Feasibility Query:
Access to Biospecimens of the Cooperative Group Banks

I. Date submitted:

II. Title of proposed correlative study:

III. Principal Investigator

Name: _____ Suffix (e.g., M.D., Ph.D.): _____

Institution: _____

Mailing address: _____

Email: _____

Phone: _____ Fax: _____

IV. Biospecimens being requested (*Description of samples requested)*

A. Disease entity:

☐ Breast ☐ Lung ☐ Melanoma

☐ GI, specify: _____

☐ GU, specify: _____

☐ GYN, specify: _____

☐ Neuro-oncology, specify: _____

☐ Peds, specify: _____

☐ Hematological, specify: _____

☐ Other, specify: _____

B. Type of specimen

Tissue:

☐ Normal tissue ☐ Primary tumor ☐ Metastatic tumor

☐ Paraffin Block ☐ Unstained Slides ☐ TMA ☐ Frozen

☐ Stained slides, specify stain: _____

☐ Other Tissue Biospecimen (not listed above): Specify: _____

Body fluids:

☐ Whole blood ☐ Plasma ☐ Serum ☐ Lymphocytes

☐ Cultured cells ☐ Saliva ☐ Urine

☐ Other Body Fluid Biospecimen (not listed above): Specify: _____

Derivatives:

☐ DNA (tumor) ☐ DNA (genomic) ☐ RNA (tumor) ☐ RNA (genomic)

C. If applicable, specific specimen attributes *(e.g., stage I only, high grade, recurrent, tissues from patients treated with paclitaxel, etc.)*

D. Number of specimens *[e.g. less than 100 samples, more than 100 samples):*

E. Amount/volume of material requested *(e.g., for number of TMA sections, whole slides, cores, amount of blood products, RNA, DNA, etc):*

F. From which cooperative group biorepository (check all that apply)

☐ ACOSOG	☐ GOG	☐ RTOG
☐ CALGB	☐ NCCTG	☐ SWOG
☐ COG	☐ NCIC-CTG	
☐ ECOG	☐ NSABP	

G. From which clinical trial(s), if known *(examples of websites that contain a listing of trials with specimens available include: clinicaltrials.gov; http://ctep.cancer.gov/resources/tbci/correlative_studies.html)*

a) Protocol number of clinical trial(s) from which specimens are requested:

b) Protocol title of clinical trial:

V. Brief Project Summary

A. Title of Project:

B. Hypothesis: *(approx 90 words)*

C. Background and Preliminary Data: *(500 words or less)*

D. Specific Aims: *(list no more than 3, total of 120 words or less)*

E. Methods: *(provide a general description of assay methods, validation of assay, and feasibility for using the requested biospecimen)*

VI. Statistical Power statement *(provide a brief rationale for your sample size estimate. Typically, this will require assumptions about the following: anticipated distribution of marker values (e.g., marker positivity rate if the marker is dichotomous); assay success rates (based on anticipated rates of technical failures, degraded or insufficient specimens, etc.); event rates or number of events anticipated for the cases included in the primary analysis; expected differences in outcomes (e.g., hazard ratio or other "effect" size). These assumptions and estimates will need to be obtained from preliminary data or previous studies that are expected to be cited in the statistical plan in the CGB Biospecimen Access Application (Template hyperlink).*

VII. Significance *(250 words or less)*

OTHER INSTRUCTIONS:

1. Attach a CV or NIH-related Biosketch for the project's lead investigator.
2. Send LOI to the designated contact representative at the respective cooperative group biorepository from which the specimens are being requested *(contact information can be found at individual websites of each cooperative group).* Note: The LOI will be forwarded to the appropriate Statistical center at the respective cooperative group.
3. Listing or other requirements as a reminder to the Investigator, such as: local IRB review, agreement including materials transfer provisions, independent funding committed and available.