NIA Aging Cell Repository
Assurance Form for Cell Lines and DNA Samples

January 17, 2011

This Assurance Form pertains to access to cell lines and DNA samples that are part of the NIA Aging Cell Repository ("NIA Repository"), and which are administered by the Coriell Institute for Medical Research, Camden, New Jersey ("Coriell").

The Institutional Official is the legal representative ("Institutional Official") of the Institution ("Institution") receiving sample(s) from the NIA Repository ("NIA Repository Sample(s)").

The Principal Investigator is the person receiving the NIA Repository Sample(s) and is responsible for the conduct of the Statement of Research Intent, defined below. The Principal Investigator's research team that is under the direct supervision of the Principal Investigator may have access to the NIA Repository Sample(s) only after they have been informed of and agreed to the provisions of this Assurance Form.

To ensure compliance with the office for Human Research Protections, Departments of Health and Human Services ("DHHS") regulations for the protection of human subjects (45 CFR Part 46), before NIA Repository Sample(s) can be shipped from the Repository by Coriell, the Principal Investigator must provide to Coriell a written description of the purpose of the research to be done using the NIA Repository Sample(s) ("Statement of Research Intent"). The Statement of Research Intent and the signed Assurance Form must be submitted to Coriell.

The Principal Investigator must acknowledge on the signature page of this Assurance Form that he/she has read and understands the terms and conditions of this Assurance Form. The Principal Investigator's Institutional Official must also sign this Assurance Form agreeing to adhere to the terms and conditions of this Assurance Form. The institution Official acknowledges that the conditions for use of the NIA Repository Sample(s) are governed by the Coriell Institutional Review Board ("Coriell IRB") in accordance with DHHS regulations (45 CFR Part 46). The Institution agrees to comply fully with all such conditions and to report promptly to the Coriell IRB any proposed changes in the Statement of Research Intent. The Institution remains subject to all applicable state and local laws or regulations and Institution policies that provide additional protections for human subjects.

Coriell will under no circumstances provide information that will allow investigators to identify human subjects. Furthermore, the Institution and the Principal Investigator agree not to try to identify or contact the submitter of the sample or the donor subject from whom the cell line or DNA sample was derived.

WARRANTY AND LIABILITY

Warranty: THE REPOSITORY AND CORIELL MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

Liability Statement for State Institutions: The Institution agrees to be responsible for any claims, costs, damages, or expenses resulting from any injury (including death), damage, or loss that may arise from the use of the NIA Repository Sample(s) to the extent permitted under the laws of the Institution's state. This provision shall also apply to any byproducts or derivatives of the NIA Repository Sample(s).

Liability Statement for U.S. Government Laboratories: The United States assumes the liability for any claims, damages, injuries, or expenses arising from the use of NIA Repository Sample(s) or any byproduct or derivatives, but only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171).

Liability Statement for All Other Institutions: The Institution agrees to indemnify and hold harmless the United States Government, Coriell, and the submitter of the sample from any claims, costs, damages, or expenses resulting from any injury (including death), death, or loss that may arise from the use of the NIA Repository Sample(s). This provision shall also apply to any byproducts or derivatives of the NIA Repository Sample(s).

HUMAN EXPERIMENTATION

Human experimentation utilizing the NIA Repository Sample(s) is strictly prohibited.

RESEARCH USE, COMMERCIAL USE, AND RESTRICTIONS ON REDISTRIBUTION AND PROHIBITIONS ON RESALE

The Repository provides biomaterials as a service to the research community. The purpose of the Repository is to stimulate and facilitate research in genetics and related fields, leading to a better understanding of normal genetic and cellular processes, to the identification and function of disease-related genes, and to the diagnosis and treatment of genetic disorders.

It is expressly understood that the NIA Repository Sample(s) delivered pursuant to this Assurance Form are experimental in nature and are for use in research, in teaching, and as reference materials in clinical genetics laboratories. Institutions using NIA Repository Sample(s) for use as reference materials or controls are responsible for complying with all laws and regulations applicable to the intended use of the NIA Repository Sample(s), including any requirements for FDA approval.

