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**STATE OF NEW HAMPSHIRE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH SERVICES**

Lori A. Shibinette
Commissioner

Lisa M. Morris
Director

29 HAZEN DRIVE, CONCORD, NH 03301
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www.dhhs.nh.gov

June 8, 2020

His Excellency, Governor Christopher T. Sununu
and the Honorable Council
State House
Concord, New Hampshire 03301

REQUESTED ACTION

Authorize the Department of Health and Human Services, Division of Public Health Services, to amend an existing **Sole Source** contract with Biomedical Research Alliance of New York, LLC (Vendor # 217598-B001), Lake Success, NY, to continue conducting biomonitoring science studies, statewide, to obtain New Hampshire-specific biomonitoring information by exercising a renewal option by increasing the price limitation by \$34,500 from \$9,500 to \$44,000 and by extending the completion date from June 30, 2020 to June 30, 2023 effective upon Governor and Council approval. 100% Federal Funds.

The original contract was approved by the Attorney General's Office on June 5, 2018.

Funds are available in the following account for State Fiscal Year 2021, and are anticipated to be available in State Fiscal Years 2022 and 2023, upon the availability and continued appropriation of funds in the future operating budget, with the authority to adjust budget line items within the price limitation and encumbrances between state fiscal years through the Budget Office, if needed and justified.

05-95-90-903010-8280 HEALTH AND SOCIAL SERVICES, DEPT OF HEALTH AND DHUMAN SVS, HHS: DIVISION OF PUBLIC HEALTH, BUREAU OF LABORATORY SERVICES, BIOMONITORING GRANT

State Fiscal Year	Class / Account	Class Title	Job Number	Current Budget	Increased (Decreased) Amount	Revised Budget
2019	102-500731	Contracts for Program Services	90082801	\$9,500	\$0	\$9,500
2020	102-500731	Contracts for Program Services	90082801	\$0	\$4,500	\$4,500
2021	102-500731	Contracts for Program Services	90082801	\$0	\$10,000	\$10,000

2022	102-500731	Contracts for Program Services	90082801	\$0	\$10,000	\$10,000
2023	102-500731	Contracts for Program Services	90082801	\$0	\$10,000	\$10,000
			Total	\$9,500	\$34,500	\$44,000

EXPLANATION

This request is **Sole Source** because the contract was originally approved as sole source and MOP 150 requires any subsequent amendments to be labeled as sole source. All biomonitoring studies funded by the Centers for Disease Control and Prevention must be reviewed by an Institutional Review Board and all studies with human subjects must have Institutional Review Board oversight in order to remain in compliance with federal law.

The Division of Public Health Services has entered into a five-year cooperative agreement with the Centers for Disease Control and Prevention Division of Laboratory Sciences to expand the capability and capacity of the New Hampshire Public Health Laboratories to conduct high quality human biomonitoring to help identify chemical exposure and environmental health concerns in New Hampshire.

The Centers for Disease Control and Prevention awarded the BiomonitoringNH Program funding to contract with an institutional review board to review study protocols and materials directed at biomonitoring study participants. The review board assures compliance with the Federal Policy for the Protection of Human Subjects. Biomedical Research Alliance of New York's review of the BiomonitoringNH Program's study protocols and materials assures that the program meets all applicable laws and regulations regarding human subjects, including requirements of the Food and Drug Administration and the Office for Human Research Protections. Failure to follow these federal regulations could result in the loss of federal funding and severe legal penalties for the principal investigators and the Department of Health and Human Services.

The BiomonitoringNH Program will be conducting four studies across the state to obtain New Hampshire-specific biomonitoring information. New Hampshire residents that are at risk for environmental chemical exposure will be invited to participate and tested for metals, pesticides, per- and polyfluoroalkyl substances, volatile organic compounds, polycyclic aromatic hydrocarbons, and nicotine exposure. The information collected from these studies will be useful in evaluating public health policy, analyzing the allocation of resources, and addressing chemical exposure risk factors facing New Hampshire residents.

As referenced in Exhibit C-1, Revisions to General Provisions, Paragraph 3 of the original contract, the parties have the option to extend the agreement for up to three (3) additional years, contingent upon satisfactory delivery of services, available funding, agreement of the parties and Governor and Council approval. The Department is exercising its option to renew services for three (3) of the three (3) years available.

His Excellency, Governor Christopher T. Sununu
and the Honorable Council
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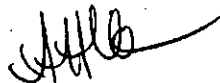
Should the Governor and Council not authorize this request there would be a loss of grant funding which equates to an annual amount of one million dollars and five full time scientists. Institutional Review Boards are governed by Title 45 of the Code of Federal Regulations Part 46, Protection of Human Subjects. Open human subject studies must remain under the oversight of an Institutional Review Board, otherwise the study must be closed. Studies that are closed before research is complete will be out of compliance with federal regulations and will be reported to the Food and Drug Administration and the Office of Human Research Protection, which would result in associated staff facing legal action. The Biomonitoring Program will have open human subject studies when the current contract expires on June 30, 2020. Maintaining contractual services with Biomedical Research Alliance of New York while biomonitoring studies are ongoing will assure the program remains in compliance with federal regulations.

Area served: Statewide

Source of Funds: CFDA #93.070 FAIN #NU88EH001327

In the event that the Federal Funds become no longer available, General Funds will not be requested to support this program.

Respectfully submitted,



LR Lori A. Shibinette
Commissioner

New Hampshire Department of Health and Human Services
Institutional Review Board Services



State of New Hampshire
Department of Health and Human Services
Amendment #1 to the Institutional Review Board Services Contract

This 1st Amendment to the Institutional Review Board Services contract (hereinafter referred to as "Amendment #1") is by and between the State of New Hampshire, Department of Health and Human Services (hereinafter referred to as the "State" or "Department") and Biomedical Research Alliance of New York, (hereinafter referred to as "the Contractor"), a limited liability company with a place of business at 1981 Marcus Avenue Suite 210, Lake Success, New York, 11042.

WHEREAS, pursuant to an agreement (the "Contract") approved by the Attorney General's Office on June 5, 2018, the Contractor agreed to perform certain services based upon the terms and conditions specified in the Contract and in consideration of certain sums specified; and

WHEREAS, pursuant to Form P-37, General Provisions, Paragraph 18, and Exhibit C-1, Revisions to General Provisions, Paragraph 3, the Contract may be amended upon written agreement of the parties and approval from the Governor and Executive Council; and

WHEREAS, the parties agree to extend the term of the agreement, increase the price limitation, or modify the scope of services to support continued delivery of these services; and

NOW THEREFORE, in consideration of the foregoing and the mutual covenants and conditions contained in the Contract and set forth herein, the parties hereto agree to amend as follows:

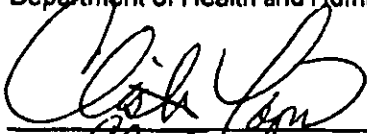
1. Form P-37 General Provisions, Block 1.7, Completion Date, to read:
June 30, 2023.
2. Form P-37, General Provisions, Block 1.8, Price Limitation, to read:
\$44,000.
3. Form P-37, General Provisions, Block 1.9, Contracting Officer for State Agency, to read:
Nathan D. White, Director.
4. Form P-37, General Provisions, Block 1.10, State Agency Telephone Number, to read:
603-271-9631.
5. Modify Exhibit B Method and Conditions Precedent to Payment, by replacing in its entirety with Exhibit B, Amendment #1, Method and Conditions Precedent to Payment, which is attached hereto and incorporated by reference herein.

All terms and conditions of the Contract not inconsistent with this Amendment #1 remain in full force and effect. This amendment shall be effective upon the date of Governor and Executive Council approval.

IN WITNESS WHEREOF, the parties have set their hands as of the date written below,

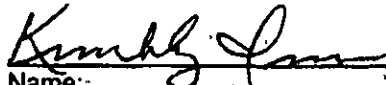
State of New Hampshire
Department of Health and Human Services

6-10-2020
Date


Name: Anita Tapan
Title: Associate Commissioner

Biomedical Research Alliance of New York

6/9/2020
Date


Name: Kimberly Irvine
Title: **Kimberly Irvine
EVP, Operations**

The preceding Amendment, having been reviewed by this office, is approved as to form, substance, and execution.

OFFICE OF THE ATTORNEY GENERAL

6/10/20
Date

Christen Lavers
Name:
Title: Assistant Attorney General

I hereby certify that the foregoing Amendment was approved by the Governor and Executive Council of the State of New Hampshire at the Meeting on: _____ (date of meeting)

OFFICE OF THE SECRETARY OF STATE

Date

Name:
Title:



Method and Conditions Precedent to Payment

1. The State shall pay the Contractor an amount not to exceed the Form P-37, Block 1.8, Price Limitation for the services provided pursuant to Exhibit A, Scope of Services.
2. This Agreement is funded with 100% Federal Funds from the Centers for Disease Control & Prevention (Biomonitoring New Hampshire), Preventive Health & Health Services Block Grant, Catalog of Federal Domestic Assistance (CFDA)#93.070, Federal Award Identification Number (FAIN)#NU88EH001327.
3. Failure to meet the scope of services may jeopardize the funded Contractor's current and/or future funding.
4. Payment for said services shall be made as follows:
 - 4.1. The Contractor shall submit an invoice on a fixed fee for service basis in a form satisfactory to the State by the twentieth (20th) working day of each month, which identifies and requests payment for authorized services provided during the prior month.
 - 4.2. Payment for services shall be on a fee for service basis utilizing the rates specified in Paragraphs 4.2.1 through 4.2.7, up to the amount specified in Form P-37, General Provisions, Block 1.8 Price Limitation.:

4.2.1. Initial Review

Review of protocol, informed consent document, drug/device brochure (if applicable) for greater than minimal risk research	\$2500
Review of protocol, informed consent (if applicable), drug/device brochure (if applicable) for minimal risk research	\$1700
Determination of Exempt Status	\$950

4.2.2. Continuing Review

Review of Protocol & Site's Application for Continuing Approval	\$1000
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KCP

6/19/2020

New Hampshire Department of Health and Human Services
 Institutional Review Board Services
Exhibit B, Amendment #1



4.2.3. Changes to Research

May include: <ul style="list-style-type: none"> • Protocol amendments/revisions • Consent form modifications • Change of Principal Investigator • Change of site/location • New/updated recruitment/retention materials • Study closeout report • Any other changes or safety information requiring IRB review 	\$325
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4.2.4. Serious Adverse Events

Review of Serious Adverse Event (occurring at local site)	\$200
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4.2.5. Safety/Adverse Event Reports Requiring Acknowledgement Only

Safety/Adverse Event Reports that are <i>not</i> serious, unexpected and associated with the use of the study agent	No Charge
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4.2.6. Foreign Language Consent


At your request, BRANY IRB will have the IRB approved consent(s) translated by a certified translation services vendor. <ul style="list-style-type: none"> • Cost of translation will be invoiced to you as a pass-through cost • BRANY will charge a nominal processing fee for this service • IRB review and acknowledgement of translations 	\$225
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4.2.7. IRB Study Transfer

Transfer of research oversight to BRANY IRB	\$550
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4.3. The Contractor shall ensure the invoice is completed, signed, dated and returned to the Department in order to initiate payment, and shall be in accordance with the approved fee schedule.

4.4. The State shall make payment to the Contractor within thirty (30) days of receipt of each invoice, subsequent to approval of the submitted invoice and if sufficient funds are available.


 Date 6/9/2020

New Hampshire Department of Health and Human Services
Institutional Review Board Services



Exhibit B, Amendment #1

5. The Contractor shall keep detailed records of their activities related to Department-funded programs and services and have records available for Department review, as requested.
6. The final invoice shall be due to the State no later than forty (40) days after the contract completion date specified in Form P-37, General Provisions Block 1.7 Completion Date.
7. In lieu of hard copies, all invoices may be assigned an electronic signature and emailed to PHLAccountsPayable@dhhs.nh.gov with a cc to Amanda.Cosser@dhhs.nh.gov, or invoices may be mailed to:

Financial Administrator
Department of Health and Human Services
29 Hazen Drive.
Concord, NH 03301
8. Payments may be withheld pending receipt of required reports or documentation as identified in Exhibit A, Scope of Services and in this Exhibit B.
9. Notwithstanding anything to the contrary herein, the Contractor agrees that funding under this agreement may be withheld, in whole or in part, in the event of non-compliance with any Federal or State law, rule or regulation applicable to the services provided, or if the said services or products have not been satisfactorily completed in accordance with the terms and conditions of this agreement.
10. Notwithstanding paragraph 18 of the General Provisions P-37, changes limited to adjusting amounts between budget line items, related items, amendments of related budget exhibits within the price limitation, and to adjusting encumbrances between State Fiscal Years, may be made by written agreement of both parties and may be made without obtaining approval of the Governor and Executive Council.

Kcf

6/9/2020

State of New Hampshire

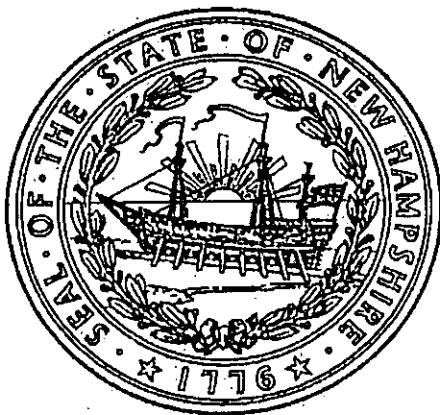
Department of State

CERTIFICATE

I, William M. Gardner, Secretary of State of the State of New Hampshire, do hereby certify that BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC is a New York Limited Liability Company registered to transact business in New Hampshire on November 04, 2010. I further certify that all fees and documents required by the Secretary of State's office have been received and is in good standing as far as this office is concerned.

Business ID: 638342

Certificate Number: 0004927904



IN TESTIMONY WHEREOF,

I hereto set my hand and cause to be affixed
the Seal of the State of New Hampshire,
this 9th day of June A.D. 2020.

A handwritten signature in black ink, appearing to read "William M. Gardner".

William M. Gardner
Secretary of State

CERTIFICATE OF AUTHORITY

I, Stephen Harvey, hereby certify that:

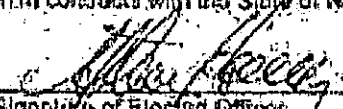
1. I am a duly elected Clerk/Secretary/Officer of Biomedical Research Alliance of New York, LLC.

2. The following is a true copy of a vote taken at a meeting of the Board of Directors/shareholders, duly called and held on July 25, 2019, at which a majority of the Director/shareholders were present and voting.

VOTED: That Kimberly Irvine is duly authorized on behalf of Biomedical Research Alliance of New York, LLC to enter into contracts or agreements with the State of New Hampshire and any of its agencies or departments and **Kevin** is authorized to execute any and all documents, agreements and other instruments, and any amendments, revisions, or modifications thereto, which may in his/her judgment be desirable or necessary to effect the purpose of the vote.

I hereby certify that said vote has not been amended or repealed and remains in full force and effect as of the date of the contract/contract amendment to which this certificate is attached. This authority remains valid for 90 (90) days from the date of this Certificate of Authority. I further certify that it is understood that the State of New Hampshire will rely on this certificate as evidence that the person(s) listed above currently occupy the said and/or indicated said that they have full authority to bind the corporation. To the extent that there are any facts on the authority of any listed individual to bind the corporation in contracts with the State of New Hampshire, said facts are expressly stated herein.

Date: 7/27/19



Signature of Elected Officer
Name: Stephen Harvey
Title: Board of Directors Member



CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
07/01/2019

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).


PRODUCER Willis of New York, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: PHONE (A/C, No, Ext): 1-877-945-7378 E-MAIL ADDRESS: certificates@willis.com		FAX (A/C, No): 1-888-467-2378
	INSURER(S) AFFORDING COVERAGE		NAIC #
INSURED Biomedical Research Alliance of NY, LLC Attn: Joanne Nicholson 1981 Marcus Avenue Suite 210 Lake Success, NY 11042 USA	INSURER A: Valley Forge Insurance Company		20508
	INSURER B: Transportation Insurance Company		20494
	INSURER C: Continental Assurance Company		62413
	INSURER D: INSURER E: INSURER F:		

COVERAGES CERTIFICATE NUMBER: W11924074 REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	<input checked="" type="checkbox"/> COMMERCIAL GENERAL LIABILITY			1089983012	06/30/2019	06/30/2020	EACH OCCURRENCE	\$ 1,000,000
	<input type="checkbox"/> CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	\$ 100,000
							MED EXP (Any one person)	\$ 15,000
							PERSONAL & ADV INJURY	\$ 1,000,000
							GENERAL AGGREGATE	\$ 2,000,000
							PRODUCTS - COMP/OP AGG	\$ 0
								\$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	\$
	<input type="checkbox"/> ANY AUTO						BODILY INJURY (Per person)	\$
	<input type="checkbox"/> OWNED AUTOS ONLY						BODILY INJURY (Per accident)	\$
	<input type="checkbox"/> HIRE AUTOS ONLY						PROPERTY DAMAGE (Per accident)	\$
	<input type="checkbox"/> SCHEDULED AUTOS NON-OWNED AUTOS ONLY							\$
	UMBRELLA LIAB						EACH OCCURRENCE	\$
	<input type="checkbox"/> EXCESS LIAB						AGGREGATE	\$
	<input type="checkbox"/> OCCUR							\$
	<input type="checkbox"/> CLAIMS-MADE							\$
	DED							\$
	RETENTION \$							\$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			1089987383	06/30/2019	06/30/2020	<input checked="" type="checkbox"/> PER STATUTE	<input type="checkbox"/> OTHER
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)	<input type="checkbox"/> Y/N	N/A				E.L. EACH ACCIDENT	\$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	\$ 1,000,000
C	Workers Compensation & Employers Liability			6045717931	06/30/2019	06/30/2020	E.L. EACH ACCIDENT	\$1,000,000
							E.L. DISEASE-EACH EMP	\$1,000,000
							E.L. DISEASE - POLICY	\$1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER NH DHHS Contracts & Procurement Unit 129 Pleasant Street Concord, NH 03301	CANCELLATION SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.
	AUTHORIZED REPRESENTATIVE 



II. Institutional Review Board Administration

II.1. Purpose of the IRB

The mission of the BRANY IRB is to protect the rights and ensure the welfare of all human research subjects. In taking on this responsibility, the BRANY IRB ensures that human subject research is conducted ethically and in compliance with applicable Federal, State, and local law (including tribal law, when applicable), and institutional requirements by performing prospective and continuing review of all human subject research conducted under its auspices. The BRANY IRB has provided written assurance to the Department of Health and Human Services in the form of its Federal Wide Assurance (FWA # 00000337). Such assurance requires the BRANY IRB to comply with the requirements of 45 CFR46. BRANY's FWA will be updated as necessary, but at least every 36 months (3 years), even if no changes have occurred, in order to maintain an active FWA, and to avoid restriction, suspension, or termination of the BRANY's FWA for the protection of human subjects.

