DEPARTMENT OF STATE HEALTH SERVICES

This Memorandum of Understanding (MOU) is entered into between the Department of State Health Services (DSHS) and Contractor Name (Contractor) who are collectively referred to as the "Parties."

I. Purpose of the MOU

DSHS agrees to provide Contractor certain confidential data for research studies or data projects approved by the DSHS Institutional Review Board (IRB). The Parties agree to the intended utilization of the data as outlined in Attachment A of this MOU. No personally identifiable or non-public data will be shared or released by Contractor without specific statutory authority and the prior written consent of DSHS.

II. Term of the MOU

Unless terminated as provided for in Section V(C), this MOU will become effective on the signature date of the latter of the Parties to sign this MOU, and end on XXXXXX. The Parties may renew this MOU for one additional three-year term by executing a written amendment. Data will not be shared between Parties without a written agreement in place. If the MOU expires or is terminated then data sharing will cease.

III. Authority

The Parties enter into this MOU under the authority of (please check all that apply):

- ☐ Title 45 Code of Federal Regulations Part 46 Protection of Human Subjects Subpart A (for all research requests involving human subjects);
- ☐ Texas Health and Safety Code, Title 3, Section 191.051 & Section 192.002(b); 25 Tex. Admin. Code Sec. 181.1(21) & 181.11 (Vital Event Data);
- ☐ Texas Health and Safety Code, Title 2, Section 82.009; 25 Tex. Admin. Code Sec. 91.12 (Data from the Texas Cancer Registry);
- ☐ Texas Health and Safety Code, Title 2, Section 87.002; Tex. Admin. Code Sec. 37.306 (Data from the Texas Birth Defects Registry);
- ☐ Texas Health and Safety Code, Title 2, Section 92.006; 25 Tex. Admin. Code Sec. 103.3 (Data from the Texas EMS & Trauma Registries);
- ☐ Texas Health and Safety Code, Title 2, Section 81.046 (Infectious Disease Registries, Data, or Biospecimens maintained by the DSHS Laboratory and Infectious Disease Section);
- ☐ Texas Health and Safety Code, Title 2, Section 33.018 (Newborn Screening Bloodspots and associated data);
- ☐ Texas Health and Safety Code, Title 2, Chapter 108; 25 Tex. Admin. Code, Chapter 421 (Data maintained by Texas Health Care Information Collection); and
- ☐ Other:

IV. Statement of Work

A. Contractor must:

1. Obtain approval for the IRB project by submitting an IRB Application.
2. Comply with the approved IRB Application as outlined in Attachment A and with approved IRB Protocol as outlined in Attachment A-1.
3. Comply with DSHS IRB policies and processes as found at the following link, https://www.dshs.texas.gov/irb/Default.shtm.
4. Maintain all documentation of the IRB process and provide such documentation to DSHS upon request.
5. Complete the Human Subject Research Training. All investigators and key personnel who participate in the protocol design, interact with any human subject for research purposes, obtain the informed consent of human subjects for research purposes, obtain identifiable information or biospecimens for research purposes or access, use, study or analyze identifiable information or biospecimens for research purposes must complete the Human Subject Research Training. DSHS-approved trainings include the Protecting Human Research Participants online training, the Collaborative Institutional Training Initiative (CITI) Program, and the Human Research Protection Training on the Office for Human Research Protections website. The links to these trainings can be found at https://www.dshs.texas.gov/irb/External-Researchers/. Contractor may request approval from DSHS to consider training certificates issued from the Contractor's institution.

B. Within ten days of the execution of this MOU, Contractor will submit Attachment B to the DSHS representative listed in Section VI. Contractor will list the names and job titles of all staff who will have access to the data. If the information changes on Attachment B, Contractor must submit an amendment application to the DSHS IRB for the requested changes.

C. DSHS will deliver data files via secure website data exchange, according to the variables submitted to and approved by DSHS on the appropriate Program Data Checklist, which shall be attached and incorporated in Attachment A as part of this MOU. Variables which will be provided include only those items in Attachment A that are available.

