NATIONAL GENE VECTOR LABORATORIES (NGVL)

APPENDIX I

Application Request

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed on Form Page 2 .
Photocopy this page or follow this format for each person.

NAME	POSITION TITLE

EDUCATION/TRAINING.(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).

INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. DO NOT EXCEED TWO PAGES.

DESCRIPTION. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Describe concisely the research design and methods for achieving these goals. Avoid summaries of past accomplishments and theuse of the first person. This description is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the application is funded, this description, as is, will become public information. Therefore, do not include proprietary/confidential inforamtion. DO NOT EXCEED THE SPACE PROVIDED.

PERFORMANCE SITE(S) (organization, city, state)

KEY PERSONNEL. See instructions on Page 11. Use continuation pages as needed to provided the required information in the format shown below.

Name	Organization	Role on Project

RESOURCES

Dear Gene Therapy Investigator,

Enclosed please find a copy of the National Gene Vector Laboratories (NGVL) "Policy and Procedures" and an "Application for NGVL Resources" (Appendix I). This is to be used by investigators wishing to obtain clinical grade vectors or pharmacology/toxicology support from the NGVL. The "Policy and Procedures" document describes the goals of the NGVL, the application and review process for obtaining NGVL resources, and the responsibilities of NGVL members and investigators. Investigators must agree to follow these guidelines to be considered for receipt of NGVL resources.

To obtain vector from the NGVL an "Application for NGVL Resources" must be completed. Please follow the instructions below and refer to Section 5.4 of the Policy and Procedures Manual when completing your application. A checklist is enclosed for your convenience.

Item 1: Routing Sheet: Fill in the requested information.

Item 2: Letter of Agreement - Sign the enclosed Letter of Agreement stating your willingness to comply with NGVL Policies.

Item 3: Abstract: Include an abstract of the proposal and list major investigators on the enclosed form, do not exceed one page (the cover page of the clinical protocol should contain the complete list of investigators).

Item 4: Biographical Sketch: The Principal Investigator and up to three additional investigators should include a 2 page NIH-formatted Biographical Sketch.

Item 5: Resources: - Describe the research and clinical funding resources and how they will be utilized to insure patient accrual and complete data analysis. If applying for toxicology, describe what non-NGVL resources are available to support the cost of toxicology and safety testing.

Item 6: Proposal Summary: A summary of the proposal (limited to 10 pages) should include the following sections: Background, vector history, preliminary data and summary of the clinical protocol, or proposed clinical application if applying for toxicology support. Include objectives, methods of assessing gene transfer and efficacy, statistical analysis to be done, and biological and clinical endpoints. In addition, a request for toxicology support should describe the proposed studies and their endpoints. See guidelines in Section 5.4 of the Policy and Procedures Manual

Item 7: Vector Map: A plasmid restriction map indicating all components of the proposed vector should be included.

Item 8: IRB Approved Clinical Protocol: Applications for clinical vector production must be accompanied by a clinical protocol describing the gene therapy trial proposed. The clinical study does not require provisional or final approval from the investigator's IRB at the time of submission to the NGVL. However, vector production will not begin until provisional IRB approval is granted. Vector will not be shipped without final IRB approval. Applications for Pharmacology/Toxicology support do not require IRB approval but should contain the proposed clinical protocol. Expedited reviews are required to have provisional IRB approval and to have been submitted to OBA before submitting to the NGVL.

Item 9: IBC Approval Letters. The clinical study does not require provisional or final IBC approval at the investigator's institution at the time of submission to the NGVL. However, vector production will not begin until provisional approval is granted. Vector will not be shipped without final IBC approval. Applications for Pharmacology/Toxicology support do not require IBC approval.

Item 10: Sequencing data (if available): if the construct has not been sequenced provide complete predicted sequence of vector including non-therapeutic regions of the construct. If the vector is a plasmid or

will be produced from a plasmid intermediate, include complete predicted sequence of plasmid backbone. The investigator may request NGVL support for vector sequencing in the application.

Item 11: Pharmacology/Safety Data (if available): The investigator may submit results of pharmacology and safety testing performed on the proposed vector.

Item 12: Relevant Publications: Up to 5 of investigator publications related to the proposed study may be included.