BRANY IRB is a division of the Biomedical Research Alliance of New York LLC (BRANY), an organization founded by the following institutions: Montefiore Medical Center, Mount Sinai School of Medicine, NYU School of Medicine, and the Northwell Health System. BRANY IRB was appointed by its owner institutions to review and monitor research involving human subjects to ensure that the rights and welfare of those who participate as subjects in research are protected. BRANY's Management Committee (Board of Directors) appoints an Institutional Official (IO) with the authority to oversee BRANY's Human Research Protection Program, including the BRANY IRB and research under its purview, and to effect changes and take action(s) as necessary to ensure protection of human subjects. The IO reports to the Management Committee. The Management Committee is composed of representatives from BRANY's owner institutions, as well as an independent member(s). BRANY IRB may also function as a Central IRB or Single IRB for multi-center research. In accordance with Federal regulations (45 CFR 46.109, and 21 CFR 56.109) the IRB has the authority to approve, require modification in (to secure approval) or disapprove research involving human subjects. The IRB has the authority to suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. The IRB has the authority to observe or have a third party observe the consent process and the conduct of the research. The charge to the IRB is as follows:

- (a) To hold regularly scheduled meetings in order to review all research proposals involving human subjects.
- (b) To approve, require modification in or disapprove research activities that involve human subjects.
- (c) To ensure that information given to subjects as part of informed consent is in accord with the guidelines of the Department of Health and Human Services (DHHS).
- (d) To ensure that risks to research subjects are minimized, that any risks are reasonable in relation to anticipated benefits, and that selection of subjects is equitable, and that informed consent will be obtained and documented (where applicable).
- (e) To notify investigators and the institution, in writing, of its decision to approve or disapprove proposed research, and if disapproved, to suggest modifications that are required to secure approval.
- (f) To conduct continuing review, at least annually, of research involving human subjects.



- (g) To certify to the Department of Health and Human Services that an application has been reviewed and approved by the IRB.
- (h) To report to the appropriate institutional officials and the Office for Human Research Protections, Department of Health and Human Services, any serious or continuing non-compliance by investigators with the requirements and determinations of the IRB.
- (i) To periodically report on the activities of this committee to the BRANY Board of Directors.
- (j) To implement policies and procedures as needed to ensure the proper protection of human subjects.

No individual or group of individuals may inappropriately try to influence the deliberations and decisions of the BRANY IRB. Any IRB member may report any attempt to influence the decision of the BRANY IRB to the Institutional Official or the Director of the BRANY IRB. The IO, the Director and/or the BRANY Quality Assurance department will investigate such allegations. The results of the investigation will be documented. A response to the allegations will be prepared along with a corrective action plan, if needed, to ensure that there is no undue influence on the IRB members or on the committee's actions and determinations.

If the BRANY IRB does not approve a research project, no BRANY Official, or Officials (Institutional Official or Institution Liaison) of the organization where the research is taking place may override the BRANY IRB's decision. Research that is approved by BRANY IRB may be subject to further approval or disapproval by the local Institutional Official (if one exists) from the organization where the research is taking place and the BRANY Institutional Official.

The BRANY IRB is able to review research for institutions/investigators that have no requirement to use a local IRB. Local IRBs may also choose to have the BRANY IRB review and oversee research by designating the BRANY IRB as an IRB for the institution. Institutions with a Federalwide Assurance (FWA) must add the BRANY IRB as one of the IRBs of record. Institutions can decide on a study-by-study basis to designate the BRANY IRB by implementing a written agreement.

Research activities should not commence at any organization until IRB approval is received and any other approvals that may be required are in place.

II.2. Definition and Scope

II.2.A. Definition of Terms

II.2.A.1. Human Subjects Research Subject to FDA Regulation:

Under FDA regulations, individuals are considered "subjects" when they become a participant in research, either as a recipient of the test article or as a control (21 CFR 50.3(g), 21 CFR 56.103(e), 21 CFR 312.3(b)). If the research involves a medical device, individuals are considered "subjects" when they participate in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control (21 CFR 812.3(p)).

Under FDA regulations "research" means an activity involves an FDA regulated test article (use of a drug, other than the use of a marketed drug in the course of medical practice). The drug is either not approved by the FDA for marketing or it is not used in the course of medical practice. (For this policy "drug" means (i) an article recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to

**BIOMEDICAL RESEARCH ALLIANCE
OF NEW YORK LLC**

INDEPENDENT AUDITORS' REPORT

FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2019 AND 2018

BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC
INDEPENDENT AUDITORS' REPORT
FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2019 AND 2018

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LEHMAN FLYNN VOLLARO PLLC
CERTIFIED PUBLIC ACCOUNTANTS
534 BROADHOLLOW ROAD • SUITE 302
MELVILLE, NEW YORK 11747

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Members:
American Institute of CPAs
New York State Society of CPAs

INDEPENDENT AUDITORS' REPORT

To the Management Committee of
Biomedical Research Alliance of New York LLC
Lake Success, New York

We have audited the accompanying financial statements of Biomedical Research Alliance of New York LLC ("BRANY"), which comprise the balance sheets as of December 31, 2019 and 2018 and the related statements of operations, members' equity, and cash flows for the years then ended, and the related notes to the financial statements.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal controls relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal controls. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of BRANY as of December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

Lehman Flynn Vollaro CPAs

May 5, 2020

BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC
BALANCE SHEETS
DECEMBER 31,

ASSETS

	<u>2019</u>	<u>As adjusted*</u> <u>2018</u>
Current assets:		
Cash and cash equivalents	\$ 2,736,222	\$ 3,778,321
Investments	21,132,691	13,784,969
Accounts receivable, net of allowance for doubtful accounts of \$260,000 for 2019 and 2018	3,337,524	2,964,959
Prepaid expenses and other assets	<u>455,186</u>	<u>425,564</u>
Total current assets	<u>27,661,623</u>	<u>20,953,813</u>
Property and equipment, net	1,364,822	1,630,562
Other assets:		
Goodwill and other intangible assets, net	1,678,533	1,800,271
Collateralized letters of credit and security deposits	262,118	259,886
Deferred commissions	144,907	100,374
Investments, net of current portion	<u>5,412,169</u>	<u>2,533,563</u>
Total other assets	<u>7,497,727</u>	<u>4,694,094</u>
Total assets	<u>\$ 36,524,172</u>	<u>\$ 27,278,469</u>

LIABILITIES AND MEMBERS' EQUITY

Current liabilities:		
Accounts payable and accrued expenses	\$ 1,020,836	\$ 590,134
Accrued payroll and related expenses	1,116,634	1,004,718
Deferred revenue	5,917,606	4,870,665
Other contract liabilities	1,215,052	1,238,474
Current portion of long-term debt	<u>8,790</u>	<u>9,589</u>
Total current liabilities	<u>9,278,918</u>	<u>7,713,580</u>
Capitalized lease obligations	<u>3,787</u>	<u>12,576</u>
Total liabilities	<u>9,282,705</u>	<u>7,726,156</u>
Members' equity:		
Equity contributions, net	7,076,368	7,076,368
Retained earnings	20,124,190	12,522,745
Accumulated other comprehensive income (loss)	<u>40,909</u>	<u>(46,800)</u>
Total members' equity	<u>27,241,467</u>	<u>19,552,313</u>
Total liabilities and members' equity	<u>\$ 36,524,172</u>	<u>\$ 27,278,469</u>

*See note 1

See accompanying notes.

BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC
STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31,

	<u>2019</u>	<u>As adjusted*</u> <u>2018</u>
Revenues:		
Research revenue, net	\$ 10,419,071	\$ 9,562,056
Online education revenue	10,795,530	8,824,239
Other income	<u>2,780,459</u>	<u>2,684,076</u>
Total revenues	<u>23,995,060</u>	<u>21,070,371</u>
Operating expenses:		
Salaries	8,486,965	8,337,348
Employee benefits	1,904,376	1,864,717
Professional and consulting fees	2,821,237	2,627,886
Occupancy costs	701,291	461,433
Insurance	166,301	149,086
Administrative and general	1,662,321	1,413,680
Supplies and other	31,041	28,226
Depreciation and amortization	<u>924,332</u>	<u>882,641</u>
Total operating expenses	<u>16,697,864</u>	<u>15,765,017</u>
Income from operations	<u>7,297,196</u>	<u>5,305,354</u>
Other income/expense:		
Interest and other income	457,481	206,821
Interest and other expense	<u>(18,461)</u>	<u>(71,493)</u>
Total other income, net	<u>439,020</u>	<u>135,328</u>
Net income before income taxes	7,736,216	5,440,682
Provision for income taxes	<u>(134,771)</u>	<u>(94,443)</u>
Net income	<u>\$ 7,601,445</u>	<u>\$ 5,346,239</u>

*See note 1

See accompanying notes.

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BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC
 STATEMENTS OF MEMBERS' EQUITY
 YEARS ENDED DECEMBER 31, 2019 AND 2018

	Equity Contributions, net	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Total Members' Equity
Balance January 1, 2018 as adjusted*	\$ 7,076,368	\$ 7,176,506	\$ (50,962)	\$ 14,201,912
Comprehensive income (loss):				
Net income	-	5,346,239	-	5,346,239
Changes in unrealized gain (loss) on investments	-	-	4,162	4,162
Total comprehensive income (loss)	-	5,346,239	4,162	5,350,401
Balance December 31, 2018 as adjusted*	\$ 7,076,368	\$ 12,522,745	\$ (46,800)	\$ 19,552,313
Comprehensive income (loss):				
Net income	-	7,601,445	-	7,601,445
Changes in unrealized gain (loss) on investments	-	-	87,709	87,709
Total comprehensive income (loss)	-	7,601,445	87,709	7,689,154
Balance December 31, 2019	\$ 7,076,368	\$ 20,124,190	\$ 40,909	\$ 27,241,467

*See note 1

See accompanying notes.

BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC
STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31,

	2019	As adjusted* 2018
Cash flows from operating activities:		
Net income	\$ 7,601,445	\$ 5,346,239
Depreciation and amortization	924,332	882,641
Bad debt expense	38,638	-
Change in unrealized holding gain or loss	87,709	4,162
Loss on disposal of assets	5,623	65,288
Changes in assets and liabilities:		
Accounts receivable	(411,203)	(277,878)
Prepaid expenses and other assets	(76,387)	(155,086)
Accounts payable and accrued expenses	430,702	(157,793)
Accrued payroll and related expenses	111,916	177,517
Other contract liabilities	(23,422)	386,463
Deferred revenue	1,046,941	1,457,964
Net cash provided by operating activities	9,736,294	7,729,517
Cash flows from investing activities:		
Acquisitions of property and equipment	(417,477)	(414,933)
Acquisition of Acentral, Inc.	(125,000)	-
Proceeds from sales of investments	16,025,000	8,097,000
Purchases of investments	(26,251,328)	(15,701,615)
Net cash used in investing activities	(10,768,805)	(8,019,548)
Cash flows from financing activities:		
Repayment of long-term debt	(9,588)	(9,161)
Net cash used in financing activities	(9,588)	(9,161)
Change in cash and cash equivalents	(1,042,099)	(299,192)
Cash and cash equivalents at beginning of year	3,778,321	4,077,513
Cash and cash equivalents at end of year	\$ 2,736,222	\$ 3,778,321
Supplemental disclosures of cash flow information:		
Cash paid during the year for:		
Interest	\$ 893	\$ 1,321
Income taxes	\$ 117,878	\$ 93,588

*See note 1

See accompanying notes.

BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2019 AND 2018

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Founded in 1998, the Biomedical Research Alliance of New York (the "Company") is a research support services company focused on assisting hospitals, academic medical centers, and investigators with conducting efficient, high quality research. The Company is currently owned by four of the five founding members: Montefiore Medical Center, New York University School of Medicine, the Icahn School of Medicine at Mount Sinai (formerly the Mount Sinai School of Medicine) and Northwell Health (formerly the North Shore Long Island Jewish Health System) (collectively referred to as the "Members"). St Vincent's Catholic Medical Centers of NY, one of the Company's original founders, withdrew its membership in 2011.

The Company's services include clinical research administration services (such as contracting, IRB review, research billing), online research education and training, research compliance consulting, and licensing of research technology support software.

The Company was organized as a limited liability company (LLC) in New York State on March 11, 1998 and commenced operations on September 1st of the same year.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less at the date of purchase to be cash equivalents.

Investments

Investments at December 31, 2019 and 2018 consist of government securities, corporate bonds, and various certificates of deposit. The Company accounts for these investments under the provisions of ASC 320, "Investments in Debt and Equity Securities." The Company has classified its investments as available-for-sale. Available-for-sale securities are recorded at fair value, which is determined based upon quoted market prices. Unrealized holding gains and losses on available-for-sale securities are excluded from earnings and are reported as a separate component of members' equity as accumulated other comprehensive income (loss), until realized. Investment income is recognized when earned. Investments with maturities of less than one year from the balance sheet date are classified as current assets. Investments with maturities greater than one year from the balance sheet date are classified as long-term assets.

The provisions of ASC 320 "Investments in Debt and Equity Securities" relate to the recognition, measurement and presentation for other than temporary impairments of debt securities, and define certain disclosure requirements. With respect to an investment in a debt security, an other than temporary impairment is recognized if the investor (a) intends to sell or expects to be required to sell the debt security

BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2019 AND 2018
(CONTINUED)

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – continued

before the amortized cost is recovered or (b) does not expect to ultimately recover the amortized cost basis even if it does not intend to sell the security. Losses under (a) are recognized in earnings. Under (b) the credit loss component is recognized in earnings and any difference between fair value and the amortized cost basis net of the credit loss is reflected in other comprehensive income (loss).

Property and Equipment

Property and equipment are recorded at cost when purchased. Depreciation is calculated on the straight-line method over the estimated useful lives of depreciable assets (three to seven years). Leasehold improvements are amortized over the life of the respective leases.

Revenue Recognition

The Company recognizes revenue, which is derived solely from its customers, when it satisfies performance obligations under the terms of its contracts and control of its services are transferred to its customers in an amount that reflects the consideration the Company expects to receive from its customers in exchange for those services. Revenue is recognized using the following steps: (1) identify the contract, (2) identify the performance obligations, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue as or when the performance obligations are satisfied. A performance obligation is considered distinct from other obligations in a contract when it (a) provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and (b) is separately identified in the contract. Revenue is recognized net of any taxes collected from customers and subsequently remitted to government authorities. Contracts with customers generally state the terms of the sale. Our contracts generally do not have any obligations for returns, refunds or warranties. There were no significant judgments made when applying Topic 606 to revenue from our customers other than identification of performance obligations. Where applicable, we determine the relative stand-alone selling price utilizing our observable prices for the sale of the underlying services.

The Company generates the majority of its revenue from providing clinical trial research administration services, online research compliance education services, and research compliance consulting services.

Disaggregation of revenue

We disaggregate revenue from contracts with customers by major service offering. We determined that disaggregating revenue into this category achieves the disclosure objective of illustrating the differences in the nature, amount, timing, and uncertainty of our revenue streams.

	Year ended December 31, 2019
<i>Major service offering</i>	
Clinical trial research administration services	\$ 10,419,071
Online research compliance education services	\$ 10,795,530
Research compliance consulting services	\$ 2,535,271
Other	\$ 245,188

Other revenue consists of software as a service (SaaS) and site brokerage revenues that are not material to overall revenues.

BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2019 AND 2018
(CONTINUED)

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – continued

Revenues are generally recognized as follows:

Clinical trial research administration

Performance obligations are determined based on the nature of services provided. Performance obligations are primarily the provision of clinical trial start-up services, Medicare coverage analysis, IRB review, and clinical trial billing. Revenue for clinical trials and the related professional services is recognized over time, using the right to invoice practical expedient. Revenue for IRB review and clinical trial startup services is recognized at a point in time when control of the service transfers to the customer. Service revenues are recorded at gross amounts (for Medicare coverage analysis, IRB review, and start-up services) and net amounts (for clinical trial billing), in accordance with the principal versus agent provisions outlined in Topic 606. Payment terms and conditions may vary by contract, and the contracts generally do not include a significant financing component. In addition, contracts typically do not contain variable consideration or non-cash consideration. Consideration payable to a customer may exist in some contracts through rebates.

Online research compliance education

Performance obligations are primarily the access to a subscription or access to a course. We determine the relative stand-alone selling price utilizing our observable prices for the sale of the underlying services. These services are generally provided under subscription arrangements which most customers renew at the end of each subscription term. Revenue primarily consists of fees to access educational content delivered electronically and is recurring in nature. Revenue is recognized over time on a ratable basis over the contract term. Payment terms and conditions may vary by contract, although generally are in advance. As a result, the contracts do not include a significant financing component. In addition, contracts typically do not contain variable consideration, non-cash consideration or consideration payable to a customer.

Research compliance consulting

Performance obligations are primarily the consulting service. Performance obligations for these services are satisfied over time based on a time elapsed measure of progress. These contracts do not include a significant financing component, variable consideration, non-cash consideration or consideration payable to a customer.

