NEI-AREDS Genetic Repository

Assurance Form for DNA Samples
Version 2: June 5, 2008

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 DNA samples can be shipped from the NEI-AREDS Genetic Repository ("Repository"), the Principal Investigator must provide the Repository with a written description of the purpose of the research project to be done using the DNA samples. Both the Principal Investigator ("Recipient") and the institutional official who is authorized to make legally binding agreements for the institution (see Appendix 1) must sign this statement agreeing to adhere to the following conditions.

The signed Statement of Research Intent and Assurance Form must be returned to the Coriell Cell Repositories.

Warranty and Liability

1. 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.

2. 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 the use of the DNA sample to the extent permitted under the laws of the Recipient's state. This provision shall also apply to any byproducts or derivatives of the DNA samples.

For U.S. Government Laboratories: The United States assumes the liability for any claims, costs, damages, injuries, or expenses arising from the use of the DNA sample 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: The Recipient institution agrees to indemnify and hold harmless the United States Government, the Coriell Institute for Medical Research, and the contributor from any claims, costs, damages, or expenses resulting from an injury (including death), damage, or loss that may arise from the use of the DNA sample. This provision shall also apply to any byproducts or derivatives of the DNA samples.

Conditions of Use

1. Protection of Human Subjects

The Recipient acknowledges that the conditions for use of the DNA samples 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 IRB of the Coriell Cell Repositories any unanticipated events involving risks to subjects or others. The Recipient remains subject to all applicable state and local laws and regulations and institutional policies that provide additional protections for human subjects.

2. Changes to Research Project or Recipient's Institution

The Recipient agrees to report promptly to the IRB of the Coriell Cell Repositories any proposed changes to the research project. The Recipient also agrees to submit a new Assurance Form to the Coriell Cell Repositories if any major changes to the research project are proposed.

The Recipient agrees that if he/she changes institutions then a new Assurance Form signed by the institutional official at the new institution will be provided by the Recipient to the Coriell Cell Repositories.

3. Non-identification of Subjects

Repository staff will under no circumstances provide information that will allow recipients 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 DNA sample was derived. (This condition is not applicable to AREDS Principal Investigators who provided the genetic samples if they have appropriate institutional approval to retain the subject identities or re-contact subjects).

4. Human Experimentation

Human experimentation utilizing the DNA samples may not be undertaken without additional prior review and approval by the Coriell Institute for Medical Research IRB and by an IRB at the Recipient's institution, which must be convened under an applicable OHRP-approved Assurance.

5. Research Use

The Coriell Cell Repositories provide biomaterials as a service to the research community. The purpose of the NEI-AREDS Genetic 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 DNA samples delivered pursuant to this Agreement are experimental and are for use in research, in teaching and as standards in clinical genetics laboratories. Recipients employing DNA samples for use as research standards or controls are responsible for complying with all laws and regulations applicable to the intended use of these samples, including any requirements for FDA approval.

6. Genetic Specimens for Eye Disease Research Only

Some genetic specimens were provided by AREDS participants who consented that their specimen only be used for eye disease research. The Recipient agrees to use any genetic information from the specimens from these participants to do research in eye disease (age-related macular degeneration and cataract) and no other type of disease.

7. Commercial Use and Intellectual Property

The Recipient and his/her institution agree not to distribute, or be party to the distribution of, NEI-AREDS Genetic Repository DNA samples (or replicated or subdivided DNA), or products derived from these DNA samples, in commercial products or services.

The National Eye Institute (NEI) recognizes the importance of the later development of Intellectual Property on downstream discoveries, especially in therapeutics, which will be necessary to support full investment in products that the public needs. As such, there is no restriction on development of commercial products resulting from the knowledge gained from studies using Repository DNA samples.

However, in order for the Repository to achieve maximum public benefit, the NEI urges the Recipient and his/her institution to adhere to the Intellectual Property (IP) policy outlined below:

- Genetic data and conclusions derived therefrom should remain freely available, without requirement for licensing, for applications such as, but not necessarily limited to, the following: the use of markers in developing assays or diagnostic tools; the use of combinations of markers in multiplex assays; and the use of markers as guides toward identification of new drug targets.
- The NEI suggests that genotypic data generated using Repository DNA samples be provided to the database of Genotype and Phenotype (dbGaP) for inclusion with other AREDS genetic data at the time that any article using these data is published.
- The NEI encourages licensing practices consistent with the recommendations cited in NIH's Best Practices for the Licensing of Genomic Inventions and in the NIH Research Tools Policy.

8. Non-transferability

The Recipient agrees to retain control over the DNA samples obtained from the NEI-AREDS Genetic Repository and further agrees not to distribute these DNA samples (or replicated or subdivided DNA) or products derived from these DNA samples, with or without charge, to any entity or individual other than his/her research staff, subject to applicable law, except under special circumstances (see Appendix 2). The Recipient and his/her institution acknowledge responsibility for ensuring appropriate use of these DNA samples and agreement to the terms of this Assurance Form by research staff.

9. Dissemination of Research Results and Acknowledgement of AREDS

It is the intent of the NEI-AREDS Genetic Repository to promote the dissemination of analyses of AREDS DNA samples as widely as possible. To further this goal, the Recipient is strongly encouraged to publish his/her results in peer-reviewed journals.

The Recipient agrees to acknowledge AREDS and the AREDS Research Group in all oral and written presentations, disclosures, and publications resulting from any analyses of DNA samples obtained from the Repository. The Recipient further agrees that the acknowledgment shall include a citation of the following paper: Age-Related Eye Disease Study Research Group. The Age-Related Eye Disease Study (AREDS): Design Implications. *Control Clin Trials.* Dec;20(6):573-600.