D. Contractor may request changes or additional variables by submitting an amendment application to the DSHS IRB for the requested changes.

E. Files containing confidential data will be delivered to Contractor as described in Section IV(C) above, as available.

F. Confidential data shall not be used for any purpose other than DSHS-approved studies or data projects specified in Attachment A-1 (IRB Protocol) unless specifically approved in writing by DSHS. DSHS will provide its approval or denial in writing.

G. The method of delivery of confidential data will be through the use of a secure file transfer protocol site or other method of data transfer with at least that same level of security and/or encryption whose internet address, log-in and password identification will be sent by DSHS personnel to the Contractor's representative listed in Section VI.

H. Upon conclusion of the research, Contractor must submit the DSHS IRB Final Report within

60 days of the completion of the study.

I. If Contractor wants to publish work based on data accessed pursuant to this MOU, and if Contractor's IRB Application does not include a statement of intent to publish, Contractor will submit an email to DSHS requesting permission to publish the results of the work under this MOU. The request must be made prior to submission for publication, and DSHS will provide written approval or denial. DSHS will have the right to comment on any written report, publication, or other literature.

V. General Terms and Conditions.

A. Amendment

This MOU may be modified by written amendment signed by the Parties.

B. Confidentiality

1. The Parties are required to comply with all applicable state and federal laws relating to the privacy and confidentiality of confidential data and records.
2. Contractor will comply with the Data Use Agreement incorporated into this MOU as Attachment C.
3. Contractor will maintain sufficient safeguards to prevent release or disclosure of any confidential records or information obtained under this MOU to anyone other than individuals who are authorized by law to receive such records or information and who will protect the records or information from re-disclosure as required by law. Data will be housed in a secure location. The foregoing shall not apply to information that:
   (i) is not disclosed in writing by DSHS or reduced to writing and marked confidential within 30 days after disclosure; or
   (ii) is already in Contractor's possession at the time of disclosure as evidenced by written records in the possession of Contractor prior to such time; or
   (iii) is or later becomes part of the public domain through no fault of Contractor; or
   (iv) is received from a third party having no obligations of confidentiality to DSHS; or
   (v) is independently developed by Contractor or by its personnel having no access to the Confidential Data.
4. Contractor will use confidential data obtained under this MOU only for purposes as described in this MOU and as otherwise allowed by law.
5. Notwithstanding any provision relating to confidentiality, the confidential information held by DSHS may be disclosed to a third party pursuant to the Texas Public Information Act (Texas Government Code Chapter 552), any open records decision or ruling by the Attorney General that such information constitutes public information, or as otherwise provided by law.
6. All confidential data provided as part of this MOU will be destroyed in accordance with the Data Destruction Provisions and Data Destruction Plan outlined by the Contractor in Attachment A-1.
7. Data no longer in use will be destroyed using software that renders these data unrecoverable.

C. Termination or Modification

The Parties agree that either Party may withdraw from this MOU for any reason.

D. Status of Parties

Contractor is not acting as an employee or agent of DSHS in providing the services and resources described in this MOU.

E. No Cost

This is a "no cost" agreement; the Contractor shall not be obligated to make any payments of any amount to DSHS or other parties as a result of this MOU. Any costs and expenses incurred under the terms of this MOU will be paid by the Party incurring the cost or expense. No funds appropriated to either Party will be exchanged under this MOU.

F. Duplicate Originals

Each Party agrees that this MOU may be executed in duplicate originals.

G. Amendment

This MOU may only be amended through a written agreement that is executed by both parties.

H. Texas Public Information Act

Each Party is responsible for complying with the provisions of Texas Government Code Chapter 552 ("Texas Public Information Act") and the attorney general opinions issued under that statute. Responses to requests for information shall be handled in accordance with the provisions of the Texas Public Information Act.

I. Right to Audit

The Parties acknowledge the State Auditor's authority to conduct audits of state agencies under Chapter 321 of the Texas Government Code.

J. Assignment

Neither Party will transfer, assign or sell its interest, in whole or in part, in this MOU without prior written consent of the other Party.