Item 13: Letters of Collaboration: Investigators must include letters of collaboration from individuals or companies that will play a significant role in the proposal. If investigators propose the clinical use of investigational agents in their protocol (such as cytokines, cell selection devices, antibodies), the source of such agents must be identified and a letter of support from the supplier must be included in the proposal.

Item 14: FDA Contact Information: Investigators are required to have initiated discussion with the FDA regarding their proposal. The date of contact and the name of the contact person should be included. If a pre-IND meeting has occurred, the suggestions of the FDA should be enclosed with the application. If submitting toxicology studies, details of such studies developed with the FDA will help facilitate a favorable review.

Item 15: Complete enclosed Vector Distribution Agreement Form. This in not required if submitting a toxicology application.

Please compile the requested information in the above order and mail four copies to:

Kenneth Cornetta, M.D.
NGVL Coordinating Center
Indiana University School of Medicine
Room MS 205, 635 Barnhill Drive
Indianapolis, IN 46202-5120
Tel: (317) 274-0448

Submission deadlines are March 1 and September 15. Packages received after the deadline will be considered at the next Steering Committee meeting. Expedited reviews can be submitted to the NGVL at any time. All investigators will be informed of the disposition of their application within three months of the submission deadline.

Additional information can be obtained by calling the NGVL Coordinating Center at 317-274-0448, fax: 317-274-4518 or e-mail: lrubin@iupui.edu.

NATIONAL GENE VECTOR LABORATORIES (NGVL) - ROUTING SHEET

Principal Investigator: _____ Institution: _____

Address: _____

_____

Phone: _____ FAX: _____E-Mail: _____

Study Title: _____

_____

_____

Study Type: ❒ Toxicology ❒ Vector Production ❒ Toxicology and Vector Production

Vector/Gene Name: _____

Delivery System: ❒ Adenovirus ❒ AAV ❒ DNA Plasmid ❒ Retrovirus

❒ Lentivirus ❒ HSV ❒ Other _____

Target Cells: _____Transduction: ❒ in vivo ❒ ex vivo

Estimated Total Patient Accrual: Total = _____ Per Year = _____

Date of IRB Approval _____/_____/_____ IRB Pending ❒

Date of IBC Approval _____/_____/_____ IBC Pending ❒

Is vector currently produced by the NGVL? ❒ Yes ❒ No ❒ Unknown

_____

Investigational New Drug Application (IND) STATUS

Has an IND been filed for the use of this agent in the submitted protocol? ❒ Yes ❒ No

If yes, who is filing the IND? _____ IND # _____

If an IND has not been filed: has the investigator contacted the FDA and discussed the proposal?

❒ Yes ❒ No If Yes: FDA Contact _____

CO-INVESTIGATOR COLLABORATION

"No" answers to any of the questions below require written explanation.

Does the proposal list all scientists who will be involved with this study? ❒ Yes ❒ No

Have all investigators listed in the proposal been consulted and are they in agreement to participate in this study?

❒ Yes ❒ No

Does the proposal list all companies/institutions involved with this study? ❒ Yes ❒ No

Have all companies and institutions listed in the proposal been consulted and are they in agreement to participate in this study and abide by NGVL Policies? ❒ Yes ❒ No

Principal Investigator Signature: _____

(Investigator must complete all of the items listed above)

FOR NGVL USE ONLY

NGVL Steering Committee Meeting Date: _____/_____/_____

Primary Reviewer: _____

SRB Reviewers: 1) _____ ***2)*** _____

Final Approval Date: _____/_____/_____

NGVL Coordinating Center Director (or Designee) Signature: _____

National Gene Vector Laboratories (NGVL)

Application for NGVL Resources

1.	**NGVL Routing Sheet**	_____
2.	**Letter of Agreement**	_____
3.	**Abstract Page**	_____
4.	**Biographical sketch of major investigators** (limit 4)	_____
5.	**Resources** (3 page limit)	_____
6	**Proposal Summary** (not to exceed 10 pages)	_____
7.	**Vector Map** (1 page)	_____
8.	**Clinical Protocol with Consent Form**	_____
9.	**Pharmacology/Toxicology/Safety Data**	_____
10.	**FDA Contact Information**	_____
11.	**Sequence Data and Vector Characterization**	_____
12.	**Relevant Publications** (not to exceed 5)	_____
13.	**Letters of Collaboration**	_____
14.	**Vector Distribution Agreement**	_____

NATIONAL GENE VECTOR LABORATORIES (NGVL)

