Research Subaward Agreement Amendment				
Pass-through Entity (PTE) Subrecipient			ient	
PTE	Sustan of Li	Subrecipient		
Temple University - Of The Commonwealth System of Hig Address		Address	of Texas At Dallas	
3340 North Broad Street, Student Faculty Center	4th Floor, Suit			
City, State, Zip+4 (Country): Philadelphia, PA	ity, State, Zip+4 (Country): Philadelphia, PA 19140-5104 City, State, Zip+4 (Country): Richardson, TX 75080-3021		rdson, TX 75080-3021	
PTE Principal Investigator (PI): Joseph Picone		Subrecipient Prir Sanda Harabagiu	ncipal Investigator (P	I):
PTE Federal Award No: 5U01HG008468-03	FAIN: U01HG0084			ng Agency: Iman Genome Research Institu
Project Title: Automatic discovery and process	sing of EEG	cohorts from clin	ical records	
Subaward Period of Performance: Start Date: Jun 1, 2015 End Date: May 31, 2018	Amount Fu		Amendment No: 002	Subaward No: 255929-UTAD
Effective Date of Amendment: Jun 8, 2017	Total Amount Funds Obliga	^	133,372.00	Subject to FFATA
Amendme This Amendment revises th		inal Terms and C enced Research S		t as follows:
 Action: 1. The Subaward Period of Performance is extended through May 31, 2018. The revised performance period is June 01, 2015 through May 31, 2018. 2. The funded amount of this Subaward is hereby increased by \$143,675 which includes \$93,905 Direct Costs and \$49,770 Indirect Costs for a total funded amount of \$433,372. 3. Applicable provisions of the Current Prime Award, which is attached hereto as Attachment 1, are hereby incorporated. 4. Applicable provision of the Current Subrecipient Commitment Short Form, which is attached hereto as Attachment 2, are hereby incorporated. 				
All other terms and conditions of this Subaward Agreement remain in full force and effect.				
By an Authorized Official of Pass-through En	-	By an Autho 12:34 EDT	rized Official of Su	Aug 3, 2017 Aug 3, 2017
Name Associate Vice President for Budget	Date		west Campbell Road, st=1 c=US, cn=Emily Lacy, email=elr102020@utdallas Date: 2017.08.03 10:21:19	Date
		THE	, <u></u> ,	

HUMAN SERVICES. LS

Notice of Award RESEARCH PROJECT COOPERATIVE AGREEMENT Federal Award Date: 06/08/2017 Department of Health and Human Services National Institutes of Health



NATIONAL HUMAN GENOME RESEARCH INSTITUTE

THIS AWARD IS FUNDED AS AN NIH ROADMAP INITIATIVE

 Grant Number:
 5U01HG008468-03

 FAIN:
 U01HG008468

Principal Investigator(s):

Sanda Maria Harabagiu Iyad Obeid, PHD Joseph Picone (contact), PHD

Project Title: Automatic discovery and processing of EEG cohorts from clinical records

Karen Mitchell Senior Director, Grants Management Temple University -Of the Commonwealth System of Higher Education 3340 North Broad Street, Rm 427C- SFC - 4th Floor Philadelphia, PA 191405104

Award e-mailed to: nih@temple.edu

Period Of Performance: Budget Period: 06/01/2017 – 05/31/2018 Project Period: 06/01/2015 – 05/31/2018

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$435,047 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to TEMPLE UNIV OF THE COMMONWEALTH in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Human Genome Research Institute of the National Institutes of Health under Award Number U01HG008468. 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.

DocuSign Envelope ID: C9EDD102-B717-4BB5-8C3C-B67C8248B820..., please contact the individual(s) referenced in Section IV.

