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 or DNA samples (biomaterials) can be shipped from the NHGRI Sample Repository for Human Genetic Research (NHGRI Repository), the principal investigator must provide the NHGRI 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 Assurance Form for Biomaterials (Assurance Form) agreeing to adhere to the following conditions.

The signed Statement of Research Intent must be submitted electronically with the online order and the signed Assurance Form must be returned to the Coriell Institute for Medical Research.

WARRANTY AND LIABILITY

The recipient acknowledges that the conditions for use of the biomaterials are governed by the Institutional Review Board (IRB) of the NHGRI Repository, 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 IRB of the NHGRI Repository any proposed changes to the research project and any unanticipated events involving risks to subjects or others. A new Statement of Research Intent must be submitted to the NHGRI Repository if any major changes to the research project are proposed.

NHGRI Repository staff will under no circumstances provide information that will allow investigators to identify subjects; the NHGRI Repository does not have identifying information for subjects who contributed samples.

CONDITIONS OF USE

1. The signatories remain subject to all applicable local, state and federal laws and regulations and institutional policies.
2. The signatories agree to report to the NHGRI Repository any proposed changes to the research project that differ from the description provided in the Statement of Research Intent.
3. The signatories agree not to, and not to attempt to, identify or contact the donor subjects (or living relatives) from whom these biomaterials were derived.
4. The signatories agree not to use biomaterials from the NHGRI Repository for human experimentation.
5. The signatories agree not to use biomaterials from the NHGRI Repository to differentiate gamete cells or embryonic cells.

6. The signatories agree not to use biomaterials from the NHGRI Repository for any therapies or transplantation.
7. The signatories agree not to sell biomaterials from the NHGRI Repository to a third party.
8. The signatories agree not to distribute biomaterials from the NHGRI Repository to a third party except after pre-approval by the NHGRI Repository (in writing) 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 NHGRI Repository a Statement of Research Intent describing such secondary use in reasonable detail.
9. 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 must 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.
10. 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 required to return the biomaterials to the NHGRI Repository immediately and will not receive financial compensation for the unused portion.
11. 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 NHGRI Repository. The signatories acknowledge their understanding that the CAG will be informed that their research group has received the biomaterials and will receive their Statement of Research Intent, and that this information may be shared publicly through the NHGRI Repository website. In addition, the NHGRI Repository may provide a link from the biomaterials to any papers which have published results based on the use of samples.
12. The signatories acknowledge their understanding that as part of an ongoing process of community consultation with the donor communities through the CAGs, a donor community could decide, after careful consideration and consultation with the NHGRI Repository and with researchers, to withdraw biomaterials that the community determines or suspects may be used in a way that the community finds unacceptable or stigmatizing. In the unlikely event that this happens, the signatories will be required to return the unused portion of the biomaterials to the NHGRI Repository and will receive financial compensation in the amount they initially paid to the NHGRI Repository for the unused and returned portion of the biomaterials.
13. The signatories agree to abide by any NIH regulations and guidelines involving induced pluripotent stem cells (iPSCs) and differentiated cells.

DISCLAIMER

THE SIGNATORIES ACKNOWLEDGE AND AGREEE THAT THE BIOMATERIALS ARE PROVIDED AS A SERVICE TO THE RESEARCH COMMUNITY, AND THAT THE NHGRI REPOSITORY MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, WITH RESPECT TO THE BIOMATERIALS. WITHOUT LIMITING THE FOREGOING, THE SIGNATORIES FURTHER ACKNOWLEDGE

AND AGREEE THAT THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR THAT THE USE OF THE BIOMATERIALS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

For State Institutions: The recipient institution agrees to be responsible for any claims, costs, damages, injury, or expenses arising from any injury (including death), damage, or loss that may arise from the use of these biomaterials. 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, costs, 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 NHGRI Repository from any claims, costs, damages, or expenses resulting from any injury (including death), damage, or loss that may arise from the use of these biomaterials. This provision shall also apply to any byproducts or derivatives of these biomaterials.

COMMERCIAL USE

There is no restriction on development of commercial products resulting from the knowledge gained from research using the NHGRI Repository materials. NHGRI Repository materials may be used for internal research purposes by commercial entities. NHGRI Repository materials or material isolated from them, such as RNA, DNA, or protein, may not themselves be used in the manufacture of commercial products or sold or distributed as commercial products themselves. The NHGRI Repository disclaims any knowledge relating to third-party property interest in the NHGRI Repository materials.

RESEARCH USE, USE AS STANDARDS IN GENETICS LABORATORIES AND ACKNOWLEDGMENT

The NHGRI Repository provides biomaterials as a service to the research community. The purpose of the NHGRI Repository is to stimulate and facilitate research in genetics, genomics, and related fields, leading to a better understanding of normal genetic and cellular processes, the identification and function of disease-related genes, and the diagnosis and treatment of genetic disorders. It is expressly understood that the biomaterials delivered pursuant to this Assurance Form are experimental and are only intended 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.

Recipients employing biomaterials for uses related to induced pluripotent stem cells (iPSCs) and/or differentiated cells derived from NHGRI Repository iPSCs must comply with all Office for Human Research Protections (OHRP), Department of Health and Human Services (DHHS), National Institutes of Health Policies and regulations for the protection of human subjects (45 CFR Part 46).

The Repository number(s) of the cell line(s) or the DNA sample(s) must be cited as follows in publications or presentations that are based on the use of these materials: "The following biospecimens donated by [list Population Descriptors here] were obtained from the NHGRI Sample Repository for Human Genetic Research at the Coriell Institute for Medical Research [list Repository ID numbers here]."

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

Name of Institution: _____

Principal Investigator (typed or printed): _____

Full Title of Principal Investigator: _____

Signature of Principal Investigator: _____

Date: _____

I, the undersigned, have read and understood this document and agree to adhere to the restrictions and warnings stated herein and acknowledge this document 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 NHGRI REPOSITORY:
Write: Coriell Institute for Medical Research, 403 Haddon Avenue, Camden, New Jersey 08103 USA
Call: 800-752-3805 in the United States; 856-757-4848 from other countries
E-mail: customerservice@coriell.org