

Becoming a Submitter to the NINDS Repository September 2016

While planning a project under which you may wish to deposit samples in the NINDS Repository, please be advised that you should contact the NINDS Program Director in your area PRIOR to submitting an NIH grant application. Please note that inclusion of sample submission to the NINDS Repository within the grant application does not guarantee approval to submit samples; all potential Repository submitters must complete the necessary approval process outlined below.

There are two ways to apply to become a submitter to the NINDS Repository. First, one can apply to become a Repository "Investigator" by submitting a completed [Investigator Tracking Data Form](#), together with an IRB approved consent that contains language specific to the Repository (please see page 2). Alternatively, one can apply to become a Repository "Collaborator" by identifying a currently-approved Repository Investigator. This latter approach is dependent on agreement from the submitting identified Investigator. If the Investigator agrees to the request for Collaborator status, the proposed collaborator must then also submit an IRB-approved consent document, as well as a [Collaborator Tracking Data Form](#).

When reviewing prospective submitters, NINDS currently gives approval preference to NINDS-funded clinical sites and to sites enrolling families or non-Caucasian patients with the diseases sought by the Repository (motor neuron diseases, parkinsonism, cerebrovascular disease, tourette, epilepsy and dystonia). Preference is also given to clinical sites enrolling patients for whom molecular characterization data is available. Other types of submissions may not be approved. This NINDS preference is based on scientific priorities at the Institute and is subject to change without notice.

Please note that the ability to submit samples and associated data to the NINDS Repository requires initial NINDS approval; re-approval occurs on an annual basis, usually coincident with local IRB protocol renewal. A copy of the current IRB-approved consent along with the appropriate Tracking Data Form must be on file at the Repository at all times.

All approved Investigators are required to report any findings regarding confirmed genetic mutations identified in individuals for whom samples are housed within the NINDS Repository. Investigators who obtain samples from the Repository are required to acknowledge the Repository and all NINDS Repository identification numbers in any publications or presentations that describe such samples.

Neither NIH/NINDS nor Coriell Institute for Medical Research make a profit from the banking and distribution of samples from the NINDS Repository

Acceptable Biological Specimen Types

Currently the NINDS Repository only accepts submissions of peripheral blood specimens from donors. Blood collection kits are provided by Coriell, with shipping costs covered by the Repository.

Required Consent Languages Specific for NINDS Repository

Minimum for consent (NINDS Requirements)

- The blood will be submitted to the NINDS Repository currently housed at the Coriell Institute for Medical Research, a research resource supported by the NIH/NINDS, or NINDS-designated Repository (NINDS Repository)
- The sample will be stored indefinitely



- No personal identifiers will be sent to the Repository, the sample will be identified by a number assigned by the Dr. or researcher
- The blood sample will be used for preparation of DNA, and may be used for cell culture from which DNA will be prepared
- The DNA and cell culture will be distributed to scientists for use in research and teaching only, and as such the Repository does not return results to donors.
- The sample could be used for research in any type of disease and other genetic factors, not just _____.
- The sample and unidentified data will be available to researchers at hospitals, universities, and commercial organizations
- There is a risk that someone could use information from the sample you submitted, via DNA, to identify you if it were matched with another DNA sample provided by you. However, any user of this sample must agree not to use it for that purpose, and the risk, while real, is small.
- You have the right to withdraw from this research project at any time. If possible, any samples you have contributed will be discarded if you request this; however, because of the sample masking, we may not always be able to identify which samples were donated by you. Your withdrawal from the study will in no way affect access to medical care for which you are otherwise eligible.
- *Optional:* The NINDS Repository has a Certificate of Confidentiality.

The following CAN NOT be on the consent:

- A longer embargo time than allowed by the Repository (Embargo time greater than 1 year requires NINDS approval)
- Any indication that the institution where the sample is collected will own the sample even after it is submitted to the NINDS Repository. Once submitted, samples are owned by NINDS.

Regarding financial benefit:

“You, the “Name of the Organization”, the NINDS Repository and other researchers that obtain your de-identified samples and clinical data will not profit directly from them. However, if research using your samples leads to new tests, drugs, or other commercial products as a result of knowledge gained using your samples, you will not share in any profits.”

A copy of the consent form for each subject should be kept on file by the submitter. Signed consent documents should not be submitted to the Repository with the biological material.

For further information regarding the process of becoming a submitter, please e-mail ninds@coriell.org. Tracking Forms and consent documents can be sent via email attachment to ninds@coriell.org.