

FDP Cost Reimbursement Subaward

Federal Awarding Agency: National Institutes of Health (NIH)	
Pass-Through Entity (PTE): Northeastern University	Subrecipient: Boston Medical Center
PTE PI: Timothy Bickmore	Sub PI: Michael Pasache-Orlow
PTE Federal Award No: 1R01MD016882-01	Subaward No: 500759-78050
Project Title: Community-based Design and Evaluation of a Conversational Agent to Promote SARS-COV2 Vaccination in Black Churches	
Subaward Budget Period: Start: 04/23/2021 End: 01/31/2022	Amount Funded This Action (USD): \$ 164,426.00
Estimated Period of Performance: Start: 04/23/2021 End: 01/31/2025	Incrementally Estimated Total (USD): \$ 667,605.00

Terms and Conditions

1. PTE hereby awards a cost reimbursable subaward, (as determined by 2 CFR 200.331), to Subrecipient. The Statement of Work and budget for this Subaward are as shown in Attachment 5. In its performance of Subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.
2. Subrecipient shall submit invoices not more often than monthly and not less frequently than quarterly for allowable costs incurred. Upon the receipt of proper invoices, the PTE agrees to process payments in accordance with this Subaward and 2 CFR 200.305. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), breakdown by major cost category, Subaward number, and certification, as required in 2 CFR 200.415(a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments shall be directed to the party's Financial Contact, shown in Attachment 3A.
3. A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Financial Contact, as shown in Attachment 3A, not later than 60 days after the final Budget Period end date. The final statement of costs shall constitute Subrecipient's final financial report.
4. All payments shall be considered provisional and are subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Subrecipient.
5. Matters concerning the technical performance of this Subaward shall be directed to the appropriate party's Principal Investigator as shown in Attachments 3A and 3B. Technical reports are required as shown in Attachment 4.
6. Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this Subaward, and any changes requiring prior approval, shall be directed to the PTE's Administrative Contact and the Subrecipient's Authorized Official Contact shown in Attachments 3A and 3B. Any such change made to this Subaward requires the written approval of each party's Authorized Official as shown in Attachments 3A and 3B.
7. The PTE may issue non-substantive changes to the Budget Period(s) and Budget Unilaterally. Unilateral modification shall be considered valid 14 days after receipt unless otherwise indicated by Subrecipient when sent to Subrecipient's Administrative Contact, as shown in Attachment 3B.
8. Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.
9. Either party may terminate this Subaward with 30 days written notice. Notwithstanding, if the Awarding Agency terminates the Federal Award, PTE will terminate in accordance with Awarding Agency requirements. PTE notice shall be directed to the Administrative Contact, and Subrecipient notice shall be directed to the Authorized Official Contact as shown in Attachments 3A and 3B. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix IX, as applicable.
10. By signing this Subaward, including the attachments hereto which are hereby incorporated by reference, Subrecipient certifies that it will perform the Statement of Work in accordance with the terms and conditions of this Subaward and the applicable terms of the Federal Award, including the appropriate Research Terms and Conditions ("RTCs") of the Federal Awarding Agency, as referenced in Attachment 2. The parties further agree that they intend this subaward to comply with all applicable laws, regulations, and requirements.

By an Authorized Official of the PTE: Name: Eva Pasadas, JD Date: _____ Title: Director of Grants and Contracts	By an Authorized Official of the Subrecipient: Name: _____ Date: _____ Title: _____
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Attachment 1
Certifications and Assurances

Subaward Number:

500759-78050

Certification Regarding Lobbying (2 CFR 200.450)

By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief, that no Federal appropriated funds have been paid or will be paid, by or on behalf of the Subrecipient, 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, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement in accordance with 2 CFR 200.450.

If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or intending 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, the Subrecipient shall complete and submit Standard Form -LLL, "Disclosure Form to Report Lobbying," to the PTE.

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 31 U.S.C. 1352. 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.

Debarment, Suspension, and Other Responsibility Matters (2 CFR 200.214 and 2 CFR 180)

By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief that neither the Subrecipient nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this transaction by any federal department or agency, in accordance with 2 CFR 200.213 and 2 CFR 180.

Audit and Access to Records

Subrecipient certifies that it will provide PTE with notice of any adverse findings which impact this Subaward. Subrecipient certifies compliance with applicable provisions of 2 CFR 200.501-200.521. If Subrecipient is not required to have a Single Audit as defined by 200.501, Awarding Agency requirements, or the Single Audit Act, then Subrecipient will provide notice of the completion of any required audits and will provide access to such audits upon request. Subrecipient will provide access to records as required by parts 2 CFR 200.337 and 200.338 as applicable.

Program for Enhancement of Contractor Employee Protections (41 U.S.C 4712)

Subrecipient is hereby notified that they are required to: inform their employees working on any federal award that they are subject to the whistleblower rights and remedies of the program; inform their employees in writing of employee whistleblower protections under 41 U.S.C §4712 in the predominant native language of the workforce; and include such requirements in any agreement made with a subcontractor or subgrantee.

