

CLINICAL RESEARCH PROTOCOL  
INITIAL REVIEW APPLICATION

PRINCIPAL INVESTIGATOR (Name of NIH Employee, Institute/Branch, Address, Telephone and email):  
Qing Lan, NCI/OOEB, 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 75  
Pediatric  None  <2 Yrs.  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.)**

- lymphoma
- hospital-based case-control study
- occupational epidemiology
- molecular epidemiology
- genetic polymorphisms

**IONIZING RADIATION USE (X-rays, e.g., CT; radionuclides, e.g., PET; etc.): check all that apply**

None  Medically indicated  Research indicated  
\*Complete NIH-98-23a, and attach to this application. Send a copy of entire protocol and NIH-98-23a 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:

Netheriel Rothman, NCI/OOEB, 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:

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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/IB, 6120 Executive Blvd, EPS 7082, 301-435-4731, rabkinc@mail.nih.gov

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5.  Lindsay Morton, NIH/REB, 6120 Executive Blvd, EPS 7040, 301-435-3972, mortonli@mail.nih.gov

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

SIGNATURE	<u>Qing Lan</u> Principal Investigator	Qing Lan Print/Type Name	Date <u>5/3/11</u>	Send to Accountable Investigator
RECOMMENDATION	<u>Qing Lan</u> Accountable Investigator	Qing Lan Print/Type Name	Date <u>5/3/11</u>	Send to Branch Chief, or CC Dept. Head of Accountable Investigator
	<u>Debra Silverman</u> BK Chief/CC Dept. Head of Acct. Invest.	Debra Silverman Print/Type Name	Date <u>5/3/11</u>	Send to Institute/Center Scientific Review Committee
APPROVALS	<u>Sheila Zahm</u> For Institute/Center Scientific Review Comm.	SHEILA ZAHM Print/Type Name	Date <u>6/14/11</u>	Send to Clinical Director
	<u>William Q</u> Clinical Director	William Q Print/Type Name	Date <u>6/14/11</u>	Send to Chair, Institutional Review Board
	<u>Katherine Schaefer</u> Chair, For Institutional Review Board	Katherine Schaefer Print/Type Name	Date <u>6/14/11</u>	Send to Office of Protocol Services, through IRB Protocol Coordinator.
PATIENT SAFETY/ RESOURCE REVIEW	<u>Don Kastner</u> Director, Clinical Center	Don Kastner Print/Type Name	Date <u>July 3, 2011</u>	Return to Office of Protocol Services, (10/1S231B)
COMPLETION	<u>Sarita Thomas</u> Protocol Specialist	DDICR Print/Type Name	Date <u>7-5-11</u>	PROTOCOL NO. <u>11-C-N206</u>



NATIONAL INSTITUTES OF HEALTH CLINICAL CENTER

Public Health Service

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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