

## **NIA Aged Cell Repository**

### **Assurance Form for Cell Lines and DNA Samples**

**Version 9.0, April 24, 2009**

This Assurance Form must be submitted by each investigator requesting cell lines or DNA samples from the NIA Aged Cell Repository, and both the Principal Investigator and the Institutional Official who is authorized to make *legally binding* agreements for the institution must sign this Assurance Form. If a substantial revision of this Assurance Form is made, investigators will be required to submit the signed revised form with their next order. The investigator must also complete a Statement of Research Intent (online) to the Coriell Cell Repositories for each order before the order can be shipped. The signed Assurance Form may be submitted by FAX, mail, or email (.PDF).

#### **HUMAN SUBJECT PROTECTIONS**

To ensure compliance with the Office for Human Research Protections (OHRP), Department of Health and Human Services (DHHS), and regulations for the protection of human subjects (45 CFR Part 46), before human cell cultures or DNA samples can be shipped from the NIA Aged Cell Repository, the Principal Investigator must provide the Repository with a Statement of Research Intent, a written description of the purpose of the research to be done using the cell cultures or DNA samples.

The recipient acknowledges that the conditions for use of the human research materials (cell cultures and DNA samples) are governed DHHS regulations ([45 CFR Part 46](#)), and that the proposed use is reviewed by NIA Repository staff under the guidance of the Coriell Institutional Review Board (IRB). The recipient agrees to comply fully with all such conditions and to report promptly to Coriell Institute any proposed changes in the research project and any unanticipated problems involving risks to subjects or others. The recipient remains subject to all applicable state and local laws or regulations and institutional policies which provide additional protections for human subjects.

Repository staff will under no circumstances provide information that will allow investigators to identify human subjects. Furthermore, the recipient agrees 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.

#### **COMMERCIAL USE, WARRANTY AND LIABILITY**

The NIA Aged Cell Repository retains ownership of the material, including any material contained or incorporated in modifications. Commercialization of the cell lines, DNA or RNA samples obtained from the NIA Aging Cell Repository, or their modified or unmodified derivatives, is strictly prohibited. There is no restriction on development of commercial products resulting from the knowledge gained from studies using Repository cell lines or DNA samples. However, the distribution of repository cell lines or nucleic acids, material isolated from them, or modified or unmodified derivatives from the cell lines, in commercial products or services is strictly prohibited. The Repository has made no attempt to determine outstanding rights in the

cell lines. The Repository disclaims any knowledge relating to property interest in the cell lines provided.

The cell cultures are provided as a service to the research community. They are provided without warranty of merchantability or fitness for a particular purpose and without any other warranty, expressed or implied.

**Warranty:** THE REPOSITORY MAKES NO REPRESENTATIONS AND EXTENDS NO 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.

**Liability Statement 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 from its use of the cell culture or DNA sample to the extent permitted under the laws of the recipient's state. This provision shall also apply to any byproducts or derivative of the cell cultures or DNA samples.

**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 material or any byproduct or derivative, but only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171). This provision shall also apply to any byproducts or derivative of the cell cultures or DNA samples.

**Liability Statement for All Other Institutions:** To the extent permitted by law, the recipient institution agrees to hold harmless the United States Government, Coriell Institute for Medical Research, and the contributor from any claims, costs, damages, or expenses resulting from any injury (including death), damage, or loss that may arise from the use of the cell culture or DNA sample. This provision shall also apply to any byproducts or derivatives of the cell culture or DNA sample.

## **HUMAN EXPERIMENTATION**

The undersigned recipients agree that cell cultures purchased from the NIA Aging Cell Repository and their progeny or derivatives will not be used in human subjects

## **RESEARCH USE, RESTRICTIONS ON REDISTRIBUTION AND PROHIBITIONS ON RESALE**

The Coriell Cell Repositories provide biomaterials as a service to the research community. The purpose of the NIA Aged Cell Repository is to stimulate and facilitate research in the study of aging, genetics and related fields, leading to a better understanding of normal genetic and cellular processes.

It is expressly understood that the biomaterials delivered pursuant to this Agreement are experimental and are for use in research, in teaching and as reference materials in clinical genetics laboratories. Recipients employing cell cultures or DNA samples for use as reference materials or controls are responsible for complying with all laws and regulations applicable to the intended use of the materials, including any requirements for FDA approval.

Other uses of the cell lines and DNA samples, and products derived from them, are subject to the following prohibitions and restrictions. Secondary distribution and shared use of cell cultures and DNA samples (including the expansion or subdivision of cell cultures or replication or subdivision of DNA) or the distribution of products derived from cell cultures or DNA samples obtained from the NIA Aged Cell Repository, with or without charge, is prohibited except under special circumstances (see “Shared Use and Secondary Distribution”).

### **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. The cell cultures shipped by the Repository should therefore not be treated as if they are free of contamination. These cells 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 these cells, the undersigned assume full responsibility for their safe and appropriate handling, to the extent allowed by law.

**I, the undersigned, have read and understand this document:**

Name of Institution: \_\_\_\_\_

Principal Investigator (typed or printed): \_\_\_\_\_

Signature of Principal Investigator: \_\_\_\_\_

Date: \_\_\_\_\_

**I, the undersigned, have read and understand this document and agree to adhere to the restrictions and warnings stated therein- Must be signed by the Institutional Official who can make legal commitments on behalf of the Institution. Please refer to our website for clarification of our policy- <http://ccr.coriell.org/Sections/Support/Global/AFSG.aspx?PgId=210>**

Institutional Official- typed or printed: \_\_\_\_\_

Full Title of Institutional Official: \_\_\_\_\_

Department or Area of Responsibility: \_\_\_\_\_

Full Signature of Institutional Official: \_\_\_\_\_

Date: \_\_\_\_\_

### **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](mailto:ccr@coriell.org)