The Subrecipient shall require that the language of the certifications above in this Attachment 1 be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

Use of Name

Neither party shall use the other party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may use factual information regarding the existence and purpose of the relationship that is the subject of this Subaward for legitimate business purposes, to satisfy any reporting and funding obligations, or as required by applicable law or regulation without written permission from the other party. In any such statement, the relationship of the parties shall be accurately and appropriately described.

Prohibition on Certain Telecommunication and Video Surveillance Services or Equipment

Pursuant to 2 CFR 200.216, Subrecipient will not obligate or expend funds received under this Subaward to: (1) procure or obtain; (2) extend or renew a contract to procure or obtain; or (3) enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that uses covered telecommunications equipment or services (as described in Public Law 115-232, section 889) as a substantial or essential component of any system, or as a critical technology as part of any system.

Attachment 2
Federal Award Terms and Conditions

Subaward Number
500759-78050

Required Data Elements

The data elements required by Uniform Guidance are incorporated in the attached Federal Award.

Awarding Agency Institute (If Applicable)

Federal Award Issue Date	FAIN	Assistance Listing No.

This Subaward Is:

- Research & Development Subject to FFATA

Assistance Listing Program Title (ALPT)

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Key Personnel Per NOA

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General Terms and Conditions

By signing this Subaward, Subrecipient agrees to the following:

1. To abide by the conditions on activities and restrictions on expenditure of federal funds in appropriations acts that are applicable to this Subaward to the extent those restrictions are pertinent. This includes any recent legislation noted on the Federal Awarding Agency's website:

<http://grants.nih.gov/policy/notices.htm>

2. 2 CFR 200 and 45 CFR Part 75.

3. The Federal Awarding Agency's grants policy guidance, including addenda in effect as of the beginning date of the period of performance or as amended found at:

<http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>

4. Research Terms and Conditions, including any Federal Awarding Agency's Specific Requirements found at:

<https://www.nsf.gov/awards/managing/rtc.jsp> except for the following :

- a. No-cost extensions require the written approval of the PTE. Any requests for a no-cost extension shall be directed to the **Administrative** Contact shown in Attachment 3A, not less than 30 days prior to the desired effective date of the requested change.
- b. Any payment mechanisms and financial reporting requirements described in the applicable Federal Awarding Agency Terms and Conditions and Agency-Specific Requirements are replaced with Terms and Conditions (1) through (4) of this Subaward; and
- c. Any prior approvals are to be sought from the PTE and not the Federal Awarding Agency.
- d. Title to equipment as defined in 2 CFR 200.1 that is purchased or fabricated with research funds or Subrecipient cost sharing funds, as direct costs of the project or program, shall vest in the Subrecipient subject to the conditions specified in 2 CFR 200.313.
- e. Prior approval must be sought for a change in Subrecipient PI or change in Key Personnel (defined as listed on the NOA).

5. Treatment of program income: **Additive**

Special Terms and Conditions:

Data Sharing and Access:

Subrecipient agrees to comply with the Federal Awarding Agency's data sharing and/or access requirements as reflected in the NOA or the Federal Awarding Agency's standard terms and conditions as referenced in General Terms and Conditions 1-4 above.

Attached is a Data Management and/or Sharing Plan that incorporates additional requirements as submitted to the Federal Awarding Agency.

Data Rights:

Subrecipient grants to PTE the right to use data created in the performance of this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Copyrights:

Subrecipient Grants to PTE an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted material (including any computer software and its documentation and/or databases) first developed and delivered under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Subrecipient grants to PTE the right to use any written progress reports and deliverables created under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its Federal Award.

Promoting Objectivity in Research (COI):

Subrecipient must designate herein which entity's Financial Conflicts of Interest policy (COI) will apply: **Subrecipient**

If applying its own COI policy, by execution of this Subaward, Subrecipient certifies that its policy complies with the requirements of the relevant Federal Awarding Agency as identified herein: **NIH - 42 CFR Part 50 Subpart F**

Subrecipient shall report any financial conflict of interest to PTE's Administrative Representative or COI contact, as designated on Attachment 3A. Any financial conflicts of interest identified shall, when applicable, subsequently be reported to Federal Awarding Agency. Such report shall be made before expenditure of funds authorized in this Subaward and within 45 days of any subsequently identified COI.

Work Involving Human or Vertebrate Animals (Select Applicable Options)

No Human or Vertebrate Animals

This section left intentionally blank.

Human Subjects Data (Select One)

Human Subjects Data will be exchanged under this Subaward (check all that apply):

- From Subrecipient to PTE
- From PTE to Subrecipient

The PTE will set forth the terms of the exchange of Human Subjects Data (Select One):

NIH Terms and Conditions

The Clinical Trial Indicator in Section IV of the PTE's NOA is stated as:

Multiple PIs (MPI)

Certificate of Confidentiality:

The Parties agree that this research funded in whole or in part by the National Institutes of Health ("NIH"), is subject to NIH Policy NOT-OD-17-109 (the "Policy") and therefore is deemed under the Policy to be issued a Certificate of Confidentiality ("Certificate") should the conditions outlined within the Policy apply. Accordingly, the subrecipients who collect or receive identifiable, sensitive information are required to adhere to the Policy and protect the privacy of individuals who are subjects of such research in accordance with the Policy and subsection 301(d) of the Public Health Service Act (the "PHS Act").

