

## LETTER OF INTENT

### **I. Agreement for use of biospecimens provided from the National Cancer Institute's AIDS and Cancer Specimen Resource (ACSR)**

The recipient/investigator hereby agrees that the biospecimens provided by the NCI sponsored AIDS and Cancer Specimen Resource will be used only for the purposes specified in this Letter of Intent (LOI). The recipient agrees not to attempt to obtain information identifying the individuals providing biospecimens to the ACSR, or products directly extracted from these biospecimens (e.g. TMAs, protein, mRNA or DNA).

The recipient agrees that he/she shall not transfer biospecimens (or a portion thereof) supplied by the ACSR to third parties, without the **prior** written permission of the ACSR. Biospecimens and their products shall NOT be sold or used for commercial purposes, nor will biospecimens be distributed further to third parties for purposes of sale or producing for sale, cells or cell products.

Biospecimens are provided as a service to the research community without warranty of merchantability or fitness for a particular purpose or any other warranty, expressed or implied. The investigator receiving these biospecimens understands that they are known to contain the infectious agent responsible for AIDS and or other infectious diseases, and assumes full responsibility for informing and training all personnel in the dangers and procedures for safe handling of these specimens. The ACSR accepts no responsibility for any injury (including death), damages or loss that may arise either directly or indirectly from their use.

**FOR STATE INSTITUTIONS:** The recipient institution 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 specimens received from the ACSR to the extent permitted under the laws of this State. The undersigned warrant that they have authority to execute this agreement on behalf of the recipient institution.

**FOR U.S. GOVERNMENT AGENCIES:** On behalf of the United States Government, the recipient assumes all risks and responsibilities in connection with the receipt, handling, storage and use of biospecimens received from the ACSR. 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. Chapter 171).

**FOR ALL OTHER INSTITUTIONS:** The recipient institution agrees to assume all risks and responsibility in connection with the receipt, handling, storage and use of biospecimens. It further agrees to indemnify and hold harmless the ACSR, NCI, and the United States Government from any claims, costs, damages or expenses resulting from the use of the biospecimens provided by the ACSR. The undersigned warrant that they have authority to execute this agreement on behalf of the recipient institution.

### **II. Acknowledgment Agreement**

The recipient agrees to make the study results available to the scientific/research community and to acknowledge the contributions of the AIDS and Cancer Specimen Resource in all abstracts, presentations, publications, grants, and patents resulting from the use of these biospecimens. Recommended wording to the methods or acknowledgment section: *"Biospecimens were provided by the AIDS and Cancer Specimen Resource which is a cooperative agreement funded by the National Cancer Institute through the following grants: U01CA066531, (Ayers, L), U01CA066529, (McGrath, M), U01CA066535 (Silver, S), and U01CA096230, (McGrath, M). Other investigators may have received specimens from the same subjects."*

### III. Data Use Agreement

This Data Use Agreement ("Agreement") is designed to permit the use of a Limited Data Set for research pursuant to the Standards for Privacy of Individually Identifiable Health Information, (Privacy Rule) 45 CFR Parts 160 and 164. All terms used in this agreement are as defined in the Privacy Rule.

The Data Use Agreement will permit the recipient to receive biospecimens and associated clinical information if such data is available. Investigators who require clinical information beyond that routinely provided must inform the ACSR at the time the biospecimens are requested. This is necessary because of ACSR operating procedures and local IRB requirements for protecting human subjects and patient privacy and confidentiality.

### IV. Investigator Data

A. Principal Investigator: \_\_\_\_\_

Title: \_\_\_\_\_

Institution: \_\_\_\_\_

Department: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

E-mail address: \_\_\_\_\_

How did you learn about the ACSR? \_\_\_\_\_

#### B. Shipping Address (If different from above)

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Name of Shipping Contact: \_\_\_\_\_

Phone\*: \_\_\_\_\_

**\*24 hour number required for Biological Hazardous Material**

### V. Study Design

A. Provide a brief description of the study, not to exceed 3 pages of text. Include the following sections:

1. Title of Project - Do not exceed 81 characters, including spaces and punctuation.
2. Hypothesis - Clearly state the question to be addressed.
3. Experimental Approach - Types of assays to be performed, markers to be measured, tissue requirements, data requirements (clinical, pathological, and outcome data) and a justification of the choice of markers, methods, and tissue needs.
4. Statistical Analysis - What analytical techniques will be applied, including power calculations to justify the numbers of specimens requested.
5. Significance - Why the study is important.
6. Resources (PHS 398 format).
7. Biographical Sketch - NIH format – limit 4 pages.

B. Biospecimen Criteria: In order for the ACSR to provide biospecimens of the highest quality, each investigator is required to complete the following detailed request. The investigator should indicate the type and amount of biospecimens needed, describe the storage and transfer conditions (e.g. media, snap freezing and sterility requirements) and specify limiting factors (e.g. age, sex, etc.).

Type of Biospecimen	Quantity and Volume	Additional Biospecimen Criteria

Biospecimens will be provided to investigators according to availability and priorities recommended by the Research Evaluation and Decision Panel (REDP) and the ACSR biostatistician. Investigators should be careful not to request samples that are in excess of that required to accomplish the study. This may lead to a denial of the request.

**VI. IRB Information**

The ACSR requires researchers to agree to follow the provisions of the ["Common Rule" \(45CFR46\) federal human subjects regulations](#) and obtain Institutional Review Board (IRB) approval before receiving biospecimens for their research. While these regulations currently do not apply to institutions that do not receive federal support, the ACSR policy requires all researchers using ACSR biospecimens to follow the Common Rule. The ACSR does not provide patient identity or other identifiers to investigators. All biospecimens are either anonymized, de-identified, or are part of a limited data set. This ensures complete confidentiality regarding medical information of patients.

All researchers should be aware of how the federal human subjects' regulations apply to the use of human biospecimens. For example, specifically, the OHRP has indicated that research using anonymized or de-identified specimens does not constitute human research and thus is not regulated by the Code of Federal Regulations (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>)

Attach copy of IRB approval letter to LOI

**VII. Funding Information:**

Biospecimens are provided to investigators with the following funding:

1. Peer reviewed funded investigators (including Federal and National laboratories)
2. New investigators and academic investigators developing new research projects.
3. Other investigators including private entities

Please include your major research grant. Institutional and other funding sources may be listed. If you are currently unfunded, please indicate below:

Funding Source: \_\_\_\_\_

Period of support: from \_\_\_\_\_ to \_\_\_\_\_

Active or Pending? Active Pending (submission date: \_\_\_\_\_ )

*In lieu of the above funding information, you may attach your "Other Support" pages from a PHS 398 application.*

BY MY SIGNATURE I AGREE TO THE TERMS SET FORTH IN THE ABOVE AGREEMENT:

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Typed Name of Recipient	Name of Institution	Typed Name of Official Authorized to Sign for the Institution
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Signature of Recipient	Date	Signature of Official Authorized to Sign for Institution	Date
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UPON RECEIPT OF THIS SIGNED AGREEMENT AND THE INFORMATION REQUESTED ABOVE, THE AIDS AND CANCER SPECIMEN RESOURCE WILL CONSIDER THIS REQUEST AND ANY FUTURE REQUESTS FOR BIOSPECIMENS.

For specific questions about your LOI please contact Ms Debra Garcia at 415-206-5268 or [dgarcia@acsr.ucsf.edu](mailto:dgarcia@acsr.ucsf.edu). Other questions may be directed to the NCI Program Director, Dr Rebecca Liddell-Huppi at 301-496-4995.

Send completed forms to:

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San Francisco, CA 94110

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Tel: (415) 206-5268  
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