

To: Potential investigators interested in using PLCO samples
From: PLCO EEMS Coordinating Center
Subject: The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial Etiologic and Early Marker Studies (EEMS), 2016 Winter Review Cycle (Round 21)

Date: November 2, 2015

Please distribute this notice to those individuals with whom you work that may be interested in submitting an EEMS application.

The PLCO EEMS Steering Committee is pleased to announce this request for applications. The application process has changed. Please see detail below.

If you are planning to submit a grant application in response to the Funding Opportunity Announcement PAR-15-297, please see below for more information.

What's new? PLCO EEMS has a new website! The previous website (<https://www.plcostars.com/>) will be migrated to a new website called CDAS (<https://biometry.nci.nih.gov/cdas/studies/plco/>) by the end of November, 2015. Applications for the upcoming review cycle need to be submitted on the new website; the previous website will not be able to accept new applications.

Additionally, the EEMS application process has changed. A **preliminary application** is now required before a full application can be submitted. The online application module on the new CDAS EEMS website will guide you through the application process. Once your preliminary application has been approved, you will be able to continue and submit a full application. Preliminary applications must be submitted by January 3, 2016.

What is the timeline for the upcoming EEMS review cycle? Due to administrative factors and uncertainty in website development, the timeline for the upcoming review cycle will be subject to changes. Please check the CDAS website (<https://biometry.nci.nih.gov/cdas/studies/plco/>) frequently for the updated timeline. The estimated timeline is below:

12/1/2015 – 1/3/2016	CDAS open for EEMS preliminary application
12/1/2015 – 1/18/2016	CDAS open for FOA PAR-15-297 preliminary application
1/3/2016 – 3/1/2016	CDAS open for EEMS full application

What is PLCO? The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial is a large randomized controlled trial evaluating screening programs for these cancers. The PLCO Biorepository contains approximately 2.7 million biologic specimens, including blood specimens collected from intervention arm participants during their six trial screening years and buccal cell specimens collected from control arm participants.

How can I access PLCO biospecimens and what is 'EEMS'? PLCO biospecimens are available to the entire scientific community. Access to the biospecimens is administered through The Etiologic and Early Marker Studies (EEMS) Program, a component of the PLCO Trial established to facilitate etiologic and early marker research using PLCO biospecimens. EEMS accepts proposal applications twice a year in the summer and in the winter. More details about PLCO EEMS are available on the PLCO website at <https://biometry.nci.nih.gov/cdas/studies/plco/>.

Does PLCO EEMS have tissue samples in addition to blood and buccal cell specimens? Recent additions to the PLCO Biorepository include tissue microarrays (TMAs) and free-standing tissue cores created from formalin-fixed paraffin-embedded pathology tissues. Tissue specimens are currently available for colorectal cancer, colorectal adenoma, ovarian cancer, prostate cancer, breast cancer (female and male), lung cancer and bladder cancer.

Is funding provided? PLCO biospecimens and associated data are provided upon approval of the EEMS application. However, funding is not provided via the PLCO EEMS review process. A separate Funding Opportunity Announcement (PAR-15-297) allows investigators to apply for funding and for the PLCO specimens at the same time by submitting a grant application in response to PAR-15-297. Detailed instructions on how to submit an application are included in the FOA (<http://grants.nih.gov/grants/guide/pa-files/PAR-15-297.html>). All grant applications must have a corresponding confirmatory letter which can be obtained by submitting a preliminary grant application through CDAS (<https://biometry.nci.nih.gov/cdas/studies/plco/>) no later than January 18, 2016.

What is the PLCO EEMS application process? Applications must be submitted online during the EEMS open review cycles. A preliminary application is required before a full application can be completed and submitted. The purpose of the preliminary application is to make sure that the requested biospecimens and data are available. Once your preliminary application is approved, you will be notified and you will be able to continue and submit a full application. You will be notified of the outcome of the preliminary application review within 3 weeks of the submission.

Once your full application is submitted, the EEMS Coordinating Center (IMS) will verify that all components are completed and forward the complete application packet to the EEMS Steering Committee for an initial suitability review. This initial review will be completed by mid-March 2016; applicants will then be notified of the results of the suitability review. The EEMS Review Panel will then review and provide comments on all suitable applications based on the study's significance, approach, innovation, compliance to PLCO priorities and policies, proposed statistical approach, proposed laboratory assays and the qualifications of the investigator team. It is anticipated that this review will be completed by April 2016, contingent upon the quantity of applications received. The EEMS Steering Committee will then make the final decision based on the review outcome of the EEMS Review Panel.

What happens after my application is approved? If your application is approved, you will have up to three years from the date of approval to request the shipment of samples and commence activities on your study; please note that an IRB approval letter, as well as an executed PLCO EEMS Material Transfer Agreement (MTA) will be required in most cases prior to the release of samples. If you are unable to request shipment of samples within this time frame due to lack of funding or other issues, please inform us. Otherwise, your application will be considered withdrawn and these samples will be released, allowing for other investigators to submit an application to use them. Similarly, you will be required to re-apply should you still wish to use these samples. Additionally, once you receive samples, you have two years to submit laboratory analysis results. Small changes to an approved EEMS study may be accepted by submitting an addendum. This process will be built into CDAS, however until such time, direct all addendum inquiries to us.

If you have any questions please do not hesitate to contact us (cdas-eems@imsweb.com). Thank you for your time and we wish you success in your PLCO related studies.