Additional Terms

Only de-identified data is approved for exchange in this subaward. In the event the parties wish to exchange identifiable human subjects data, a modification to this agreement will be needed, signed by institutional officials of both parties.

Attachment 3A
Pass-Through Entity (PTE) Contacts

Subaward Number:

500759-78050

PTE Information

Entity Name: Northeastern University

Legal Address:
360 Huntington Ave
Boston, MA 02115

Website: www.northeastern.edu

PTE Contacts

Central Email: NU-RES@northeastern.edu

Principal Investigator Name: Timothy Bickmore

Email: bickmore@ccs.neu.edu

Telephone Number: (617) 373-5477

Administrative Contact Name: Nancy Thomas

Email: nan.thomas@northeastern.edu

Telephone Number: 617-373-8507

COI Contact email (if different to above):

Financial Contact Name: Alex Tran

Email: research_invoices@northeastern.edu

Telephone Number: 617-373-6504

Email invoices? Yes No Invoice email (if different): research_invoices@northeastern.edu

Authorized Official Name: Eva Pasadas, JD

Email: e.pasadas@northeastern.edu

Telephone Number: 617-373-7269

PI Address:

Northeastern University
360 Huntington Ave
Boston, MA 02115

Administrative Address:

Northeastern University
Research Administration
Mail Stop 540-177 (5th floor)
360 Huntington Ave
Boston, MA 02115

Invoice Address:

research_invoices@northeastern.edu

Attachment 3BResearch Subaward Agreement
Subrecipient Contacts

Subaward Number:

500759-78050

Subrecipient Information for [FFATA](#) reporting

Entity's DUNS Name: Boston Medical Center Corporation

EIN No.: 04-3314093

Institution Type: Nonprofit with 501c3 Status (other than Inst. of Higher Ed.)

DUNS: 00-549-2160

Currently registered in SAM.gov: Yes NoExempt from reporting executive compensation: Yes No (if no, complete 3Bpg2)

Parent DUNS: 00-549-2160

*This section for U.S. Entities:*Zip Code [Look-up](#)

Congressional District: MA-007

Zip Code+4: 02118-2908

Place of Performance Address801 Massachusetts Ave, 2nd floor
Boston, MA 02118**Subrecipient Contacts**

Central Email: subaward@bmc.org

Website: www.bmc.org

Principal Investigator Name: Michael Paasche-Orlow

Email: mpo@bu.edu

Telephone Number: 617-414-5877

Administrative Contact Name: Lori Henault

Email: lori.henault@bmc.org

Telephone Number: 617-414-6935

Financial Contact Name: Sr Research Finance Manager

Email: Research.Finance@bmc.org

Telephone Number: 617-638-8000

Invoice Email: BMCsubinvoice@bmc.org

Authorized Official Name: Stephanie Wasserman

Email: stephanie.wasserman@bmc.org

Telephone Number: 617-414-2860

Legal Address:One Boston Medical Center Place
Boston, MA**Administrative Address:**One Boston Medical Center Place
Boston, MA**Payment Address:**One Boston Medical Center Place
Boston, MA

Attachment 3B-2
Highest Compensated Officers

Subaward Number:
500759-78050

Subrecipient:

Institution Name: Boston Medical Center

PI Name: Michael Pasache-Orlow

Highest Compensated Officers

The names and total compensation of the five most highly compensated officers of the entity(ies) must be listed if the entity in the preceding fiscal year received 80 percent or more of its annual gross revenues in Federal awards; and \$25,000,000 or more in annual gross revenues from Federal awards; and the public does not have access to this information about the compensation of the senior executives of the entity 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. See FFATA § 2(b)(1) Internal Revenue Code of 1986.

Officer 1 Name:

Officer 1 Compensation:

Officer 2 Name:

Officer 2 Compensation:

Officer 3 Name:

Officer 3 Compensation:

Officer 4 Name:

Officer 4 Compensation:

Officer 5 Name:

Officer 5 Compensation:

Attachment 4
Reporting and Prior Approval Terms

Subaward Number:
500759-78050

Subrecipient agrees to submit the following reports (PTE contacts are identified in Attachment 3A):

Technical Reports:

- Monthly technical/progress reports will be submitted to the PTE's within days of the end of the month.
- Quarterly technical/progress reports will be submitted within 30 days after the end of each project quarter to the PTE's .
- Annual technical / progress reports will be submitted within days prior to the end of each budget period to the PTE's . Such report shall also include a detailed budget for the next Budget Period, updated other support for key personnel, certification of appropriate education in the conduct of human subject research of any new key personnel, and annual IRB or IACUC approval, if applicable.
- A Final technical/progress report will be submitted to the PTE's within days of the end of the Project Period or after termination of this award, whichever comes first.
- Technical/progress reports on the project as may be required by PTE's in order for the PTE to satisfy its reporting obligations to the Federal Awarding Agency.

