

# NIDDK Repository Usage Policy

March 27, 2015

Background: The NIDDK Central Repositories support research by providing a source of samples derived from NIDDK funded clinical trials and studies for future uses. This policy helps the Repositories maximize their cost-efficiency and value by housing only samples that are likely to be useful to the broader research community.

Current policy: NIDDK policy is that NIDDK-designated multi-center clinical research studies supported through cooperative agreements should set aside a portion of collected biosamples for later distribution to the scientific community for further research, unless NIDDK declines to acquire these samples. NIDDK will acquire such samples if they are judged to be scientifically valuable to the broader research community. Samples must also be appropriately consented and free of personally identifying information so that they can be distributed to other users. Samples that meet these criteria can be shipped to the NIDDK Repositories for storage, at no cost to the study.

## Applying the policy:

- 1) The study group should propose a sample collection and archiving plan, justifying the proposed size of the archival collection in terms of anticipated future utility. The plan should take into account the following principles, as relevant:
  - a. Screening samples – these should not be archived unless there is a compelling justification
  - b. Baseline samples – there is generally significant demand for baseline samples, so more baseline samples should be archived than for samples from ongoing study visits
  - c. Excess – the Repository cannot accept samples that exceed the proposed total for a given participant and visit. Therefore, if the proposal is to archive up to 12 ml of serum from two collection tubes, the Repository will not accept more than 12 mls even if additional tubes are collected.
  - d. Planned use - The Repositories will not store samples that are designated for use by the study group as part of its planned analysis or clinical testing unless the cost of sample acquisition and storage is paid by the study.
- 2) The Repositories will pay for all associated costs to receive samples and will send labels and shipping materials as needed.
- 3) The Repositories can provide tubes that are returned with sample, provided that this represents a cost-effective use of NIDDK resources. A comparative pricing estimate should be provided, documenting the cost to the study of providing tubes, in order to determine whether it is less expensive to have the Repositories provide them.

- 4) The Repositories will not store Paxgene tubes, or similar tubes containing blood or other fluids preparatory to further processing, as they cannot be distributed. Studies should extract the DNA, RNA or other analyte and then send aliquots to the Repositories.
- 5) If necessary, Repositories can create aliquots from shipped samples. It is preferable if the aliquoting can be done as part of sample processing to fulfill approved access requests.
- 6) The Genetics Repository only provides cell immortalization services for studies in which it is impossible to obtain sufficient whole blood to extract DNA (pediatric studies). All other studies are expected to arrange DNA extraction independently and ship DNA to the Repository for archiving.

# Authorizing creation of cell lines

Finalized: January, 2004

Background: The NIDDK Genetics Repository supports studies by providing a range of genetic sample services. Using whole blood samples, the Repository can extract DNA, cryopreserve the lymphocytes for future use, or create immortalized cell lines. A maximum of approximately 5-10 micrograms of DNA can be extracted from each ml of whole blood. Immortalized cell lines are a renewable source of DNA, and can be used to readily extract mg quantities. Cryopreserved lymphocytes can be immortalized at a later date with an excellent success rate (>90%), or can be used as a source of DNA. The cost of immortalization is significantly higher than that of cryopreservation or simple DNA extraction.

Current policy: NIDDK policy is that studies must receive NIDDK authorization to use the services of any of the Central Repositories, including the NIDDK Genetics Repository. In order to be granted access to the specific services of the Genetics Repository, studies must provide a justification.

## Applying the policy:

- 1) The study group should provide information about the anticipated uses of genetic samples. This can come in the form of study protocols that rely on genetic samples, plans for ancillary studies using genetic samples, or, at a minimum, a description of studies that could be carried out in the future using genetic samples.
- 2) The NIDDK Program Officer should provide an estimate of the number of NIDDK grantees carrying out R01 or R21 research in the specific disease area.
- 3) The study group should provide any information about potential outside funding sources for covering the costs of the genetics sample services.
- 4) NIDDK Repository and Senior Staff will evaluate each request based on the above information to determine which Genetics Repository services will be made available to the study group.