The Repository number(s) of the cell line(s) or the DNA sample(s) must be cited in publications or presentations that are based on the use of these materials.

There is no restriction on development of commercial products resulting from the knowledge gained form studies using the NIA Repository Sample(s). However, NIA Repository Sample(s), or material isolated from them such as RNA, DNA, or protein, may not themselves be used in the manufacture of commercial products.

SECONDARY DISTRIBUTION AND SHARED USE OF CELL CULTURES AND DNA SAMPLES FROM THE NIA REPOSITORY

Genetic research often involves collaborations among several investigators of several laboratories that share materials toward a common goal. Also, as a result of new genomic technologies, data are often generated by multi-user core facilities. Many laboratories benefit from using common biological reference materials for research or clinical purposes. Thus, consistent with the mission to facilitate genetic research, the Repository will permit secondary distribution to accommodate certain situations if it can be established that protection of human subjects and quality control of the samples can be ensured. Secondary distribution, defined as the sharing of NIA Repository Sample(s) from the Repository **with members of laboratories other than the Principal Investigator's**, is permitted only under certain clearly defined circumstances. Principal investigators who might wish to share NIA Repository Sample(s) with other investigators should read the information below very carefully and must contact Coriell before proceeding with a secondary distribution.

Permitted Uses:

1. **Single purpose collaboration:** Two or more investigators initiate a collaborative project that requires the use by each laboratory of the same NIA Repository Sample(s). One Principal Investigator obtains NIA Repository Sample(s) and explains in the Statement of Research Intent that the sample will be shared with specific, named collaborator(s) for a common research project. Secondary distribution to named collaborator(s) is permitted when the Statement of Research Intent is identical for all the named collaborator(s) and is consistent with this Assurance Form. Each collaborating investigator and his or her Institutional Official must sign and submit a copy of this Assurance Form.

2. **Multi-user core facility:** A core facility (for high-throughput genotyping, for example) purchases NIA Repository Sample(s) for use by the investigators within the facility to perform assays for investigators at his or her Institution or at a consortium of institutions. The Statement of Research Intent describes the range of studies that will be conducted using the NIA Repository Sample(s). In this situation, the use of these NIA Repository Sample(s) in the core facility may be permitted after the Coriell IRB assures that the use of these samples is consistent with the research subject's informed consent. Since the NIA Repository Sample(s) will be used in the same facility by multiple investigators, quality can be ensured.

3. **Distribution of aliquots of samples for use as reference materials:** An Institution purchases a sample and describes in the Statement of Research Intent that the NIA Repository Sample(s) will be distributed for use as a reference material (for proficiency testing, for example). The Statement of Research Intent may not be able to specify the laboratories that will receive the materials. Prior approval by the Coriell IRB for this use

of the NIA Repository is required. The Coriell IRB will decide this type of request on a case-by-case basis with the advice of the NIA Repository's Project Officer. The NIA Repository Sample(s) that are distributed must be accompanied by a disclaimer of the Repository's responsibility regarding safety and quality. Furthermore, residual NIA Repository Sample(s) must be returned to the Principal Investigator or destroyed.

4. **Development of a Highly Unique Biological Resource:** An Institution purchases a cell line from the Repository and develops it into a Highly Unique Resource that requires significant modification or specialized expertise to grow, characterize, and maintain (such as an induced pluripotent stem cell line). A Highly Unique Resource is substantially different from the original NIA Repository Sample obtained from the Repository. Simply modifying an NIA Repository Sample obtained from the Repository through the introduction of a gene (*e.g.*, hTERT or green fluorescent protein) would not qualify as creating a Highly Unique Resource. The Principal Investigator may distribute aliquots of the Highly Unique Resource material by using an appropriate agreement between the Principal Investigator and/or the Principal Investigator's Institution and the secondary institution receiving the Highly Unique Resource ("Secondary Recipient"). Often a material transfer agreement is used for transfers of research materials for this purpose.

