

**FOR US POSTAL SERVICE DELIVERY:**

Office of Laboratory Animal Welfare  
Division of Assurances  
6705 Rockledge Drive  
RKL1, Suite 360, MSC 7982  
Bethesda, Maryland 20892-7982

May 31, 2017

**FOR EXPRESS MAIL:**

Office of Laboratory Animal Welfare  
Division of Assurances  
6705 Rockledge Drive, Suite 360  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Fax: (301) 451-5672

Project #: 2-R44-AI080009-05A1  
Project Title: Delivery of Nanoencapsulated TGFb and ATRA  
for the Treatment of Inflammatory Bowel Disease  
Principal Investigator: Dr. Dominick Auci  
Animal Facility: State University of New York- University of  
Buffalo

Dr. Nejat Egilmez  
Executive Vice President  
TherapyX, Inc.  
138 Farber Hall, 3435 Main Street  
Buffalo, New York 14214

Dear Dr. Egilmez:

The Division of Assurances, Office of Laboratory Animal Welfare (OLAW) has reviewed and approved the new Inter-institutional Assurance which was submitted by your Institution in compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) revised August 2015.

This Assurance with identification **A1287-13** became effective on **5/31/2017**. The Assurance is good for the current period of project support. Under your approved Assurance with **State University of New York- University of Buffalo**, their institutional Animal Care and Use Committee (IACUC) is authorized to conduct subsequent reviews of this project.

The Assurance is a key document in defining the relationship of your Institution to the PHS and the cooperating Institution's IACUC since they set forth the responsibilities and procedures of your Institution regarding the care and use of laboratory animals.

A copy of the approved Assurance is enclosed. If I can be of any further assistance, please feel free to contact me by phone or mail.

Sincerely,

Venita Thornton, D.V.M., M.P.H.  
Senior Assurance Officer, Division of Assurances  
Office of Laboratory Animal Welfare (OLAW)

Enclosure

Cc:

Dr. Stanley W. Halvorsen  
Dr. Kenneth M. Trampusch  
Ms. Cheryl Wall, NIAID



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

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May 24, 2017

Project #: 2-R44-AI080009-05  
Project Title: Delivery of Nanoencapsulated  
TGFbeta and ATRA for the Treatment of IBD  
Principal Investigator: Dr. Dominick Auci  
Animal Facility: State University of New York-  
University of Buffalo

Dr. Nejat Egilmez  
Executive Vice President  
Therapyx, Inc.  
138 Farber Hall  
3435 Main Street  
Buffalo, New York 14214-3000

Dear Dr. Egilmez:

It has been brought to our attention that the above referenced proposal which is being considered for funding involves the use of animals. Accordingly, it will be necessary for you to complete and submit an Animal Welfare Assurance of Compliance (Assurance) with the revised Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) as soon as possible.

Safeguarding the care and use of animals in activities supported by PHS grants and contracts is a shared responsibility of the grantee institution and the cooperating institution at which the research is to be conducted.

An example of the Inter-institutional Assurance and *PHS Policy* are enclosed. Please follow the example as closely as possible because the elements in the example are there to satisfy policy requirements. Major deviations from it, especially any omission of required information, will mean additional correspondence which will delay our acceptance of the Assurance, and in turn, delay final action on the proposal.

When we receive your Assurance material we will notify you regarding its acceptability. If you have any questions, please let me know.

Sincerely,

/s/

Neera Gopee, D.V.M., Ph.D., DACALM, DABT  
Veterinary Medical Officer  
Office of Laboratory Animal Welfare (OLAW)

Enclosures

Cc:

Ms. Cherly Wall, NIAID

## Interinstitutional Assurance

The Interinstitutional Assurance is used by U.S. institutions that receive Public Health Service (PHS) funds through a grant or contract award when the Institution has neither its own animal care and use program, facilities to house animals, nor an Institutional Animal Care and Use Committee (IACUC) and will conduct the animal activity at an Assured institution (named as a performance site).

### I. Awardee Institution

Name of Awardee Institution: TherapyX, Inc.

Address: (street address, city, state, zip code)

138 Farber Hall, 3435 Main Street  
Buffalo NY 14214

Project Title: (from grant application/contract proposal)

Delivery of Nanoencapsulated TGFb and ATRA for the Treatment of Inflammatory Bowel Disease

Grant/Contract Number: 2 R44 AI080009-05A1

Principal Investigator: D. Auci

#### A. Applicability

This Interinstitutional Assurance between the awardee institution and the Assured institution is applicable to research, research training, and biological testing involving live vertebrate animals supported by the PHS and conducted at the Assured institution.

#### B. Awardee and Assured Institutional Responsibilities

- i. The Institutions agree to comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- ii. The Institutions agree to be guided by the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training and comply with the PHS Policy on Humane Care and Use of Laboratory Animals (Policy).
- iii. The institutions acknowledge and accept responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, the institutions will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use.
- iv. The awardee institution acknowledges and accepts the authority of the IACUC of the Assured institution where the animal activity will be performed and agrees to abide by all conditions and determinations as set forth by that IACUC.

Name of Assured Institution: University at Buffalo, State University of New York

Address: (street address, city, state, zip code)

12 Capen Hall, Buffalo, New York 14260-1660

### II. Institutional Endorsement

By signing this document, the authorized official at the awardee institution and the Institutional Official and IACUC Chairperson at the Assured institution (performance site) provide their assurances that the project identified in Part I will be conducted in compliance with the PHS Policy and the Assurance of the Assured institution.

**A. Endorsement of Awardee Institution**

Name of Awardee Institution: TherapyX, Inc.

Authorized Official: Negat Egilmez

Signature: 

Date: MAY 8th, 2017

Title: Executive Vice President

Address: (street address, city, state, zip code)

138 Farber Hall, 3435 Main Street  
Buffalo NY 14214

Phone: 716 829-2528

Fax: 716 829-2530

E-mail: Negilmez@therapyXinc.com

**B. Endorsement of Assured Institution**

Name of Assured Institution: University at Buffalo, State University of New York

Institutional Official: Kenneth M Tramposch

Signature: 

Date: 5-11-2017

Title: Senior Associate Vice President for Research

Address: (street address, city, state, zip code)

516 Capen Hall  
Buffalo, NY 14260

Phone: 716-645-3321

Fax: 716-645-6792

E-mail: kmt1@buffalo.edu

IACUC Chairperson: Stanley W. Halvorsen

Signature: 

Date: 5/8/2017

Title: Institutional Animal Care and Use Committee

Address: (street address, city, state, zip code)

207 Sherman Hall  
3435 Main Street, Buffalo, NY 14214

Phone: 716-829-2651

Fax:

E-mail: stanh@buffalo.edu

Date of IACUC Approval: (within 3 years, pending not acceptable) January 17, 2017

**III. PHS Approval (to be completed by OLAW)**

Signature of OLAW Official: 

Date: 5/31/17

Venita B. Thornton, D.V.M., M.P.H.

Senior Assurance Officer, Division of Assurances

Office of Laboratory Animal Welfare (OLAW)

NIH/OD/OER

6705 Rockledge Drive

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Grant/Contract #: 2R44AT060009

Animal Welfare Assurance #: A1287-13

Effective Date: 5/31/17

Expiration Date: (duration of project, up to 5 years)