

CDC Cell and DNA Repository Statement of Research Intent and Assurance Form

January 10, 2005

To ensure compliance with the Office for Human Research Protections (OHRP), Department of Health and Human Services (DHHS) regulations for the protection of human subjects (45 CFR Part 46), before human cell cultures or DNA samples can be shipped from the CDC Cell and DNA Repository, the principal investigator must provide the Repository with a description of the purpose of the research to be done using the cell cultures or DNA samples. The principal investigator and the legally binding, authorized institutional official must also sign this statement agreeing to adhere to the following conditions.

The written description of purpose and the signed assurance form should be returned to the Coriell Cell Repositories.

1. List the Repository number for each cell culture or DNA sample you wish to order.

Repository Number	Description

2. These samples will be used in the following ways (check all that apply).

- Perform functional studies
- Serve as positive or negative controls
- SNP discovery/genotyping/haplotyping
- Sequence portions of the genome
- Map genes
- Identify novel genes
- Characterize genes and mutations
- Study gene expression
- Study molecular phylogenies
- Determine the ancestral state of a polymorphism/haplotype
- Conduct proteomic studies
- Other (please specify) _____

3. Please describe more specifically the study or studies you will be conducting using these samples. (You may type and attach the description if you wish)

BIOHAZARD

All cultured animal and human cells have the potential for carrying viruses, latent viral genomes, and other infectious agents in an inapparent 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.

WARRANTY AND LIABILITY

The recipient acknowledges that the conditions for use of the research materials (cell cultures and DNA samples) are governed by the CDC Cell and DNA Repository Institutional Review Board (IRB) in accordance with DHHS regulations (45 CFR Part 46). The recipient agrees to comply fully with all such conditions and to report promptly to the CDC Cell and DNA Repository IRB any proposed changes in the research project and any unanticipated problems involving risks to subjects or others. The recipient remains subject to 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 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.

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 solely from the use of the cell culture or DNA sample to the extent permitted under the laws of this 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).

Liability Statement for All Other Institutions: The recipient institution agrees to indemnify and 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.

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

The Coriell Cell Repositories provide biomaterials as a service to the research community. The purpose of the CDC Cell and DNA Repository is to provide validated materials for molecular genetic studies. There is no restriction on development of commercial products resulting from the knowledge gained from studies using Repository cell lines or DNA samples. However, use of the cell lines and DNA samples, and products derived from them, are subject to the prohibitions and restrictions below, to which the undersigned agree.

Commercial use of products derived from the DNA samples and cell cultures obtained from the CDC Cell and DNA Repository is not permitted.

It is expressly understood that the biomaterials delivered pursuant to this Agreement are experimental and are FOR RESEARCH PURPOSES ONLY. Cell cultures and DNA samples obtained from the CDC Cell and DNA Repository may be used as research standards or controls only by the original recipient laboratory. Recipients of cell cultures or DNA samples for this use are responsible for complying with all laws and regulations applicable to the intended use of the materials including any requirements for FDA approval.

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 CDC Cell and DNA, with or without charge, is prohibited. Recipients of materials from the Repository agree not to provide these materials to other laboratories outside the direct control of the principal investigator to whom the samples are shipped. The fees charged for samples obtained from the Repository are modest specifically to encourage each potential user to obtain his/her own samples.

By accepting these cells, the undersigned assume full responsibility for their safe and appropriate handling.

ASSURANCE

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

Name of Institution: _____

Principal Investigator (typed or printed): _____

E-mail: _____

Signature: _____

Institutional Official who can make legal commitments on behalf of the Institution (typed or printed): _____

Title: _____

Signature of Institutional Official: _____

Date: _____

January 10, 2005

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.umdj.edu