   The agreement to transfer the Highly Unique Resource to a Secondary Recipient must include: (1) a statement naming the Highly Unique Resource as well as naming the Repository number of the cell line from which the Highly Unique Resource was derived; (2) a statement that the Secondary Recipient must acknowledge the Repository and the cell line numbers(s) in any publications or presentations based on the utilization of the NIA Repository Sample(s); (3) a statement prohibiting the use of the Highly Unique Resource for human experimentation or commercialization; and (4) a statement prohibiting sale of the Highly Unique Resource for profit; and (5) a statement that the Highly Unique Resource obtained from different sources will not have undergone the standard quality control of the Repository; (6) the requirement to submit a copy of the agreement to the NIA Repository.

   The terms of the agreement between the investigator who developed the Highly Unique Resource and the Secondary Recipient who obtains the Highly Unique Resource must be executed by the Principal Investigator and an institutional official at the Principal Investigator's Institution. A copy of such executed agreements must be submitted to the NIA Repository within 10 business days of the executive of the agreement.

   <u>The NIA Repository Sample(s) may not be sold, leased, or licensed for commercial purposes but may be used for internal non-profit and for-profit research purposes.</u>

   An institution that purchases the NIA Repository Sample(s) is encouraged to make available aliquots of the Highly Unique Resource derived from the NIA Repository Sample and appropriate protocols and training to the Repository for the Repository to expand, characterize, and distribute the unique resource through the Repository, should the Repository wish to do so.

Prohibited Uses:

1. **Multi-purpose use:** An investigator working on a particular project submits a Statement of Research Intent describing that project and obtains NIA Repository Sample(s). At some time after obtaining the NIA Repository Sample(s), the Principal Investigator wishes to give a portion of the NIA Repository Sample(s) or a culture derived from the NIA Repository Sample(s) to an investigator who is working on another project. In this case, secondary distribution is prohibited because the use of the NIA Repository Sample(s) by the second investigator may not be consistent with this Assurance Form and the Statement of Research Intent. In addition, errors in cell culture technique and identification of cultures or DNA samples can occur and could compromise the Repository's reputation.

2. **The Secondary Distribution or sale of NIA Repository Sample(s) for any purpose not specified above is prohibited.**

BIOHAZARD

All cultured animal and human cells have the potential for carrying viruses, latent viral genomes, and other infectious agents in a latent or inactive state. NIA Repository Sample(s) shipped by the Repository should therefore not be treated as if they are free of contamination. These NIA Repository Sample(s) should always be handled carefully by trained persons under laboratory conditions which afford adequate biohazard containment following MINIMUM SAFETY GUIDELINES RECOMMENDED FOR WORKING WITH HUMAN CELL CULTURES. By accepting NIA Repository Sample(s), the undersigned assume full responsibility for their safe and appropriate handling.

SEE NEXT PAGE FOR SIGNATURE SECTION

We, the undersigned, have read and understand this document and agree to adhere to the restrictions and warnings stated herein.

Name of Institution: The Regents of the University of California

Name of Institutional Official authorized to make legal commitments on behalf of the Institution

(typed or printed): Brenda J. Hefti, Ph.D., J.D.

Title of Institutional Official: Industry Contracts Officer
Industry Contracts Division
University of California
San Francisco

Signature of Institutional Official: [signature]

Date: 2-24-12

Name of Principal Investigator (typed or printed):

NAM D TRAN

Signature of Principal Investigator: [signature]

Date: 02/23/2012

FAX COMPLETED FORM TO 856-757-9737
OR
EMAIL .PDF TO CCR@CORIELL.ORG

To contact the CORIELL CELL REPOSITORIES:
Write: 403 Haddon Avenue, Camden, New Jersey 08103 USA
Call: 800-752-3805 in the United States; 856-757-4848 from other countries
Fax: 856-757-9737
e-mail: ccr@coriell.org