LETTER OF AGREEMENT

DATE:

TO: DIRECTOR OF THE NGVL COORDINATING CENTER

I have read the enclosed NGVL "Policy and Procedures," and as an Investigator submitting an "Application for NGVL Resources", agree to abide fully with the terms outlined below:

a. All documents and requests in the application packet that apply will be completed.

b. Documentation of all required provisional and final approvals will be supplied to the NGVL Coordinating Center.

c. I/we agree to meet the goals of post-distribution monitoring as stated in the NGVL "Policy and Procedures" document. (See section 7.0 of the Policy and Procedures).

d. I/we agree to provide the NGVL with all major amendments made to the clinical protocol following release of vector. I/we recognize that this is important since it may affect the resources originally approved through the NGVL.

e. Discussions with the NGVL will be held confidential, unless mutually agreed upon.

f. Access to relevant NGVL records by the FDA is allowed.

For investigators submitting AAV/HSV/Lentivirus applications the following apply:

a. I/we agree to place in the pharmacology/toxicology database, all data, that has been submitted previously, presently or will be submitted in the future to the FDA in support of the relevant IND application. (See Section 9.3 of the Policy and Procedures).

b. I/we agree to place in the pharmacology/toxicology database, all of the information that derives from the relevant clinical trial. (See Section 9.3 of the Policy and Procedures).

It is understood that failure to comply with these terms may serve as grounds for suspension of the NGVL support.

It is also understood that immediate suspension of NGVL support will occur if the study is suspended by the Food and Drug Administration (FDA), Institutional Biosafety Committee (IBC), Institutional Review Board (IRB), Office for Human Research Protections (OHRP) or the NIH Office of Biotechnology Activities (OBA): any studies that are conducted in violation of regulatory guidelines will result in immediate suspension.

Sincerely yours,

Investigator

NATIONAL GENE VECTOR LABORATORIES (NGVL)
VECTOR STATUS GUIDELINES

I. In Protocol Summary (included in Proposal Summary, Part A) of the Application please include the following information:

1. Briefly describe the strategy used in construction of the vector and the reasons for including viral sequences, the specific transgene sequences, and any enhancer/promoter or other regulatory regions.

2. Describe the cell line utilized in generating the vector. Describe vector titer and level of transgene expression.

3. Briefly describe the steps taken to confirm the correct assembly of the vector construct.

4. What are the criteria for the therapeutic gene expression?

5. Identify the originator of the vector? Are there any legal or contractual constraints on the use of vector?

II. In Part B of the Application include the following information:

1. Detail the following, including the size of restriction fragments used and restriction enzyme cloning sites:

   (a) vector type
   (b) notation of modifications (e.g., deletions, antibiotic resistance genes, regulatory elements, non-therapeutic genetic insertions, tag sequences, insertions, or mutations) in the genome or vector plasmid.
   (c) origin and any modification of inserted regulatory elements (e.g., promoter, poly A signals).

2. Attach DNA sequence information. If construct has not been sequenced, provide complete predicted sequence of vector including non-therapeutic regions of the construct. If the vector is a plasmid or will be produced from a plasmid intermediate, include complete predicted sequence of plasmid backbone.

3. Describe methods used to demonstrate correct assembly of vector construct?

4. Describe the assay method used to determine vector titer. Describe its sensitivity.

5. If applicable, submit a detailed history of vector packaging cell line generation, including its source and number of passages at all steps. Identify the intermediate packaging cell lines utilized and their history, detailed method of vector transfection and shuttle packaging (if applicable). Indicate if the packaging cell line represents a single clone or multiple clones. If clonal, indicate the number of clones screened to obtain the current clone. Describe growth conditions for packaging cell lines, including antibiotics and selection agents used. Has the packaging cell line been grown without antibiotics and selection agents? If so, for how many passages?

6. How will gene transfer and expression be detected in vivo? Indicate the sensitivity and specificity for DNA, RNA and protein assays currently utilized for vector detection.

7. After the final vector batch has been produced, a Certificate of Analysis will be required to assess titer and transgene function. Describe the assays to be used to determine the titer and transgene function to prepare the Certificate of Analysis. Discuss the validation and standardization of these assays. Where will the assays be performed and how long will they take to perform?

8. Does the vector induce cytopathic effects in target cells following *in vitro* transduction? Does the vector transform cells in tissue culture following transduction?