Prior Approvals:

Carryover:

Other Reports:

- In accordance with 37 CFR 401.14, Subrecipient agrees to notify both the Federal Awarding Agency via iEdison and PTE's within 60 days after Subrecipient's inventor discloses invention(s) in writing to Subrecipient's personnel responsible for patent matters. The Subrecipient will submit a final invention report using Federal Awarding Agency specific forms to the PTE's within 60 days of the end of the Project Period to be included as part of the PTE's final invention report to the Federal Awarding Agency.
A negative report is required:
- Property Inventory Report (only when required by Federal Awarding Agency), specific requirements below.

Additional Technical and Reporting Requirements:

Attachment 5
Statement of Work, Cost Sharing, Indirects & Budget

Subaward Number:

500759-78050

Statement of Work

Below Attached, pages

If award is FFATA eligible and SOW exceeds 4000 characters, include a *Subrecipient Federal Award Project Description*

Year 01:

Investigators at Boston Medical Center will work with programmers at Northeastern, the Black Ministerial Alliance, and participants from member churches to design and add content to the Embodied Conversational Agent smartphone application. This new content will focus on vaccine promotion and mitigating vaccine hesitancy.

Year 02:

Investigators at Boston Medical Center will participate in the effort of outreach and initiation of participating churches as well as ongoing support of the intervention. Investigators at Boston Medical Center will also participate in the routine monitoring of system parameters that may need to be altered based on changes in vaccination guidelines and emerging topics that relate to vaccine hesitancy.

Year 03:

Investigators at Boston Medical Center will participate in the ongoing effort of supporting members of participating churches as needed during the intervention. Investigators at Boston Medical Center will also participate in the routine monitoring of system parameters that may need to be altered based on changes in vaccination guidelines and emerging topics that relate to vaccine hesitancy.

Year 04:

Investigators at Boston Medical Center will participate in analyses and the presentation of findings at conferences and in the peer-reviewed literature.

Budget Information

Indirect Information Indirect Cost Rate (IDC) Applied %

Cost Sharing

Rate Type:

If Yes, include Amount: \$

Budget Details Below Attached, pages

Budget Totals

Direct Costs \$

Indirect Costs \$

Total Costs \$

All amounts are in United States Dollars

Attachment 6

Notice of Award (NOA) and any additional documents

- The following pages include the NOA and if applicable any additional documentation referenced throughout this Subaward.
- Not incorporating the NOA or any additional documentation to this Subaward.



Recipient Information	Federal Award Information																										
1. Recipient Name NORTHEASTERN UNIVERSITY 360 HUNTINGTON AVE BOSTON, MA 02115 2. Congressional District of Recipient 07 3. Payment System Identifier (ID) 1041679980A1 4. Employer Identification Number (EIN) 041679980 5. Data Universal Numbering System (DUNS) 001423631 6. Recipient's Unique Entity Identifier 7. Project Director or Principal Investigator TIMOTHY W. BICKMORE, PHD (Contact) Professor BICKMORE@CCS.NEU.EDU (617) 373-5477 8. Authorized Official Kelly Basner	11. Award Number 1R01MD016882-01 12. Unique Federal Award Identification Number (FAIN) R01MD016882 13. Statutory Authority 42 USC 241 42 CFR 52 14. Federal Award Project Title Community-based Design and Evaluation of a Conversational Agent to Promote SARS-COV2 Vaccination in Black Churches 15. Assistance Listing Number 93.307 16. Assistance Listing Program Title Minority Health and Health Disparities Research 17. Award Action Type New Competing (REVISED) 18. Is the Award R&D? Yes																										
Federal Agency Information 9. Awarding Agency Contact Information Sy Shackelford NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES shackelfords@mail.nih.gov 301-402-1366 10. Program Official Contact Information Nancy Lynne Jones Health Scientist Administrator NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES jonesna@mail.nih.gov 301-594-8945	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2" style="background-color: #e1eef6; text-align: center;">Summary Federal Award Financial Information</th> </tr> </thead> <tbody> <tr> <td colspan="2" style="background-color: #e1eef6;">19. Budget Period Start Date 04/23/2021 – End Date 01/31/2022</td> </tr> <tr> <td>20. Total Amount of Federal Funds Obligated by this Action</td> <td style="text-align: right;">\$0</td> </tr> <tr> <td style="padding-left: 20px;">20 a. Direct Cost Amount</td> <td style="text-align: right;">\$0</td> </tr> <tr> <td style="padding-left: 20px;">20 b. Indirect Cost Amount</td> <td style="text-align: right;">\$0</td> </tr> <tr> <td>21. Authorized Carryover</td> <td style="text-align: right;">\$0</td> </tr> <tr> <td>22. Offset</td> <td style="text-align: right;">\$0</td> </tr> <tr> <td>23. Total Amount of Federal Funds Obligated this budget period</td> <td style="text-align: right;">\$766,758</td> </tr> <tr> <td>24. Total Approved Cost Sharing or Matching, where applicable</td> <td style="text-align: right;">\$0</td> </tr> <tr> <td>25. Total Federal and Non-Federal Approved this Budget Period</td> <td style="text-align: right;">\$766,758</td> </tr> <tr> <td colspan="2" style="text-align: center;">-----</td> </tr> <tr> <td colspan="2" style="background-color: #e1eef6;">26. Project Period Start Date 04/23/2021 – End Date 01/31/2025</td> </tr> <tr> <td>27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period</td> <td style="text-align: right;">\$766,758</td> </tr> </tbody> </table> 28. Authorized Treatment of Program Income Additional Costs 29. Grants Management Officer - Signature Priscilla Grant	Summary Federal Award Financial Information		19. Budget Period Start Date 04/23/2021 – End Date 01/31/2022		20. Total Amount of Federal Funds Obligated by this Action	\$0	20 a. Direct Cost Amount	\$0	20 b. Indirect Cost Amount	\$0	21. Authorized Carryover	\$0	22. Offset	\$0	23. Total Amount of Federal Funds Obligated this budget period	\$766,758	24. Total Approved Cost Sharing or Matching, where applicable	\$0	25. Total Federal and Non-Federal Approved this Budget Period	\$766,758	-----		26. Project Period Start Date 04/23/2021 – End Date 01/31/2025		27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	\$766,758
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27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	\$766,758																										
30. Remarks Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.																											