Contract assets and contract liabilities

Deferred Commissions (contract asset)

Sales commissions earned by our sales force are capitalized as costs to obtain a contract when the costs incurred are incremental and are expected to be recovered. Deferred sales commissions are amortized on a systematic basis that is consistent with the transfer to the customer of the goods or services to which the asset relates.

Deferred Revenue (contract liability)

Deferred revenue is recorded when cash payments are received or due in advance of the transfer of the related services.

BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2019 AND 2018
(CONTINUED)

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – continued

Asset Recoverability

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

Income Taxes

The Company, with the consent of the Members, has elected to have its income or loss taxed as a partnership. This election provides that the Members are taxed on their proportionate share of the Company's taxable income or loss. The Company is subject to New York City Unincorporated Business Tax and various other state income and fee based taxes.

New Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606). This standard outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry specific guidance. The main principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. We adopted Topic 606 using the full retrospective method which applied Topic 606 to all periods presented.

Adoption of the new standard resulted in changes to our revenue recognition policies in the areas of clinical trial administration and sales commissions. Refer to our accounting policies section above for additional information on our accounting policies for revenue recognition and capitalized sales commissions.

In July 2018, the FASB issued ASU 2018-11, Leases (Topic 842): Targeted Improvements, which provides an optional transition method that allows entities to initially apply ASC 842 at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings on the adoption date. We will elect to adopt ASC 842 using the new transition method provided by ASU 2018-11. We will elect the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allows us to carryforward the historical lease classification. We will also elect the practical expedient to keep leases with an initial term of 12 months or less off of the balance sheet. The Company is currently in the process of evaluating the impact of the pending adoption of this accounting guidance on its financial statements, which is effective as of January 1, 2021.

Subsequent Events

ASC 855 "Subsequent Events" sets forth general accounting and disclosure requirements for events that occur subsequent to the balance sheet date but before the Company's financial statements are issued. We have evaluated events through May 5, 2020.

BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2019 AND 2018
(CONTINUED)

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – continued

In March 2020, the World Health Organization declared the outbreak of novel coronavirus disease (“COVID-19”) as a pandemic, and on March 7, 2020, the Governor of New York issued Executive Order Number 202, declaring a state disaster emergency for the entire State of New York. Consequently, many clinical trials in the New York region have instituted an enrollment pause and have suspended in-person clinical visits. In addition, stay at home orders across the country have paused research related consulting activities at the Company’s higher education and healthcare clients. Management is currently evaluating the impact of the COVID-19 pandemic on the industry and has concluded that while it is reasonably possible that the pandemic could have a negative effect on the Company’s financial position and results of its operations, the specific impact is not readily determinable as of the date of these financial statements.

In addition, the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”) was signed into federal law March 27, 2020, and includes, among other things, relief for small businesses under the Paycheck Protection Program (PPP). Due to the economic uncertainty of the current environment with respect to clinical trial research, the Company applied for a PPP loan, and subsequently received funding on May 5, 2020 in the amount of \$1,041,054. The loan must be used to pay for qualifying payroll, rent, and utility expenses, and may be partially or fully forgiven in accordance with the requirements of the PPP, including the provisions of Section 1106 of the CARES Act (P.L. 116-136). The Company may apply for loan forgiveness eight weeks after the loan disbursement date. Any amount of the loan that is not forgiven will be payable in 18 equal monthly installment beginning six months after the loan disbursement date, at an annual interest rate of 1%.

2. FAIR VALUE MEASUREMENTS

The estimated fair values of our financial instruments as of December 31, 2019 and 2018 are shown in the following table. The carrying values of cash and cash equivalents, accounts receivable and accounts payable, accruals, and other liabilities are deemed to be reasonable estimates of their fair value.

	Fair Market Value		Carrying Value	
	2019	2018	2019	2018
Investments in fixed maturity securities	\$ 26,544,860	\$ 16,318,532	\$ 26,544,860	\$ 16,318,532

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants as of the measurement date. Fair value measurements assume the asset or liability is exchanged in an orderly manner; the exchange is in the principal market for that asset or liability (or in the most advantageous market when no principal market exists); and the market participants are independent, knowledgeable, able and willing to transact an exchange.

Fair values for substantially all of our financial instruments were measured using market or income approaches. Considerable judgment may be required in interpreting market data used to develop the estimates of fair value. Accordingly, the estimates presented herein are not necessarily indicative of the amounts that could be realized in an actual current market exchange. The use of different market assumptions and/or estimation methodologies may have a material effect on the estimated fair value.

The hierarchy for measuring fair value consists of Levels 1 through 3.

BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2019 AND 2018
(CONTINUED)

2. FAIR VALUE MEASUREMENTS – continued

Level 1 – Inputs represent unadjusted quoted prices for identical assets or liabilities exchanged in active markets. Substantially all of our fixed maturity securities are traded on an exchange in active markets and fair value is based on the closing prices as of the balance sheet date.

Level 2 – Inputs include directly or indirectly observable inputs (other than Level 1 inputs) such as quoted prices for similar assets or liabilities exchanged in active or inactive markets; quoted prices for identical assets or liabilities exchanged in inactive markets; other inputs that may be considered in fair value determinations of the assets or liabilities, such as interest rates and yield curves, volatilities, prepayment speeds, loss severities, credit risks and default rates; and inputs that are derived principally from or corroborated by observable market data by correlation or other means. Pricing evaluations are based on yield curves for instruments with similar characteristics, such as credit rating, estimated duration, and yields for other instruments of the issuer or entities in the same industry sector.

Level 3 – Inputs include unobservable inputs used in the measurements of assets and liabilities. Management is required to use its own assumptions regarding unobservable inputs because there is little, if any, market activity in the assets or liabilities or related observable inputs that can be corroborated at the measurement date. Unobservable inputs require management to make certain projections and assumptions about the information that would be used by market participants in pricing assets or liabilities. Measurements of non-exchange traded derivative contracts and certain other investments carried at fair value are based primarily on valuation models, discounted cash flow models or other valuation techniques that are believed to be used by market participants.

Financial assets and liabilities measured and carried at fair value on a recurring basis in our financial statements as of December 31, 2019 and 2018 are summarized according to the hierarchy previously described as follows:

	Total Fair Value	Quoted Prices Level (1)	Significant Other Observable Inputs Level (2)	Significant Unobservable Inputs Level (3)
December 31, 2019				
US Government Securities	\$ 23,103,314	\$ 23,103,314	\$ -	\$ -
Certificates of Deposit	2,443,544	2,443,544	-	-
Corporate Bonds	998,002	-	998,002	-
	<u>\$ 26,544,860</u>	<u>\$ 25,546,858</u>	<u>\$ 998,002</u>	<u>\$ -</u>
	Total Fair Value	Quoted Prices Level (1)	Significant Other Observable Inputs Level (2)	Significant Unobservable Inputs Level (3)
December 31, 2018				
US Government Securities	\$ 13,256,338	\$ 13,256,338	\$ -	\$ -
Certificates of Deposit	2,568,457	2,568,457	-	-
Corporate Bonds	493,737	-	493,737	-
	<u>\$ 16,318,532</u>	<u>\$ 15,824,795</u>	<u>\$ 493,737</u>	<u>\$ -</u>

BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2019 AND 2018
(CONTINUED)

3. PROPERTY AND EQUIPMENT

At December 31, 2019 and 2018, property and equipment, at cost, and accumulated depreciation and amortization are as follows:

	2019	2018
Information technology	\$ 2,284,544	\$ 2,123,501
Course content library	1,605,822	1,466,262
Telephones and other equipment	75,587	71,893
Furniture & fixtures	314,226	266,701
Leasehold improvements	250,249	232,707
	4,530,428	4,161,064
Less accumulated depreciation and amortization	(3,165,606)	(2,530,502)
Property and equipment - net	\$ 1,364,822	\$ 1,630,562

4. RELATED PARTY TRANSACTIONS

The Company earns revenue from its Members for research administration, consulting, and online education services provided. Revenues received from the Members amounted to \$1,372,000 in 2019 and \$1,504,000 in 2018.

The Company performs clinical trial billing and collection services on behalf of its Members pursuant to negotiated agreements between the respective Member and clinical trial sponsor, whereby the Company acts as agent on behalf of its Members. Fees collected on behalf of the Members amounted to approximately \$16,762,000 in 2019 and \$16,202,000 in 2018.

5. RETIREMENT PLAN

The Company maintains a 401(k) Profit Sharing Plan that allows eligible employees to allocate up to 75% of their salary through payroll deductions. An employee is eligible to participate in the plan after completing six months of service. Eligible employees will receive a 100% match of their employee contributions up to a discretionary maximum percentage (8% in 2019 and 2018). Employees vest in employer contributions in 20% increments, beginning with the second year of service and become fully vested after six years of service. Expenses related to the 401(k) plan, including administrative expenses, were approximately \$464,000 and \$445,000 for the years ended December 31, 2019 and 2018, respectively.

BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2019 AND 2018
(CONTINUED)

6. INCOME TAXES

The Company files income tax returns in the U.S. federal jurisdiction, and state and local jurisdictions. The Company is no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations by tax authorities for years before 2016.

The provision for income taxes consists of the following:

	2019	2018
New York City Unincorporated Business Tax	\$ 131,721	\$ 93,067
Other	3,050	1,376
	\$ 134,771	\$ 94,443

7. COMMITMENTS AND CONTINGENCIES

The Company is insured under a professional liability policy of \$5 million per occurrence and \$5 million in the aggregate. This coverage is for claims arising in the ordinary course of business. The Company's contracts with its sponsors carry indemnification clauses to indemnify the Company from liability associated with the sponsor's experimental medication and sponsor's defined protocols.

The Company leases certain equipment under various capital lease arrangements that expire at various dates through 2021. Assets recorded under capitalized lease arrangements are included in property and equipment and consist of the following:

	2019	2018
Computers and office equipment	\$ 44,274	\$ 44,274
Accumulated depreciation	(32,793)	(23,419)
	\$ 11,481	\$ 20,855

In 2018, the Company extended its long-term operating lease agreement for its New York location. The original lease was effective March 1, 2009 and was scheduled to expire February 29, 2020. The new lease extension expires August 31, 2028. In 2018, the Company also entered into an operating lease for its Florida location. The lease was effective November 1, 2018 and expires March 31, 2026.

BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2019 AND 2018
(CONTINUED)

7. COMMITMENTS AND CONTINGENCIES – continued

The following is a schedule by year of future minimum lease payments under capital and operating leases that have initial or remaining lease terms in excess of one year as of December 31, 2019:

Year ending December 31,	Capital Leases	Operating Leases
2020	\$ 9,235	\$ 522,304
2021	3,907	654,961
2022	-	676,232
2023	-	698,252
2024	-	720,980
Thereafter	-	2,260,772
Total minimum lease payments	13,142	5,533,501
Less amounts representing interest	(565)	-
Present value of minimum lease payments	12,577	\$ 5,533,501
Less current maturities	(8,790)	
Long-term obligations	<u>\$ 3,787</u>	

Rent expenses under the agreements approximated \$669,000 and \$457,000 for the years ended December 31, 2019 and 2018, respectively.

8. CONCENTRATIONS

As of December 31, 2019 and 2018, financial instruments that potentially subject the Company to a concentration of credit risk include cash accounts with two major financial institutions that are over FDIC insurance limits of \$250,000. Management believes that credit risk related to these accounts is minimal.



Management Committee Membership

Brian Currie, MD

Chairman

Montefiore Medical Center

Donna Drummond

Senior Vice President, Consolidated Services
Northwell Health System

Stephen T. Harvey

Secretary

Senior Vice President Finance
Mount Sinai School Of Medicine

David N. Deutsch

Treasurer

President
David N. Deutsch & Company LLC

Imad Alsayed

Vice President
Clinical Research Operations & Regulatory Affairs
NYU Langone Health

Robert Van Nostrand

Member

Raffaella Hart, MS, CIP

1981 Marcus Ave, Ste 210 Telephone (516) 318-6877
Lake Success, NY 11042 Email: rhart@brany.com

Summary

- Experienced in attaining and maintaining HRPP accreditation; AAHRPP site visitor.
- Broad understanding of the clinical trials/pharmaceutical industry, academic medical centers, and medical practices.
- In-depth knowledge of DHHS and FDA research regulations, the ICH Guidelines, and the *NIH Guidelines for Research Involving Synthetic or Recombinant Nucleic Acid Molecules*.
- Excellent analytical, oral and written communication skills.
- Successful team leader and team worker.

Experience

2000—Present Biomedical Research Alliance of New York (BRANY) Great Neck, NY
VP, IRB and IBC Services

- Responsible for BRANY's IRB, which serves as a central IRB for sponsors, and an independent IRB serving 6 major academic medical centers, their affiliates in the tri-state and NY metropolitan area, several New York City hospitals, independent research facilities throughout the US, and 2 hospital systems outside New York.
- Oversee activities of BRANY's IBC Services, administering IBCs for academic medical centers, their affiliates in the tri-state and NY metropolitan area, and independent research facilities throughout the US.
- Oversee activities of BRANY's Independent Conflict of Interest Committee, reviewing and managing study-specific disclosures for organizations/institutions requiring infrastructure support.
- Responsible for company-wide efforts resulting in obtaining full accreditation for BRANY's Human Research Protection Program (HRPP) from the Association for Accreditation of Human Research Protection Programs (AAHRPP), and maintaining full accreditation since December 2006.
- Co-directed company-wide effort resulting in national accreditation for the IRB from the Partnership for Human Research Protections, Inc. (PHRP), a JCAHO/NCQA collaboration, in April 2004.
- Maintain, update, and develop current HRPP and IRB policies and procedures; provide continuing education to IRB membership and HRPP staff.
- Communicate with regulatory agencies, investigators, sponsors, CROs, and committee membership to ensure projects are conducted in accordance with Federal regulations, state law and BRANY Standard Operating Procedures.
- Collaborate with BRANY Quality Assurance team to provide continuous quality improvement to BRANY's HRPP and IRB functions.
- Coach, train and educate administrative and support staff of 15.
- Participate in BRANY's strategic and operational planning.
- Auditor and consultant to IRBs of other research institutions. Provide guidance in complying with Federal regulations, including research of technical issues, and detailed report of findings.
- Provided consultation for initial and continued development of IRBManager™, a proprietary software specific to IRB management.

Raffaella Hart, MS, CIP

2009–present Association for Accreditation of Human Research Protection Programs (AAHRPP)

Site Visitor

- Participate on team of individuals charged with reviewing applications for accreditation and conducting an on-site review to ensure policies, procedures and practices described in the organization's application are being carried out.
- Conduct interviews with all levels of organizational personnel to understand the individual's role in the Human Research Protection Program at the institution.
- Conduct thorough records inspection to evaluate organization's adherence to policies.
- Serve mainly as site visitor for academic medical centers.

1998–2000 Financial Medical Management Ronkonkoma, NY

Billing Manager

- Within 8 months progressed from billing clerk to supervisor, and to billing manager one year later.
- Interviewed, oriented, trained and supervised staff of 5 with ultimate responsibility for the processing of greater than 1000 weekly physician invoices.
- Provided troubleshooting of accounts via telephone, letters, and personal contact, including assistance of foreign language speaking clients.
- Analyzed physician coding weaknesses and compiled proposals with reference materials necessary to rectify these weaknesses, emphasizing guideline compliance.
- Streamlined billing procedures to coordinate processing of accounts for 4 different medical practices, resulting in a substantial increase in client and company revenue.
- Assisted in conversion from DOS-based to Windows-based computer billing system.

Education/ Certifications

2011–2016 The George Washington University Washington, DC

- Master of Science in Health Science, Clinical Research Administration (May 2016)

2001-Present CIP – Certified IRB Professional

- Certification provided by the Council for Certification of IRB Professionals (CCIP), through PRIM&R

1993–1997 S.U.N.Y Binghamton Binghamton, NY

- Bachelor of Science, Psychobiology.
- Minor: Russian Language and Literature.

Publications

- O'Rourke, P., Carrithers, J., Patrick-Lake, B. Rice, T.W., Corsmo, J., Hart, R., Drezner, M.K., Lantos, J.D. (2015). Harmonization and streamlining of research oversight for pragmatic clinical trials. *Clinical Trials*, 12(5). 449-456. DOI: 10.1177/1740774515597685
- Hart, R. (2014). FDA guidance for IRBs: Implications for investigators. *The Monitor*.
- Hart, R. (2013, April). Implications of FDA draft guidance: Assessing investigator qualifications. *The CenterWatch Monthly*.
- Hart, R., & Belotto, M. (2010). The Institutional Review Board. *Seminars in Nuclear Medicine*, 40(5). 385-392. doi:10.1053/j.semnuclmed.2010.03.007

Raffaella Hart, MS, CIP

- Contributing author: *Working Effectively With and Within IRBs*, edited by Eileen Hilton, MD and Deirdre Hall, CCRC, CCRA, CIP, University Publishing Group, 2005.

Affiliations / Membership

- PCORnet IRB Workgroup Member
- New York City's INSIGHT Clinical Data Research Network (INSIGHT CDRN) – Privacy Committee Chair (2013 – present)
- CTTI – Clinical Trials Transformation Initiative
- PRIM&R (Public Responsibility in Medicine and Research) Member
- Founding Member, Delta Epsilon Mu Pre-Health Fraternity, which provides social and educational opportunities for those in pursuit of careers in the health field, including pre-medical, nursing, dental, physical therapy, clinical psychology and health administration – S.U.N.Y. Binghamton, Binghamton, NY

CONTRACTOR NAME

Key Personnel

Name	Job Title	Salary	% Paid from this Contract	Amount Paid from this Contract
Raffaella Hart, MS, CIP	VP, IRB & IBC Services	164, 727.42	0.71%	1176.63

Subject: Institutional Review Board Services/SS-2018-DPHS-04-INST1

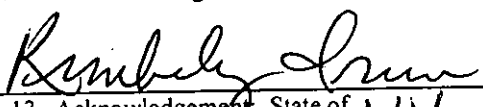
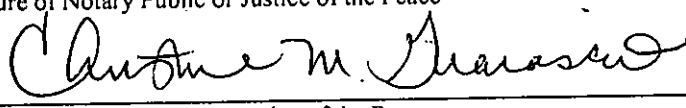


Notice: This agreement and all of its attachments shall become public upon submission to Governor and Executive Council for approval. Any information that is private, confidential or proprietary must be clearly identified to the agency and agreed to in writing prior to signing the contract.