9. Have toxicity studies been done in animal models, and how do these tests relate to the clinical design? What additional animal studies would be necessary for IND approval? Discussions with the FDA should be described. If applicable, describe changes in the following parameters and the level of gene expression at which the changes occurred (organ pathology, serum biochemistry, immune parameters, hematologic parameters).

10. What is the stability of gene transfer? Is gene expression transient? If gene expression is transient, over what time period do expression levels change?

11. Has gene expression been monitored for spread beyond the immediate site of gene transfer in animals?

12. What criteria will determine toxicity in patients?

NATIONAL GENE VECTOR LABORATORIES (NGVL)

Vector Distribution Agreement.

The goal of the National Gene Vector Laboratories (NGVL) is to promote access to gene therapy vectors for use in clinical trials of outstanding scientific merit. Investigators submitting vector (donors) are encouraged to make their vector available to others (recipients). The restrictions placed on agents submitted for production by the NGVL must be stated at the time a "Request for Vector" application is made and must conform to one of the categories listed below:

Category	Conditions
A	Reagent may be used by other investigators without restriction for NGVL-approved Requests.
B	Reagent may be used by any investigator for NGVL-approved Requests after the recipient agrees to negotiate with the donor institution in good faith about any financial benefit arising from the use of the agent
C	Reagent may be used by any investigator for NGVL-approved Requests but the recipient must agree to relinquish to the donor all benefits arising from the commercialization of the agent.
D	Reagent can be shared with other investigators for NGVL-approved Requests only after approval by the donor.
E	Reagent is not for distribution.

The following statement must be co-signed by the investigator and an authorized representative of the investigator's institution:

_____ (investigator) is requesting that the vector _____ (vector name) be generated by the National Gene Vector Laboratory. Use of the vector by other investigators outside of our institution is limited to the conditions listed in Category ____ above.

Investigator's Signature _____

Printed Name and Title _____

Date _____

Institutional Representative Signature _____

Printed Name and Title _____

Date _____

NATIONAL GENE VECTOR LABORATORIES (NGVL)

APPENDIX II

Vector Use and Post-Distribution Monitoring Form and Inventory Record

NGVL Post-Distribution Monitoring – Review Committee Reporting Record

NGVL Protocol # _____ Production Center _____

Vector Name: _____ P.I. _____

			YEAR 1			YEAR 2	
Committee	Date of Approval	Date Received	Date Reviewed	Q/A Date	Date Received	Date Reviewed	Q/A Date
IRB							
IBC							
RAC							
FDA							
Release Date							
Post Release Annual Reports							
RAC							
IRB							
FDA							
Vector Use							
Inventory							

			YEAR 3			YEAR 4	
Committee	Date of Approval	Date Received	Date Reviewed	Q/A Date	Date Received	Date Reviewed	Q/A Date
Post Release Annual Reports							
RAC							
IRB							
FDA							
Vector Use							
Inventory							

			YEAR 5			YEAR 6	
Committee	Date of Approval	Date Received	Date Reviewed	Q/A Date	Date Received	Date Reviewed	Q/A Date
Post Release Annual Reports							
RAC							
IRB							
FDA							
Vector Use							
Inventory							

DATE:

Protocol: Study title: Vector release date: Information Prior to release of vector due: Annual Report due date:

Dear Investigator:

We would like to remind you that the National Gene Vector Laboratories (NGVL) is responsible for post-distribution safety monitoring as means of quality control and quality assurance for NGVL-generated vectors.

The NGVL will attempt to gather the majority of this information *via* the periodic reports that are required by the Food and Drug Administration (FDA) and the NIH Office of Biotechnology Activities (OBA). Accordingly, we ask that you simultaneously send a copy of each such report to the NGVL Coordinating Center. We have based the above due dates on the initial vector release date. You should complete and/or update only the Pre-Release Columns on the enclosed "Review Committee Reporting Record"

The following documentation is required from the Investigator prior to release of vector for clinical use:

- Final Institutional Review Board (IRB) Approval Letter
- Institutional Biosafety Committee (IBC)Approval Letter
- Confirmation of OBA registration
- Letter from the investigator to the NGVL Coordinating Center confirming or demonstrating that the 30-day IND waiting period has passed, or provide other documentation that the FDA has agreed to let the clinical trial proceed.