SECTION I – AWARD DATA – 1R01MD016882-01 REVISED

Principal Investigator(s):

TIMOTHY W. BICKMORE (contact), PHD
Michael Paasche-Orlow, MD
Andrea G Parker, PHD

Award e-mailed to: ORAF@neu.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see “Award Calculation” in Section I and “Terms and Conditions” in Section III) to NORTHEASTERN UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as “Research reported in this publication was supported by the National Institute On Minority Health And Health Disparities of the National Institutes of Health under Award Number R01MD016882. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.” Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

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

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Priscilla Grant
Grants Management Officer
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	\$132,606
Fringe Benefits	\$27,211
Personnel Costs (Subtotal)	\$159,817
Consultant Services	\$63,000
Materials & Supplies	\$11,700
Travel	\$2,700
Other	\$12,323
Subawards/Consortium/Contractual Costs	\$335,902

Federal Direct Costs	\$585,442
Federal F&A Costs	\$181,316
Approved Budget	\$766,758
Total Amount of Federal Funds Authorized (Federal Share)	\$766,758
TOTAL FEDERAL AWARD AMOUNT	\$766,758

AMOUNT OF THIS ACTION (FEDERAL SHARE) \$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	THIS AWARD	CUMULATIVE TOTALS
1	\$766,758	\$766,758
2	\$723,305	\$723,305
3	\$705,630	\$705,630
4	\$698,072	\$698,072

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier: 1041679980A1
Document Number: RMD016882A
PMS Account Type: P (Subaccount)
Fiscal Year: 2021

IC	CAN	2021	2022	2023	2024
OD	8045155	\$766,758			
MD	8472687		\$723,305	\$705,630	\$698,072

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:

PCC: CPS12NJ / **OC:** 41021 / **Released:** Grant, Priscilla 09/27/2021
Award Processed: 09/28/2021 12:05:29 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01MD016882-01 REVISED

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

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01MD016882-01 REVISED

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

- a. The grant program legislation and program regulation cited in this Notice of Award.

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

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

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

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

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

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

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

This award has been assigned the Federal Award Identification Number (FAIN) R01MD016882. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

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

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of [Public Law 110-85](#)), the “responsible party” must register “applicable clinical trials” on the [ClinicalTrials.gov Protocol Registration System Information Website](#). NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

Office Of The Director, National Institutes Of Health (OD)
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In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – MD SPECIFIC AWARD CONDITIONS – 1R01MD016882-01 REVISED

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

INFORMATION: This revised award reflects the NIMHD's acceptance of the awardee's letter dated August 16th, 2021, certifying IRB approval on September 10, 2021. Accordingly, the special condition prohibiting research involving human subjects on the Notice of Grant Award issue on April 27th, 2021 is removed, effective as of the date of IRB approval.

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects at any site engaged in such research for any period not covered by both (1) the awardee's OHRP-approved Assurance and if performance sites are involved, each performance site's OHRP-approved Assurance(s) and (2) appropriate IRB approvals consistent with all OHRP-approved Assurances.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ISSUED ON 04/27/2021 ALSO APPLY TO THIS AWARD:

INFORMATION: This award has been revised to correct the Common Account Number in future years.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF GRANT AWARD ISSUED ON 4/23/2021 ALSO APPLY TO THIS AWARD:

REQUIREMENT: This award is subject to the conditions set forth in NOT-MD-21-008, *Notice of Special Interest (NOSI): Research to Address Vaccine Hesitancy, Uptake, and Implementation among Populations that Experience Health Disparities*, NIH Guide to Grants and Contracts, December 17, 2020; and PA-20-183, *Research Project Grant (Parent R01 Clinical Trial Required)*, NIH Guide to Grants and Contracts, 5/5/2020, which are hereby incorporated by reference as special terms and conditions of this award.