AGREEMENT

The State of New Hampshire and the Contractor hereby mutually agree as follows:

GENERAL PROVISIONS

I. IDENTIFICATION.

1.1 State Agency Name NH Department of Health and Human Services		1.2 State Agency Address 129 Pleasant Street Concord, NH 03301-3857	
1.3 Contractor Name Biomedical Research Alliance of New York		1.4 Contractor Address 1981 Marcus Avenue Suite 210 Lake Success, New York, 11042	
1.5 Contractor Phone Number 516-470-6909	1.6 Account Number 05-095-090-903010-8280000-102-500731-90082801	1.7 Completion Date June 30, 2020	1.8 Price Limitation \$9,500
1.9 Contracting Officer for State Agency E. Maria Reinemann, Esq. Director of Contracts and Procurement		1.10 State Agency Telephone Number 603-271-9330	
1.11 Contractor Signature 		1.12 Name and Title of Contractor Signatory Kimberly Irvine, EVP	
1.13 Acknowledgement: State of <u>NY</u> , County of <u>Nassau</u> On <u>May 9th, 2018</u> , before the undersigned officer, personally appeared the person identified in block 1.12, or satisfactorily proven to be the person whose name is signed in block 1.11, and acknowledged that s/he executed this document in the capacity indicated in block 1.12.			
1.13.1 Signature of Notary Public or Justice of the Peace  [Seal]		CHRISTINE M GUARASCIO NOTARY PUBLIC-STATE OF NEW YORK No. 01GU6209959 Qualified in Suffolk County My Commission Expires 08-03-2021	
1.13.2 Name and Title of Notary or Justice of the Peace Christine M. Guarascio			
1.14 State Agency Signature 	1.15 Name and Title of State Agency Signatory LISA MARRIS, DIRECTOR DPHS		
1.16 Approval by the N.H. Department of Administration, Division of Personnel (if applicable) By: _____ Director, On: _____			
1.17 Approval by the Attorney General (Form, Substance and Execution) (if applicable) By:  On: <u>6.5.18</u>			
1.18 Approval by the Governor and Executive Council (if applicable) By: _____ On: _____			

2. EMPLOYMENT OF CONTRACTOR/SERVICES TO BE PERFORMED. The State of New Hampshire, acting through the agency identified in block 1.1 ("State"), engages contractor identified in block 1.3 ("Contractor") to perform, and the Contractor shall perform, the work or sale of goods, or both, identified and more particularly described in the attached EXHIBIT A which is incorporated herein by reference ("Services").

3. EFFECTIVE DATE/COMPLETION OF SERVICES.

3.1 Notwithstanding any provision of this Agreement to the contrary, and subject to the approval of the Governor and Executive Council of the State of New Hampshire, if applicable, this Agreement, and all obligations of the parties hereunder, shall become effective on the date the Governor and Executive Council approve this Agreement as indicated in block 1.18, unless no such approval is required, in which case the Agreement shall become effective on the date the Agreement is signed by the State Agency as shown in block 1.14 ("Effective Date").

3.2 If the Contractor commences the Services prior to the Effective Date, all Services performed by the Contractor prior to the Effective Date shall be performed at the sole risk of the Contractor, and in the event that this Agreement does not become effective, the State shall have no liability to the Contractor, including without limitation, any obligation to pay the Contractor for any costs incurred or Services performed. Contractor must complete all Services by the Completion Date specified in block 1.7.

4. CONDITIONAL NATURE OF AGREEMENT.

Notwithstanding any provision of this Agreement to the contrary, all obligations of the State hereunder, including, without limitation, the continuance of payments hereunder, are contingent upon the availability and continued appropriation of funds, and in no event shall the State be liable for any payments hereunder in excess of such available appropriated funds. In the event of a reduction or termination of appropriated funds, the State shall have the right to withhold payment until such funds become available, if ever, and shall have the right to terminate this Agreement immediately upon giving the Contractor notice of such termination. The State shall not be required to transfer funds from any other account to the Account identified in block 1.6 in the event funds in that Account are reduced or unavailable.

5. CONTRACT PRICE/PRICE LIMITATION/PAYMENT.

5.1 The contract price, method of payment, and terms of payment are identified and more particularly described in EXHIBIT B which is incorporated herein by reference.

5.2 The payment by the State of the contract price shall be the only and the complete reimbursement to the Contractor for all expenses, of whatever nature incurred by the Contractor in the performance hereof, and shall be the only and the complete compensation to the Contractor for the Services. The State shall have no liability to the Contractor other than the contract price.

5.3 The State reserves the right to offset from any amounts otherwise payable to the Contractor under this Agreement those liquidated amounts required or permitted by N.H. RSA 80:7 through RSA 80:7-c or any other provision of law.

5.4 Notwithstanding any provision in this Agreement to the contrary, and notwithstanding unexpected circumstances, in no event shall the total of all payments authorized, or actually made hereunder, exceed the Price Limitation set forth in block 1.8.

6. COMPLIANCE BY CONTRACTOR WITH LAWS AND REGULATIONS/ EQUAL EMPLOYMENT OPPORTUNITY.

6.1 In connection with the performance of the Services, the Contractor shall comply with all statutes, laws, regulations, and orders of federal, state, county or municipal authorities which impose any obligation or duty upon the Contractor, including, but not limited to, civil rights and equal opportunity laws. This may include the requirement to utilize auxiliary aids and services to ensure that persons with communication disabilities, including vision, hearing and speech, can communicate with, receive information from, and convey information to the Contractor. In addition, the Contractor shall comply with all applicable copyright laws.

6.2 During the term of this Agreement, the Contractor shall not discriminate against employees or applicants for employment because of race, color, religion, creed, age, sex, handicap, sexual orientation, or national origin and will take affirmative action to prevent such discrimination.

6.3 If this Agreement is funded in any part by monies of the United States, the Contractor shall comply with all the provisions of Executive Order No. 11246 ("Equal Employment Opportunity"), as supplemented by the regulations of the United States Department of Labor (41 C.F.R. Part 60), and with any rules, regulations and guidelines as the State of New Hampshire or the United States issue to implement these regulations. The Contractor further agrees to permit the State or United States access to any of the Contractor's books, records and accounts for the purpose of ascertaining compliance with all rules, regulations and orders, and the covenants, terms and conditions of this Agreement.

7. PERSONNEL.

7.1 The Contractor shall at its own expense provide all personnel necessary to perform the Services. The Contractor warrants that all personnel engaged in the Services shall be qualified to perform the Services, and shall be properly licensed and otherwise authorized to do so under all applicable laws.

7.2 Unless otherwise authorized in writing, during the term of this Agreement, and for a period of six (6) months after the Completion Date in block 1.7, the Contractor shall not hire, and shall not permit any subcontractor or other person, firm or corporation with whom it is engaged in a combined effort to perform the Services to hire, any person who is a State employee or official, who is materially involved in the procurement, administration or performance of this

Agreement. This provision shall survive termination of this Agreement.

7.3 The Contracting Officer specified in block 1.9, or his or her successor, shall be the State's representative. In the event of any dispute concerning the interpretation of this Agreement, the Contracting Officer's decision shall be final for the State.

8. EVENT OF DEFAULT/REMEDIES.

8.1 Any one or more of the following acts or omissions of the Contractor shall constitute an event of default hereunder ("Event of Default"):

8.1.1 failure to perform the Services satisfactorily or on schedule;

8.1.2 failure to submit any report required hereunder; and/or

8.1.3 failure to perform any other covenant, term or condition of this Agreement.

8.2 Upon the occurrence of any Event of Default, the State may take any one, or more, or all, of the following actions:

8.2.1 give the Contractor a written notice specifying the Event of Default and requiring it to be remedied within, in the absence of a greater or lesser specification of time, thirty (30) days from the date of the notice; and if the Event of Default is not timely remedied, terminate this Agreement, effective two (2) days after giving the Contractor notice of termination;

8.2.2 give the Contractor a written notice specifying the Event of Default and suspending all payments to be made under this Agreement and ordering that the portion of the contract price which would otherwise accrue to the Contractor during the period from the date of such notice until such time as the State determines that the Contractor has cured the Event of Default shall never be paid to the Contractor;

8.2.3 set off against any other obligations the State may owe to the Contractor any damages the State suffers by reason of any Event of Default; and/or

8.2.4 treat the Agreement as breached and pursue any of its remedies at law or in equity, or both.

9. DATA/ACCESS/CONFIDENTIALITY/PRESERVATION.

9.1 As used in this Agreement, the word "data" shall mean all information and things developed or obtained during the performance of, or acquired or developed by reason of, this Agreement, including, but not limited to, all studies, reports, files, formulae, surveys, maps, charts, sound recordings, video recordings, pictorial reproductions, drawings, analyses, graphic representations, computer programs, computer printouts, notes, letters, memoranda, papers, and documents, all whether finished or unfinished.

9.2 All data and any property which has been received from the State or purchased with funds provided for that purpose under this Agreement, shall be the property of the State, and shall be returned to the State upon demand or upon termination of this Agreement for any reason.

9.3 Confidentiality of data shall be governed by N.H. RSA chapter 91-A or other existing law. Disclosure of data requires prior written approval of the State.

10. **TERMINATION.** In the event of an early termination of this Agreement for any reason other than the completion of the Services, the Contractor shall deliver to the Contracting Officer, not later than fifteen (15) days after the date of termination, a report ("Termination Report") describing in detail all Services performed, and the contract price earned, to and including the date of termination. The form, subject matter, content, and number of copies of the Termination Report shall be identical to those of any Final Report described in the attached EXHIBIT A.

11. **CONTRACTOR'S RELATION TO THE STATE.** In the performance of this Agreement the Contractor is in all respects an independent contractor, and is neither an agent nor an employee of the State. Neither the Contractor nor any of its officers, employees, agents or members shall have authority to bind the State or receive any benefits, workers' compensation or other emoluments provided by the State to its employees.

12. **ASSIGNMENT/DELEGATION/SUBCONTRACTS.** The Contractor shall not assign, or otherwise transfer any interest in this Agreement without the prior written notice and consent of the State. None of the Services shall be subcontracted by the Contractor without the prior written notice and consent of the State.

13. **INDEMNIFICATION.** The Contractor shall defend, indemnify and hold harmless the State, its officers and employees, from and against any and all losses suffered by the State, its officers and employees, and any and all claims, liabilities or penalties asserted against the State, its officers and employees, by or on behalf of any person, on account of, based or resulting from, arising out of (or which may be claimed to arise out of) the acts or omissions of the Contractor. Notwithstanding the foregoing, nothing herein contained shall be deemed to constitute a waiver of the sovereign immunity of the State, which immunity is hereby reserved to the State. This covenant in paragraph 13 shall survive the termination of this Agreement.

14. INSURANCE.

14.1 The Contractor shall, at its sole expense, obtain and maintain in force, and shall require any subcontractor or assignee to obtain and maintain in force, the following insurance:

14.1.1 comprehensive general liability insurance against all claims of bodily injury, death or property damage, in amounts of not less than \$1,000,000 per occurrence and \$2,000,000 aggregate; and

14.1.2 special cause of loss coverage form covering all property subject to subparagraph 9.2 herein, in an amount not less than 80% of the whole replacement value of the property.

14.2 The policies described in subparagraph 14.1 herein shall be on policy forms and endorsements approved for use in the State of New Hampshire by the N.H. Department of Insurance, and issued by insurers licensed in the State of New Hampshire.

14.3 The Contractor shall furnish to the Contracting Officer identified in block 1.9, or his or her successor, a certificate(s) of insurance for all insurance required under this Agreement. Contractor shall also furnish to the Contracting Officer identified in block 1.9, or his or her successor, certificate(s) of insurance for all renewal(s) of insurance required under this Agreement no later than thirty (30) days prior to the expiration date of each of the insurance policies. The certificate(s) of insurance and any renewals thereof shall be attached and are incorporated herein by reference. Each certificate(s) of insurance shall contain a clause requiring the insurer to provide the Contracting Officer identified in block 1.9, or his or her successor, no less than thirty (30) days prior written notice of cancellation or modification of the policy.

15. WORKERS' COMPENSATION.

15.1 By signing this agreement, the Contractor agrees, certifies and warrants that the Contractor is in compliance with or exempt from, the requirements of N.H. RSA chapter 281-A ("*Workers' Compensation*").

15.2 To the extent the Contractor is subject to the requirements of N.H. RSA chapter 281-A, Contractor shall maintain, and require any subcontractor or assignee to secure and maintain, payment of Workers' Compensation in connection with activities which the person proposes to undertake pursuant to this Agreement. Contractor shall furnish the Contracting Officer identified in block 1.9, or his or her successor, proof of Workers' Compensation in the manner described in N.H. RSA chapter 281-A and any applicable renewal(s) thereof, which shall be attached and are incorporated herein by reference. The State shall not be responsible for payment of any Workers' Compensation premiums or for any other claim or benefit for Contractor, or any subcontractor or employee of Contractor, which might arise under applicable State of New Hampshire Workers' Compensation laws in connection with the performance of the Services under this Agreement.

16. WAIVER OF BREACH. No failure by the State to enforce any provisions hereof after any Event of Default shall be deemed a waiver of its rights with regard to that Event of Default, or any subsequent Event of Default. No express failure to enforce any Event of Default shall be deemed a waiver of the right of the State to enforce each and all of the provisions hereof upon any further or other Event of Default on the part of the Contractor.

17. NOTICE. Any notice by a party hereto to the other party shall be deemed to have been duly delivered or given at the time of mailing by certified mail, postage prepaid, in a United States Post Office addressed to the parties at the addresses given in blocks 1.2 and 1.4, herein.

18. AMENDMENT. This Agreement may be amended, waived or discharged only by an instrument in writing signed by the parties hereto and only after approval of such amendment, waiver or discharge by the Governor and Executive Council of the State of New Hampshire unless no

such approval is required under the circumstances pursuant to State law, rule or policy.

19. CONSTRUCTION OF AGREEMENT AND TERMS.

This Agreement shall be construed in accordance with the laws of the State of New Hampshire, and is binding upon and inures to the benefit of the parties and their respective successors and assigns. The wording used in this Agreement is the wording chosen by the parties to express their mutual intent, and no rule of construction shall be applied against or in favor of any party.

20. THIRD PARTIES. The parties hereto do not intend to benefit any third parties and this Agreement shall not be construed to confer any such benefit.

21. HEADINGS. The headings throughout the Agreement are for reference purposes only, and the words contained therein shall in no way be held to explain, modify, amplify or aid in the interpretation, construction or meaning of the provisions of this Agreement.

22. SPECIAL PROVISIONS. Additional provisions set forth in the attached EXHIBIT C are incorporated herein by reference.

23. SEVERABILITY. In the event any of the provisions of this Agreement are held by a court of competent jurisdiction to be contrary to any state or federal law, the remaining provisions of this Agreement will remain in full force and effect.

24. ENTIRE AGREEMENT. This Agreement, which may be executed in a number of counterparts, each of which shall be deemed an original, constitutes the entire Agreement and understanding between the parties, and supersedes all prior Agreements and understandings relating hereto.

Contractor Initials

Date

Ked
5/9/13



Scope of Services

1. Provisions Applicable to All Services

- 1.1. The Contractor will submit a detailed description of the language assistance services they will provide to persons with limited English proficiency to ensure meaningful access to their programs and/or services within ten (10) days of the contract effective date.
- 1.2. The Contractor agrees that, to the extent future legislative action by the New Hampshire General Court or federal or state court orders may have an impact on the Services described herein, the State Agency has the right to modify Service priorities and expenditure requirements under this Agreement so as to achieve compliance therewith.
- 1.3. The Contractor shall comply with Title 45 Code of Federal Regulations (CFR) Part 46. The regulations implement provisions of the National Research Act of 1974. The Contractor shall comply with all state rules and state and/or other federal laws relating to safeguarding the confidentiality of the information included in the Scope of Work. Institutional Review Board oversight is valid for one year and requires annual review of all applicable research programs implemented by the program.
- 1.4. The Contract period for all services in this agreement shall be from July 1, 2017 through the date indicated in Form P-37, General Provisions, Block 1.7, Completion Date.

2. Scope of Work

- 2.1. The Contractor shall provide Institutional Review Board (IRB) oversight and conduct reviews of all research projects implemented by the New Hampshire Department of Health & Human Services Public Health Laboratories. The Contractor shall conduct activities that include, but are not limited to:
 - 2.1.1. Reviewing research methods to determination of level of risk to human subjects.
 - 2.1.2. Providing written notification of IRB decisions to the Department within two (2) business days of the Board meeting.
 - 2.1.3. Providing formal written communication of Board meeting results within five (5) days of each Board meeting.
 - 2.1.4. Providing both written and oral communication regarding documents submitted by the Department to the IRB, including but not limited to redlined recommendations.



- 2.1.5. Access to IRB-Manager collaborative software; and
- 2.1.6. Ensuring emergency availability to the Department by telephone twenty-four (24) hours a day, seven (7) days a week.
- 2.2. The Contractor shall maintain current IRB designation and registration with the US Department of Health and Human Services Office for Human Research Protections as required under the US Food and Drug Administration regulations at 21 CFR 56.106.
- 2.3. The Contractor shall provide documentation of staff training, licensing, education, experience and orientation to the Department, upon request.

3. Deliverables

- 3.1. The Contractor shall submit initial letters of approval to the Department for each Public Health Laboratory research project reviewed.
- 3.2. The Contractor shall submit annual letters of approval to the Department that document ongoing reviews of all project in process at the Public Health Laboratories within twenty-eight (28) days of the contract completion date.



