American Cancer Society’s (ACS) Epidemiology Research Program investigators recognize the value of and welcome externally proposed studies judged to be of general interest and high scientific merit. Therefore, investigators who are not employed in ACS’s Epidemiology Research Program may request access to CPS data and/or biospecimens to conduct a study. Steps 1, 2 and 3 below can happen anytime throughout the year. However, the initial evaluation of full proposals (step 4) occurs only on the first Monday of each month.

1. **Prior to Contacting ACS Epidemiology Research Program Investigators:** Applicants should first review the Cancer Prevention Studies website and questionnaires (http://www.cancer.org/research/researchtopreventcancer/index) to be sure we have information appropriate for answering the research question.

2. **Initial Contact with ACS Epidemiology Research Program Investigators:** Applicant should contact the Vice President of Epidemiology Research (Susan Gapstur at susan.gapstur@cancer.org) or another Epidemiology Research Program investigator (see link above) who will provide an initial evaluation of your research idea. This is best accomplished through email by sending a short bio of your training and experience, as well as a single paragraph description of your idea (no more than 300 words) to Dr. Gapstur or another ACS Epidemiology Research Program Investigator. A decision on whether or not a full proposal should be submitted can often be made within a week by quickly evaluating your research idea for:
   a. Overlap with existing research using CPS resources
   b. Feasibility to address the research question using the CPS resources
   c. Appropriateness of ACS prospective data to answer the research question
   d. Consistency with ACS mission and goals
   e. Burden to participants and/or staff
   f. Potential costs to ACS
   g. Potential conflict of interest

3. **Submission of Full Proposal:** If a full proposal is requested, then one of the PhD or MD level ACS Epidemiology Research Program investigators will assume the role of collaborator with the applicant on the project and will guide the applicant through the proposal submission. The collaborating ACS investigator may provide simple frequencies and cross tabs for proposal development, and evaluation of statistical power. However, during development of the proposal, no data will be released. The proposal must include:
   a. External Investigators Name, Institutional Affiliation
   b. ACS Epidemiology Research Program collaborator
   c. Title of Project
   d. Timeline/Funding Source; Include grant application deadlines (if appropriate) and projected start/end dates of the project.
   e. Description of the study (4 pages maximum), including
      i. Background and Significance (including a statement on impact)
      ii. Specific aims
      iii. Design/Methods (including statistical power, analyses and quality control plans.)
iv. Data and/or biologic materials requested
   f. NIH Biosketch of key investigators involved in proposal.

4. **Review of Full Proposal:** The completed application should be submitted to the collaborating ACS investigator who will present to the full committee of CPS Epidemiology Research Program investigators. To allow for adequate time to review the full proposal, it should be submitted at least one-week before the first Monday of the month. The proposal will be reviewed according to the criteria described below. If the program investigators feel they do not have the appropriate expertise, then we might seek input from a) ACS staff in other Programs (e.g., Behavioral Research Center, Statistics and Evaluation) in the Intramural Research Department or in the Extramural Research Department. On occasion, we might also seek input from one to two members of our CPS Biospecimen Repository Advisory Group.

5. **Approved Studies:** If a proposal is approved by the Epidemiology Research Program and either subgrant information or a letter of support is needed, then additional internal ACS approvals and documentation will be needed. This can take several weeks to obtain so be sure to allow adequate time. **We will not consider proposal that require less then six weeks from the date of the first full proposal submission to the date a letter of support or subgrant is needed.**

6. **Additional Documents Required after Study Approval:**
   a. ACS Collaboration Agreement (see review criteria below for details)
   b. Proof of external investigators completion of IRB Human Subjects training
   c. Study IRB approval or letter from an IRB indicating project is exempt.

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### Cancer Prevention Study Research Proposals

**Review Criteria**

1. The proposed research question should be reasonably focused, and of considerable public health, clinical and/or scientific interest. The proposal should demonstrate the current state-of-knowledge via an up-to-date, relevant literature review.

2. The proposed research question cannot be undertaken without prospectively collected data/samples or is best addressed using prospectively collected data/samples, and/or enhances the value of the ACS database and/or sample repository.

3. Given the finite biospecimen resource, the amount of material requested for a biospecimen-based research proposal is appropriate, and not excessive. **Please note,** we will not exhaust any individual participant’s specimens without a compelling reason.

4. The study design is appropriate to address the question.

   a. The study sample (i.e., inclusion/exclusion criteria, subgroups) is well described and appropriate.
b. The researchers can demonstrate acceptable laboratory standards and quality control procedures (if appropriate).

c. The sample size will provide adequate power for answering the question, or the number of available ACS samples will make a sufficient impact on the proposed analysis (i.e., in a consortium analysis) to justify our sample handling and collaboration efforts.

d. The statistical analytic approach is appropriate.

5. The collective research team has appropriate knowledge, qualifications and experience to conduct the study.

6. All studies proposed by external investigators, if approved, will be conducted collaboratively with ACS investigators and all publications will be co-authored by the ACS collaborator. The researchers understand that they and their institution will be asked to sign our organization’s “Collaboration Agreement”. This agreement includes, but is not limited to, the following:

   a. Role of ACS collaborator(s) on project, and authorship for specific publications arising from the work using the ACS data/biospecimens.

   b. Prohibited use of the material for any purpose other than that explicitly stated in their proposal. Modifications to the original proposal may be made only with the agreement of all investigators, including both ACS and external investigators.

   c. Release of biospecimen material to the researcher (not approval of concept) is conditional on the researchers obtaining sufficient funds and resources to cover all aspects of the proposed study including sample preparation (e.g., sample retrieval and restocking from repository, extracting, quantifying, and subaliquoting DNA) unless there is agreement with ACS staff that ACS will cover a portion of these expenses.

   d. Ethics approval for researcher and the ACS (if different) has been given by, or is being sought from, the appropriate IRBs.

   e. The researchers can guarantee the confidentiality of any data arising from the study, and will not release them to any other person or group for any purpose, except with the explicit permission of ACS investigators.