

Secondary Distribution and Shared Use of Cell Cultures and DNA Samples from the NINDS Human Genetics DNA and Cell Repository

Secondary distribution, or the sharing of cell cultures or DNA samples (“resource materials”) from the NINDS Human Genetics DNA and Cell Repository (NINDS Repository) **with members of laboratories other than your own**, is not permitted except under certain clearly defined circumstances and only with prior written authorization. Investigators should read the information below very carefully and must contact the Coriell Cell Repositories before distributing biomaterials.

Permitted Uses:

Genetic research often involves collaborations among several investigators or 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 benefit from using common biological reference materials for research or clinical purposes. Thus, consistent with the mission to facilitate genetic research, the NINDS Repository will permit secondary distribution to accommodate certain situations if it can be established that protection of human subjects and quality control of the resource materials can be ensured. Situations in which the issue of secondary distribution or shared use might be raised are described below, along with the NINDS Repository's policy and the rationale behind the policy.

1. Single purpose, multi investigator collaboration - Two or more investigators initiate a collaborative project that requires the use by each laboratory of the same resource material. At the time the order is placed, the ordering investigator explains in the Statement of Research Intent that the resource material will be shared with specific, named collaborator(s) for a common research project. Secondary distribution to named collaborator(s) may be permitted when the Research Intent is identical for all the named collaborator(s) and is thus consistent with the NINDS Assurance Form. Each collaborating investigator must have a current, executed Assurance Form on file with Coriell Cell Repositories.

2. Multi-user core facility - A core facility (for high-throughput genotyping, for example) places an order for samples to be used by the investigators within the facility to perform assays for investigators at that institution or for a consortium. The Statement of Research Intent describes the range of studies that will be conducted using the resource materials. In this situation, the use of the resource materials in the core facility may be permitted if the NINDS Repository Review Board is assured that the use of the material is consistent with the research subject's informed consent.

3. Distribution of aliquots or derivatives of samples for use as reference materials – An investigator may place an order for one or more resource material(s) and describes in the Statement of Research Intent that the material(s) will be distributed, either with or without modification, for use as a reference material. The statement may not be able to specify the laboratories that will receive the materials. The NINDS Repository Review Board will decide this type of request on a case-by-case basis with the advice of the NINDS Repository's Project Officer. The investigator should maintain a record of where he or she sends resource materials.

Distributed materials must be accompanied by a disclaimer of the NINDS Repository's responsibility regarding safety and quality. Furthermore residual materials must be returned to the ordering investigator or destroyed. Resource materials and their derivatives may not be transferred to a third party.

4. Development of a unique biological resource – In the event an investigator purchases a cell line from the NINDS Repository and develops it into a highly unique living resource that requires specialized expertise to grow, characterize, and maintain (such as an induced pluripotent cell line or iPSC), the investigator may request permission of the NINDS Repository to distribute the unique biological resource to secondary recipients. The investigator seeking to distribute the unique biological resource must provide to the NINDS Repository the Statement of Research Intent Form and Assurance Form completed by the secondary recipient with whom the purchasing investigator wishes to share. The documentation will be reviewed by NINDS. Prior to distribution, the requesting investigator must obtain signed, written documentation from the secondary recipients acknowledging understanding and agreement to the following: (1) the same cell line (unique resource) obtained from the different sources may have different properties and will not have undergone the standard quality control of the NINDS Repository and (2) the secondary recipient must acknowledge the NINDS Repository in any presentations or publications utilizing the materials.

Simply modifying a cell line through the introduction of a gene (*e.g.*, hTERT or green fluorescent protein) does not qualify as a unique resource and will be subject to the NINDS Repository's prohibition of secondary distribution.

Prohibited Uses:

1. Use of samples for commercial purposes - The sale of clinical data, cell cultures, DNA samples or derivatives of samples of NINDS Repository materials for profit or in exchange for services is prohibited under all circumstances.

2. Multi-purpose use - A purchaser shall submit a Statement of Research Intent describing how they will use resource material(s) from the NINDS Repository. While at some time after obtaining the resource materials, the investigator may wish to give a portion of the DNA sample or a culture derived from the original cell culture to a colleague who is working on another project, in this case, that secondary distribution is prohibited because the use of the resource material by the original requester's colleague may not be consistent with the NINDS Assurance Form and Statement of Research Intent. Colleagues should be directed to the NINDS Repository to purchase the resource materials for their own use.

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