Copies of the NOSI may be accessed at the following internet address:

<https://grants.nih.gov/grants/guide/notice-files/NOT-MD-21-008.html>

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

INFORMATION: This award has been funded by the NIH Office of the Director.

REQUIREMENT In addition to the annual RPPR, the recipient is required to email an interim progress report on September 15th during the first year to the Program Official with copies to the Grants Management Specialist and pg38h@nih.gov. The interim report must include a statement on the progress made toward key milestones for each of the specific aims, and a brief summary of major activities, significant results, and key outcomes or other achievements for each specific aim. It should also include a description of all interim research data/products or findings released and shared with the public.

NOTICE OF SPECIAL INTEREST (NOSI) TERMS

A trans-NIH working group is making existing COVID-19 survey items and investigator contact information publicly available through several NIH-supported platforms: the NIH CDE Repository (<https://cde.nlm.nih.gov/home>) the NIH Public Health Emergency and Disaster Research Response (DR2) [<https://dr2.nlm.nih.gov/>], the NCI CDE Browser (<https://cdebrowser.nci.nih.gov/cdebrowserClient/cdeBrowser.html#/search>) and the PhenX Toolkit [<https://www.phenxtoolkit.org/index.php>]. Researchers addressing COVID19 questions, whether population-based or for clinical research, are strongly encouraged to consider these COVID-19 specific survey item repositories and select existing survey items or protocol modules currently being fielded when they address questions of interest. Additionally, researchers with funding through this NOSI are required to share their survey items to make them public for other researchers to consider by submitting their surveys to NIHCOVID19Measures@nih.gov

REQUIREMENT The recipient is required to follow the data and safety monitoring plan included in the application and may not implement any changes in the plan without the written prior approval of the NIMHD.

INFORMATION: In accordance with the National Institute on Minority Health and Health Disparities' (NIMHD's) Fiscal Year (FY) 2021 funding policies, this award has been issued at 90% of the adjusted requested level. Future year committed levels* have been adjusted accordingly.

** committed level: The level of support calculated by applying the NIMHD funding plan to the corrected recommended level for each budget category for all years of the project period

RESTRICTION The clinical trial(s) supported by this award is subject to the plan in the competing application submitted to NIH and the NIH policy on *Dissemination of NIH-Funded Clinical Trial Information*. The plan states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance. This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:

In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

REQUIREMENT: Use of humans and animals in any new activities must be requested prior to the start of the activity and must be approved in writing in advance by the NIMHD. See NOT-MD-08-002, "Guidance and Clarification on NCMHD Policy on Prior Approval for Subprojects and Pilot Projects Involving Human Subjects or Vertebrate Animals," NIH Guide to Grants and Contracts, April 29, 2008, which is hereby incorporated by reference as special terms and conditions of this award. See also NOT-OD-15-129, "Prior NIH Approval of Human Subjects Research in Active Awards Initially Submitted without Definitive Plans for Human Subjects Involvement (Delayed Onset Awards): Updated Notice," and NIH-OD-15-128, "Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval: Updated Notice."

Copies of these Notices may be accessed at the following internet address: <http://www.nih.gov/grants/guide/index.html>

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

RESTRICTION: Stipends and payments made for educational assistance (e.g., scholarships, fellowships, and student aid costs) may not be paid from NIH research grant funds even when they would appear to benefit the research project (NIH GPS Section 7.9.1). Compensation must be in accordance with organizational policies consistently applied to both federally and non-federally supported activities and must be supported by acceptable accounting records that reflect the employer-employee relationship. Under these conditions, the funds provided as compensation for services rendered are not considered stipend supplementation; they are allowable charges to Federal grants, including PHS research grants. (A stipend is a payment made to an individual under a fellowship or training grant in accordance with pre-established levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.) See the NIH Grants Policy Statement for allowable forms of student compensation, available at <http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>.

INFORMATION: In order to redistribute awards more evenly throughout the year, budget periods are being adjusted. This award is issued with a 9.3-month budget period and with 12 months of support. Continuation awards will cycle each year on February 1st.

INFORMATION: Although the budget period start date for this award is 4/23/21, this award includes funds for 12 months of support. Future year budget periods will cycle on February 1st. Allowable preaward costs may be charged to this award, in accordance with the conditions outlined in the NIH Grants Policy Statement, and with institutional requirements for prior approval. The NIH GPS can be found on the internet at <http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>.

INFORMATION: This award reflects the NIMHD's acceptance of the certification that all key personnel have completed education on the protection of human subjects, in accordance with NIH policy, "Required Education in the Protection of Human Research Participants," as announced in the June 5, 2000 NIH Guide (revised August 25, 2000) (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>).

Any individual involved in the design and conduct of the study that is not included in the certification must satisfy this requirement prior to participating in the project. Failure to comply can result in the suspension and/or termination of this award, withholding of support of the continuation award, audit disallowances, and/or other appropriate action.

INFORMATION: See "Federalwide Assurance Requirements" and "Certification of IRB Approval" under the Human Subjects Protections section in the NIH Grants Policy Statement (NIHGPS), for specific requirements and recipient responsibilities related to the protection of human subjects, which are applicable to and are a term and condition of this award. The NIHGPS can be found on the internet at <http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>.

