

GBC A&M Subcommittee Approval: 10-09-08

GBC Steering Committee Approval: 12-05-08

Group Chairs' Approval: 6-30-09 (active approval: ACOSOG, CALGB, COG, GOG, NCCTG, NCI-CTG, NSABP, SWOG; passive approval: ECOG, RTOG)

Cooperative Group Banking (CGB) Biospecimen Access Application Template

As Principal Investigator for this study, my submission of this proposal indicates my willingness to discuss with and enter into a research agreement with the [Cooperative Group], according to standard procedures for data analysis, data confidentiality, authorship, and intellectual property sharing.

I. Submission Type:

(Please mark appropriate box with an "X")

Original Submission

Revised Submission

II. Date Submitted:

III. Title of proposed correlative study:

IV. Principal Investigator:

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

Institution: _____

Mailing address: _____

Email: _____

Phone: _____ Fax: _____

V. Co-investigators

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

Institution: _____

Mailing address: _____ Email: _____

(please repeat for additional co- investigators if necessary)

VI. From which clinical trial(s) are you requesting specimens? *(including study arm, time point or other treatment requirement). Websites that contain a listing of trials with specimens available include: clinicaltrials.gov; http://ctep.cancer.gov/resources/tbci/correlative_studies.html. If you are requesting specimens from more than one trial, your proposal should provide a clear rationale for including samples from different trials.*

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

Protocol title of clinical trial:

VII. Hypotheses

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VIII. Study Objectives:

Primary Objectives:

Secondary Objectives:

IX. Brief justification:

A. Background and choice of trial:

B. Preliminary data (*include at least top 3-5 references*):

X. Methods

A. Experimental research techniques/tests employed

B. Expertise of PI:

XI. Biospecimens (*Description of samples requested*):

A. Disease entity: Breast Lung GI Specify: _____ Neuro-oncology Specify: _____
Hematological Specify: _____ Melanoma

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)

a. Required number and thickness of sections from each sample; slide specifications (*if solid tissue is requested*):

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

C. Number of specimens:

D. Other requirements for processing the requested samples prior to shipment to your facility:

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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)

- | | |
|---------------------------------|-----------------------------------|
| <input type="checkbox"/> ACOSOG | <input type="checkbox"/> NCCTG |
| <input type="checkbox"/> CALGB | <input type="checkbox"/> NCIC-CTG |
| <input type="checkbox"/> COG | <input type="checkbox"/> NSABP |
| <input type="checkbox"/> ECOG | <input type="checkbox"/> RTOG |
| <input type="checkbox"/> GOG | <input type="checkbox"/> SWOG |

XII. Statistical Design (*This is typically developed in collaboration between the Investigator and the Cooperative Group Biostatistical Center*)

- A. Clinical Endpoint(s) to be used in analyses (*please state what, if any, demographic or clinical data will be needed for analysis; this may require a separate review*):
- B. Primary Comparisons:
- C. Power Justification:
- a. Samples size estimate (*i.e., number of cases required to achieve the primary objectives of your study*):
 - b. Number of available specimens and source of this information:
- D. Data analysis performed by: MUA POLICY CONSIDERATION

XIII. Budget Considerations:

- A. Estimated expenses (*please account for the costs of the tissue bank, e.g., sectioning of tissue, nucleic acid extraction, shipping costs of materia., etc*)
- B. Funding source (*check all that apply*):
- Industry, []
 - Grant (specify program announcement), []
 - Institutional, []
 - Other (specify) []

XIV. Project Milestones (*expected timeline of project completion; must be within 2 years of receipt of specimens*):

XV. Disclosure of Conflict of Interest:

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XVI. Material Use Agreement (MUA) and other Contract Issues:

Before delivery of biospecimens, it is required that an appropriate Material Use Agreement (MUA) incorporating the guidelines included in the Group Banking Committee (GBC) MUA template, is signed by the requestor and signing official from the Cooperative Group that is providing the specimens.

- A. Name and contact information of the Contracts person at requesting institution:
- B. Name and contact information of the Contracts person at Cooperative Group:
- C. Have preliminary discussions taken place about the MUA **Yes** []; **No** [].

Are there any independent contractual issues associated with this proposal (e.g., third part involvement, someone else performing the actual assay (commercial entity, ref lab??) or data analyses)? **Yes** []; **No** []; If yes, please provide details:

XVII. Data Sharing Policy: The National Institutes of Health data sharing policy

(grants.nih.gov/grants/policy/data_sharing) will be enforced for all research activity associated with use of biospecimens from Cooperative Groups.