Sincerely yours,

Monika Christman Grants Management Officer NATIONAL HUMAN GENOME RESEARCH INSTITUTE

Additional information follows

Award Calculation (U.S. Dollars)	¢100.010
Salaries and Wages	\$120,610
Fringe Benefits	\$23,417
Personnel Costs (Subtotal)	\$144,027
Consultant Services	\$25,000
Materials & Supplies	\$1,750
Travel	\$16,000
Subawards/Consortium/Contractual Costs	\$143,675
Federal Direct Costs	\$330,452
Federal F&A Costs	\$104,595
Approved Budget	\$435,047
Total Amount of Federal Funds Obligated (Federal Share)	\$435,047
TOTAL FEDERAL AWARD AMOUNT	\$435,047
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$435,047

SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
3	\$435,047	\$435,047

t
-

IC	CAN	2017
OD	8018959	\$435,047

NIH Administrative Data: PCC: X4HS / OC: 414P / Released: CHRISTMANM 06/07/2017 Award Processed: 06/08/2017 12:34:36 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 5U01HG008468-03

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

SECTION III – TERMS AND CONDITIONS – 5U01HG008468-03

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 VI Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

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) U01HG008468. 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: <u>http://publicaccess.nih.gov/</u>.

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

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports,

http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the

DocuSign Envelope ID: <u>C9EDD102-B717-4BB5-8C3C-B67C8248B820</u>, ward at the lower amount. This could be considered a debt or result in disallowed costs.

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

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

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

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

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

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

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

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)

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 – HG Special Terms and Conditions – 5U01HG008468-03

The requested budget was considered and determined not to represent significant rebudgeting. Therefore, categorical amounts reflect the direct and facilities and administrative cost levels previously recommended for the current year.

This award is issued as a Cooperative Agreement, a financial assistance mechanism in which substantial NIH scientific and/or programmatic involvement is anticipated in the performance of the activity. This award is subject to the Terms and Conditions of Award as set forth in the Section VI. Award Administration Information of RFA-HG-14-020 "Development of Software and Analysis Methods for Biomedical Big Data in Targeted Areas of High Need", released on 2/19/14 which are hereby incorporated by reference as special terms and conditions of this award.

This RFA may be accessed at: <u>http://grants.nih.gov/grants/guide/index.html</u> or obtained from the Grants Management Contact referenced in the award.

These special Terms and Conditions of Award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, Federal Regulations, including DHHS Grant Administration Regulations at 42 CFR Part 52, 45 CFR Parts 74 and 92, other DHHS and NIH grant administration policies, and the NIH Grants Policy Statement.

Dissemination of software will be in accord with the Grantee's Software Dissemination Plan as stated on page 77 of the application. Failure to adhere to the sharing plan as mutually agreed upon by the Grantee and the National Cancer Institute may result in Enforcement Actions as described in the NIH Grants Policy Statement under Administrative Requirements. A link to the NIH GPS is available through the following NIH Guide

Notice:http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-087.html

This award includes funds awarded for consortium activity with The University of Texas at Dallas in the amount of \$143,675 (\$93,905 direct costs + \$49,770 facilities and administrative costs). 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/HTML5/section_15/15.1_general.htm

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Anneliese B. Galczynski Email: galczynskia@mail.nih.gov Phone: 301-443-4935 Fax: 301-451-5434

Program Official: Heidi J Sofia Email: heidi.sofia@nih.gov Phone: 301.496.7531 Fax: 301.480.2770

SPREADSHEET SUMMARY GRANT NUMBER: 5U01HG008468-03

INSTITUTION: TEMPLE UNIV OF THE COMMONWEALTH

Budget	Year 3
Salaries and Wages	\$120,610
Fringe Benefits	\$23,417
Personnel Costs (Subtotal)	\$144,027
Consultant Services	\$25,000
Materials & Supplies	\$1,750

Page-6

DocuSign Envelope ID: C9EDD102-B717-4BB5-8C3C-B67C8248B820	\$16,000
Subawards/Consortium/Contractual Costs	\$143,675
TOTAL FEDERAL DC	\$330,452
TOTAL FEDERAL F&A	\$104,595
TOTAL COST	\$435.047

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	56%
F&A Cost Base 1	\$186,777
F&A Costs 1	\$104,595



SUBRECIPIENT COMMITMENT SHORT FORM

RESET FORM

Office of the Vice President for Research Administration, Division of Grants Management Complete and return a signed copy to Grants Management at <u>subawards@temple.edu</u>

RETURN BY: 06/16/a. All Subrecipients must complete and return this form for renewal and continuation awards issued by TEMPLE UNIVERSITY. It provides a checklist of documents and certifications required by sponsors and it must be endorsed by the Subrecipient's Authorized Official.

