REQUEST FORM FOR SPECIMEN VERIFICATION FOR

PAR-25-248: UTILIZING THE PLCO BIOSPECIMENS RESOURCE TO BRIDGE GAPS IN CANCER ETIOLOGY AND EARLY DETECTION RESEARCH (U01)

The National Cancer Institute has issued a Funding Opportunity Announcement (FOA), Utilizing the PLCO Biospecimens Resource to Bridge Gaps in Cancer Etiology and Early Detection Research (PAR-18-913), for soliciting grant applications to utilize the PLCO Biorepository. This FOA supports a wide range of cancer research including, but not limited to, biochemical and genetic analyses of cancer risk, as well as discovery and validation of early detection biomarkers. The proposed research project must involve use of PLCO biospecimens; additionally, it should also take advantage of the unique characteristics of the PLCO biospecimens. Research projects that do not involve the use of PLCO biospecimens will not be supported under this FOA. For more information about this funding opportunity and for how to submit a grant application, please refer to the NIH Guide (https://grants.nih.gov/grants/guide/pa-files/PAR-25-248.html).

Prior to submitting a grant application, applicants must first submit a Request Form for Specimen Verification through the CDAS. The Request Form for Specimen Verification will be reviewed to ensure that the required PLCO biospecimens, and data, are available for the proposed research. Once the Request Form for Specimen Verification is approved by the NCI, the applicant will receive a Confirmatory Letter. This letter must be included in the grant application.

To submit a Request Form for Specimen Verification, follow the instructions below.

1. REGISTRATION

In order to submit a Request Form for Specimen Verification, you must first <u>register</u> with the <u>Cancer</u> <u>Data Access System</u> (CDAS). You may establish your username/password at one of the following login services:

- ID.me
- Login.gov
- The NIH Login Service

Unless you have previously established credentials at NIH, it is suggested that you use either ID.me or Login.gov

CHECK FOR DUPLICATIVE RESEARCH

Before submitting a Request Form for Specimen Verification, you should first check the <u>approved PLCO Projects</u> or Funded grants to be sure that you are not proposing a project similar to one that has already been approved.

3. Prepare and Submit a Request Form for Specimen Verification

Once you are logged in to CDAS, you can prepare and submit a Request Form for Specimen Verification (NOTE: Make sure your web browser has JavaScript enabled or you will not be able to complete certain sections of the form). Completing the request form involves the following steps:

- Agree to the Usage Policies. In particular, you must agree not to identify or contact any
 patients or physicians whose information is contained in the data. You must also agree to
 publicly display the abstract of your research proposal and your contact information
 (provided in your application) on this website.
- Complete your Project and PI information. You must provide contact information for your Principal Investigator, as well as project information such as a title, brief description, and aims.
- **Complete your Case Definitions.** You must select all case definitions that apply, and fill in any information that applies to each one, such as your requirements and distributions.
- **Define your Controls and Matchings.** You must state how many controls you need, specific requirements, and variables you plan to match on.
- Indicate your Specimen Requirements. You must select all types of specimens you would like. Each specimen type has other information you must provide, such as amount.

The Request Form for Specimen Verification is designed to collect all relevant information that will determine which participants have adequate materials for your study. If you find there are questions that you do not understand or do not know immediately, submit the Request Form for Specimen Verification completed to the best of your ability and we will work with you to better define the details.

4. Await review of Request Form for Specimen Verification

Once your Request Form for Specimen Verification is submitted, it will be reviewed based on the following criteria:

- **Feasibility**. A determination will be made regarding the project feasibility and whether specimens and data that meet your requirements are available.
- **Duplication**. It will be determined if your proposed project duplicates effort that has been previously approved.

If your Request Form for Specimen Verification is approved, you will receive a **Confirmatory Letter** no later than 3 weeks after it is submitted. If PLCO cannot provide the specimens and/or data that meet your needs, you will receive an email to inform you so. This Confirmatory Letter must be included in the grant application. **The Request Form for Specimen Verification must be submitted within 3 months of, but no later than 30 days before, the grant due date, and is only valid for that grant cycle.**

Your grant application in response to this FOA is handled outside of CDAS. Please refer to the program announcement <u>PAR-25-248</u> for more information about how to submit an application. After receiving the Confirmatory Letter, no further steps are required in CDAS until your grant has been funded.

Note that investigators who have already obtained funding from the NIH or other sources can apply for specimens during the PLCO EEMS open review cycles. Information about the review cycle can be found on the homepage of this website.

Investigators are prohibited from submitting an application to both <u>PAR-25-248</u> and PLCO EEMS at the same time. The NOFO PAR-25-248 is designed for applicants to apply for funding and for access to the PLCO specimens at the same time. Applications that are funded will automatically gain access to the requested PLCO specimens. Applications that do not receive funding may be revised and submitted either for a future PAR round or a subsequent PLCO EEMS review cycle (a request for access to specimens without funding).