INFORMATION: Funds awarded for direct cost compensation for Graduate Research Assistants are limited in accordance with the NIH policy.

INFORMATION: None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. See the new Salary Limitations on Grants: https://grants.nih.gov/grants/policy/salcap_summary.htm

INFORMATION: Unobligated balances may be used by the NIMHD to reduce or offset funding for a subsequent budget period.

INFORMATION: Regarding changes in scope, attention is called to the NIH Grants Policy Statement. The Change in Scope section is found in Section 8.1.2 at <http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>. The recipient must obtain prior approval from the NIMHD for a change in the direction, aims, objectives, purposes, or type of research or training, or other areas that constitute a significant change in the approved project. Specific examples are provided.

INFORMATION: Regarding allowability of selected items of cost, attention is called to the NIH Grants Policy Statement. The Selected Items of Cost section is found in Section 7.9.1 at <http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>.

INFORMATION: Honoraria are unallowable when the primary intent is to confer distinction on, or to symbolize respect, esteem, or admiration for, the recipient of the honorarium. A payment for services rendered, such as a speaker's fee under a conference grant, is allowable. See Section 7.9.1 at <http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>.

INFORMATION: This award includes funds awarded for consortium activity. Consortia are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH GPS is available at: <http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>. See "Consortium Agreements" in Section 15 for specific responsibilities and requirements for recipients and consortium participants, which are applicable to and are a term and condition of this award.

INFORMATION: For administrative and management concerns, contact the Grants Management Specialist, Sy L. Shackelford, at (301) 451-8542. For programmatic and scientific concerns, contact the Program Director, Dr. Nancy L. Jones, at (301) 594-8945.

SPREADSHEET SUMMARY

AWARD NUMBER: 1R01MD016882-01 REVISED

INSTITUTION: NORTHEASTERN UNIVERSITY

Budget	Year 1	Year 2	Year 3	Year 4
Salaries and Wages	\$132,606	\$92,081	\$88,991	\$87,137
Fringe Benefits	\$27,211	\$20,076	\$19,273	\$18,791
Personnel Costs (Subtotal)	\$159,817	\$112,157	\$108,264	\$105,928
Consultant Services	\$63,000	\$117,000	\$117,000	\$117,000
Materials & Supplies	\$11,700	\$5,760	\$4,050	\$540
Travel	\$2,700	\$2,700	\$2,700	\$2,700
Other	\$12,323	\$6,144	\$21,390	\$21,390
Subawards/Consortium/Contractual Costs	\$335,902	\$336,928	\$307,786	\$309,406
TOTAL FEDERAL DC	\$585,442	\$580,689	\$561,190	\$556,964
TOTAL FEDERAL F&A	\$181,316	\$142,616	\$144,440	\$141,108

TOTAL COST	\$766,758	\$723,305	\$705,630	\$698,072
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Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4
F&A Cost Rate 1	57%	57%	57%	57%
F&A Cost Base 1	\$318,098	\$250,203	\$253,404	\$247,558
F&A Costs 1	\$181,316	\$142,616	\$144,440	\$141,108

RESOURCE SHARING PLAN

OVERALL

Sharing of data and resources generated by this project is an essential part of our proposed activities and will be carried out in several different ways. We wish to make our results available both to the community of scientists interested in using health IT to help mitigate disparities and the effects of public health emergencies, as well as to the communities that would benefit most from implementation of such technologies. In addition, we would welcome collaboration with others who could make use of the technologies developed as part of our activities.

RESOURCE SHARING

Resource/data developed: Smartphone application

If the smartphone application that is developed as part of this effort is effective and accepted, we plan to expand its use to churches that were not involved in the research, and the ECA-based smartphone app developed will be available for download without charge through the App Store.

DATA SHARING PLAN

We view data sharing as an important part of the responsible conduct of research and are committed to sharing all data generated by this grant. We will follow NIH Grants Policies concerning the sharing of research data (<http://grants.nih.gov/grants/guide/noticefiles/NOT-OD-03-032.html>), and will make available to the public the results of any projects arising from this cohort and any accompanying data that were supported by the grant.

Subject to institutional policies, local IRB guidelines, and local, state and Federal laws and regulations we will make finished research data available through scientific presentations, publications (paper, web and other), depositing data in searchable electronic repositories, attendance at scientific meetings and extending invitations to scientists from other institutions for discussion. In accordance with the NIH policy, such data shall be made widely and freely available while safeguarding the privacy of participants and protecting our confidential and proprietary data.

The rights and privacy of people who participate in NIH-sponsored research will be protected at all times. In the event that data are intended for broader use, the data will be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. Sharing of more sensitive data will use methods such as encrypting the data files (e.g., using PGP encryption) to ensure that the file remains secure during transmission to the authorized recipient. Fully de-identified data sets, in which all HIPAA-defined individual identifiers are removed, will be suitable for many types of exploratory data analyses. No efforts will be made to identify individual cases, and any shared archive data will not be linked to other identifiable data. Only select members of the research team will have access to any linking files.

