

CITY OF EL PASO, TEXAS  
AGENDA ITEM  
DEPARTMENT HEAD'S SUMMARY FORM

DEPARTMENT: Public Health

AGENDA DATE: 1/22/19

CONTACT PERSON NAME AND PHONE NUMBER: Robert Resendes 915-212-6500

DISTRICT(S) AFFECTED: All

STRATEGIC GOAL: Goal 8: Nurture and Promote a Healthy, Sustainable Community

**SUBJECT:**

Be it resolved by the City Council of the City of El Paso that the Mayor be authorized to sign a Second Amendment to the Interlocal Agreement between the City of El Paso (the "City") and Texas Tech University Health Sciences Center at El Paso ("TTUHSC EP"), to extend the ending date to January 31, 2020, to allow TTUHSC EP additional time to complete the research activities and findings on the research subjects currently enrolled, without further subject enrollment, in order to develop a regional human dental tissue and fluid bank for the research project entitled "Oral Health El Paso 1115 Waiver Program Project;" and to reduce the cost to the City by an amount of \$315,091.00, for a total payment by the City to TTUHSC EP of \$642,967.00, paid with funding from the Texas Healthcare and Quality Improvement Program 1115 Demonstration Waiver Program to support Medicaid Waiver projects.

**BACKGROUND / DISCUSSION:**

n/a

**PRIOR COUNCIL ACTION:**

Previously approved on February 9, 2016 and May 30, 2017

**AMOUNT AND SOURCE OF FUNDING:**

Previously approved \$642,967.00 funding from the Texas Healthcare and Quality Improvement Program 1115 Demonstration Waiver Program.

**BOARD/COMMISSION ACTION:**

\*\*\*\*\*REQUIRED AUTHORIZATION\*\*\*\*\*

**DEPARTMENT HEAD:**



*Information copy to appropriate Deputy City Manager*

CITY CLERK DEPT  
2019 JAN 16 PM 2:45

## RESOLUTION

### BE IT RESOLVED BY THE CITY COUNCIL OF THE CITY OF EL PASO:

That the Mayor be authorized to sign a Second Amendment to the Interlocal Agreement between the City of El Paso (the "City") and Texas Tech University Health Sciences Center at El Paso ("TTUHSC EP"), to extend the ending date to January 31, 2020, to allow TTUHSC EP additional time to complete the research activities and findings on the research subjects currently enrolled, without further subject enrollment, in order to develop a regional human dental tissue and fluid bank for the research project entitled "Oral Health El Paso 1115 Waiver Program Project;" and to reduce the cost to the City by an amount of \$315,091.00, for a total payment by the City to TTUHSC EP of \$642,967.00, paid with funding from the Texas Healthcare and Quality Improvement Program 1115 Demonstration Waiver Program to support Medicaid Waiver projects.

Dated this \_\_\_\_\_ day of January, 2019.

CITY OF EL PASO

\_\_\_\_\_  
Dee Margo, Mayor

ATTEST:

\_\_\_\_\_  
Laura D. Prine  
City Clerk

APPROVED AS TO FORM

  
\_\_\_\_\_  
Elizabeth Ruhmann  
Assistant City Attorney

APPROVED AS TO CONTENT

  
\_\_\_\_\_  
Robert Resendes, MBA, MT (ASCP)  
Department of Public Health, Director

THE STATE OF TEXAS     §  
                                  §  
COUNTY OF EL PASO     §

**SECOND AMENDMENT TO  
INTERLOCAL AGREEMENT**

This Second Amendment to Interlocal Agreement (the Amendment) is entered into on \_\_\_\_\_, 2019 between the following parties:

The **CITY OF EL PASO** (the CITY) and **TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER AT EL PASO (TTUHSC EP)**, witnesseth:

**WHEREAS**, the Texas Interlocal Cooperation Act, V.T.C.A., Government Code, §791.001, *et seq.* allows local governments and political subdivisions of the state to contract among each other for governmental functions and services, including all or part of a function in the area of public health and welfare; and,

**WHEREAS**, on February 9, 2016, the CITY and TTUHSC EP entered into an Interlocal Agreement for TTUHSC EP researchers to conduct the research entitled “Oral Health El Paso 1115 Waiver Program Project” funded by the Texas Healthcare and Quality Improvement Program 1115 Demonstration Waiver Program to support Medicaid Waiver projects, as approved by the Centers for Medicare and Medicaid Services (the CMS); and