Exhibit B

Method and Conditions Precedent to Payment

1. The State shall pay the contractor an amount not to exceed the Form P-37, Block 1.8, Price Limitation for the services provided by the Contractor pursuant to Exhibit A, Scope of Services.
 - 1.1. This contract is funded with funds from the Catalog of Federal Domestic Assistance (CFDA) #93.070, United States Department of Health and Human Services, Centers for Disease Control and Prevention, Environmental Public Health and Emergency Response.
 - 1.2. The Contractor agrees to provide the services in Exhibit A, Scope of Service in compliance with funding requirements. Failure to meet the scope of services may jeopardize the funded contractor's current and/or future funding.
2. The Contractor shall submit an invoice to the Department upon ten (10) days of the contract effective date.
3. The Department shall make payment to the Contractor within thirty (30) days of receipt of invoice.
4. Invoices may be assigned and electronic signature and may be emailed to DPHScontractbilling@dhhs.nh.gov, or invoices may be mailed to:
 - 4.1. NH Public Health
Attn: Amy Bergquist
29 Hazen Drive
Concord, NH 03301



SPECIAL PROVISIONS

Contractors Obligations: The Contractor covenants and agrees that all funds received by the Contractor under the Contract shall be used only as payment to the Contractor for services provided to eligible individuals and, in the furtherance of the aforesaid covenants, the Contractor hereby covenants and agrees as follows:

1. **Compliance with Federal and State Laws:** If the Contractor is permitted to determine the eligibility of individuals such eligibility determination shall be made in accordance with applicable federal and state laws, regulations, orders, guidelines, policies and procedures.
2. **Time and Manner of Determination:** Eligibility determinations shall be made on forms provided by the Department for that purpose and shall be made and remade at such times as are prescribed by the Department.
3. **Documentation:** In addition to the determination forms required by the Department, the Contractor shall maintain a data file on each recipient of services hereunder, which file shall include all information necessary to support an eligibility determination and such other information as the Department requests. The Contractor shall furnish the Department with all forms and documentation regarding eligibility determinations that the Department may request or require.
4. **Fair Hearings:** The Contractor understands that all applicants for services hereunder, as well as individuals declared ineligible have a right to a fair hearing regarding that determination. The Contractor hereby covenants and agrees that all applicants for services shall be permitted to fill out an application form and that each applicant or re-applicant shall be informed of his/her right to a fair hearing in accordance with Department regulations.
5. **Gratuities or Kickbacks:** The Contractor agrees that it is a breach of this Contract to accept or make a payment, gratuity or offer of employment on behalf of the Contractor, any Sub-Contractor or the State in order to influence the performance of the Scope of Work detailed in Exhibit A of this Contract. The State may terminate this Contract and any sub-contract or sub-agreement if it is determined that payments, gratuities or offers of employment of any kind were offered or received by any officials, officers, employees or agents of the Contractor or Sub-Contractor.
6. **Retroactive Payments:** Notwithstanding anything to the contrary contained in the Contract or in any other document, contract or understanding, it is expressly understood and agreed by the parties hereto, that no payments will be made hereunder to reimburse the Contractor for costs incurred for any purpose or for any services provided to any individual prior to the Effective Date of the Contract and no payments shall be made for expenses incurred by the Contractor for any services provided prior to the date on which the individual applies for services or (except as otherwise provided by the federal regulations) prior to a determination that the Individual is eligible for such services.
7. **Conditions of Purchase:** Notwithstanding anything to the contrary contained in the Contract, nothing herein contained shall be deemed to obligate or require the Department to purchase services hereunder at a rate which reimburses the Contractor in excess of the Contractors costs, at a rate which exceeds the amounts reasonable and necessary to assure the quality of such service, or at a rate which exceeds the rate charged by the Contractor to ineligible individuals or other third party funders for such service. If at any time during the term of this Contract or after receipt of the Final Expenditure Report hereunder, the Department shall determine that the Contractor has used payments hereunder to reimburse items of expense other than such costs, or has received payment in excess of such costs or in excess of such rates charged by the Contractor to ineligible individuals or other third party funders, the Department may elect to:
 - 7.1. Renegotiate the rates for payment hereunder, in which event new rates shall be established;
 - 7.2. Deduct from any future payment to the Contractor the amount of any prior reimbursement in excess of costs;

KLP
Date 5/9/14



- 7.3. Demand repayment of the excess payment by the Contractor in which event failure to make such repayment shall constitute an Event of Default hereunder. When the Contractor is permitted to determine the eligibility of individuals for services, the Contractor agrees to reimburse the Department for all funds paid by the Department to the Contractor for services provided to any individual who is found by the Department to be ineligible for such services at any time during the period of retention of records established herein.

RECORDS: MAINTENANCE, RETENTION, AUDIT, DISCLOSURE AND CONFIDENTIALITY:

8. **Maintenance of Records:** In addition to the eligibility records specified above, the Contractor covenants and agrees to maintain the following records during the Contract Period:
- 8.1. **Fiscal Records:** books, records, documents and other data evidencing and reflecting all costs and other expenses incurred by the Contractor in the performance of the Contract; and all income received or collected by the Contractor during the Contract Period, said records to be maintained in accordance with accounting procedures and practices which sufficiently and properly reflect all such costs and expenses, and which are acceptable to the Department, and to include, without limitation, all ledgers, books, records, and original evidence of costs such as purchase requisitions and orders, vouchers, requisitions for materials, inventories, valuations of in-kind contributions, labor time cards, payrolls, and other records requested or required by the Department.
- 8.2. **Statistical Records:** Statistical, enrollment, attendance or visit records for each recipient of services during the Contract Period, which records shall include all records of application and eligibility (including all forms required to determine eligibility for each such recipient), records regarding the provision of services and all invoices submitted to the Department to obtain payment for such services.
- 8.3. **Medical Records:** Where appropriate and as prescribed by the Department regulations, the Contractor shall retain medical records on each patient/recipient of services.
9. **Audit:** Contractor shall submit an annual audit to the Department within 60 days after the close of the agency fiscal year. It is recommended that the report be prepared in accordance with the provision of Office of Management and Budget Circular A-133, "Audits of States, Local Governments, and Non Profit Organizations" and the provisions of Standards for Audit of Governmental Organizations, Programs, Activities and Functions, issued by the US General Accounting Office (GAO standards) as they pertain to financial compliance audits.
- 9.1. **Audit and Review:** During the term of this Contract and the period for retention hereunder, the Department, the United States Department of Health and Human Services, and any of their designated representatives shall have access to all reports and records maintained pursuant to the Contract for purposes of audit, examination, excerpts and transcripts.
- 9.2. **Audit Liabilities:** In addition to and not in any way in limitation of obligations of the Contract, it is understood and agreed by the Contractor that the Contractor shall be held liable for any state or federal audit exceptions and shall return to the Department, all payments made under the Contract to which exception has been taken or which have been disallowed because of such an exception.
10. **Confidentiality of Records:** All information, reports, and records maintained hereunder or collected in connection with the performance of the services and the Contract shall be confidential and shall not be disclosed by the Contractor, provided however, that pursuant to state laws and the regulations of the Department regarding the use and disclosure of such information, disclosure may be made to public officials requiring such information in connection with their official duties and for purposes directly connected to the administration of the services and the Contract; and provided further, that the use or disclosure by any party of any information concerning a recipient for any purpose not directly connected with the administration of the Department or the Contractor's responsibilities with respect to purchased services hereunder is prohibited except on written consent of the recipient, his attorney, or guardian.

KCP
3/2/18

New Hampshire Department of Health and Human Services
Exhibit C



Notwithstanding anything to the contrary contained herein the covenants and conditions contained in the Paragraph shall survive the termination of the Contract for any reason whatsoever.

11. **Reports: Fiscal and Statistical:** The Contractor agrees to submit the following reports at the following times if requested by the Department.
 - 11.1. **Interim Financial Reports:** Written interim financial reports containing a detailed description of all costs and non-allowable expenses incurred by the Contractor to the date of the report and containing such other information as shall be deemed satisfactory by the Department to justify the rate of payment hereunder. Such Financial Reports shall be submitted on the form designated by the Department or deemed satisfactory by the Department.
 - 11.2. **Final Report:** A final report shall be submitted within thirty (30) days after the end of the term of this Contract. The Final Report shall be in a form satisfactory to the Department and shall contain a summary statement of progress toward goals and objectives stated in the Proposal and other information required by the Department.

12. **Completion of Services: Disallowance of Costs:** Upon the purchase by the Department of the maximum number of units provided for in the Contract and upon payment of the price limitation hereunder, the Contract and all the obligations of the parties hereunder (except such obligations as, by the terms of the Contract are to be performed after the end of the term of this Contract and/or survive the termination of the Contract) shall terminate, provided however, that if, upon review of the Final Expenditure Report the Department shall disallow any expenses claimed by the Contractor as costs hereunder the Department shall retain the right, at its discretion, to deduct the amount of such expenses as are disallowed or to recover such sums from the Contractor.

13. **Credits:** All documents, notices, press releases, research reports and other materials prepared during or resulting from the performance of the services of the Contract shall include the following statement:
 - 13.1. The preparation of this (report, document etc.) was financed under a Contract with the State of New Hampshire, Department of Health and Human Services, with funds provided in part by the State of New Hampshire and/or such other funding sources as were available or required, e.g., the United States Department of Health and Human Services.

14. **Prior Approval and Copyright Ownership:** All materials (written, video, audio) produced or purchased under the contract shall have prior approval from DHHS before printing, production, distribution or use. The DHHS will retain copyright ownership for any and all original materials produced, including, but not limited to, brochures, resource directories, protocols or guidelines, posters, or reports. Contractor shall not reproduce any materials produced under the contract without prior written approval from DHHS.

15. **Operation of Facilities: Compliance with Laws and Regulations:** In the operation of any facilities for providing services, the Contractor shall comply with all laws, orders and regulations of federal, state, county and municipal authorities and with any direction of any Public Officer or officers pursuant to laws which shall impose an order or duty upon the contractor with respect to the operation of the facility or the provision of the services at such facility. If any governmental license or permit shall be required for the operation of the said facility or the performance of the said services, the Contractor will procure said license or permit, and will at all times comply with the terms and conditions of each such license or permit. In connection with the foregoing requirements, the Contractor hereby covenants and agrees that, during the term of this Contract the facilities shall comply with all rules, orders, regulations, and requirements of the State Office of the Fire Marshal and the local fire protection agency, and shall be in conformance with local building and zoning codes, by-laws and regulations.

16. **Equal Employment Opportunity Plan (EEOP):** The Contractor will provide an Equal Employment Opportunity Plan (EEOP) to the Office for Civil Rights, Office of Justice Programs (OCR), if it has received a single award of \$500,000 or more. If the recipient receives \$25,000 or more and has 50 or



more employees, it will maintain a current EEOP on file and submit an EEOP Certification Form to the OCR, certifying that its EEOP is on file. For recipients receiving less than \$25,000, or public grantees with fewer than 50 employees, regardless of the amount of the award, the recipient will provide an EEOP Certification Form to the OCR certifying it is not required to submit or maintain an EEOP. Non-profit organizations, Indian Tribes, and medical and educational institutions are exempt from the EEOP requirement, but are required to submit a certification form to the OCR to claim the exemption. EEOP Certification Forms are available at: <http://www.ojp.usdoj/about/ocr/pdfs/cert.pdf>.

17. **Limited English Proficiency (LEP):** As clarified by Executive Order 13166, Improving Access to Services for persons with Limited English Proficiency, and resulting agency guidance, national origin discrimination includes discrimination on the basis of limited English proficiency (LEP). To ensure compliance with the Omnibus Crime Control and Safe Streets Act of 1968 and Title VI of the Civil Rights Act of 1964, Contractors must take reasonable steps to ensure that LEP persons have meaningful access to its programs.
18. **Pilot Program for Enhancement of Contractor Employee Whistleblower Protections:** The following shall apply to all contracts that exceed the Simplified Acquisition Threshold as defined in 48 CFR 2.101 (currently, \$150,000)

CONTRACTOR EMPLOYEE WHISTLEBLOWER RIGHTS AND REQUIREMENT TO INFORM EMPLOYEES OF WHISTLEBLOWER RIGHTS (SEP 2013)

(a) This contract and employees working on this contract will be subject to the whistleblower rights and remedies in the pilot program on Contractor employee whistleblower protections established at 41 U.S.C. 4712 by section 828 of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112-239) and FAR 3.908.

(b) The Contractor shall inform its employees in writing, in the predominant language of the workforce, of employee whistleblower rights and protections under 41 U.S.C. 4712, as described in section 3.908 of the Federal Acquisition Regulation.

(c) The Contractor shall insert the substance of this clause, including this paragraph (c), in all subcontracts over the simplified acquisition threshold.

19. **Subcontractors:** DHHS recognizes that the Contractor may choose to use subcontractors with greater expertise to perform certain health care services or functions for efficiency or convenience, but the Contractor shall retain the responsibility and accountability for the function(s). Prior to subcontracting, the Contractor shall evaluate the subcontractor's ability to perform the delegated function(s). This is accomplished through a written agreement that specifies activities and reporting responsibilities of the subcontractor and provides for revoking the delegation or imposing sanctions if the subcontractor's performance is not adequate. Subcontractors are subject to the same contractual conditions as the Contractor and the Contractor is responsible to ensure subcontractor compliance with those conditions.

When the Contractor delegates a function to a subcontractor, the Contractor shall do the following:

- 19.1. Evaluate the prospective subcontractor's ability to perform the activities, before delegating the function
- 19.2. Have a written agreement with the subcontractor that specifies activities and reporting responsibilities and how sanctions/revocation will be managed if the subcontractor's performance is not adequate
- 19.3. Monitor the subcontractor's performance on an ongoing basis



- 19.4. Provide to DHHS an annual schedule identifying all subcontractors, delegated functions and responsibilities, and when the subcontractor's performance will be reviewed
- 19.5. DHHS shall, at its discretion, review and approve all subcontracts.

If the Contractor identifies deficiencies or areas for improvement are identified, the Contractor shall take corrective action.

DEFINITIONS

As used in the Contract, the following terms shall have the following meanings:

COSTS: Shall mean those direct and indirect items of expense determined by the Department to be allowable and reimbursable in accordance with cost and accounting principles established in accordance with state and federal laws, regulations, rules and orders.

DEPARTMENT: NH Department of Health and Human Services.

FINANCIAL MANAGEMENT GUIDELINES: Shall mean that section of the Contractor Manual which is entitled "Financial Management Guidelines" and which contains the regulations governing the financial activities of contractor agencies which have contracted with the State of NH to receive funds.

PROPOSAL: If applicable, shall mean the document submitted by the Contractor on a form or forms required by the Department and containing a description of the Services to be provided to eligible individuals by the Contractor in accordance with the terms and conditions of the Contract and setting forth the total cost and sources of revenue for each service to be provided under the Contract.

UNIT: For each service that the Contractor is to provide to eligible individuals hereunder, shall mean that period of time or that specified activity determined by the Department and specified in Exhibit B of the Contract.

FEDERAL/STATE LAW: Wherever federal or state laws, regulations, rules, orders, and policies, etc. are referred to in the Contract, the said reference shall be deemed to mean all such laws, regulations, etc. as they may be amended or revised from the time to time.

CONTRACTOR MANUAL: Shall mean that document prepared by the NH Department of Administrative Services containing a compilation of all regulations promulgated pursuant to the New Hampshire Administrative Procedures Act. NH RSA Ch 541-A, for the purpose of implementing State of NH and federal regulations promulgated thereunder.

SUPPLANTING OTHER FEDERAL FUNDS: The Contractor guarantees that funds provided under this Contract will not supplant any existing federal funds available for these services.

Kol
5/9/18



REVISIONS TO GENERAL PROVISIONS

1. Subparagraph 4 of the General Provisions of this contract, Conditional Nature of Agreement, is replaced as follows:
 4. **CONDITIONAL NATURE OF AGREEMENT.**
Notwithstanding any provision of this Agreement to the contrary, all obligations of the State hereunder, including without limitation, the continuance of payments, in whole or in part, under this Agreement are contingent upon continued appropriation or availability of funds, including any subsequent changes to the appropriation or availability of funds affected by any state or federal legislative or executive action that reduces, eliminates, or otherwise modifies the appropriation or availability of funding for this Agreement and the Scope of Services provided in Exhibit A, Scope of Services, in whole or in part. In no event shall the State be liable for any payments hereunder in excess of appropriated or available funds. In the event of a reduction, termination or modification of appropriated or available funds, the State shall have the right to withhold payment until such funds become available, if ever. The State shall have the right to reduce, terminate or modify services under this Agreement immediately upon giving the Contractor notice of such reduction, termination or modification. The State shall not be required to transfer funds from any other source or account into the Account(s) identified in block 1.6 of the General Provisions, Account Number, or any other account, in the event funds are reduced or unavailable.
2. Subparagraph 10 of the General Provisions of this contract, Termination, is amended by adding the following language:
 - 10.1 The State may terminate the Agreement at any time for any reason, at the sole discretion of the State, 30 days after giving the Contractor written notice that the State is exercising its option to terminate the Agreement.
 - 10.2 In the event of early termination, the Contractor shall, within 15 days of notice of early termination, develop and submit to the State a Transition Plan for services under the Agreement, including but not limited to, identifying the present and future needs of clients receiving services under the Agreement and establishes a process to meet those needs.
 - 10.3 The Contractor shall fully cooperate with the State and shall promptly provide detailed information to support the Transition Plan including, but not limited to, any information or data requested by the State related to the termination of the Agreement and Transition Plan and shall provide ongoing communication and revisions of the Transition Plan to the State as requested.
 - 10.4 In the event that services under the Agreement, including but not limited to clients receiving services under the Agreement are transitioned to having services delivered by another entity including contracted providers or the State, the Contractor shall provide a process for uninterrupted delivery of services in the Transition Plan.
 - 10.5 The Contractor shall establish a method of notifying clients and other affected individuals about the transition. The Contractor shall include the proposed communications in its Transition Plan submitted to the State as described above.
3. The Division reserves the right to renew the Contract for up to three (3) additional years, subject to the continued availability of funds, satisfactory performance of services and approval by the Governor and Executive Council.

