MATERIAL USE AGREEMENT

Term – "Cooperative Group" used throughout this document includes the following organizations; ACOSOG, CALGB, COG, ECOG, GOG, NCCTG, NSABP, RTOG, SWOG and NCIC CTG.

(Cooperative Group), henceforth known as "PROVIDER" is pleased to be able to provide samples or derivatives thereof, ("MATERIAL") specified in Exhibit A, a research project proposal reviewed and approved by PROVIDER (incorporated by reference and hereinafter referred to as "RESEARCH", to Investigator at _____ [Institution] (collectively "RECIPIENT"). PROVIDER is interested in supporting the research described in Exhibit A using the MATERIAL and will provide you with the MATERIAL subject to the following conditions on RECIPIENT's use of the MATERIAL. The conditions described below are necessary to insure that the MATERIAL is used solely for research and that PROVIDER's and RECIPIENT's interests in any possible commercialization of the product of research performed on the MATERIAL are protected.

Explanation of the agreement
This agreement outlines the responsibilities and expectations of the listed RECIPIENT and PROVIDER. By signing the document RECIPIENT agrees to all terms and conditions defined below and understands that PROVIDER will uphold and enforce all terms and conditions outlined in the agreement, in accordance with Cooperative Group policy, upon release of any MATERIALS to RECIPIENT.

1. **Scope of Work**
   MATERIAL is furnished to RECIPIENT for the purpose of the RESEARCH defined in Exhibit A and approved by appropriate scientific review committee defined by PROVIDER. Scope and nature of RESEARCH must be limited to that described in Exhibit A unless amended and approved by RECIPIENT and PROVIDER.

2. **Funding**
   All aspects of the RESEARCH must be financially supported.
   a. RECIPIENT agrees to arrange for payment of all additional charges associated with the processing and distribution of MATERIALS from the biorepository according to charge table provided to RECIPIENT (if applicable).
   b. Documentation that the project has financial support must be furnished, signed by RECIPIENT's financial office, [Institutional Official] and must be provided to PROVIDER prior to RESEARCH activation and MATERIAL distribution.

If financial support is discontinued during the course of the study and alternative funding is not secured all research specimens and derivative samples will be

returned to the respective biorepository, as specified herein under section entitled '*Termination of Agreement'.*

3. **Safety of personnel**

   RECIPIENT assumes all responsibility for informing and training personnel in the dangers and procedures for safe handling of human biospecimens and biohazards. All biorepository personnel must abide by OSHA regulations pertaining to the handling of human specimens. RECIPIENT acknowledges awareness of and required compliance with OSHA regulations and will instruct staff to abide by these rules.

4. **Stewardship of Material**

   All MATERIAL provided to RECIPIENT remains subject to PROVIDER'S stewardship and management. The Chairs of the Cooperative Groups agree that if samples are housed in more than one Cooperative Group, transfer of those samples to the PROVIDER or lead Cooperative Group repository will take place independently from this agreement.

5. **Transfer of Material**

   a. The MATERIAL may not be assigned or sold to any other parties.

   b. The MATERIAL may not be transferred by RECIPIENT to a third party/collaborator without first having obtained written approval of the transfer from PROVIDER. All such approved transfers must be accompanied by an agreement between RECIPIENT and the third party. The RECIPIENT is responsible for third party/collaborator to understand and abide by this agreement.

   c. If the MATERIAL was obtained in connection with a study using a proprietary agent (i.e., device or drug in additional to the human specimen) PROVIDER will refer to specific agreements or contingencies during review of RESEARCH proposal so that RECIPIENT may obtain a written agreement from the PROVIDER to perform the stated RESEARCH on the MATERIAL.

   d. Both parties shall comply with all applicable laws and regulations, as amended from time to time, with respect to the collection, use, storage and disclosure of the MATERIAL and any related data, including without limitation, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), its implementing regulations (45 C.F.R. et. seq.) and the Common Rule (45 C.F.R. 46)

   e. RECIPIENT acknowledges that the conditions for use of MATERIAL are governed by Institutional Review Board (IRB) in accordance with Department of Health and Human Services regulations at 45 CFR 46. RECIPIENT agrees to comply fully with all such conditions and to report

promptly to PROVIDER any proposed changes in RESEARCH and any unanticipated problems involving risks to subjects or others. RECIPIENT remains subject to applicable state or local laws or regulations and institution policies, which provide additional protections for human subjects. The MATERIAL may only be utilized in accordance with the conditions stipulated by IRB. Any additional use of MATERIAL beyond the RESEARCH requires prior review and approval by the PROVIDER, and, where appropriate, by an IRB at the RECIPIENT site, which must be convened under an applicable OHRP-approved Assurance.