**WHEREAS**, on May 30, 2017, the CITY and TTUHSC EP entered into a First Amendment to the Interlocal Agreement (the Interlocal Agreement and First Amendment thereto are collectively referred to as the Agreement) to authorize other referral sources for research subjects and extend the project completion date to January 31, 2019; and

**WHEREAS**, the continued unavailability of the desired age distribution of research participants at City facilities or other referral sources has led to a lower recruitment of research subjects than expected; and

**WHEREAS**, the researchers have determined that a sufficient number of research subjects and associated biosamples are available to complete the research activities and maintain scientific rigor for peer review and publication of findings; and

**WHEREAS**, TTUHSC EP can complete the “Oral Health El Paso 1115 Waiver Program Project” with the current number of subjects/samples at a project cost reduction of \$315,091.00; and

**WHEREAS**, to allow TTUHSC EP sufficient time for analysis of specimens, interpretation of results, peer review of findings, and preparation of scientific articles and submission for publication, the Parties agree to extend the term of the Agreement to January 31, 2020, with no additional monetary compensation to be exchanged between the Parties for said extension of time; and

**WHEREAS**, the change in the end date will not detract from the final results of the research, which will develop a regional human DNA tissue and fluid bank, allow researchers to analyze said DNA, tissue and fluid samples for factors which may contribute to acute and chronic health conditions, with the results to be disseminated to the City in its capacity as a public health authority and other stakeholders to improve the health status of underserved populations in the El Paso region; and

**WHEREAS**, the City serves as El Paso's public health authority as defined by federal law; and

**WHEREAS**, any protected health information disclosed by TTUHSC EP to the City pursuant to this Agreement is for public health activities and purposes.

**NOW, THEREFORE**, for and in consideration of the following mutual promises, the parties agree to the following:

**1.0 Article I of the Agreement is deleted and replaced in its entirety as follows:**

## **ARTICLE I**

### **SERVICES**

TTUHSC EP will provide professional research services, specifically development of a regional human DNA tissue and fluid bank for 90 research subjects for (a) storage and classification using Laboratory Information Management System (LIMS software and methodologies, (b) DNA/RNA extraction and storage, and (c) salivary cytokine determination. In addition to testing of saliva samples for Human Immunodeficiency Virus infection (HIV), Hepatitis C Virus infection (HCV) and Human Papilloma Virus infection (HPV), Herpes Simplex Virus (HSV) plus biochemical and characterization of fluids.

Oral fluid and tissue samples will be collected from select patients receiving care at the City's fixed site Dental Clinic, Mobile Dental Clinic, with Dr. Ruben Roncallo, Dr. Hector Ocaranza and through other dental clinics. Saliva, DNA, tissue specimens, and other body fluids as available will be collected, prepared and stored by the TTUHSC EP Core Laboratories on behalf of the City's Department of Public Health located at 5115 El Paso Drive, El Paso, Texas (DPH).

The following services (the Services) will be provided by TTUHSC EP researchers who are qualified to conduct the project entitled "Oral Health El Paso 1115 Waiver Program Project":

1. Conduct an inventory of sample collection policies and procedures;
2. Obtain Institutional Biohazard Committee and Institutional Review Board (IRB) approval;
3. Collect and store data only from subjects who have provided an informed consent/assent and a HIPAA-appropriate medical authorization;
4. Complete REAL standardized surveys (attachment C) on all research participants and communicate results to the City of El Paso Department of Public Health if requested under the Common Rule as pertinent to the subject population being sampled;
5. Collaborate with City of El Paso fixed-site Dental Clinic, Mobile Dental Clinic, Dr. Ruben Roncallo, Dr. Hector Ocaranza pediatric offices and any other dental clinics or medical offices proposed by TTUHSC EP and approved in writing by the City's Public Health Director to perform requested oral health testing on those individuals who have signed an informed consent/assent and HIPAA-appropriate patient consent authorization;
6. Create a reliable coded data set for patient health information (PHI) collected and

- corresponding test results obtained on the oral health profile samples from the population covered by the City Dental Clinics and other City-approved referral sources;
7. Submit monthly activity and quarterly sustainability progress reports and the integrated final report to DPH; and
  8. Disseminate de-identified results to stakeholders that do not have the right to know PHI including, but not limited to, Texas Health and Human Services Commission, the Border Public Health Interest Group, TTUHSC El Paso faculty and other scientific professional organizations; and
  9. Actively participate in Border Public Health Interest Group activities.

Due to a change in the Common Rule 45 CFR 164.512, which takes effect in January 2019, data collected after the aforementioned legal change will be available to waiver staff. For all data collected prior to the aforementioned revision to the Common Rule, TTUHSC EP will share the research subject's identification number with the City of El Paso in its capacity as the public health authority. The public health authority will cross-reference the subject's identification number with the dental clinic patient's number. The waiver staff will be able to collect the necessary information from the subject's dental record.

