

NHGRI SAMPLE REPOSITORY FOR HUMAN GENETIC RESEARCH

ASSURANCE FORM FOR BIOMATERIALS

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 lines, DNA samples, BAC or Fosmid clones (biomaterials) can be shipped from the NHGRI Sample Repository for Human Genetic Research, the principal investigator must provide the Repository with a written description of the purpose of the research project to be conducted using these biomaterials. Both the principal investigator and the [institutional official](#) who is authorized to make legally binding agreements for the institution must sign this statement agreeing to adhere to the following conditions.

The Statement of Research Intent must be submitted electronically with the online order and the signed Assurance forms must be returned to the Coriell Cell Repositories.

WARRANTY AND LIABILITY

The recipient acknowledges that the conditions for use of the biomaterials are governed by the Institutional Review Board (IRB) of the Coriell Cell Repositories, 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 Institutional Review Board (IRB) of the Coriell Cell Repositories any proposed changes to the research project and any unanticipated events involving risks to subjects or others. A new Statement of Research Intent Form must be submitted if any major changes to the research project are proposed. The recipient remains subject to all applicable state and local laws and regulations and institutional policies that provide additional protections for human subjects.

Repository staff will under no circumstances provide information that will allow investigators to identify subjects; the repository does not have identifying information for subjects who contributed samples to the HapMap Project or to the 1000 Genomes Project.

CONDITIONS OF USE

- 1) The signatories agree to report to the Coriell Cell Repositories any proposed changes to the research project that differ from the description provided in the Statement of Research Intent.
- 2) The signatories agree not to try to identify or contact the donor subjects from whom these biomaterials were derived.
- 3) The signatories agree that the biomaterials are provided without warranty of merchantability or fitness.
- 4) The signatories agree not to use biomaterials for human experimentation without the approval of the Coriell Cell Repositories' IRB and of an IRB at the recipient site.
- 5) The signatories agree not to sell biomaterials from the Repository to a third party.
- 6) The signatories agree not to distribute biomaterials from the Repository to a third party except after pre-approval by the Coriell Cell Repositories for specific circumstances, which include: (a) single purpose collaborations; or (b) the distribution of aliquots or derivatives of biomaterials for use as biological standards. Approval will be contingent upon the requestor submitting to the Coriell Cell Repositories a Statement of Research Intent describing such secondary use.

- 7) The signatories acknowledge that cultured cells have the potential to carry viruses and other infectious agents and that appropriate precautions will be taken. These cells should always be handled carefully by trained persons under laboratory conditions that afford adequate biohazard containment following [minimum safety guidelines recommended for working with human cell cultures](#).
- 8) The signatories acknowledge that if it is found that the biomaterials are used for purposes other than those explicitly stated in the Statement of Research Intent they will be asked to return the biomaterials to the Coriell Cell Repositories immediately and will not receive financial compensation for the unused portion.
- 9) The signatories acknowledge their understanding that each donor community has set up a Community Advisory Group (CAG) to serve as a liaison between the community and the Coriell Cell Repositories. The signatories acknowledge their understanding that the CAG will be informed that their research group has received the biomaterials and their statement of the purpose of the research. In addition, the Coriell Cell Repositories provide a link from the biomaterials to any papers which have published results based on the use of the samples.
- 10) The signatories acknowledge their understanding that as part of an ongoing process of community consultation with the donor communities through the CAGs, a community could decide, after careful discussion and consultation with the Coriell Cell Repositories and with researchers, to withdraw its biomaterials from the Coriell Cell Repositories. This might occur based on the use of the biomaterials in a way that the community found unacceptable or stigmatizing. In the unlikely event that this happens, the signatories will be asked to return the biomaterials to the Coriell Cell Repositories and will receive financial compensation in the amount they initially paid to the Coriell Cell Repositories for the biomaterials if they had not yet used any of the samples, and a prorated amount for any biomaterials not used.

WARRANTIES:

1. 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.
2. The biomaterials 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.

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 these biomaterials to the extent permitted under the laws of this state. This provision shall also apply to any byproducts or derivatives of these biomaterials

For U.S. Government Laboratories: The United States assumes the liability for any claims, damages, injury, 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).

For All Other Institutions: To the extent permitted under the Laws of the recipient State. 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 its use of these biomaterials. This provision shall also apply to any byproducts or derivatives of these biomaterials.

RESEARCH USE, COMMERCIAL USE, AND USE AS STANDARDS IN GENETICS LABORATORIES

The Coriell Cell Repositories provide biomaterials as a service to the research community. The purpose of the NHGRI Sample Repository for Human Genetic Research is to stimulate and facilitate research in genetics, genomics, 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 biomaterials delivered pursuant to this Agreement are experimental and are for use in research, in teaching and as standards in clinical genetics laboratories. Recipients employing biomaterials for use as research standards 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.

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 see the document regarding the Institutional Official.](#)

Institutional Official (typed or printed): _____

Full Title of Institutional Official: _____

Department or Area of Responsibility: _____

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