Prime: Temple University-Of The Comm	nonwealth System of Higher Education	
SPONSOR AWARD #: 5U01HG008468-03	TEMPLE PI NAME: Joseph Picone	eRA#: 255929-03 SUB AWARD # 255929-UTAD
Title of Proposal: Automatic Discovery an	d Processing EEG Cohorts from Clir	nical Records
Period of Performance: FROM: 06/01/2017	^{TO:} 05/31/2018	e viter de la constance de la c
Sponsor: National Human Gen B. SUBRECIPIENT INFORMATION	ome Research Institute	
Subrecipient's Legal Name: The University	e of Toyon at Dallas	
PI Name: Sanda Harabagiu	or rexas at Dallas	
Address where work will be performed: 80	0 W Campbell Rd ECSS-3 411 Richar	dson TX 75080 2021
DUNS# 800188161 EIN #: 75-1305566		uson, 1X / 5000-5021
C. PROPOSAL DOCUMENTS		
The following \checkmark documents are required fr	om the subrecipient and covered by the ce	ertification below. Return all documents ✓.
STATEMENT OF WORK		
BUDGET AND BUDGET JUSTIFICATION: 1	TOTAL AMOUNT REQUESTED FOR THIS PERI	OD:\$
PROGRESS REPORT:		
CARRY FORWARD REQUEST:		
REGULATORY APPROVALS (IRB, IACUC, I		
ADMINISTRATOR NAME & EMAIL: Lela	a Paksoy, Grants Specialist, osp@utdallas	s.edu
OTHER:		
D. SPECIAL REVIEW & CERTIFICATIONS		
conflicts of interest have or will have	reby certifies that it has an active and enforced e been satisfactorily managed, reduced, or licy prior to the expenditure of any funds.	eliminated in accordance with
What year is the most recent fiscal year If there are findings, submit a copy of th (Provide URL or attach the most rece	audit complete? 2016 Were there any finding e most recent report that describes the findin nt audit):	$gs? \square Yes No$ ng and steps to be taken to correct the finding.
Is the PI or any other employee or student part (If yes please explain:	rticipating in this project debarred, suspended or othe	erwise excluded from or ineligible? Yes 🖌 No
SUBRECIPIENT CERTIFIES: The informatian authorized official of the subrecipient name	on, certifications, and representations abov ed herein. Authorized official affirms a	e have been read, signed and made by an Il statements are true.
ma		
Signature of Authorized Official for Subrecipient		
Rafael Martin	<u> </u>	
Type or Print Name	Date	
Interim VP for Research	osp@utdallas.edu	•
Title of Authorized Official	Email Address of Author	rized Official

Statement of Work

A consortium/contractual arrangement will be established between the Temple University and the University of Texas at Dallas (UTD). Dr. Harabagiu will lead activities at UTD. Dr. Harabagiu will lead the development of the system capable of automatically recognizing critical concepts in the EEG reports as well as the patient cohort retrieval system. She will collaborate with Professors Joseph Picone and Iyad Obeid from Temple University that will provide her with (a) the EEG reports and the annotations required for training the various classifiers she will develop for automatically detecting in EEG reports (1) clinical events, (2) their attributes, (3) their types, (4) polarity and (5) modality, as well as (6) medical concepts; (7) spatial expressions; (8) temporal expressions; (9) temporal relations and (10) spatial relations; and (b) EEG events that are derived automatically from the EEG signal as well as the features used at Temple University for processing such events. Prof. Harabagiu will also develop an active-learning framework that will accelerate the annotations on EEG reports produced at Temple University. Professor Harabagiu will also collaborate with Professors Joseph Picone and Iyad Obeid from Temple University to evaluate the patient cohort retrieval system that she will develop at UTD by designing the evaluation protocol and using the feedback to improve the system.

