

CLINICAL RESEARCH PROTOCOL

INITIAL REVIEW APPLICATION

PRINCIPAL INVESTIGATOR (Name of NIH Employee, Institute/Branch, Address, Telephone and email):

Dr. Lee E Moore, NCI/DCEG, 6120 Executive Blvd EPS 8102 Rockville MD 20852, 3014966427, moorele@mail.nih.gov

PROTOCOL TITLE:

Follow-up of Kidney Cancer Patients from the Central European Multicenter Case-Control Study

ABBREVIATED TITLE (30 characters or less): Survival ECERCC Study

PROPOSED START DATE: 9/30/07

END DATE: 4/1/10

TOTAL SUBJECTS TO BE ACCRUED (Attach target table for Phase 3-4): 1097

MULTI-SITE COLLABORATION:

Is this a multi-site collaboration? [X] Yes (complete this section) [] No
Will subjects participate on the protocol at the NIH CC? [] Yes [X] No
Will subjects participate on the protocol at other sites? [X] Yes [] No
If yes, are the sites [] Domestic [X] Foreign [] Both
Is NIH the coordinating site? [] Yes... [X] No. Coordinating Site is IARC

REQUESTED ACCRUAL EXCLUSION (Check all that apply):

[] None [X] Asian
[] Male [X] Black or African American
[] Female [X] White
[X] Children <18 [X] Hispanic or Latino
[X] American Indian/ Alaskan Native [X] Native Hawaiian or Pacific Islander

SUBJECT ACCRUAL CHARACTERISTICS:

Minimum Age Permitted 29
Maximum Age Permitted 98
Pediatric [X] None [] <2 Yr. [] 2-6 Yrs. [] 7-17 Yrs.
Protocol involves healthy volunteers? [] Yes [X] No
Are Healthy Volunteers NIH Employees? [] Yes [X] No
Does the protocol permit self referral? [] Yes [X] No
Will the protocol involve adults unable to give informed consent? [] Yes [] No

PROTOCOL TYPE: (Check one):

[] Screening
[] Training
[X] 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. Survival Study
2. Kidney Cancer
3. Renal Cell Cancer (RCC)
4. Genetic Susceptibility
5. Tumor Markers/Heterogeneity

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

[X] 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: [X] 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 [X] 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) [X] No

Has the NIH IRP COI Guide been distributed to NIH Investigators? [X] Yes [] No

Has the NIH IRP COI Guide been distributed to Non-NIH Investigators? [X] Yes [] No [] N/A

CONFLICTS OF INTEREST REVIEW:

Date submitted to IC DEC: 11/16/07 Date cleared by IC DEC: 11/20/07

Is an Extramural Investigator an ADJUNCT PRINCIPAL INVESTIGATOR? [X] Yes [] No

Name of Adjunct PI: Dr. Paul Brennan

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:

[X] Dr. Wong-Ho Chow, NCI/DCEG, 3014354708, 6120 Executive Blvd EPS 8100 Rockville MD 20852, choww@exchange.nih.gov

RESEARCH CONTACT: Name, Inst/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line:

[X] Dr. Wong-Ho Chow, NCI/DCEG, 3014354708, 6120 Executive Blvd EPS 8100 Rockville MD 20852, choww@exchange.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. [X] Dr. Lee E Moore, NCI/DCEG, 3014966427, 6120 Executive Blvd EPS 8102 Rockville MD 20852, moorele@mail.nih.gov
2. [X] Dr. Wong-Ho Chow, NCI/DCEG, 3014354708, 6120 Executive Blvd EPS 8100 Rockville MD 20852, choww@exchange.nih.gov
3. [X] Dr. Nat Rothman, NCI/DCEG, 3014354719, 6120 Executive Blvd EPS 8116 Rockville MD 20852, rothmann@exchange.nih.gov
4. [] Dr. Paul Brennan, IARC, 33-4-72738391, 150 cours Albert Thomas 69008 Lyon France, brennan@iarc.fr
5. [] Dr. Mia Hashibe, IARC, 33-4-72738320, 150 cours Albert Thomas 69008 Lyon France, hashie@iarc.fr

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

SIGNATURE: Dr. Lee E Moore, Date: 7-2-07
RECOMMENDATION: DR. Lee E. Moore, Date: 11-20-07
Debra T. Silverman, Date: 12-4-07
Shelia Zahm, Date: 4/3/08
F. Balis, Date: 4/5/08
Maureen Hatch, Date: 4/3/08
G. Allan, Date: 4/10/08
COMPLETION: Protocol Specialist, 4-17-08

PROTOCOL NO. 08-C-N107

Handwritten initials/signature