

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?  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 IARC

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 29  
 Maximum Age Permitted 98  
 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. 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  
 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: 11/16/07 Date cleared by IC DEC: 11/20/07

Is an Extramural Investigator an ADJUNCT PRINCIPAL INVESTIGATOR?  Yes  No  
 Name of Adjunct PI: Dr. Paul Brennan

MEDICAL ADVISORY INVESTIGATOR (if necessary) Name, Inst/Branch, Telephone, Address, Email and initial line:  
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LEAD ASSOCIATE INVESTIGATOR - Name, Inst/Branch, Telephone, Address, Email, Check box if an NIH employee and initial line:  
 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:  
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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.  Dr. Lee E Moore, NCI/DCEG, 3014966427, 6120 Executive Blvd EPS 8102 Rockville MD 20852, moorele@mail.nih.gov  
 2.  Dr. Wong-Ho Chow, NCI/DCEG, 3014354708, 6120 Executive Blvd EPS 8100 Rockville MD 20852, choww@exchange.nih.gov  
 3.  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, hashibe@iarc.fr

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

|                                    |                           |                    |              |           |  |
|------------------------------------|---------------------------|--------------------|--------------|-----------|--|
| SIGNATURE                          | <i>Lee E Moore</i>        | Dr. Lee E Moore    | Date         | 7-2-07    | Send to Accountable Investigator   |
| RECOMMENDATION                     | <i>Lee E Moore</i>        | DR. Lee E. Moore   | Date         | 11-20-07  | Send to Branch Chief, or CC<br>Dept. Head of Accountable Investigator    |
| APPROVALS                          | <i>Debra T. Silverman</i> | Debra T. Silverman | Date         | 12-4-07   | Send to Institute/Center Scientific Review Committee                     |
|                                    | <i>Shelia Zahm</i>        | Shelia Zahm        | Date         | 4/3/08    | Send to Clinical Director  |
|                                    | <i>F. Balis</i>           | F. Balis           | Date         | 4/5/08    | Send to Chair, Institutional Review Board                                |
|                                    | <i>Maureen Hatch</i>      | Maureen Hatch      | Date         | 4/3/08    | Send to Office of Protocol Services,<br>through IRB Protocol Coordinator |
| PATIENT SAFETY/<br>RESOURCE REVIEW | <i>G. Allan</i>           | G. Allan           | Date         | 4/10/08   | Return to Office of Protocol Services,<br>(10/1S231B)                    |
| COMPLETION                         | <i>Marwan Surtabchi</i>   | 4-17-08            | PROTOCOL NO. | 08-C-N107 |  |

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