

CLUE STUDY ANCILLARY PROPOSAL FORM

Please allow 3 weeks for review prior to submission.

DATE OF SUBMISSION: ____ / ____ / 20____
Month Day Year

WHAT BEST DESCRIBES THE STUDY TYPE:
[MARK ONLY ONE]

- RO1 MHS
 NCI Sponsored Other
 MPH Capstone

PROJECT TITLE:

NAME OF CORRESPONDING INVESTIGATOR: Principal Investigator/Advisor
Principal Investigator of Consortium if applicable, Student Investigator

CONTACT ADDRESS OF CORRESPONDING INVESTIGATOR:

Institution: _____ Phone: ____ - ____ - ____
Street: _____ Fax: ____ - ____ - ____
City: _____ State: _____ Zip: _____ Email: _____

MEMBERS OF INVESTIGATOR TEAM:

Name	Institution or Department	Email Address

EXPECTED TIME PERIOD FOR STUDY:

From: ____ / ____ / 20____ to ____ / ____ / 20____
Month Day Year Month Day Year

DO YOU HAVE HUMAN SUBJECTS APPROVAL FROM YOUR INSTITUTION FOR THE PROPOSED STUDY?

- Yes:
Approving Institute: _____
Approval/IRB Number: _____
- Attached a copy of IRB approval letter

- No
- Pending: expected date: _____ / _____ /20____
Month Day Year

DETAILED RESEARCH PLAN:

Provide a 3-page research plan specifically addressing all items listed below. (single space, 12-point font, including tables and figures).

A.1 ABSTRACT:

Provide a brief abstract of 300 words or less.

A.2 SPECIFIC AIMS OF THE PROPOSAL:

Provide 3-5 sentences describing each specific aim of the study including the hypotheses to be tested. Ensure each specific aim is described separately.

A.3 SIGNIFICANCE OF RESEARCH:

Provide a narrative describing the significance and the benefits this research will have to the scientific understanding of cancer disease processes, chronic health outcomes and general health of the public.

A.4 BACKGROUND:

Provide a brief synopsis of the rationale for the specific aim(s) presented.

A.5 PRELIMINARY DATA IF AVAILABLE

Provide preliminary data supporting the above specific aims, including data on assays to be performed – volume required, CVs (inter- and intra – individual variability).

A.6 METHODS

A.6.1 STUDY POPULATION

A.6.2 STUDY DESIGN, METHODOLOGY:

Provide a detailed description of the study design including eligible individuals, matching criteria, methodology, demographics, and number of participants. Each specific aim must be supported by the proposed methodology presented in this section. Provide a paragraph detailing your data and statistical analysis plans.

What is your sample size?	
Total # of Cases:	
Total # of Controls:	
What is your definition of a Case?	
What is your definition of a Control?	
What are your matching criteria?	

A.6.3 ANALYSIS PLAN INCLUDING: STATISTICAL DESIGN, SAMPLE SIZE AND POWER CALCULATION

A.6.4 OTHER PROCEDURES (i.e. questionnaires, laboratory assay including CVs and inter - and intra-individual variability)

A.7 JUSTIFICATION/SUITABILITY TO CLUE COHORT:

Provide the advantage both to Clue and yourself of conducting the study within the Clue Cohort versus another population.

A.8 REFERENCES:

Provide a list of publications supporting the scientific basis of this study.

A.9 HOW WILL CONFIDENTIALITY OF CLUE PARTICIPANTS BE MAINTAINED?

Describe the methods for safeguarding the confidentiality of the study data and/or the measures for protecting anonymity of the subjects. Include a description of the plans for record keeping and data security, who will have access to identifying information, and plans for disposal at the completion of the study.

SAMPLE REQUEST:

- Type
- Serum Volume requested _____
 - Plasma Volume requested _____
 - DNA Volume requested _____

DATA REQUEST:

DATA CATEGORY : [MARK ALL THAT APPLY]

- Prostate
- Lung
- Colon
- Ovary
- Other Cancer (specify) _____
- Baseline Questionnaire – *CLUE I 1974*
- Baseline Questionnaire – *CLUE II 1989*
- Dietary Questionnaire
- Follow-up Questionnaire(s) - Year _____
- Cardiovascular Disease
- Screening Information
- Cancer Diagnosis
- Tumor Characteristics (*stage, grade, etc.*)
- Diagnostic Evaluation (*follow-up procedures, biopsies, surgeries, etc.*)*
- Laboratory Analysis Results
- Previous Study Analysis
- Other (specify) _____

** For Prostate, Lung, Colon, and Ovary Cancers Only*

FUNDING:

HAVE FUNDS BEEN RECEIVED FOR THIS PROJECT?

- Yes – Source _____
- No
- Not Needed

IF NOT FUNDED: WHAT IS THE EXPECTED SOURCE OF FUNDING FOR THIS PROJECT?

- NIH - Institute
- Foundation
- Private Corporation
- Existing Funds
- Other: _____

IF NOT YET FUNDED: PLANNED SUBMISSION DATE TO FUNDING AGENCY:

___ / ___ / 20___
Month Day Year

Project Approval Date: ___ / ___ / 20___
Month Day Year

For Administration Use

Reviewer's Comments