KJ
5/9/17



CERTIFICATION REGARDING DRUG-FREE WORKPLACE REQUIREMENTS

The Contractor identified in Section 1.3 of the General Provisions agrees to comply with the provisions of Sections 5151-5160 of the Drug-Free Workplace Act of 1988 (Pub. L. 100-690, Title V, Subtitle D; 41 U.S.C. 701 et seq.), and further agrees to have the Contractor's representative, as identified in Sections 1.11 and 1.12 of the General Provisions execute the following Certification:

ALTERNATIVE I - FOR GRANTEES OTHER THAN INDIVIDUALS

**US DEPARTMENT OF HEALTH AND HUMAN SERVICES - CONTRACTORS
US DEPARTMENT OF EDUCATION - CONTRACTORS
US DEPARTMENT OF AGRICULTURE - CONTRACTORS**

This certification is required by the regulations implementing Sections 5151-5160 of the Drug-Free Workplace Act of 1988 (Pub. L. 100-690, Title V, Subtitle D; 41 U.S.C. 701 et seq.). The January 31, 1989 regulations were amended and published as Part II of the May 25, 1990 Federal Register (pages 21681-21691), and require certification by grantees (and by inference, sub-grantees and sub-contractors), prior to award, that they will maintain a drug-free workplace. Section 3017.630(c) of the regulation provides that a grantee (and by inference, sub-grantees and sub-contractors) that is a State may elect to make one certification to the Department in each federal fiscal year in lieu of certificates for each grant during the federal fiscal year covered by the certification. The certificate set out below is a material representation of fact upon which reliance is placed when the agency awards the grant. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or government wide suspension or debarment. Contractors using this form should send it to:

Commissioner
NH Department of Health and Human Services
129 Pleasant Street,
Concord, NH 03301-6505

1. The grantee certifies that it will or will continue to provide a drug-free workplace by:
 - 1.1. Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;
 - 1.2. Establishing an ongoing drug-free awareness program to inform employees about
 - 1.2.1. The dangers of drug abuse in the workplace;
 - 1.2.2. The grantee's policy of maintaining a drug-free workplace;
 - 1.2.3. Any available drug counseling, rehabilitation, and employee assistance programs; and
 - 1.2.4. The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;
 - 1.3. Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);
 - 1.4. Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will
 - 1.4.1. Abide by the terms of the statement; and
 - 1.4.2. Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;
 - 1.5. Notifying the agency in writing, within ten calendar days after receiving notice under subparagraph 1.4.2 from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer on whose grant activity the convicted employee was working, unless the Federal agency

KJ
5/9/10

New Hampshire Department of Health and Human Services
Exhibit D



- has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;
- 1.6. Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph 1.4.2, with respect to any employee who is so convicted:
 - 1.6.1. Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or
 - 1.6.2. Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;
 - 1.7. Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs 1.1, 1.2, 1.3, 1.4, 1.5, and 1.6.
2. The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant.

Place of Performance (street address, city, county, state, zip code) (list each location)

Check if there are workplaces on file that are not identified here.

Contractor Name:

5/9/18
Date

Kolm
Name: Kimberly Irvine
Title: Exp



CERTIFICATION REGARDING LOBBYING

The Contractor identified in Section 1.3 of the General Provisions agrees to comply with the provisions of Section 319 of Public Law 101-121, Government wide Guidance for New Restrictions on Lobbying, and 31 U.S.C. 1352, and further agrees to have the Contractor's representative, as identified in Sections 1.11 and 1.12 of the General Provisions execute the following Certification:

US DEPARTMENT OF HEALTH AND HUMAN SERVICES - CONTRACTORS
US DEPARTMENT OF EDUCATION - CONTRACTORS
US DEPARTMENT OF AGRICULTURE - CONTRACTORS

Programs (indicate applicable program covered):

- *Temporary Assistance to Needy Families under Title IV-A
- *Child-Support Enforcement Program under Title IV-D
- *Social Services Block Grant Program under Title XX
- *Medicaid Program under Title XIX
- *Community Services Block Grant under Title VI
- *Child Care Development Block Grant under Title IV

The undersigned certifies, to the best of his or her knowledge and belief, that:

1. No Federal appropriated funds have been paid or will be paid by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement (and by specific mention sub-grantee or sub-contractor).
2. If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement (and by specific mention sub-grantee or sub-contractor), the undersigned shall complete and submit Standard Form LLL, (Disclosure Form to Report Lobbying, in accordance with its instructions, attached and identified as Standard Exhibit E-I.)
3. The undersigned shall require that the language of this certification be included in the award document for sub-awards at all tiers (including subcontracts, sub-grants, and contracts under grants, loans, and cooperative agreements) and that all sub-recipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by Section 1352, Title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

Contractor Name:

5/9/18
Date

Kimberly Irvine
Name: **Kimberly Irvine**
Title: **EVP, Operations**

Contractor Initials KI
Date 5/9/18



**CERTIFICATION REGARDING DEBARMENT, SUSPENSION
AND OTHER RESPONSIBILITY MATTERS**

The Contractor identified in Section 1.3 of the General Provisions agrees to comply with the provisions of Executive Office of the President, Executive Order 12549 and 45 CFR Part 76 regarding Debarment, Suspension, and Other Responsibility Matters, and further agrees to have the Contractor's representative, as identified in Sections 1.11 and 1.12 of the General Provisions execute the following Certification:

INSTRUCTIONS FOR CERTIFICATION

1. By signing and submitting this proposal (contract), the prospective primary participant is providing the certification set out below.
2. The inability of a person to provide the certification required below will not necessarily result in denial of participation in this covered transaction. If necessary, the prospective participant shall submit an explanation of why it cannot provide the certification. The certification or explanation will be considered in connection with the NH Department of Health and Human Services' (DHHS) determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.
3. The certification in this clause is a material representation of fact upon which reliance was placed when DHHS determined to enter into this transaction. If it is later determined that the prospective primary participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, DHHS may terminate this transaction for cause or default.
4. The prospective primary participant shall provide immediate written notice to the DHHS agency to whom this proposal (contract) is submitted if at any time the prospective primary participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.
5. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of the rules implementing Executive Order 12549: 45 CFR Part 76. See the attached definitions.
6. The prospective primary participant agrees by submitting this proposal (contract) that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by DHHS.
7. The prospective primary participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion - Lower Tier Covered Transactions," provided by DHHS, without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.
8. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or involuntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List (of excluded parties).
9. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and



information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

10. Except for transactions authorized under paragraph 6 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal government, DHHS may terminate this transaction for cause or default.

PRIMARY COVERED TRANSACTIONS

11. The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals:
 - 11.1. are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;
 - 11.2. have not within a three-year period preceding this proposal (contract) been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State or local) transaction or a contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;
 - 11.3. are not presently indicted for otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph (I)(b) of this certification; and
 - 11.4. have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State or local) terminated for cause or default.
12. Where the prospective primary participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal (contract).

LOWER TIER COVERED TRANSACTIONS

13. By signing and submitting this lower tier proposal (contract), the prospective lower tier participant, as defined in 45 CFR Part 76, certifies to the best of its knowledge and belief that it and its principals:
 - 13.1. are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
 - 13.2. where the prospective lower tier participant is unable to certify to any of the above, such prospective participant shall attach an explanation to this proposal (contract).
14. The prospective lower tier participant further agrees by submitting this proposal (contract) that it will include this clause entitled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion - Lower Tier Covered Transactions," without modification in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

Contractor Name:

5/9/18
Date

Kimberly Irvine
Name: **Kimberly Irvine**
Title: **EVP, Operations**

Contractor Initials KI
Date 5/9/18



**CERTIFICATION OF COMPLIANCE WITH REQUIREMENTS PERTAINING TO
FEDERAL NONDISCRIMINATION, EQUAL TREATMENT OF FAITH-BASED ORGANIZATIONS AND
WHISTLEBLOWER PROTECTIONS**

The Contractor identified in Section 1.3 of the General Provisions agrees by signature of the Contractor's representative as identified in Sections 1.11 and 1.12 of the General Provisions, to execute the following certification:

Contractor will comply, and will require any subgrantees or subcontractors to comply, with any applicable federal nondiscrimination requirements, which may include:

- the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. Section 3789d) which prohibits recipients of federal funding under this statute from discriminating, either in employment practices or in the delivery of services or benefits, on the basis of race, color, religion, national origin, and sex. The Act requires certain recipients to produce an Equal Employment Opportunity Plan;
- the Juvenile Justice Delinquency Prevention Act of 2002 (42 U.S.C. Section 5672(b)) which adopts by reference, the civil rights obligations of the Safe Streets Act. Recipients of federal funding under this statute are prohibited from discriminating, either in employment practices or in the delivery of services or benefits, on the basis of race, color, religion, national origin, and sex. The Act includes Equal Employment Opportunity Plan requirements;
- the Civil Rights Act of 1964 (42 U.S.C. Section 2000d, which prohibits recipients of federal financial assistance from discriminating on the basis of race, color, or national origin in any program or activity);
- the Rehabilitation Act of 1973 (29 U.S.C. Section 794), which prohibits recipients of Federal financial assistance from discriminating on the basis of disability, in regard to employment and the delivery of services or benefits, in any program or activity;
- the Americans with Disabilities Act of 1990 (42 U.S.C. Sections 12131-34), which prohibits discrimination and ensures equal opportunity for persons with disabilities in employment, State and local government services, public accommodations, commercial facilities, and transportation;
- the Education Amendments of 1972 (20 U.S.C. Sections 1681, 1683, 1685-86), which prohibits discrimination on the basis of sex in federally assisted education programs;
- the Age Discrimination Act of 1975 (42 U.S.C. Sections 6106-07), which prohibits discrimination on the basis of age in programs or activities receiving Federal financial assistance. It does not include employment discrimination;
- 28 C.F.R. pt. 31 (U.S. Department of Justice Regulations – OJJDP Grant Programs); 28 C.F.R. pt. 42 (U.S. Department of Justice Regulations – Nondiscrimination; Equal Employment Opportunity; Policies and Procedures); Executive Order No. 13279 (equal protection of the laws for faith-based and community organizations); Executive Order No. 13559, which provide fundamental principles and policy-making criteria for partnerships with faith-based and neighborhood organizations;
- 28 C.F.R. pt. 38 (U.S. Department of Justice Regulations – Equal Treatment for Faith-Based Organizations); and Whistleblower protections 41 U.S.C. §4712 and The National Defense Authorization Act (NDAA) for Fiscal Year 2013 (Pub. L. 112-239, enacted January 2, 2013) the Pilot Program for Enhancement of Contract Employee Whistleblower Protections, which protects employees against reprisal for certain whistle blowing activities in connection with federal grants and contracts.

The certificate set out below is a material representation of fact upon which reliance is placed when the agency awards the grant. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or government wide suspension or debarment.

Exhibit G

Contractor Initials

Certification of Compliance with requirements pertaining to Federal Nondiscrimination, Equal Treatment of Faith-Based Organizations and Whistleblower protections

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3/9/16

New Hampshire Department of Health and Human Services
Exhibit G



In the event a Federal or State court or Federal or State administrative agency makes a finding of discrimination after a due process hearing on the grounds of race, color, religion, national origin, or sex against a recipient of funds, the recipient will forward a copy of the finding to the Office for Civil Rights, to the applicable contracting agency or division within the Department of Health and Human Services, and to the Department of Health and Human Services Office of the Ombudsman.

The Contractor identified in Section 1.3 of the General Provisions agrees by signature of the Contractor's representative as identified in Sections 1.11 and 1.12 of the General Provisions, to execute the following certification:

1. By signing and submitting this proposal (contract) the Contractor agrees to comply with the provisions indicated above.

Contractor Name:

5/7/18
Date

Kimberly Irvine
Name:
Title: **Kimberly Irvine**
EVP, Operations

Exhibit G

Certification of Compliance with requirements pertaining to Federal Nondiscrimination, Equal Treatment of Faith-Based Organizations and Whistleblower protections

Contractor Initials KI

Date 3/5/18



CERTIFICATION REGARDING ENVIRONMENTAL TOBACCO SMOKE


Public Law 103-227, Part C - Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted for by an entity and used routinely or regularly for the provision of health, day care, education, or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, and portions of facilities used for inpatient drug or alcohol treatment. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to \$1000 per day and/or the imposition of an administrative compliance order on the responsible entity.

The Contractor identified in Section 1.3 of the General Provisions agrees, by signature of the Contractor's representative as identified in Section 1.11 and 1.12 of the General Provisions, to execute the following certification:

1. By signing and submitting this contract, the Contractor agrees to make reasonable efforts to comply with all applicable provisions of Public Law 103-227, Part C, known as the Pro-Children Act of 1994.

Contractor Name:

5/9/18
Date


Name: **Kimberly Irvine**
Title: **EVP, Operations**

Contractor Initials KI
Date 5/9/18



Exhibit I

HEALTH INSURANCE PORTABILITY ACT
BUSINESS ASSOCIATE AGREEMENT

The Contractor identified in Section 1.3 of the General Provisions of the Agreement agrees to comply with the Health Insurance Portability and Accountability Act, Public Law 104-191 and with the Standards for Privacy and Security of Individually Identifiable Health Information, 45 CFR Parts 160 and 164 applicable to business associates. As defined herein, "Business Associate" shall mean the Contractor and subcontractors and agents of the Contractor that receive, use or have access to protected health information under this Agreement and "Covered Entity" shall mean the State of New Hampshire, Department of Health and Human Services.

(1) **Definitions.**

- a. "**Breach**" shall have the same meaning as the term "Breach" in section 164.402 of Title 45, Code of Federal Regulations.
- b. "**Business Associate**" has the meaning given such term in section 160.103 of Title 45, Code of Federal Regulations.
- c. "**Covered Entity**" has the meaning given such term in section 160.103 of Title 45, Code of Federal Regulations.
- d. "**Designated Record Set**" shall have the same meaning as the term "designated record set" in 45 CFR Section 164.501.
- e. "**Data Aggregation**" shall have the same meaning as the term "data aggregation" in 45 CFR Section 164.501.
- f. "**Health Care Operations**" shall have the same meaning as the term "health care operations" in 45 CFR Section 164.501.
- g. "**HITECH Act**" means the Health Information Technology for Economic and Clinical Health Act, Title XIII, Subtitle D, Part 1 & 2 of the American Recovery and Reinvestment Act of 2009.
- h. "**HIPAA**" means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 and the Standards for Privacy and Security of Individually Identifiable Health Information, 45 CFR Parts 160, 162 and 164 and amendments thereto.
- i. "**Individual**" shall have the same meaning as the term "individual" in 45 CFR Section 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR Section 164.501(g).
- j. "**Privacy Rule**" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Parts 160 and 164, promulgated under HIPAA by the United States Department of Health and Human Services.
- k. "**Protected Health Information**" shall have the same meaning as the term "protected health information" in 45 CFR Section 160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity.

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Exhibit I

- l. "Required by Law" shall have the same meaning as the term "required by law" in 45 CFR Section 164.103.
- m. "Secretary" shall mean the Secretary of the Department of Health and Human Services or his/her designee.
- n. "Security Rule" shall mean the Security Standards for the Protection of Electronic Protected Health Information at 45 CFR Part 164, Subpart C, and amendments thereto.
- o. "Unsecured Protected Health Information" means protected health information that is not secured by a technology standard that renders protected health information unusable, unreadable, or indecipherable to unauthorized individuals and is developed or endorsed by a standards developing organization that is accredited by the American National Standards Institute.
- p. Other Definitions - All terms not otherwise defined herein shall have the meaning established under 45 C.F.R. Parts 160, 162 and 164, as amended from time to time, and the HITECH Act.

(2) Business Associate Use and Disclosure of Protected Health Information.

- a. Business Associate shall not use, disclose, maintain or transmit Protected Health Information (PHI) except as reasonably necessary to provide the services outlined under Exhibit A of the Agreement. Further, Business Associate, including but not limited to all its directors, officers, employees and agents, shall not use, disclose, maintain or transmit PHI in any manner that would constitute a violation of the Privacy and Security Rule.
- b. Business Associate may use or disclose PHI:
 - I. For the proper management and administration of the Business Associate;
 - II. As required by law, pursuant to the terms set forth in paragraph d. below; or
 - III. For data aggregation purposes for the health care operations of Covered Entity.
- c. To the extent Business Associate is permitted under the Agreement to disclose PHI to a third party, Business Associate must obtain, prior to making any such disclosure, (i) reasonable assurances from the third party that such PHI will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the third party; and (ii) an agreement from such third party to notify Business Associate, in accordance with the HIPAA Privacy, Security, and Breach Notification Rules of any breaches of the confidentiality of the PHI, to the extent it has obtained knowledge of such breach.
- d. The Business Associate shall not, unless such disclosure is reasonably necessary to provide services under Exhibit A of the Agreement, disclose any PHI in response to a request for disclosure on the basis that it is required by law, without first notifying Covered Entity so that Covered Entity has an opportunity to object to the disclosure and to seek appropriate relief. If Covered Entity objects to such disclosure, the Business

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Associate shall refrain from disclosing the PHI until Covered Entity has exhausted all remedies.

- e. If the Covered Entity notifies the Business Associate that Covered Entity has agreed to be bound by additional restrictions over and above those uses or disclosures or security safeguards of PHI pursuant to the Privacy and Security Rule, the Business Associate shall be bound by such additional restrictions and shall not disclose PHI in violation of such additional restrictions and shall abide by any additional security safeguards.

(3) Obligations and Activities of Business Associate.