Budget

Salaries	
S. Harabagiu	\$ 42,612
TBD, Graduate Student	\$ 33,714
Total Salaries	\$ 76,326
FRINGE BENEFITS	\$ 13,580
TOTAL SALARIES AND FRINGE BENEFITS	\$ 89,906
TRAVEL	
Domestic	\$ 3,000
OTHER DIRECT COSTS	
Publications	\$ 1,000
TOTAL OTHER DIRECT COSTS	\$ 1,000
TOTAL DIRECT COSTS	\$ 93,906
INDIRECT COSTS @ 53% MTDC	\$ 49,770
TOTAL COSTS	\$143,675

Salaries and Wages: Salaries for all personnel are based upon current University of Texas at Dallas academic and staff salary scales.

Prof. Sanda Harabagiu, Principal Investigator, will provide the overall direction and management of the Aim 2: Automatically Critical Clinical Concepts in EEG Report, and Aim 3: Automatic Patient Cohort Retrieval of the project entitled "Automatic Processing and Discovery of Patient Cohorts from EEGs and EEG Reports" as well as participating in the technical research and publication activities. Prof. Sanda Harabagiu, will collaborate closely with Professors Joseph Picone and Iyad Obeid from Temple University as well as the physicians from Temple Hospital involved in the project. She will work closely with Prof. Picone and Obeid to design the annotations required for Aim 2 a well as to integrate the results from Temple University in her work. In addition, she will collaborate on the evaluation of the patient cohort retrieval system as well as the evaluation of the results of the automatic processing of critical clinical concepts that she will develop at UTD. Prof. Harabagiu will also supervise the research of two graduate PhD students. This research will form the core of two PhD dissertations. We request summer salary support for Prof. Sanda Harabagiu at a level of 3 months each year for the duration of the project. However, Prof. Harabagiu shall direct the research of this project throughout the year.

We request salary support for 1.5 graduate research assistants. One graduate assistant will have a support each year at 50% time during the academic year, and at 50% time during the summer months. The role of this graduate research assistant includes conducting original research in Clinical Natural Language Processing for Aim 2. The second PhD student will focus on developing the patient cohort retrieval system with the clinical information that is going to be derived in Aim 2 as well as in Aim 1 of the project. In addition, both PhD students will participate in the design and testing of the patient cohort retrieval system as well as the clinical processing developed in Aim 2. The two PhD students that will be assigned to work on this project will be paid at \$1883/month for their activity.

Benefits: Employee benefits were estimated using the published University of Texas at Dallas rates. Benefit rates used in this proposal are 20% of salary of the PI and 15% for graduate students during the academic year and summer months.

Travel: A total of 2 domestic trips are requested yearly to attend technical meetings and workshops that are relevant to the project's overall research, and for scientific exchange. Domestic trips are estimated at \$1500 each roundtrip. Expenses include estimates for airfare, ground transportation, hotel accommodations, registration for conferences and workshops (if applicable), and per diem. Relevant conferences where we anticipate publishing the results are the annual AMIA symposium and the annual AMIA Summit on Clinical Research.

Materials and Supplies: No costs for materials and supplied are requested.

Publications Costs/page charges: A total of \$3000 is requested for the cost of preparing and publishing the results of the work conducted under the award. We are requesting for \$1000 in year 1 and in each subsequent year.

Other: Tuition reimbursement is requested for the graduate research assistants at a level of \$0 per year. Under agreement by The University of Texas at Dallas, tuition for "doctorally qualified" PhD students, who are supported by an RA on an externally funded grant, will have their tuition paid by the Provost. The students proposed to be used on this project qualify for this benefit, and therefore, no tuition is being requested.

Indirect Costs: Indirect costs were estimated in accordance with UTD's rate agreement, which was approved by DHHS, the Federal Cognizant Audit Agency for UTD on 02/04/2016. The organized research F&A cost rate of 53% MTDC was used based on the nature of the proposed work.