1. **Project Title:**
2. **Date:** Click here to enter a date.
3. **Principal Investigator:**

Current Position:

Academic Department:

Telephone:       Fax:

Street Address:

City, State, Zip:

E-mail Address:

1. **Other Involved Investigators and Contact Information:**

1. **Funding plan/source(s):**

1. **Project Description:**Attach a brief description (7 page maximum, 11 font; not including budget and cited literature) that addresses specific aims, background and significance, preliminary results (if available), and experimental methods and design. The design and methods section should describe the study population (e.g., inclusion/exclusion criteria, case-control matching criteria), data and specimens being requested, laboratory methods, and statistical analyses and power calculations, as appropriate. When requesting specimens please specify the types of sample needed for analyses (serum, plasma, whole blood, processed dna); volume of specimen needed for proposed assays; the maximum allowable number of freeze-thaw cycles undergone by the sample; and timing of the blood draw with respect to CARET intervention (baseline/pre-intervention vs post-baseline) and diagnosis of cancer (specify years prior to diagnosis, etc.).
2. **Type of project proposed (check all that apply):**

[ ]  Mechanism of CARET’s Intervention Effect

[ ]  Early Detection of Disease

[ ]  Risk Factors for Disease

[ ]  Prognostic Factors

[ ]  Pooled-data Analysis

[ ]  Other (specify):

1. **If access to CARET data will be requested from an existing data repository, please specify the repository/gatekeeper:**

[ ]  Harvard Pooling Project (S. Smith-Warner)

[ ]  IARC (P. Brennan)

[ ]  ILCCO (R. Hung)

[ ]  TRICL (C. Amos)

[ ]  dbGaP

[ ]  Other (specify):

[ ]  N/A (data are requested directly from CARET data repository only)

1. **Estimated study sample size required:** Cases       / Controls

9a. Case Type:

9b. Brief description of study inclusion/exclusion criteria:

Cases:

Controls:

1. **Required data (attach list separately if preferred)**

10a. Outcome data:

10b. Covariates:

1. **Intervention arm / population to be studied (check all that apply):**

[ ]  Placebo participants

[ ]  Active intervention participants

[ ]  Current smokers

[ ]  Ex-smokers

[ ]  Asbestos workers

[ ]  Other (specify):

**If CARET specimens are to be requested for this project please complete items 12-16 on the next page.
 If only data are requested, skip to item 17.**

**Sample Blinding Policy:**All laboratory analyses will be conducted in blinded fashion with respect to case-control status. CARET will maintain the blind until all laboratory assay data have been delivered to CARET and all samples exhausted or returned. Any exception to the blinding policy will require approval of the CARET Scientific Committee.

1. **Analytes:**
2. **Sample type requested (check all that apply), and amount of specimen requested for proposed assay(s):**

|  |  |  |
| --- | --- | --- |
|  | **Amount** | **Can samples be previously thawed\*?** |
|  |  | No | Yes | If “yes,” maximum # of thaws\* |
| Serum |       µL | [ ]  | [ ]  |       |
| Plasma |       µL | [ ]  | [ ]  |       |
| DNA (from peripheral blood) |       µg | [ ]  | [ ]  |       |
| Tissue |       | N/A (FFPE blocks and slides) |

\*Blood samples aliquots for approved studies are created at a FHCRC laboratory, undergoing a single freeze-thaw cycle. Samples that have been accessed for previous studies will have undergone one or more prior freeze-thaws. Please specify the total number of freeze-thaw cycles that are acceptable.

1. **Timing of blood draw (CARET samples are all pre-diagnosis; no post-diagnosis samples available)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Check all that apply:** | baseline / pre-intervention | post-baseline | prior to, but close to time of diagnosis | serial samples |
| Serum | [ ]  | [ ]  | [ ]  | [ ]  |
| Plasma | [ ]  | [ ]  | [ ]  | [ ]  |
| DNA (from peripheral blood) | [ ]  | [ ]  | [ ]  | [ ]  |

1. Comments:
2. **Laboratory name and location:**
3. **Budget for costs incurred by CARET:**There are CARET costs associated with sample selection, pulling of samples, data analyses, IRB approval, downsizing of samples, restocking of samples, etc. that will need to be incurred by the applicant. These costs will need to be negotiated with the CARET Project Manager. If submitting a grant proposal, please discuss costs with the CARET Project Manager to include in your grant.
4. **Publication Policy:**All presentations and manuscripts utilizing CARET data will include at least two (2) authors from CARET. Conduct with respect to research publications and co-authorship will be agreed to and circulated to CARET investigators for review two (2) weeks prior to submission of abstracts or manuscripts. All publications will acknowledge the author’s academic affiliation and the support of the CARET grant awards, U01-CA36373, UM1-CA167462 and U01-CA167462.
5. **Use of human subjects requires approval of the appropriate Institutional Review Board (IRB). Has an application for IRB approval been submitted for review?**

**[ ]  Yes [ ]  No [ ]  Pending**

**IRB approval date:** Click here to enter a date.

**IRB File#**

      Click here to enter a date.
Applicant Signature Date

**Please submit applications to:
e-mail:** **CARET@fredhutch.org** **or fax: 206-667-5964**

**Questions about the application process may be sent to** **CARET@fredhutch.org****, or to the CARET Project Coordinator at 206-667-6113**