- a. The Business Associate shall notify the Covered Entity's Privacy Officer immediately after the Business Associate becomes aware of any use or disclosure of protected health information not provided for by the Agreement including breaches of unsecured protected health information and/or any security incident that may have an impact on the protected health information of the Covered Entity.
- b. The Business Associate shall immediately perform a risk assessment when it becomes aware of any of the above situations. The risk assessment shall include, but not be limited to:
 - o The nature and extent of the protected health information involved, including the types of identifiers and the likelihood of re-identification;
 - o The unauthorized person used the protected health information or to whom the disclosure was made;
 - o Whether the protected health information was actually acquired or viewed
 - o The extent to which the risk to the protected health information has been mitigated.

The Business Associate shall complete the risk assessment within 48 hours of the breach and immediately report the findings of the risk assessment in writing to the Covered Entity.

- c. The Business Associate shall comply with all sections of the Privacy, Security, and Breach Notification Rule.
- d. Business Associate shall make available all of its internal policies and procedures, books and records relating to the use and disclosure of PHI received from, or created or received by the Business Associate on behalf of Covered Entity to the Secretary for purposes of determining Covered Entity's compliance with HIPAA and the Privacy and Security Rule.
- e. Business Associate shall require all of its business associates that receive, use or have access to PHI under the Agreement, to agree in writing to adhere to the same restrictions and conditions on the use and disclosure of PHI contained herein, including the duty to return or destroy the PHI as provided under Section 3 (I). The Covered Entity shall be considered a direct third party beneficiary of the Contractor's business associate agreements with Contractor's intended business associates, who will be receiving PHI

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Exhibit I

pursuant to this Agreement, with rights of enforcement and indemnification from such business associates who shall be governed by standard Paragraph #13 of the standard contract provisions (P-37) of this Agreement for the purpose of use and disclosure of protected health information.

- f. Within five (5) business days of receipt of a written request from Covered Entity, Business Associate shall make available during normal business hours at its offices all records, books, agreements, policies and procedures relating to the use and disclosure of PHI to the Covered Entity, for purposes of enabling Covered Entity to determine Business Associate's compliance with the terms of the Agreement.
- g. Within ten (10) business days of receiving a written request from Covered Entity, Business Associate shall provide access to PHI in a Designated Record Set to the Covered Entity, or as directed by Covered Entity, to an individual in order to meet the requirements under 45 CFR Section 164.524.
- h. Within ten (10) business days of receiving a written request from Covered Entity for an amendment of PHI or a record about an individual contained in a Designated Record Set, the Business Associate shall make such PHI available to Covered Entity for amendment and incorporate any such amendment to enable Covered Entity to fulfill its obligations under 45 CFR Section 164.526.
- i. Business Associate shall document such disclosures of PHI and information related to such disclosures as would be required for Covered Entity to respond to a request by an individual for an accounting of disclosures of PHI in accordance with 45 CFR Section 164.528.
- j. Within ten (10) business days of receiving a written request from Covered Entity for a request for an accounting of disclosures of PHI, Business Associate shall make available to Covered Entity such information as Covered Entity may require to fulfill its obligations to provide an accounting of disclosures with respect to PHI in accordance with 45 CFR Section 164.528.
- k. In the event any individual requests access to, amendment of, or accounting of PHI directly from the Business Associate, the Business Associate shall within two (2) business days forward such request to Covered Entity. Covered Entity shall have the responsibility of responding to forwarded requests. However, if forwarding the individual's request to Covered Entity would cause Covered Entity or the Business Associate to violate HIPAA and the Privacy and Security Rule, the Business Associate shall instead respond to the individual's request as required by such law and notify Covered Entity of such response as soon as practicable.
- l. Within ten (10) business days of termination of the Agreement, for any reason, the Business Associate shall return or destroy, as specified by Covered Entity, all PHI received from, or created or received by the Business Associate in connection with the Agreement, and shall not retain any copies or back-up tapes of such PHI. If return or destruction is not feasible, or the disposition of the PHI has been otherwise agreed to in the Agreement, Business Associate shall continue to extend the protections of the Agreement, to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business

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Exhibit I

Associate maintains such PHI. If Covered Entity, in its sole discretion, requires that the Business Associate destroy any or all PHI, the Business Associate shall certify to Covered Entity that the PHI has been destroyed.

(4) Obligations of Covered Entity

- a. Covered Entity shall notify Business Associate of any changes or limitation(s) in its Notice of Privacy Practices provided to individuals in accordance with 45 CFR Section 164.520, to the extent that such change or limitation may affect Business Associate's use or disclosure of PHI.
- b. Covered Entity shall promptly notify Business Associate of any changes in, or revocation of permission provided to Covered Entity by individuals whose PHI may be used or disclosed by Business Associate under this Agreement, pursuant to 45 CFR Section 164.506 or 45 CFR Section 164.508.
- c. Covered entity shall promptly notify Business Associate of any restrictions on the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 CFR 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.

(5) Termination for Cause

In addition to Paragraph 10 of the standard terms and conditions (P-37) of this Agreement the Covered Entity may immediately terminate the Agreement upon Covered Entity's knowledge of a breach by Business Associate of the Business Associate Agreement set forth herein as Exhibit I. The Covered Entity may either immediately terminate the Agreement or provide an opportunity for Business Associate to cure the alleged breach within a timeframe specified by Covered Entity. If Covered Entity determines that neither termination nor cure is feasible, Covered Entity shall report the violation to the Secretary.

(6) Miscellaneous

- a. Definitions and Regulatory References. All terms used, but not otherwise defined herein, shall have the same meaning as those terms in the Privacy and Security Rule, amended from time to time. A reference in the Agreement, as amended to include this Exhibit I, to a Section in the Privacy and Security Rule means the Section as in effect or as amended.
- b. Amendment. Covered Entity and Business Associate agree to take such action as is necessary to amend the Agreement, from time to time as is necessary for Covered Entity to comply with the changes in the requirements of HIPAA, the Privacy and Security Rule, and applicable federal and state law.
- c. Data Ownership. The Business Associate acknowledges that it has no ownership rights with respect to the PHI provided by or created on behalf of Covered Entity.
- d. Interpretation. The parties agree that any ambiguity in the Agreement shall be resolved to permit Covered Entity to comply with HIPAA, the Privacy and Security Rule.

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Contractor Initials

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Exhibit I

- e. Segregation. If any term or condition of this Exhibit I or the application thereof to any person(s) or circumstance is held invalid, such invalidity shall not affect other terms or conditions which can be given effect without the invalid term or condition; to this end the terms and conditions of this Exhibit I are declared severable.
- f. Survival. Provisions in this Exhibit I regarding the use and disclosure of PHI, return or destruction of PHI, extensions of the protections of the Agreement in section (3) I, the defense and indemnification provisions of section (3) e and Paragraph 13 of the standard terms and conditions (P-37), shall survive the termination of the Agreement.

IN WITNESS WHEREOF, the parties hereto have duly executed this Exhibit I.

Department of Health and Human Services

The State

Signature of Authorized Representative

LISA MORRIS
Name of Authorized Representative

DIRECTOR, DPHS
Title of Authorized Representative

5/31/18
Date

Name of the Contractor

Signature of Authorized Representative

Name of Authorized Representative

Kimberly Irvine
EVP, Operations
Title of Authorized Representative

5/9/18
Date

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CERTIFICATION REGARDING THE FEDERAL FUNDING ACCOUNTABILITY AND TRANSPARENCY ACT (FFATA) COMPLIANCE

The Federal Funding Accountability and Transparency Act (FFATA) requires prime awardees of individual Federal grants equal to or greater than \$25,000 and awarded on or after October 1, 2010, to report on data related to executive compensation and associated first-tier sub-grants of \$25,000 or more. If the initial award is below \$25,000 but subsequent grant modifications result in a total award equal to or over \$25,000, the award is subject to the FFATA reporting requirements, as of the date of the award.

In accordance with 2 CFR Part 170 (Reporting Subaward and Executive Compensation Information), the Department of Health and Human Services (DHHS) must report the following information for any subaward or contract award subject to the FFATA reporting requirements:

1. Name of entity
2. Amount of award
3. Funding agency
4. NAICS code for contracts / CFDA program number for grants
5. Program source
6. Award title descriptive of the purpose of the funding action
7. Location of the entity
8. Principle place of performance
9. Unique identifier of the entity (DUNS #)
10. Total compensation and names of the top five executives if:
 - 10.1. More than 80% of annual gross revenues are from the Federal government, and those revenues are greater than \$25M annually and
 - 10.2. Compensation information is not already available through reporting to the SEC.

Prime grant recipients must submit FFATA required data by the end of the month, plus 30 days, in which the award or award amendment is made.

The Contractor identified in Section 1.3 of the General Provisions agrees to comply with the provisions of The Federal Funding Accountability and Transparency Act, Public Law 109-282 and Public Law 110-252, and 2 CFR Part 170 (Reporting Subaward and Executive Compensation Information), and further agrees to have the Contractor's representative, as identified in Sections 1.11 and 1.12 of the General Provisions execute the following Certification:

The below named Contractor agrees to provide needed information as outlined above to the NH Department of Health and Human Services and to comply with all applicable provisions of the Federal Financial Accountability and Transparency Act.

Contractor Name:

5/9/18
Date

Kimberly Irvine
Name: **Kimberly Irvine**
Title: **EVP, Operations**



FORM A

As the Contractor identified in Section 1.3 of the General Provisions, I certify that the responses to the below listed questions are true and accurate.

1. The DUNS number for your entity is: 11-200-7062
2. In your business or organization's preceding completed fiscal year, did your business or organization receive (1) 80 percent or more of your annual gross revenue in U.S. federal contracts, subcontracts, loans, grants, sub-grants, and/or cooperative agreements; and (2) \$25,000,000 or more in annual gross revenues from U.S. federal contracts, subcontracts, loans, grants, subgrants, and/or cooperative agreements?

NO YES

If the answer to #2 above is NO, stop here

If the answer to #2 above is YES, please answer the following:

3. Does the public have access to information about the compensation of the executives in your business or organization through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986?

NO YES

If the answer to #3 above is YES, stop here

If the answer to #3 above is NO, please answer the following:

4. The names and compensation of the five most highly compensated officers in your business or organization are as follows:

Name: _____	Amount: _____
Name: _____	Amount: _____
Name: _____	Amount: _____
Name: _____	Amount: _____
Name: _____	Amount: _____

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A. Definitions

The following terms may be reflected and have the described meaning in this document:

1. "Breach" means the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, unauthorized access, or any similar term referring to situations where persons other than authorized users and for an other than authorized purpose have access or potential access to personally identifiable information, whether physical or electronic. With regard to Protected Health Information, "Breach" shall have the same meaning as the term "Breach" in section 164.402 of Title 45, Code of Federal Regulations.
2. "Computer Security Incident" shall have the same meaning "Computer Security Incident" in section two (2) of NIST Publication 800-61, Computer Security Incident Handling Guide, National Institute of Standards and Technology, U.S. Department of Commerce.
3. "Confidential Information" or "Confidential Data" means all confidential information disclosed by one party to the other such as all medical, health, financial, public assistance benefits and personal information including without limitation, Substance Abuse Treatment Records, Case Records, Protected Health Information and Personally Identifiable Information.

Confidential Information also includes any and all information owned or managed by the State of NH - created, received from or on behalf of the Department of Health and Human Services (DHHS) or accessed in the course of performing contracted services - of which collection, disclosure, protection, and disposition is governed by state or federal law or regulation. This information includes, but is not limited to Protected Health Information (PHI), Personal Information (PI), Personal Financial Information (PFI), Federal Tax Information (FTI), Social Security Numbers (SSN), Payment Card Industry (PCI), and or other sensitive and confidential information.

4. "End User" means any person or entity (e.g., contractor, contractor's employee, business associate, subcontractor, other downstream user, etc.) that receives DHHS data or derivative data in accordance with the terms of this Contract.
5. "HIPAA" means the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated thereunder.
6. "Incident" means an act that potentially violates an explicit or implied security policy, which includes attempts (either failed or successful) to gain unauthorized access to a system or its data, unwanted disruption or denial of service, the unauthorized use of a system for the processing or storage of data; and changes to system hardware, firmware, or software characteristics without the owner's knowledge, instruction, or consent. Incidents include the loss of data through theft or device misplacement, loss or misplacement of hardcopy documents, and misrouting of physical or electronic

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DHHS Information Security Requirements



mail, all of which may have the potential to put the data at risk of unauthorized access, use, disclosure, modification or destruction.

7. "Open Wireless Network" means any network or segment of a network that is not designated by the State of New Hampshire's Department of Information Technology or delegate as a protected network (designed, tested, and approved, by means of the State, to transmit) will be considered an open network and not adequately secure for the transmission of unencrypted PI, PFI, PHI or confidential DHHS data.
8. "Personal Information" (or "PI") means information which can be used to distinguish or trace an individual's identity, such as their name, social security number, personal information as defined in New Hampshire RSA 359-C:19, biometric records, etc., alone, or when combined with other personal or identifying information which is linked or linkable to a specific individual, such as date and place of birth, mother's maiden name, etc.
9. "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Parts 160 and 164, promulgated under HIPAA by the United States Department of Health and Human Services.
10. "Protected Health Information" (or "PHI") has the same meaning as provided in the definition of "Protected Health Information" in the HIPAA Privacy Rule at 45 C.F.R. § 160.103.
11. "Security Rule" shall mean the Security Standards for the Protection of Electronic Protected Health Information at 45 C.F.R. Part 164, Subpart C, and amendments thereto.
12. "Unsecured Protected Health Information" means Protected Health Information that is not secured by a technology standard that renders Protected Health Information unusable, unreadable, or indecipherable to unauthorized individuals and is developed or endorsed by a standards developing organization that is accredited by the American National Standards Institute.

I. RESPONSIBILITIES OF DHHS AND THE CONTRACTOR

A. Business Use and Disclosure of Confidential Information.

1. The Contractor must not use, disclose, maintain or transmit Confidential Information except as reasonably necessary as outlined under this Contract. Further, Contractor, including but not limited to all its directors, officers, employees and agents, must not use, disclose, maintain or transmit PHI in any manner that would constitute a violation of the Privacy and Security Rule.
2. The Contractor must not disclose any Confidential Information in response to a

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request for disclosure on the basis that it is required by law, in response to a subpoena, etc., without first notifying DHHS so that DHHS has an opportunity to consent or object to the disclosure.

3. If DHHS notifies the Contractor that DHHS has agreed to be bound by additional restrictions over and above those uses or disclosures or security safeguards of PHI pursuant to the Privacy and Security Rule, the Contractor must be bound by such additional restrictions and must not disclose PHI in violation of such additional restrictions and must abide by any additional security safeguards.
4. The Contractor agrees that DHHS Data or derivative there from disclosed to an End User must only be used pursuant to the terms of this Contract.
5. The Contractor agrees DHHS Data obtained under this Contract may not be used for any other purposes that are not indicated in this Contract.
6. The Contractor agrees to grant access to the data to the authorized representatives of DHHS for the purpose of inspecting to confirm compliance with the terms of this Contract.

II. METHODS OF SECURE TRANSMISSION OF DATA

1. Application Encryption. If End User is transmitting DHHS data containing Confidential Data between applications, the Contractor attests the applications have been evaluated by an expert knowledgeable in cyber security and that said application's encryption capabilities ensure secure transmission via the internet.
2. Computer Disks and Portable Storage Devices. End User may not use computer disks or portable storage devices, such as a thumb drive, as a method of transmitting DHHS data.
3. Encrypted Email. End User may only employ email to transmit Confidential Data if email is encrypted and being sent to and being received by email addresses of persons authorized to receive such information.
4. Encrypted Web Site. If End User is employing the Web to transmit Confidential Data, the secure socket layers (SSL) must be used and the web site must be secure. SSL encrypts data transmitted via a Web site.
5. File Hosting Services, also known as File Sharing Sites. End User may not use file hosting services, such as Dropbox or Google Cloud Storage, to transmit Confidential Data.
6. Ground Mail Service. End User may only transmit Confidential Data via *certified* ground mail within the continental U.S. and when sent to a named individual.
7. Laptops and PDA. If End User is employing portable devices to transmit Confidential Data said devices must be encrypted and password-protected.
8. Open Wireless Networks. End User may not transmit Confidential Data via an open



wireless network. End User must employ a virtual private network (VPN) when remotely transmitting via an open wireless network.

9. Remote User Communication. If End User is employing remote communication to access or transmit Confidential Data, a virtual private network (VPN) must be installed on the End User's mobile device(s) or laptop from which information will be transmitted or accessed.
10. SSH File Transfer Protocol (SFTP), also known as Secure File Transfer Protocol. If End User is employing an SFTP to transmit Confidential Data, End User will structure the Folder and access privileges to prevent inappropriate disclosure of information. SFTP folders and sub-folders used for transmitting Confidential Data will be coded for 24-hour auto-deletion cycle (i.e. Confidential Data will be deleted every 24 hours).
11. Wireless Devices. If End User is transmitting Confidential Data via wireless devices, all data must be encrypted to prevent inappropriate disclosure of information.

III. RETENTION AND DISPOSITION OF IDENTIFIABLE RECORDS

The Contractor will only retain the data and any derivative of the data for the duration of this Contract. After such time, the Contractor will have 30 days to destroy the data and any derivative in whatever form it may exist, unless, otherwise required by law or permitted under this Contract. To this end, the parties must:

A. Retention

1. The Contractor agrees it will not store, transfer or process data collected in connection with the services rendered under this Contract outside of the United States. This physical location requirement shall also apply in the implementation of cloud computing, cloud service or cloud storage capabilities, and includes backup data and Disaster Recovery locations.
2. The Contractor agrees to ensure proper security monitoring capabilities are in place to detect potential security events that can impact State of NH systems and/or Department confidential information for contractor provided systems.
3. The Contractor agrees to provide security awareness and education for its End Users in support of protecting Department confidential information.
4. The Contractor agrees to retain all electronic and hard copies of Confidential Data in a secure location and identified in section IV. A.2
5. The Contractor agrees Confidential Data stored in a Cloud must be in a FedRAMP/HITECH compliant solution and comply with all applicable statutes and regulations regarding the privacy and security. All servers and devices must have currently-supported and hardened operating systems, the latest anti-viral, anti-hacker, anti-spam, anti-spyware, and anti-malware utilities. The environment, as a



whole, must have aggressive intrusion-detection and firewall protection.