The following documentation is required from the investigator after release of vector:

- Serious adverse event reports related to the gene transfer submitted to the IRB, OBA and FDA
- Protocol amendments filed with the IRB or FDA
- Annual Report to the IRB
- Annual Report to the FDA (including all safety testing data)
- Annual reports to OBA.
- Vector use records (Appendix II)
- Report of vector inventory every six months (Appendix II)
- All publications resulting from vector or other resources provided by the NGVL
- If applicable, documentation of acceptance of the protocol by the GCRC Advisory Committee.

Notification of Study Suspension:

If the relevant protocol is suspended or terminated by the FDA, IRB or IBC, the NGVL Coordinating Center must be notified by telephone within 24 hours of the suspension. Documentation of this action, including suspension letters, should be forwarded to the NGVL Coordinating Center within 72 hours.

If you have any questions regarding this, please call the NGVL Coordinating Center at 317-274-0448.

Sincerely,

Ken Cornetta, M.D.
Coordinating Director - NGVL

NATIONAL GENE VECTOR LABORATORIES(NGVL)
INVENTORY RECORD

Principal Investigator: ________________________ Institution: ____________________

Study Title: ____

____

NGVL Vector Number: ___________Vector Name: _______________ Protocol _______

Material	Lot Number	Vial Number	Expiration Date	Date Received	Date of Use

NATIONAL GENE VECTOR LABORATORIES(NGVL)

VECTOR USE RECORD

Principal Investigator: _____ Institution: _____

Study Title: _____

_____

NGVL Vector Number _____ Vector Name_____

Protocol _____ Date of Use _____

Transduction ___ *in vivo* ___ *ex vivo* Route of *in vivo* administration_____

Total amount/volume of material used _____

Total amount/volume of material remaining unused _____

If material is to be used *ex vivo*, were target cells introduced into recipient? Yes No

Material	Lot Number	Vial Numbers	Date of Use

Investigators Name (Print): _____

Investigators Signature _____

Date: _____

THIS RECORD MUST BE UPDATED EACH TIME THAT NGVL VECTOR IS UTILIZED.

NATIONAL GENE VECTOR LABORATORIES (NGVL)

APPENDIX III

NGVL Application Review Forms

For Scientific Review Board Member Use

NATIONAL GENE VECTOR LABORATORIES(NGVL)
APPLICATION FOR NGVL RESOURCES

Principal Investigator: _____ Institution: _____

Study Title:_____

_____

Study Type: ❒ Vector ❒ Toxicology ❒ Both

Vector/Gene: _____

Delivery System: _____

Target Cells: _____ Transduction: ❒ in vivo ❒ ex vivo

Scientific Review Board Member: _____ Institution: _____

Confidential Findings and Comments (revealed only to the NGVL Steering Committee)**:**

Using the following scale, please rate the proposal, using a numerical score, in each of the categories listed below; Outstanding (1-1.5), Excellent (1.5-2.0), Very Good (2.0-2.5), Good (2.5-3.5), Acceptable (3.5-5.0), and Not Recommended for Further Consideration:

	Score
Strength of Preliminary Data	_____
Clinical Relevance	_____
Feasibility	_____
Protocol Design	_____
Originality	_____
Overall Scientific Merit	_____

Items below are not applicable to toxicology studies:

Is the protocol approved or provisionally approved by the IRB?	**Yes**	**No**
Is the protocol approved by the IBC?	**Yes**	**No**
Are all proposed collaborations and industrial support documented?	**Yes**	**No**
Are there ethical or legal or human subjects concerns issues which require additional explanation?	**Yes**	**No**
Are there any gender or minority issues?	**Yes**	**No**

Please attach written anonymous critique of the proposal which will be shared with the investigator. Please address the issues listed above, including both strengths and weaknesses of the proposals. Reviewers are encouraged to include suggestions which will be beneficial to the investigator, regardless of whether NGVL resources will be awarded. Attach additional pages as needed.

NATIONAL GENE VECTOR LABORATORIES(NGVL)
REQUEST FOR VECTOR REVIEW

Principal Investigator: _____ **Institution:** _____

Study Title: _____

_____

Critique - Reviewer # ____ :

NATIONAL GENE VECTOR LABORATORIES (NGVL)

APPENDIX IV

Sample NGVL Steering Committee Agenda

NATIONAL GENE VECTOR LABORATORIES (NGVL)

PROPOSED STEERING COMMITTEE AGENDA

1. Approval of the minutes of the previous Meeting.

2. Facility Report - each NGVL Facility is required to summarize a written report addressing the following:

    a) Goals met.

    b) Outstanding commitments.

    c) Technical difficulties encountered.

    d) Estimates of vector production or testing capabilities in the upcoming six month period.