These Services will be performed through the following three subprojects of the "Oral Health El Paso 1115 Waiver Program Project."

**(Subproject 1.) "Inflammatory, Microbiological, Genetic, Epigenetic and Environmental Factors Involved in Dental Caries and Periodontal Disease in El Paso Del Norte Region" (*El Paso Saliva and Dental Tissues Bio-Repository*):**

- TTUHSC EP will collect and store saliva, dental materials and oral tissues from uninsured and Medicaid-covered populations who have provided an informed consent/assent and a HIPAA-appropriate medical authorization. Saliva collected in approved collection kits from the City Dental Clinic, the Mobile Dental Clinic and other City-approved recruitment sites will be cataloged, processed, for DNA/RNA and made available to the other subprojects after testing for types of oral bacteria, HCV, HIV HPV, and HSV.
- Extraction, quantification, and storage of DNA/RNA bio-bank using standard genomics methodologies for genetic studies (DNA biobank).
- Selective release of DNA, saliva and oral tissue specimens from the bank to local, state and federal entities for advancement of scientific knowledge in oral health and other diseases as well as use of saliva for the development of biomarkers for systemic, localized and chronic diseases, e.g., cancer and diabetes.
- Use of HIPAA compliant Laboratory Information Management System (LIMS) bio-bank software to facilitate designation/inclusion as a regional repository under the direction of a board-certified pathologist.
- Cost of collection, preparation, storage, retrieval and analysis services including bacterial and viral analysis will be \$126,931.00 in year one; \$116,036.00 in year two; \$0 in year three; and \$0 in year four, for a total Sub-project 1 cost of \$242,967.00.

**(Subproject 2.) "Role of Inflammation and Obesity in Chronic Disease in Hispanics in El Paso, TX" (*levels of Cytokines in Inflammatory Chronic Disease*):**

- Test saliva from up to 90 obese or lean subjects (between the ages of 10-21 years old), who have provided an informed consent/assent and a HIPAA-appropriate medical

- authorization, to determine levels of 25 pro-inflammatory cytokines.
- Share identifiable PHI data with the City of El Paso public health authority, if requested.
- Cost of specimen testing, data analysis, including complete uni-variant and multi-variant analysis, and interpretation/reporting of findings will be \$100,000.00 in year one; \$100,000.00 in year two; \$0 in year three; and \$0 in year four, for a total Sub-project 2 cost of \$200,000.00.

**(Subproject 3.) “Bacterial Cariogenic Salivary Profiles in El Paso TX” (“Oral Bacterial Genomics”)**

- Conduct multi-parametric molecular diagnostics tests for the detection of oral pathogens.
- Share identifiable data through the health authority, as pertinent.
- Cost of specimen testing, data analysis, and interpretation/reporting of findings will be \$100,000.00 in year one; \$100,000.00 in year two; \$0 in year three; and \$0 in year four, for a total Sub-project 3 cost of \$200,000.00.

All Services are to be performed by TTUHSC EP in accordance with the deliverables described in this Agreement and the attached Exhibit A, and in accordance with the Provisions of the Delivery System Reform Incentive Payment (DSRIP) guidelines, if appropriate to the research. TTUHSC EP shall perform the aforementioned Services according to the Deliverables and Reporting Requirements attached hereto as Exhibit A, and as may be modified by this amendment.

**2.0 The first paragraph of Article II of the Agreement shall be amended and replaced in its entirety as follows:**

**ARTICLE II**

**COMPENSATION**

The City agrees to pay TTUHSC EP for the aforementioned Services THREE HUNDRED TWENTY-SIX THOUSAND NINE HUNDRED AND THIRTY-ONE DOLLARS (\$326,931) on or before the 1<sup>st</sup> of March 2016, with the condition precedent of completion of deliverables for the 1<sup>st</sup> payment, as described in Exhibit “A”; and THREE HUNDRED SIXTEEN THOUSAND THIRTY-SIX DOLLARS (\$316,036) on the 31<sup>st</sup> of March 2017, with the condition precedent of completion of deliverables for the 2<sup>nd</sup> payment, as described in Exhibit “A”. No further payments will be made by the City. The total compensation from the City to TTUHSC EP shall not exceed SIX HUNDRED FORTY-TWO THOUSAND NINE HUNDRED SIXTY-SEVEN DOLLARS (\$642,967) during the term of this Agreement. The parties agree that the indirect cost for this project shall not exceed 10%. Indirect cost shall be included in, not in addition to, the above amounts.