An example of a possible acknowledgment is:
"The DNA samples used for the analyses described in this manuscript were obtained from the National Eye Institute - Age-Related Eye Disease Study (NEI-AREDS) Genetic Repository. Funding support for AREDS was provided by the National Eye Institute (N01-EY-0-2127). We would like to thank the AREDS participants and the AREDS Research Group for their valuable contribution to this research."

Signatures

By signing and dating this Assurance Form, the Recipient and his/her Institutional Official certify their agreement to the principles, policies and procedures for the use of NEI-AREDS Genetic Repository DNA samples as articulated in this document. Recipients further acknowledge that they have shared this document with any research staff that will participate in the use of the Repository DNA samples.

Institutional Business Officials also acknowledge that they have shared this document with the appropriate institutional organizations, such as the Office of Technology Transfer and the Office for Human Subjects Research.

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): _____

Signature: _____

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

Title of Institutional Official _____

Signature of Institutional Official: _____

Date: _____

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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; OR **Fax**: 856-757-9737
E-mail:ccr@coriell.org

Appendix 1
Assurance Form Signatory Guidelines

With regard to the requirement for the signature of an "Institutional Official" who can make legal commitments on behalf of the institution receiving DNA samples:

The Assurance Form requires that the **institution** (in addition to the Principal Investigator receiving the DNA samples) assure:

1. That the DNA samples will be used in compliance with all regulations protecting human subjects.
2. That the DNA samples or any products derived from them will not be commercialized.
3. That the DNA samples will not be distributed to a third party (that the researcher will not "share" with a colleague) without authorization by the Coriell Institute for Medical Research as agent for the National Eye Institute.
4. That the research laboratory is properly equipped and provides the appropriate training for the handling of potentially hazardous biomaterials.
5. That the institution will assume liability for use of the DNA samples, as detailed in the Assurance Form.

These are **legal** commitments by the institution. If the researcher or end-user (or laboratory technician or other staff) fails to abide by the commitments or misuses the DNA samples in any way, the institution is liable for failure to fulfill the terms of the assurance agreement.

The individual who can make such commitments is usually a senior institutional official (president, vice-president, director) with responsibility for scientific and technological research and development or legal affairs. **This individual is likely to be the person authorized to sign grant applications or contract proposals on behalf of the institution.**

It is unlikely that staff of a purchasing department would be authorized to make assurances about the scientific use of biomaterials.

We request that sufficient detail be included in the "title" used by the signer of the Assurance Form so that the level and scope of responsibility is clear and unambiguous (the title of "Dr." or "Professor" does not in itself provide sufficient information about the responsibilities of the signer).

Appendix 2
Secondary Distribution and Shared Use of DNA Samples

Principal Investigators who intend to purchase samples that are to be shared should read the statement below and then contact the Order Department of Coriell Cell Repositories by calling 800-752-3805 before proceeding with the order.

Genetic research often involves collaborations among 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 labs often benefit from using common biological standards 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 can be assured. Examples of situations in which the issue of secondary distribution or shared use might be raised are described below, along with recommendations and the rationale behind the recommendations.

1. **Single purpose collaboration** - Two or more Principal Investigators initiate a collaborative project that requires the use by each laboratory of the same DNA sample. One Principal Investigator purchases a sample and explains in the statement of research intent that the sample will be shared with specific, named collaborators for a common research purpose. Secondary distribution to named collaborators is permitted when the research intent is identical for the collaborators and is thus consistent with the informed consent and quality can be reasonably assured by virtue of the collaboration. *In addition to the Principal Investigator placing the order, all collaborating Principal Investigators must submit an Assurance Form (or have a current Assurance Form on file) and also submit a separate Statement of Research Intent.*

2. **Multi-purpose use** - A Principal Investigator working on a particular project purchases a sample and submits a statement of research intent describing that project. At some time after obtaining the sample, the investigator wishes to give a portion of the DNA sample to a colleague who is working on another project. In this case, secondary distribution is prohibited because the Coriell Institute for Medical Research (CIMR) IRB cannot assure that use of the sample by the original purchaser's colleague is consistent with the informed consent. In addition, errors in identification of DNA samples can occur and could compromise the Repository's reputation.

3. **Multi-user core facility** - A core facility (for high-throughput genotyping, for example) purchases samples for use by the scientists in the facility to perform assays for investigators at that institution or at a consortium of institutions. The statement of research intent describes the range of studies (i.e., the kinds of phenotypes for which genotyping studies would be performed) but explains that the number of users and the exact phenotypes cannot be predicted. In this situation, the use of the samples in the core facility is permitted after the CIMR IRB is assured that the use of the samples is consistent with the informed consent. Since the samples will be used in the same facility for multiple investigators, quality can be assured.

4. **Distribution of aliquots or derivatives of samples for use as biological standards** - An organization purchases a sample and describes in the statement of research intent that the sample will be distributed, either with or without modification, for use as standards. The statement may or may not be able to specify the purpose(s) for which the distributed material will be used or the laboratories that would receive the materials. The Repository must decide this type of request on a case-by-case basis.

In cases where the CIMR staff, with the advice of the Repository's project officer, can reasonably expect that the organization would produce high quality control standards (based on the proposed methods of quality control and the expertise and past experience of the organization), and where the CIMR IRB can assure that the uses of distributed samples are limited to those that the IRB approves, secondary distribution should be permitted. The secondary distribution of aliquots or derivatives of samples of Repository materials for commercial purposes is prohibited under all circumstances. The burden of proof must be on the purchaser of the sample from the Repository. Furthermore, samples that are distributed must be accompanied by a disclaimer of the Repository's responsibility regarding safety and quality.