f. RECIPIENT acknowledges that PROVIDER will not provide any information through which RECIPIENT may directly or indirectly identify the human subjects from whom the transferred Materials and/or data were obtained. RECIPIENT agrees not to seek such identifying information or attempt to identify subjects by any other means. If identifying information is received, RECIPIENT must notify PROVIDER immediately. RECIPIENT must promptly return the identifying information and/or MATERIAL as instructed by PROVIDER.

6. **Use of Material**

a. Use of the MATERIAL must be the RESEARCH and in compliance with any applicable laws and regulations governing the RECIPIENTS jurisdiction.

b. The MATERIAL must not be used in human subjects, in clinical trials, for diagnostic purposes involving human subjects, or to make any derivatives or progeny, as applicable, thereof without the written consent of PROVIDER.

c. With respect to any invention or discovery arising from the RESEARCH, the PROVIDER shall have an option to license to practice the invention or have it practiced for or on the PROVIDER's behalf with terms to be determined, as consistent with the NCI Cooperative Group agreement and Cooperative Group Guidelines.

7. Satellite Repository Responsibility of RECIPIENT

Any MATERIAL obtained as part of the RESEARCH are collected under the auspices and guidelines of PROVIDER whether or not the specimen is stored in the main repository or the RECIPIENT's laboratory. As such, all specimens and their derivatives are considered property of PROVIDER and remain under the stewardship of PROVIDER. RECIPIENT facility will serve as the interim repository for those specimens for the duration of the RESEARCH or until requested for return to PROVIDER's repository.

8. Data Submission and Analysis

a. Data analysis on data generated from RECIPIENT will be done by PROVIDER's statistical center or under their direction, according to design and analysis considerations agreed upon at the initiation of the project. All data must be submitted in the appropriate pre-approved format.

b. Availability of data generated in Cooperative Group studies will be in compliance with NIH and NCI data sharing policies and with Cooperative Group procedures.

9. Intellectual Property

The policy of the PROVIDER governing **intellectual property** rights continues through this agreement. This policy is based on PROVIDER's Cooperative agreement with the NCI and NCI Cooperative Group Guidelines and is available for review at http://ctep.cancer.gov/industry/ipo.html.

10. Publication

PROVIDER must be acknowledged in all abstracts and manuscripts, following guidelines agreed upon at the initiation of the specific project. All publications shall be submitted to PROVIDER for review and comment sixty (60) days prior to publication.

11. Confidentiality

a. In general, RECIPIENT will utilize only coded specimens and data and will not have access to the link to identify individuals who have contributed specimens. RECIPIENT agrees to maintain the confidentiality of all data and not to seek access to the link or seek any method to identify study subjects. Patient contact is forbidden for any reason, except in cases of specific IRB approval for specific protocol conditions and as approved by PROVIDER.

b. This agreement sets forth the terms and conditions pursuant to which PROVIDER may disclose certain Protected Health Information (PHI) to RECIPIENT. PHI may include associated demographic and clinical data that have been rendered a Limited Data set in compliance with 45 CFR 164.514(e)(1).

c. RECIPIENT ensures that any collaborator, as approved in writing by PROVIDER, working with RECIPIENT will agree to the same restrictions and conditions in writing that apply throughout this agreement.

12. Conflict of Interest

It is assumed that conflict of interest issues are dealt with internally by RECIPIENT, according to institutional policies. Investigator agrees by his/her signature and date on this agreement that such an institutional process has been followed and that no conflict of interest exists.

13. Termination of Agreement

a. Agreement will terminate upon conclusion of research to be performed using the Materials, or as a result of just cause upon request by PROVIDER. RECIPIENT agrees to discontinue use of the MATERIAL and will arrange for the return to PROVIDER, or its agent, or for the lawful disposal of all unused MATERIAL, as elected by PROVIDER.

b. This agreement may be terminated by PROVIDER upon five (5) days written notice to RECIPIENT if RECIPIENT breaches any provision contained in this agreement and such breach is not remedied within the five (5) day period. If such remedy is provided, proof of remedy will be required within the five (5) day period. Non-cause termination may be invoked by the PROVIDER, in certain cases.