6. The Contractor agrees to and ensures its complete cooperation with the State's Chief Information Officer in the detection of any security vulnerability of the hosting infrastructure.

B. Disposition

1. If the Contractor will maintain any Confidential Information on its systems (or its sub-contractor systems), the Contractor will maintain a documented process for securely disposing of such data upon request or contract termination; and will obtain written certification for any State of New Hampshire data destroyed by the Contractor or any subcontractors as a part of ongoing, emergency, and or disaster recovery operations. When no longer in use, electronic media containing State of New Hampshire data shall be rendered unrecoverable via a secure wipe program in accordance with industry-accepted standards for secure deletion and media sanitization, or otherwise physically destroying the media (for example, degaussing) as described in NIST Special Publication 800-88, Rev 1, Guidelines for Media Sanitization, National Institute of Standards and Technology, U. S. Department of Commerce. The Contractor will document and certify in writing at time of the data destruction, and will provide written certification to the Department upon request. The written certification will include all details necessary to demonstrate data has been properly destroyed and validated. Where applicable, regulatory and professional standards for retention requirements will be jointly evaluated by the State and Contractor prior to destruction.
2. Unless otherwise specified, within thirty (30) days of the termination of this Contract, Contractor agrees to destroy all hard copies of Confidential Data using a secure method such as shredding.
3. Unless otherwise specified, within thirty (30) days of the termination of this Contract, Contractor agrees to completely destroy all electronic Confidential Data by means of data erasure, also known as secure data wiping.

IV. PROCEDURES FOR SECURITY

- A. Contractor agrees to safeguard the DHHS Data received under this Contract, and any derivative data or files, as follows:
 1. The Contractor will maintain proper security controls to protect Department confidential information collected, processed, managed, and/or stored in the delivery of contracted services.
 2. The Contractor will maintain policies and procedures to protect Department confidential information throughout the information lifecycle, where applicable, (from creation, transformation, use, storage and secure destruction) regardless of the media used to store the data (i.e., tape, disk, paper, etc.).



3. The Contractor will maintain appropriate authentication and access controls to contractor systems that collect, transmit, or store Department confidential information where applicable.
4. The Contractor will ensure proper security monitoring capabilities are in place to detect potential security events that can impact State of NH systems and/or Department confidential information for contractor provided systems.
5. The Contractor will provide regular security awareness and education for its End Users in support of protecting Department confidential information.
6. If the Contractor will be sub-contracting any core functions of the engagement supporting the services for State of New Hampshire, the Contractor will maintain a program of an internal process or processes that defines specific security expectations, and monitoring compliance to security requirements that at a minimum match those for the Contractor, including breach notification requirements.
7. The Contractor will work with the Department to sign and comply with all applicable State of New Hampshire and Department system access and authorization policies and procedures, systems access forms, and computer use agreements as part of obtaining and maintaining access to any Department system(s). Agreements will be completed and signed by the Contractor and any applicable sub-contractors prior to system access being authorized.
8. If the Department determines the Contractor is a Business Associate pursuant to 45 CFR 160.103, the Contractor will execute a HIPAA Business Associate Agreement (BAA) with the Department and is responsible for maintaining compliance with the agreement.
9. The Contractor will work with the Department at its request to complete a System Management Survey. The purpose of the survey is to enable the Department and Contractor to monitor for any changes in risks, threats, and vulnerabilities that may occur over the life of the Contractor engagement. The survey will be completed annually, or an alternate time frame at the Departments discretion with agreement by the Contractor, or the Department may request the survey be completed when the scope of the engagement between the Department and the Contractor changes.
10. The Contractor will not store, knowingly or unknowingly, any State of New Hampshire or Department data offshore or outside the boundaries of the United States unless prior express written consent is obtained from the Information Security Office leadership member within the Department.
11. Data Security Breach Liability. In the event of any security breach Contractor shall make efforts to investigate the causes of the breach, promptly take measures to prevent future breach and minimize any damage or loss resulting from the breach. The State shall recover from the Contractor all costs of response and recovery from

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New Hampshire Department of Health and Human Services

Exhibit K

DHHS Information Security Requirements



the breach, including but not limited to: credit monitoring services, mailing costs and costs associated with website and telephone call center services necessary due to the breach.

12. Contractor must, comply with all applicable statutes and regulations regarding the privacy and security of Confidential Information, and must in all other respects maintain the privacy and security of PI and PHI at a level and scope that is not less than the level and scope of requirements applicable to federal agencies, including, but not limited to, provisions of the Privacy Act of 1974 (5 U.S.C. § 552a), DHHS Privacy Act Regulations (45 C.F.R. §5b), HIPAA Privacy and Security Rules (45 C.F.R. Parts 160 and 164) that govern protections for individually identifiable health information and as applicable under State law.
13. Contractor agrees to establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality of the Confidential Data and to prevent unauthorized use or access to it. The safeguards must provide a level and scope of security that is not less than the level and scope of security requirements established by the State of New Hampshire, Department of Information Technology. Refer to Vendor Resources/Procurement at <https://www.nh.gov/doiit/vendor/index.htm> for the Department of Information Technology policies, guidelines, standards, and procurement information relating to vendors.
14. Contractor agrees to maintain a documented breach notification and incident response process. The Contractor will notify the State's Privacy Officer, and additional email addresses provided in this section, of any security breach within two (2) hours of the time that the Contractor learns of its occurrence. This includes a confidential information breach, computer security incident, or suspected breach which affects or includes any State of New Hampshire systems that connect to the State of New Hampshire network.
15. Contractor must restrict access to the Confidential Data obtained under this Contract to only those authorized End Users who need such DHHS Data to perform their official duties in connection with purposes identified in this Contract.
16. The Contractor must ensure that all End Users:
 - a. comply with such safeguards as referenced in Section IV A. above, implemented to protect Confidential Information that is furnished by DHHS under this Contract from loss, theft or inadvertent disclosure.
 - b. safeguard this information at all times.
 - c. ensure that laptops and other electronic devices/media containing PHI, PI, or PFI are encrypted and password-protected.
 - d. send emails containing Confidential Information only if encrypted and being sent to and being received by email addresses of persons authorized to receive such information.



- e. limit disclosure of the Confidential Information to the extent permitted by law.
- f. Confidential Information received under this Contract and individually identifiable data derived from DHHS Data, must be stored in an area that is physically and technologically secure from access by unauthorized persons during duty hours as well as non-duty hours (e.g., door locks, card keys, biometric identifiers, etc.).
- g. only authorized End Users may transmit the Confidential Data, including any derivative files containing personally identifiable information, and in all cases, such data must be encrypted at all times when in transit, at rest, or when stored on portable media as required in section IV above.
- h. in all other instances Confidential Data must be maintained, used and disclosed using appropriate safeguards, as determined by a risk-based assessment of the circumstances involved.
- i. understand that their user credentials (user name and password) must not be shared with anyone. End Users will keep their credential information secure. This applies to credentials used to access the site directly or indirectly through a third party application.

Contractor is responsible for oversight and compliance of their End Users. DHHS reserves the right to conduct onsite inspections to monitor compliance with this Contract, including the privacy and security requirements provided in herein, HIPAA, and other applicable laws and Federal regulations until such time the Confidential Data is disposed of in accordance with this Contract.

V. LOSS REPORTING

The Contractor must notify the State's Privacy Officer, Information Security Office and Program Manager of any Security Incidents and Breaches within two (2) hours of the time that the Contractor learns of their occurrence.

The Contractor must further handle and report Incidents and Breaches involving PHI in accordance with the agency's documented Incident Handling and Breach Notification procedures and in accordance with 42 C.F.R. §§ 431.300 - 306. In addition to, and notwithstanding, Contractor's compliance with all applicable obligations and procedures, Contractor's procedures must also address how the Contractor will:

1. Identify Incidents;
2. Determine if personally identifiable information is involved in Incidents;
3. Report suspected or confirmed Incidents as required in this Exhibit or P-37;
4. Identify and convene a core response group to determine the risk level of Incidents and determine risk-based responses to Incidents; and

Kep
5/9/18



5. Determine whether Breach notification is required, and, if so, identify appropriate Breach notification methods, timing, source, and contents from among different options, and bear costs associated with the Breach notice as well as any mitigation measures.

Incidents and/or Breaches that implicate PI must be addressed and reported, as applicable, in accordance with NH RSA 359-C:20.

VI. PERSONS TO CONTACT

- A. DHHS contact for Data Management or Data Exchange issues:

DHHSInformationSecurityOffice@dhhs.nh.gov

- B. DHHS contacts for Privacy issues:

DHHSPrivacyOfficer@dhhs.nh.gov

- C. DHHS contact for Information Security issues:

DHHSInformationSecurityOffice@dhhs.nh.gov

- D. DHHS contact for Breach notifications:

DHHSInformationSecurityOffice@dhhs.nh.gov

DHHSPrivacy.Officer@dhhs.nh.gov

KF
5/9/18

State of New Hampshire

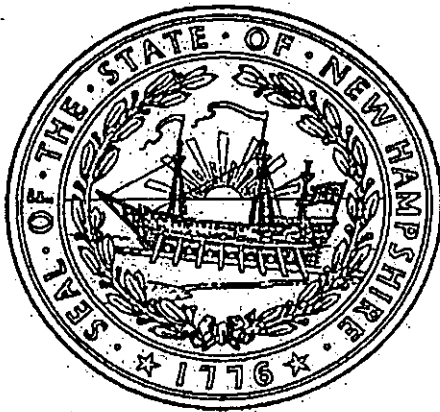
Department of State

CERTIFICATE

I, William M. Gardner, Secretary of State of the State of New Hampshire, do hereby certify that BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC is a New York Limited Liability Company registered to transact business in New Hampshire on November 04, 2010. I further certify that all fees and documents required by the Secretary of State's office have been received and is in good standing as far as this office is concerned.

Business ID: 638342

Certificate Number: 0004097004



IN TESTIMONY WHEREOF,
I hereto set my hand and cause to be affixed
the Seal of the State of New Hampshire,
this 14th day of May A.D. 2018.

A handwritten signature in cursive script, appearing to read "William M. Gardner".

William M. Gardner
Secretary of State

CERTIFICATE OF VOTE/AUTHORITY

I, Stephen Harvey, of the Biomedical Research Alliance of New York LLC ("Company"), do hereby certify that:

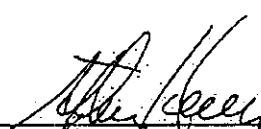
1. I am the duly elected member of the Board of Directors of the Biomedical Research Alliance of New York LLC;

This company may enter into any and all contracts, amendments, renewals, revisions or modifications thereto, with the State of New Hampshire, acting through its Department of Health and Human Services.

RESOLVED: That the Executive Vice President of Operations is hereby authorized on behalf of this company to enter into said contracts with the State, and to execute any and all documents, agreements, and other instruments, and any amendments, revisions, or modifications thereto, as he/she may deem necessary, desirable or appropriate. Kimberly Irvine is the duly elected Executive Vice President of Operations of the company.

3. The foregoing resolutions have not been amended or revoked and remain in full force and effect as of May 3, 2018.

IN WITNESS WHEREOF, I have hereunto set my hand as a member of the Board of Directors of the company on May 3, 2018.



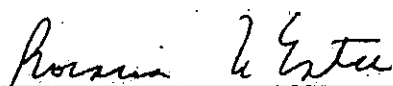
Stephen Harvey, Board of Directors Member
Biomedical Research Alliance of New York LLC

STATE OF NEW YORK
COUNTY OF NEW YORK

The foregoing instrument was acknowledged before me on May 3, 2018 by Stephen Harvey, member of the Board of Directors.

(NOTARY SEAL)

ROSARIA MCENTEE
NOTARY PUBLIC-STATE OF NEW YORK
NO. 01MC6178194
QUALIFIED IN NASSAU COUNTY
MY COMMISSION EXPIRES 11-19-2019



Notary Public/Justice of the Peace
My Commission Expires: _____

CERTIFICATE OF VOTE/AUTHORITY

I, Stephen Harvey, of the Biomedical Research Alliance of New York LLC ("Company"), do hereby certify that:


- 1. I am the duly elected member of the Board of Directors of the Biomedical Research Alliance of New York LLC;

This company may enter into any and all contracts, amendments, renewals, revisions or modifications thereto, with the State of New Hampshire, acting through its Department of Health and Human Services.

RESOLVED: That the Executive Vice President of Operations is hereby authorized on behalf of this company to enter into said contracts with the State, and to execute any and all documents, agreements, and other instruments, and any amendments, revisions, or modifications thereto, as he/she may deem necessary, desirable or appropriate. Kimberly Irvine is the duly elected Executive Vice President of Operations of the company.

- 3. The foregoing resolutions have not been amended or revoked and remain in full force and effect as of May 9, 2018.

IN WITNESS WHEREOF, I have hereunto set my hand as a member of the Board of Directors of the company on May 9, 2018.



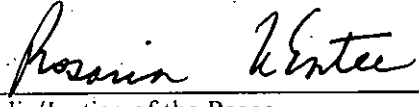
 Stephen Harvey, Board of Directors Member
 Biomedical Research Alliance of New York LLC

STATE OF NEW YORK
 COUNTY OF NEW YORK

The foregoing instrument was acknowledged before me on May 9³¹, 2018 by Stephen Harvey, member of the Board of Directors. RM

(NOTARY SEAL)

ROSARIA MCENTEE
NOTARY PUBLIC-STATE OF NEW YORK
NO. 01MC6178194
QUALIFIED IN NASSAU COUNTY
MY COMMISSION EXPIRES 11-19-2019



 Notary Public/Justice of the Peace
 My Commission Expires: _____



CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
12/28/2017

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Willis of New York, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: PHONE (A/C No. Ext): 1-877-945-7378 FAX (A/C No): 1-888-467-2378 E-MAIL ADDRESS: certificates@willis.com	
	INSURER(S) AFFORDING COVERAGE	
INSURED Biomedical Research Alliance of NY, LLC Attn: Joanne Nicholson 1981 Marcus Avenue Suite 210 Lake Success, NY 11042 USA	INSURER A: Valley Forge Insurance Company NAIC# 20508	
	INSURER B: National Fire Insurance Company of Hartford 20478	
	INSURER C: Continental Casualty Company 20443	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER: W4892146** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS
A	<input checked="" type="checkbox"/> COMMERCIAL GENERAL LIABILITY <input type="checkbox"/> CLAIMS-MADE <input checked="" type="checkbox"/> OCCUR			1089983012	12/31/2017	06/30/2018	EACH OCCURRENCE \$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER: <input type="checkbox"/> POLICY <input type="checkbox"/> PRO-JECT <input type="checkbox"/> LOC OTHER:						DAMAGE TO RENTED PREMISES (Ea occurrence) \$ 100,000
	AUTOMOBILE LIABILITY <input type="checkbox"/> ANY AUTO OWNED AUTOS ONLY <input type="checkbox"/> SCHEDULED AUTOS NON-OWNED AUTOS ONLY <input type="checkbox"/> HIRED AUTOS ONLY						MED EXP (Any one person) \$ 5,000
	UMBRELLA LIAB <input type="checkbox"/> OCCUR EXCESS LIAB <input type="checkbox"/> CLAIMS-MADE DED RETENTION \$						PERSONAL & ADV INJURY \$ 1,000,000
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below		Y/N	1089987383	12/31/2017	06/30/2018	GENERAL AGGREGATE \$ 2,000,000
	Workers Compensation & Employers Liability Per Statute		N/A	6045717931	12/31/2017	06/30/2018	PRODUCTS - COMP/OP AGG \$ 0
							COMBINED SINGLE LIMIT - (Ea accident) \$
							BODILY INJURY (Per person) \$
							BODILY INJURY (Per accident) \$
							PROPERTY DAMAGE (Per accident) \$
							EACH OCCURRENCE \$
							AGGREGATE \$
							\$
							<input checked="" type="checkbox"/> PER STATUTE <input type="checkbox"/> OTH-ER
							E.L. EACH ACCIDENT \$ 1,000,000
							E.L. DISEASE - EA EMPLOYEE \$ 1,000,000
							E.L. DISEASE - POLICY LIMIT \$ 1,000,000
							E.L. EACH ACCIDENT \$1,000,000
							E.L. DISEASE - EACH EMP \$1,000,000
							E.L. DISEASE - POLICY \$1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER **CANCELLATION**

NH DHHS
 Contracts & Procurement Unit
 129 Pleasant Street
 Concord, NH 03301

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE



Jeffrey A. Meyers
Commissioner

E. Marie Reinemann, Esq.
Director

STATE OF NEW HAMPSHIRE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF BUSINESS OPERATIONS
Bureau of Contracts & Procurement

129 PLEASANT STREET, CONCORD, NH 03301-3857
603-271-9564 1-800-852-3345 Ext. 9564
Fax: 603-271-8431 TDD Access: 1-800-735-2964 www.dhhs.nh.gov

June 14, 2018

Kimberly Irvine
Biomedical Research Alliance of New York
1981 Marcus Avenue
Suite 210
Lake Success, NY 11042

Re: SS-2018-DPHS-04-INST, Institutional Review Board Services

Dear Ms. Irvine:

Congratulations on the approval by the Department of the minor contract between you and the Department of Health and Human Services, Division of Public Health Services.

Your minor contract was approved by the Department on June 5, 2018. A countersigned copy of your approved minor contract is enclosed for your files.

Amy Bergquist from the Division of Public Health will be in touch with you to address a start date and invoicing. You may contact Amy at 603 271-9295.

Sincerely,

Shannon DuBreuil

Shannon DuBreuil
Contract Specialist