

## Behavioral & Epidemiology Research Group (BERG) Data Access Policies and Procedures

American Cancer Society's (ACS) BERG investigators recognize the value of and welcome externally proposed studies that utilize the Cancer Prevention Studies or other BERG research resources (e.g., Studies of Cancer Survivors) that are judged to be of high interest and scientific merit. Therefore, investigators outside of the BERG may request access to our 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 during the first week of each month.

1. **Prior to Contacting BERG Investigators, we encourage potential collaborators to** be sure we have information appropriate for answering your research question. For those interested in the Cancer Prevention Studies, study descriptions and questionnaires are available at <https://www.cancer.org/research/we-conduct-cancer-research/epidemiology.html>
  
2. **Initial Contact with a BERG Investigator:** The applicant should contact the Senior Vice President of Behavioral and Epidemiology Research (Susan Gapstur at [susan.gapstur@cancer.org](mailto:susan.gapstur@cancer.org)) or another BERG investigator 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). 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
  - b. Feasibility to address the research question using BERG research resources
  - c. Appropriateness of our data to answer the research question
  - d. Consistency with the ACS priorities
  - 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 BERG investigators will assume the role of collaborator with the applicant on the project and will guide the applicant through the proposal submission. The collaborating BERG 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 Investigator's Name(s), Institutional Affiliation
  - b. ACS BERG 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 (10 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 BERG investigator who will present to the full committee of BERG investigators. To allow for adequate time to review the full proposal, it must be submitted at least one-week before the first week of the month. The proposal will be reviewed according to the criteria described below. On occasion, we might also seek input from one or more external advisors.
5. **Approved Studies:** If a proposal is approved by the BERG 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 proposals that require less than four 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. An IRB approval letter or appropriate documentation indicating the project is non-human subjects research.

## **Research Proposal Review Criteria for BERG External Collaborations**

1. The proposed research question should be reasonably focused, and of high public health, clinical and/or scientific significance. The proposal should demonstrate the current state-of-knowledge via an up-to-date, relevant literature review.
2. For proposals involving the Cancer Prevention Studies, 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.
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. Return of any remaining biological samples after completion of the project and laboratory measures resulting from the ACS biologic samples.
  - e. If appropriate, ethics approval for researcher and the ACS (if different) has been given by, or is being sought from, the appropriate IRBs.
  - f. 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.