SMALL BUSINESS INNOVATION RESEARCH PROG **Federal Award Date:** 05/31/2019

Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 5R44AI080009-07
FAIN: R44AI080009

Principal Investigator(s):
DOMINICK AUCI

Project Title: Delivery of Nanoencapsulated TGFbeta and ATRA for the Treatment of IBD

Dr. Nejat Egilmez
Executive Vice President
138 Farber Hall
3435 Main Street
Buffalo, NY 142143000

Award e-mailed to: dauci@therapyxinc.com

Period Of Performance:
Budget Period: 06/01/2019 – 05/31/2020
Project Period: 07/20/2008 – 05/31/2020

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $999,998 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to THERAPYX, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 15 USC 638 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R44AI080009. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Tseday G Girma
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

SECTION I – AWARD DATA – 5R44AI080009-07

Award Calculation (U.S. Dollars)

Salaries and Wages	$125,674
Fringe Benefits	$34,846
Personnel Costs (Subtotal)	$160,520
Consultant Services	$38,083
Other	$468,953
Federal Direct Costs	$667,556
Federal F&A Costs	$267,022
Approved Budget	$934,578
Fee	$65,420
Total Amount of Federal Funds Obligated (Federal Share)	$999,998
TOTAL FEDERAL AWARD AMOUNT	$999,998
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$999,998

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
7	$999,998	$999,998

Fiscal Information:

CFDA Name:	Allergy and Infectious Diseases Research
CFDA Number:	93.855
EIN:	1161613097A1
Document Number:	RAI080009C
PMS Account Type:	P (Subaccount)
Fiscal Year:	2019

IC	CAN	2019
AI	8476981	$999,998

NIH Administrative Data:
PCC: I5E / **OC**: 414E / **Released**: GIRMATG 05/30/2019
Award Processed: 05/31/2019 12:05:10 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R44AI080009-07

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 5R44AI080009-07

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This award is subject to the life cycle certification requirements set forth in Section 18.5.5.4 of the NIH Grants Policy Statement. Awardees are not required to submit this certification directly to NIH but must instead complete the certification, maintain it on file in accordance with the records and retention policy in Section 8.4.2 of the NIH Grants Policy Statement, and make these certifications available to Federal officials upon request.

A certification is required at the following times:

- For SBIR Phase I Awardees: At the time of receiving final payment or disbursement from the Payment Management System.
- For SBIR Phase II Awardees: Prior to receiving more than 50% of the total award amount and prior to final payment or disbursement from the Payment Management System.

If the grantee cannot complete this certification or cannot ensure compliance with the certification process, it should notify the GMO immediately. If resolution cannot be reached, the GMO will void or terminate the grant, as appropriate.

The certification form is available in fillable format at: http://grants.nih.gov/grants/forms.htm#sbir.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R44AI080009. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

This award is not subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that

reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.
Treatment of Program Income:
Additional Costs

SECTION IV – AI Special Terms and Conditions – 5R44AI080009-07

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

This award includes funds for activity with Comparative Bioscience.

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INTELLECTUAL PROPERTY RIGHTS: Normally, the awardee organization retains the principal worldwide patent rights to any invention developed with United States Government support. Under Title 37 Code of Federal Regulations Part 401, the Government receives a royalty-free license for its use, reserves the right to require the patent holder to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it substantially in the United States.

Rights and obligations related to inventions created or reduced to practice as a result of this award are detailed in 35 U.S.C. 205 and 37 CFR Part 401. These inventions must be reported to the Extramural Invention Reporting and Technology Resources Branch, OPERA, NIH, 6701 Rockledge Drive, MSC 7750, Bethesda, MD 20892-7750, (301) 435-1986. For additional information, access the NIH link on the Interagency Edison web site (www.iedison.gov) which includes an electronic invention reporting system, reference information and the text to 37 CFR 401.

To the extent authorized by 35 U.S.C., Section 205, the Government will not make public any information disclosing an NIH-supported invention for a 4-year period to allow the awardee organization a reasonable time to file a patent application, nor will the Government release any information that is part of that patent application.

When purchasing equipment or products under this SBIR award, the grantee shall use only American-made items, whenever possible.

If provided as part of this Notice of Award, the fee is in addition to direct and facilities and administrative costs. The fee is to be drawn down from the DHHS Payment Management System in increments proportionate to the draw down of costs.

Allowable costs conducted by for-profit organizations will be determined by applying the cost principles of Contracts with Commercial Organizations set forth in 48 CFR, Subpart 31.2.

The Code of Federal Regulations (Title 45 Part 74.425) stipulates that a commercial organization is subject to audit requirements for a non-federal audit if, during its fiscal year, it expended $750,000 or more under HHS awards and **at least one award is an HHS grant or subrecipient**. Therefore, the organization must have one grant or subgrant in order to be required to obtain a non-federal audit, but other HHS awards are included in the threshold calculations and the scope of the audit. (See threshold calculation examples, http://oamp.od.nih.gov/sites/default/files/DFASDocs/examplesthresholdcalcs_508.pdf

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an

Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Tseday G Girma
Email: tseday.girma@nih.gov **Phone**: 240-747-7388 **Fax**: 301-493-0597

Program Official: Michael Minnicozzi
Email: minnicozzim@niaid.nih.gov **Phone**: 240-627-3532

SPREADSHEET SUMMARY
GRANT NUMBER: 5R44AI080009-07

INSTITUTION: THERAPYX, INC.

Budget	Year 7
Salaries and Wages	$125,674
Fringe Benefits	$34,846
Personnel Costs (Subtotal)	$160,520
Consultant Services	$38,083
Other	$468,953
FEE	$65,420
TOTAL FEDERAL DC	$667,556
TOTAL FEDERAL F&A	$267,022
TOTAL COST	$999,998

Facilities and Administrative Costs	Year 7
F&A Cost Rate 1	40%
F&A Cost Base 1	$667,556
F&A Costs 1	$267,022