Adjunct PI: _____

MEDICAL ADVISORY INVESTIGATOR (if necessary) Name, Inst/Branch, Telephone, Address, Email and initial line:

LEAD ASSOCIATE INVESTIGATOR – Name, Inst/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line:
☒ Nathaniel Rothman, NCI/OEEB, 6120 Executive Blvd, EPS 8116, 301-496-9093, rothmann@mail.nih.gov

RESEARCH CONTACT: Name, Inst/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line:
☒ Qing Lan,NCI/OEEB,6120 Executive Blvd, EPS 8010, 301-435-4706,qingl@mail.nih.gov

ASSOCIATE INVESTIGATOR(S): Name, Institute/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line. Attach list if necessary.
1. ☒ Martha Linet,NIH/REB, 6120 Executive Blvd, EPS 7054, 301-496-6600, linetm@mail.nih.gov
2. ☒ Charles Rabkin,NIH/IIB,6120 Executive Blvd, EPS 7082, 301-435-4731, rabkinc@mail.nih.gov
3. ☒ Lynn Goldin, NIH/GEB, 6120 Executive Blvd, EPS 7006, 301-402-9656, Lynn.Goldin@nih.gov
4. ☒ Sholom Wacholder, NIH/BB, 6120 Executive Blvd, EPS 5060, 301-496-3358, wacholde@mail.nih.gov
5. ☒ Lindsay Morton, NIH/REB, 6120 Executive Blvd, EPS 7040, 301-435-3972, mortonl@mail.nih.gov

**(Principal Investigator: Be sure to include PRECIS <=400 words as first section of protocol)**

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|---|---|---|---|---|
| SIGNATURE | Qing Lan (Principal Investigator) | Qing Lan (Print/Type Name) | Date 5/3/11 | Send to Accountable Investigator |
| RECOMMENDATION | Qing Lan (Accountable Investigator) | Qing Lan (Print/Type Name) | Date 5/3/11 | Send to Branch Chief, or CC Dept. Head of Accountable Investigator |
| | Debra Silverman (BC Chief/CC Dept. Head of Accty Invest.) | Debra Silverman (Print/Type Name) | Date 5/3/11 | Send to Institute/Center Scientific Review Committee |
| APPROVALS | (For Institute/Center Scientific Review Comm.) | SHELIA ZAHM (Print/Type Name) | Date 6/14/11 | Send to Clinical Director |
| | (Clinical Director) | William D (Print/Type Name) | Date 6/21/11 | Send to Chair, Institutional Review Board |
| | (Chair, For Institutional Review Board) | Katherine Schaner (Print/Type Name) | Date 6/14/11 | Send to Office of Protocol Services, through IRB Protocol Coordinator |
| PATIENT SAFETY/ RESOURCE REVIEW | (Director, Clinical Center) DDCC | Dan Kastner (Print/Type Name) | Date July 3, 2011 | Return to Office of Protocol Services, (10/1S231B) |
| COMPLETION | Sarita Thomas (Protocol Specialist) | Date 7-5-11 | PROTOCOL NO. 11-C-N206 | |

NATIONAL INSTITUTES OF HEALTH CLINICAL CENTER Public Health Service

Warren G. Magnuson Clinical Center
Mark O. Hatfield Clinical Research Center

Building 10, Room 1S231B
10 Center Drive, MSC 1192
Bethesda, MD 20892
Telephone: (301) 496-0744

Date: July 5, 2011

To: Qing Lan, M.D.
EPS/214

From: Sarita Thomas, Protocol Specialist
Office of Protocol Services

Subject: Initial Protocol Approval

Title: A Multi-Center International Hospital-Based Case-Control Study of Lymphoma in Asia (AsiaLymph)

Protocol Number: 11-C-N206

The final patient safety and resource review was conducted by John I. Gallin, M.D., Associate Director for Clinical Research of the National Institutes of Health Clinical Center on 07/03/2011. The Office of Protocol Services has assigned your intramural research protocol, number **11-C-N206** which will be due for continuing review on **05/15/2012**.

OPS or your IRB Office will notify you 120 days prior to the review. However, Federal regulation and NIH policy require that you report promptly any unanticipated problems involving risks to subjects or others, or serious harm involving subjects, to your IRB. In addition, substantive changes in research activities, during the period for which IRB approval has been given, may not be initiated by you without prior review and approval by your IRB, except where necessary to eliminate apparent immediate hazard to subjects.

If you have any questions regarding protocol review, approval or reporting procedures, please contact Susan Privot, your Protocol Coordinator at (301) 402-7221.

cc: Protocol Coordinator