14. **Damage Waiver**

a. MATERIAL is provided as a service to the research community without warranty, express or implied. PROVIDER assumes no responsibility for any injury (including death, damages, or loss) that may arise either directly or indirectly from their use. RECIPIENT agrees to assume all risks and responsibilities in connection with the receipt, handling, storage and use of MATERIAL.

b. Any material delivered pursuant to this agreement is understood to be experimental in nature and may have hazardous properties. Any material provided is provided as is and PROVIDER makes none and hereby disclaims all representations of warranties of any kind, either expressed or implied. There are no express or implied warranties of merchantability or fitness for a particular purpose, or that the use of the material will not infringe any patent, copyright, trademark or other proprietary rights.

c. **FOR STATE INSTITUTIONS:** RECIPIENT agrees to be responsible for any claims, costs, damages, or expenses resulting from any injury (including death), damage or loss that

may arise solely from the receipt, handling, storage and use of biospecimens received from PROVIDER to the extent permitted under the laws of this State.

d. **FOR U.S. GOVERNMENT AGENCIES**: On behalf of the United States Government, RECIPIENT assumes all risks and responsibilities in connection with the receipt, handling, storage and use of biospecimens received from PROVIDER. The United States assumes liability for any claims, damages, injury or expense arising from the use of the material or any derivative, but only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chap. 171).

e. **FOR ALL OTHER INSTITUTIONS:** RECIPIENT agrees to assume all risks and responsibility in connection with the receipt, handling, storage and use of biospecimens. RECIPIENT agrees to defend, indemnify and hold PROVIDER and its directors, trustees, employees, agents harmless from any claims, liabilities, damages and losses that might arise as a result of RECIPIENT'S use of the MATERIALS.

15. **Use of Name**

Neither party shall use the names or trademarks of the other party or of any of the other party's affiliated entities in any advertising, publicity, endorsement, or promotion unless the other party has provided prior written consent for the particular use contemplated. The terms of this section survive the termination, expiration, non-renewal, or rescission of this Agreement.

16. **Signatory Requirements**

a. The undersigned warrant that they have authority to execute this agreement on behalf of the recipient institution.

b. This agreement constitutes the final, complete and exclusive agreement between the parties with respect to its subject matter and supercedes all past and contemporaneous agreements, promises, and understandings, whether oral or written, between the parties. This agreement shall be binding upon and inure to the benefit of the parties, their heirs, legal representatives, successors and assigns. This agreement may not be amended or modified except by a writing signed by both parties and identified as an amendment to this agreement. Neither this agreement nor any of the rights or obligations under the agreement may be assigned by

RECIPIENT without the written consent of PROVIDER. The failure of PROVIDER to insist at any time upon the strict observance or performance of any of the provisions of this agreement, or to exercise any right or remedy as provided in this agreement, will not impair any such right or remedy and will not be construed to be a waiver or relinquishment of the right or remedy. Execution of this agreement can be effected by facsimile signatures.

c. If you agree to these conditions, please sign in the space provided below as RECIPIENT Investigator and have an authorized representative of your Institution sign it also. The authorized representative should have authority over all investigators who might need access to the MATERIAL according to the terms of the research defined in Exhibit A.

d. Return the original signed copy of the agreement to:

_____

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ACCEPTED AND AGREED

The undersigned expressly certify or affirm that the contents of any statements made or reflected in this document are truthful and accurate. The undersigned further agree to examine and consider the subject matter of the Confidential Information on the foregoing basis.

FOR PROVIDER
Administrative Executive, Authorized Signatory

_____
Printed Name

_____
Title of Signatory

_____
Signature

_____
Date

Address:

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FOR PROVIDER
Scientific/Medical oversight, Authorized Signatory

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Printed Name

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Title of Signatory

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Signature

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Date

Address:

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FOR RECIPIENT INSTITUTION, Authorized Signatory

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Printed Name

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Title of Signatory

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Signature

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RECIPIENT INVESTIGATOR, Authorized Signatory

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Printed Name

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Signature

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