3. Discussion of innovations/findings of significance to members.

4. Quality Control Issues:

    a) Report by NGVL Coordinating Center of post-distribution monitoring, specifically highlighting unexpected serious adverse events relating to vector use or non-compliance.
    b) b) Recommendations for termination or reinstatement of NGVL privileges.

5. Review of submitted proposals:

NGVL Prioritization Committee Breakout Meeting

    a) Reports by Scientific Review Board members and NGVL Prioritization Sub-Committee Presenter and assignment of priority score.

    b) Discussion of resubmitted proposals.

NGVL Steering Committee

    a) Determination of vector production and pharmacology/toxicology schedules.

6. New Business.

NATIONAL GENE VECTOR LABORATORIES (NGVL)

APPENDIX V

Conflict of Interest Disclosure Statements

For NGVL Steering Committee Member and Reviewer Use

NGVL CONFLICT OF INTEREST, CONFIDENTIALITY, AND NON-DISCLOSURE RULES AND INFORMATION FOR "APPLICATION FOR NGVL RESOURCES" REVIEWERS

A conflict of interest in scientific peer review exists when a reviewer has an interest in an application or a proposal that is likely to bias his or her evaluation. An individual who has a real conflict on interest with an application or proposal may not participate in its review. Appearance of a conflict of interest should be avoided whenever possible but, if it is established that there is no real conflict of interest and the NGVL Coordinating Center Director determines that the integrity of the process would not be impaired, the individual in question may participate in the review.

Since reviewers are most familiar with their own situation, it is their responsibility: (1) to bring to the attention of the NGVL Coordinating Center any conflict of interest situations that may pertain, whether real or apparent, and (2) and to identify on the relevant NGVL Conflict of Interest forms (a) any applications where they have a conflict of interest and (b) certify that they will not be, and have not been, involved in the review of any application where their participation constitutes a conflict of interest and they will not disclose any matters related to the review proceedings. Federal employees should be aware that federal conflict of interest statutes carry criminal penalties for violation.

In addition, the NGVL Coordinating Center may determine that a particular situation involves a conflict of interest and require that the potential reviewer not be involved in the review of the application or proposal in question. In rare circumstances, with disclosure to the full NGVL Steering Committee, the NGVL Coordinating Director may waive the conflict if it is determined that the interest is not substantial and that no other practical means exist to secure the necessary expertise to provide a competent review of an application or proposal.

The following guidance, derived from 42 CFR Part 52h, will assist you in determining whether you are faced with a real or apparent conflict of interest (http://www.access.gpo.gov/nara/cfr/waisidx_00/42cfr52h_00.html). The guidance is not all-inclusive, due to the nature of the conflict of interest subject matter. Therefore, you should consult the NGVL Coordinating Center Director when there is a question about your participation in a review.

BASES FOR CONFLICT OF INTEREST

There are several bases for a real conflict of interest. Any one may serve to disqualify a reviewer from participating in the review of an application or proposal.

Employment: A reviewer who is a salaried employee, whether full- or part-time, of the applicant institution or who is negotiating with the organization for employment, shall generally be considered to have a conflict of interest with regard to applications/proposals from that organization. A reviewer is in conflict if he/she conducts activities for the applicant, such as serving as an officer, director, trustee, or partner. However, in large organizations or multi-component organizations there may be circumstances where the components are sufficiently independent that an employee of one component can review an application/proposal from another component, with which a conflict of interest exists. Officers or employees of the U.S. government may not participate in the review of a specific grant application or contract project for which they have had or are expected to have any other responsibilities or involvement in their role as an office of employee of the United States. Membership on a scientific review group does not make an individual an employee of the Federal Government.

FINANCIAL: (1) Where a review has received or could receive direct financial benefit of any amount, other than from employment, from an applicant institution or principal investigator related to the application or proposal under review or, (2) where a review has received, or could receive, a financial benefit that, though clearly unrelated to the application or proposal under review, has a value of $5,000 or more per year, a conflict of interest exists. Regardless of the level of financial involvement, if the individual feels unable to provide objective advice, he/she must recuse him/herself from the review of the application or proposal at issue.