**3.0 The first paragraph of Article VI of the Agreement shall be amended and replaced in its entirety as follows:**

**ARTICLE VI**

This Agreement became effective February 9, 2016, and will continue in full force until January 31, 2020.

**4.0 The first paragraph of Article XIII of the Agreement shall be amended and replaced in its entirety as follows:**

**ARTICLE XIII**

For those City and non-City-supplied patients who have executed an informed consent/assent and a HIPAA-appropriate medical authorization, TTUHSC EP shall have access to the complete patient medical records.

**5.0 Exhibit “A” is deleted and replaced with the 2<sup>nd</sup> Amended Exhibit “A” attached hereto.**

**6.0 Section A, Paragraph 3, of the Business Associate Agreement, which is attached as Exhibit “B” to the original agreement, shall be amended and replaced in its entirety in as follows:**

**Stated Purposes for which BUSINESS ASSOCIATE May Use or Disclose Information.**  
The Parties hereby agree that BUSINESS ASSOCIATE shall be permitted to use and/or disclose Information provided or made available from CITY for the following stated purposes:

To provide public health research and development, and related publication and communication to stakeholders and others to the community of the CITY for the mutual benefit and general welfare of BUSINESS ASSOCIATE and the CITY (ref. 45 C.F.R. 164.504(e)(2)(i); 65 Fed. Reg. 82505.)

**6.0 Section B, Paragraph 1, of the Business Associate Agreement, which is attached as Exhibit “B” to the original agreement, shall be amended and replaced in its entirety in as follows:**

**B. Term and Termination**

1. Term. The Term of this Agreement became effective February 9, 2016 and shall terminate on January 31, 2020 or on the date covered entity terminates for cause as authorized in paragraph (B.2.) of this Section, whichever is sooner.

**7.0 Except as amended by this Second Amendment, the Agreement shall remain in full force and effect.**

APPROVED this \_\_\_\_\_ day of \_\_\_\_\_, 2019.

**CITY OF EL PASO:**

\_\_\_\_\_  
Dee Margo  
Mayor

ATTEST:

\_\_\_\_\_  
Laura D. Prine  
City Clerk

APPROVED AS TO FORM:


  
\_\_\_\_\_  
Elizabeth Ruhmann  
Assistant City Attorney

APPROVED AS TO CONTENT:

  
\_\_\_\_\_  
Robert Resendes, MBA, MT (ASCP)  
Department of Public Health, Director

**TEXAS TECH UNIVERSITY HEALTH  
SCIENCES CENTER AT EL PASO:**

  
\_\_\_\_\_  
Frank G. Stout  
Vice President for Operations  
Chief Operating Officer

  
\_\_\_\_\_  
Sue M. Fuciarelli, MBA, CPA  
Vice President for Finance and Administration  
Chief Financial Officer



**2<sup>nd</sup> Amendment to Exhibit “A”**  
**Texas Tech University Health Sciences Center at El Paso**  
**Deliverables and Reporting Requirements**

	<b>Deliverable/Requirement</b>	<b>Due Date</b>
<b>Initial Required for 1<sup>st</sup> payment</b>	Study protocol and data collection instrument for each study	February 28, 2016
	Inventory data collection policies and procedures	February 28, 2016
	Institutional Review Board (IRB) approval	March 1, 2016
<b>2<sup>nd</sup> payment</b>		
	Progress Report to be submitted by end of each March, September and December	March 31, 2016 September 30, 2016 December 31, 2016 March 31, 2017 September 30, 2017 December 31, 2017 March 31, 2018  Annual Institutional Review Board (IRB) Review September 30, 2018
<b>No payment</b>	Data reported to City of El Paso in its capacity as the public health authority	November 15, 2018
	REAL data Questionnaire – as pertinent to the population under study – has been collected and shared with the City.	January 31, 2019
	Identifiable data has not been shared with the City, but will be shared once amendment is executed and IRB has approved its release (90 patients as of November 1, 2018).	February 15, 2019
<b>On-going</b>	Active participation in Border Public Health Interest Group, monthly	On-going through January 31, 2020
	Progress Report to be submitted by end of each March, September and December	December 31, 2018

<b>No payment</b>	Disseminate results at BPHIG meeting and other avenues, including peer-reviewed research publications.	March 31, 2019 September 30, 2019 December 31, 2019  On-going through January 31, 2020
<b>Final</b>	Final Report	January 31, 2020

**Study Title: Oral Health El Paso 1115 Waiver Program Project**