

## PLCO EEMS Application Research Plan

### **1 Introduction to Resubmission (Resubmission Applications only)**

An Introduction must be included that addresses point-by-point each comment of the previous review highlighted in the decision letter. The substantial scientific changes to the application must be marked in the text of the application by bracketing, indenting, or changing typography. Deleted sections should be described here but not included in the application. If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction.

### **2 Specific Aims**

State concisely the goals of the proposed research and summarize expected outcome(s), including how the results of the proposed research will advance relevant research field(s).

List succinctly the specific objectives of the research proposed.

Specific Aims are limited to one page.

### **3 Research Strategy**

Organize the Research Strategy section using the specified order and instructions below. Start each section with the appropriate sub-section heading—Significance, Available Preliminary Data, etc. Provide relevant references, published or unpublished, to justify for the hypotheses, methods, and analytical assays proposed.

The Research Strategy section should not exceed 12 pages.

#### ***3.1 Significance***

Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. Describe the significance and benefits this proposed research will have to the scientific understanding of cancer disease processes, genetic predictions, or general health of the public.

#### ***3.2 Available Preliminary Data***

Describe the current scientific understanding and available data to support the study aims and hypotheses. It is highly recommended to include any pilot and reliability data that support the proposed assays to establish feasibility and credibility of the assays proposed.

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### ***3.3 Study Design, Methodology, Statistical Approach, Sample Size and Power Calculation***

Describe in sufficient detail the study design and methodology proposed, including desired population, demographics, numbers of participants, proposed assays, laboratory data, anticipated specimen type and quantity, statistical analytic plans and power calculations to justify the numbers of participants. Laboratory data and statistical analytic plans should be provided for each proposed aim.

### **4 Justification for Use of PLCO Samples**

Provide specific and detailed justification for why the PLCO samples are suitable to address the specific aims of the study. For example, explain why pre-diagnostic samples are needed.

### **5 Justification for Sample Quantity**

Provide detailed explanation for the amount of the sample requested. List all assays, including the manufacturer, to be conducted and the minimum amount of sample required (by the manufacturer, if applicable) for each assay. Do not add “dead volume” to the minimum required amount. The standard allowable dead volume is 10%. However, up to 10% additional volume can be separately listed, if needed for sample handling.

### **6 QC plan**

Provide a detailed QC plan that includes the following information: the proportion of quality control (QC) samples, estimated batch size, use of a pooled sample or individual replicates, plan for evaluating assay performance (inter-batch, intra-batch CV, ICC, kappa, etc.), and source of QC samples. Examples of source QC samples include non-PLCO samples, samples from PLCO Brooklyn participants who were later removed from the trial, and PLCO control samples.

### **7 References**

Provide a complete list of publications pertinent to the proposed research and cited in the Research Plan.