RELATIVES OR ASSOCIATES: A conflict of interest exists if a close relative[1] or a professional associate[2] of a reviewer submits an application or proposal, or receives or could receive financial benefits from or provides financial benefits to an applicant. In such case, it will be treated as the reviewer's financial benefit.

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[1] A close relative is defined as a parent, spouse/domestic partner, or child.

MULTI-SITE OR MULTI-COMPONENT PROJECT: Persons serving as either the principal investigator, as one of the key personnel, or as a consultant on one component of a multi-site or multi-component project, have a conflict of interest with all of the application(s) or proposal(s) connected with the same project. Furthermore, they may have a conflict of interest with other application(s) or proposal(s) submitted by the principal investigator, other key personnel or consultants on the same project.

LONGSTANDING DISAGREEMENTS: A conflict of interest exists where a potential reviewer has had longstanding scientific or personal differences with an applicant.

APPEARANCE OF CONFLICT OF INTEREST: Where there appears to be a conflict of interest, but insufficient grounds for disqualifying the reviewer, the NGVL Coordinating Center will document that: (1) no real conflict of interest exists; and (2) at the time of the review, no practical alternative exists for obtaining the necessary scientific advice from the reviewer with the apparent conflict.

CONFIDENTIALITY AND NON-DISCLOSURE OF MATERIAL AND PROCEEDINGS

The application(s) and proposal(s) and associated material made available to reviewers, as well as the discussions that take place during review meetings, are strictly confidential and must not be disclosed to or discussed with any one who has not been officially designated to participate in the review process. Reviewers must certify that they will maintain the confidentiality of the review and not disclose this information to any other individual except as authorized by the NGVL Coordinating Center Director.

Document created: 8/14/01

NGVL PRE-REVIEW CERTIFICATION FORM REGARDING CONFLICT OF INTEREST, CONFIDENTIALITY, AND NON-DISCLOSURE FOR "APPLICATION FOR NGVL RESOURCES" REVIEWERS

NAME _____

INSTITUTION _____

SCIENTIFIC REVIEW BOARD OR STEERING COMMITTEE (circle one)

DATES OF REVIEW_____

Check only one:

- ❒ I have read the attached "NGVL Conflict of Interest, Confidentiality, and Non-Disclosure Rules and Information for reviewers" and have examined the list of application(s)/proposal(s) to be reviewed. I hereby certify that, based on the information provided to me, **I do not have a conflict of interest in reviewing these applications or proposals**.

- ❒ I have read the attached "NGVL Conflict of Interest Confidentiality, and Non-Disclosure Rules and Information for Reviewers" and examined the list of application(s)/proposal(s) to be reviewed and hereby certify that, based on the information provided, **I have a conflict of interest in reviewing the specific application(s) listed below,** and hereby recuse myself from their review.

I fully understand the confidential nature of the review process and agree: (1) to destroy or return all materials related to it; (2) not to disclose or discuss the materials associated with the review, my evaluation, or the review meeting with any other individual except as authorized by the NGVL Coordinating Center; (3) not to disclose information regarding the disposition of the application(s)/proposal(s) to the applicant or other parties; and (4) to refer all inquiries concerning the review to the NGVL Coordinating Center.

Signature: _____ Date _____

I am in conflict with the following application(s)/proposal(s): identify by number and investigator.

_____
_____
_____
_____

Document created: 8/14/01

NATIONAL GENE VECTOR LABORATORIES (NGVL)

CONFLICT OF INTEREST AND CONFIDENTIALITY STATEMENT

This will certify that in the review of applications conducted by the National Gene Vector Laboratory Prioritization Sub-Committee and Steering Committee on _____, I absented myself from the room during the review of any application from an organization, institution, or university system of which I am an employee, consultant, officer, director or trustee or in which have a financial interest. I was not present during the review of any application when my presence would have constituted a real or apparent conflict of interest.

In addition, I understand that review materials and proceedings are privileged information prepared for use by consultants and staff, and that under no circumstances do consultants communicate with applicants or others about recommendations or review proceedings outside the review group.

(Signature and Printed Name)	(Signature and Printed Name)
_____	_____
_____	_____
_____	_____
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