We also anticipate maintaining awareness of, and possibly participating in, discussions between members of multiple scientific and technical disciplines and their professional societies concerning data sharing, standards and best practices, and to create an environment that supports and develops data sharing tools. We will participate in or make ourselves aware of the outcome of any workshops the NIH convene to address data sharing and that may address areas such as cleaning and formatting data, writing documentation, redacting data to protect subjects' identities and proprietary information, and estimating costs to prepare documentation and data for sharing. We will work closely to develop and update plans and procedures to protect the security of data.

SHARING MODEL ORGANISMS

N/A – There is no development of model organisms anticipated in this project

GENOMIC DATA SHARING PLAN

N/A – There will be no genomic data generated from this project. There will be no biospecimen samples collected as part of this project.

MULTIPLE PRINCIPAL INVESTIGATOR LEADERSHIP PLAN

Drs. Timothy Bickmore, Michael Paasche-Orlow, and Andrea Grimes Parker will serve as PIs together for the project.

Dr. Bickmore will supervise activities at Northeastern University, including finalizing the intervention, enrollment, randomization, and data collection and all aspects of the clinical trial to evaluate the intervention. He will supervise the project manager, Dr. Lin Shi (intervention technology development management, IRB protocol management, subject tracking, database development, data entry, data quality control), and the BMA Liaison during the first year of technology development. He will also supervise the research assistants engaged in enrollment, informed consent and data collection, and Dr. Cabral, the statistician, during the two clinical trials.

Dr. Paasche-Orlow will supervise activities at Boston Medical Center including collaboration on the development of the intervention. He will supervise the BMC project manager, Lori Henault, in addition to Drs. Joseph, Perkins, Dedier, and Johnson.

Dr. Parker will supervise activities at Georgia Tech, including direction of all qualitative assessments (focus groups, interviews) and participatory design activities on the project, and will supervise Northeastern and BMC personnel assisting with these activities.

The three PIs will collaborate on all data analysis.

The PIs will form a Steering Committee (membership will include the PIs, Dr. Shi, Lori Henault, and Dr. Cabral) that will manage the oversight and coordination of project management, research administration, publications and data sharing, and integration of all resources needed for the project.

Northeastern will subdivide the award funds and each PI will be responsible for his/her own budget. The Steering Committee will oversee decisions on minor changes in research direction and have the authority to reallocate funds and resources between PIs. Dr. Bickmore will serve as Chair of the Steering Committee and be responsible for communication among the PIs, including meeting schedules and agendas. Dr. Bickmore will be designated the contact PI and be responsible for submitting all necessary documents to NIH, including IRB approvals, and annual progress reports.

Intellectual Property

The PIs will grant necessary access rights to the pre-existing patents and or the patents potentially generated within the frame of this project for the purpose of this research project to each other and key personnel on a non-exclusive royalty-free basis. Each PI shall take appropriate measures to ensure that he/she can grant these access rights. Right in any pre-existing intellectual property will remain the property of the party that created and/or controls it.

Conflict Resolution

If a potential conflict develops, the appropriate Departmental administrators representing the PIs shall meet and attempt in good faith to settle any dispute, claim or controversy arising out of or relating to the interpretation, performance or breach of this disagreement. However, if the Departmental administrators fail to resolve the disagreement within thirty business days, then such disagreement shall be referred for resolution to a designated senior executive of the parties who has the authority to settle the disagreement but who is not directly involved in the disagreement.

Attachment 7
Human Subjects Data Transfer and Use Terms

Human Subjects Data (“Data”) will be exchanged under this Subaward (check all that apply):

- From Subrecipient to PTE
- From PTE to Subrecipient

1. The Party providing the Data will be referred to as the “Provider,” and the Party receiving the Data will be referred to as the “Recipient” as reflected above in this section.
2. The Data to be shared will be
3. Provider authorizes Recipient to share the Data as may be required under the data sharing plan for this project, as may be required by the Data Sharing & Access section of this Agreement.
4. Upon completion of the Recipient shall retain or destroy the Data as instructed by the Provider; provided, however, that Recipient may retain one (1) archival copy of the Data.
5. Description of Data (Description is required if data is categorized as “Other” above; Optional otherwise):

Description of Data:

Only de-identified data is approved for exchange in this subaward. In the event the parties wish to exchange identifiable human subjects data, a modification to this agreement will be needed, signed by institutional officials of both parties.

De-identified Additional Terms and Conditions:

The Data will not include personally identifiable information as defined in NIST Special Publication 800-122. If the Data being provided is coded, the Provider will not release, and the Recipient will not request, the key to the code.

If Provider is a Covered Entity, the Data will be de-identified data, as defined by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

Recipient will not use the Data to identify or contact individuals who are or may be the sources of Data. Should Recipient inadvertently receive identifiable information or otherwise identify a subject, Recipient shall promptly notify Provider and follow Provider's reasonable written instructions, which may include return or destruction of the identifiable information.

Recipient shall promptly report to the Provider any use or disclosure of the Data not provided for by this Agreement of which it becomes aware.