



NATIONAL CENTER FOR
RESEARCH RESOURCES
NATIONAL INSTITUTES OF HEALTH
DEPARTMENT OF HEALTH
AND HUMAN SERVICES

The National Center for Research Resources ensures that essential tools and research resources are readily available to NIH-supported investigators nationwide. NCCR-supported resources—a comprehensive range of human, animal, technology, and more—enable biomedical research advances.

National Gene Vector Laboratories

The National Gene Vector Laboratories (NGVLs) provide researchers with clinical-grade vectors for human gene transfer protocols. The National Center for Research Resources (NCRR) supports the infrastructure of these laboratories.

The NGVLs consist of three vector production centers at: Baylor College of Medicine; City of Hope National Medical Center and Beckman Research Institute; and Indiana University, which also serves as the Coordinating Center for the activities of all the laboratories and provides certain repository services. Two additional laboratories conduct toxicology studies of vectors for NGVL-approved protocols. These centers are located at the Southern Research Institute and the University of Florida.

The NGVLs have two primary goals. The first is to provide gene vectors to eligible investigators for use in clinical Phase I and Phase II gene transfer protocols. The NGVLs accept requests for the following types of vectors: retrovirus, adenovirus, adeno-associated virus (AAV), DNA plasmid, herpes virus, and lentivirus. The second goal is to support the development of toxicology data for an applicant's Investigational New Drug (IND) application to the Food and Drug Administration (FDA). An investigator may request vector production, toxicology support, or both.

Participating National Institutes of Health (NIH) components* will assume the costs of vector production and toxicology studies. NGVL resources used in clinical protocols are supplied at no cost to investigators.

The NGVL Coordinating Center has developed a database that summarizes information of NGVL-supported toxicology studies. This resource is Web-based and facilitates investigators' efforts to obtain cross-reference letters in support of their IND applications. The database can be accessed at www.ngvl.org/pharmtox/.



The NGVLs also support the production of an AAV reference standard that is produced at the University of Florida. Samples of the reference vector will be made available to investigators to foster protocol standardization.

Investigators can submit DNA obtained from protocol participants for storage at the Coordinating Center repository. In addition, the Indiana NGVL performs clonality testing of blood specimens to facilitate patient follow-up in certain protocols. These services are provided at no cost to the clinical investigator.

NGVL resources are available to domestic not-for-profit organizations, or federal or state government agencies that are eligible to receive NIH support. Applicants must supply preclinical data, provide evidence of technical feasibility of the proposed gene transfer approach, and demonstrate that suitable clinical and laboratory resources are present to conduct the proposed clinical protocol. The applicant also must agree to provide post-distribution monitoring data to the NGVL. Application forms are available at www.ngvl.org and also can be obtained by contacting the NGVL Coordinating Center at (317) 274-4518.

Requests for NGVL resources are accepted by the Coordinating Center on the annual receipt dates of March 1 and September 15. Initially, these applications are evaluated by at least two members of the 30-member NGVL Scientific Review Board. The applicants may respond to the

reviewers' comments prior to final review of the proposal by the NGVL Prioritization Committee. The Prioritization Committee conveys its scientific review recommendations to the NGVL Steering Committee. Decisions regarding financial support are made by the NIH, based on availability of funds, priority score, and compatibility with the mission of specific NIH Institutes and Centers. Applicants are normally notified within three months of the disposition of their applications.

** While NCRR has been the lead NIH component for the NGVL funding, the program also receives support from many NIH institutes: the National Cancer Institute; National Institute of Diabetes & Digestive & Kidney Diseases; National Heart, Lung, and Blood Institute; National Institute of Allergy and Infectious Diseases; National Institute of Child Health & Human Development; National Institute of Arthritis and Musculoskeletal and Skin Diseases; National Institute of Neurological Disorders and Stroke; National Institute of Dental and Craniofacial Research; and Office of Rare Diseases.*



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