K. Dispute Resolution

The Parties agree to use good faith efforts to resolve all questions, difficulties, or disputes of any nature that may arise under or by this MOU; provided however, nothing in this paragraph shall preclude either Party from pursuing any remedies available under Texas law.

L. Force Majeure

Neither Party shall be liable to the other for any delay in, or failure of performance of, any requirement included in this MOU caused by force majeure. The existence of such causes of delay or failure shall extend the period of performance until after the causes of delay or failure have been removed provided the non-performing Party exercises all reasonable due diligence to

perform. Force majeure is defined as acts of God, war, fires, explosions, hurricanes, floods, failure of transportation, or other causes that are beyond the reasonable control of either Party and that by exercise of due foresight such Party could not reasonably have been expected to avoid, and which, by the exercise of all reasonable due diligence, such Party is unable to overcome.

M. Severability

If any provision of this MOU is construed to be illegal or invalid, that provision will be deemed stricken to the same extent as if it was never an element of the MOU, but all other provisions will continue in effect.

N. No Waiver

This MOU shall not constitute or be construed as a waiver of any of the privileges, rights, defenses, remedies, or immunities available to either Party as an agency of the State of Texas or otherwise available to the Party. The failure to enforce or any delay in the enforcement of any privileges, rights, defenses, remedies, or immunities available to a Party under this MOU or under applicable law shall not constitute a waiver of such privileges, rights, defenses, remedies, or immunities or be considered as a basis for estoppel. Neither Party waives any privileges, rights, defenses, or immunities available to it as an agency of the State of Texas, or otherwise available to it, by entering into this MOU or by its conduct prior to or subsequent to entering into this MOU.

O. Governing Law and Venue

The Parties agree that this MOU in all respects shall be governed by and constructed in accordance with the laws of the state of Texas, except for its provisions regarding conflicts of laws. The venue of any suit sought in connection with terms and conditions of this agreement is fixed in any court of competent jurisdiction in Travis County, Texas, unless mandated otherwise by statute.

VI. Authorized Representatives

The following will act as the representative authorized to administer activities under this MOU on behalf of their respective Party.

Contract Management Section (CMS)	DSHS	Contractor
Maria Acuña, Contract Manager 1100 W 49th Street, MC 1990 Austin, Texas 78756 Telephone: (512) 776-6629 Email: maria.acuna@dshs.texas.gov	Christopher Webb 1100 W 49th Street Austin, Texas 78756 Telephone: (512) 776-3216 Email: Christopher.webb@dshs.texas.gov	

VII. Legal Notices

Legal notices under this MOU shall be deemed delivered when deposited either in the United States mail, postage paid, certified, return receipt requested; or with a common carrier, overnight, signature required, to the appropriate address below:

DSHS
Department of State Health Services
Attn: General Counsel
1100 W. 49th Street, MC1919

Contractor
Contractor Name
Attn:
[street address]

Austin, Texas 78756 [city/state/zip]

Notice given in any other manner shall be deemed effective only when received by the Party to be notified. Either Party may change its address for receiving legal notice by notifying the other Party in writing.

SIGNATURE PAGE

By signing below, the Parties agree that this MOU constitutes the entire agreement between them. The Parties acknowledge that they have read the MOU and agree to its terms, and that the persons whose signatures appear below have the authority to execute this MOU on behalf of their respective Party.

Department of State Health Services	**Contractor**
_____	_____
Date of Execution: _____	Date of Execution: _____

THE FOLLOWING ATTACHMENTS TO ARE HEREBY ATTACHED AND INCORPORATED BY REFERENCE:

ATTACHMENT A	**APPLICATION FOR IRB PROJECT**
ATTACHMENT A-1	**PROTOCOL FORM**
ATTACHMENT B	**RESEARCH TEAM LOG**
ATTACHMENT C	**DATA USE AGREEMENT**

Attachment A: IRB Application

Reason for Submission (select one)	For DSHS IRB Office Use Only
☐ Initial Review	DSHS IRB# Number
☐ Existing DSHS IRB# Number	
Select submission request from the dropdown list.	
Submission Dropdown List	

Project Dates	
Estimated Project Start Date	Click to enter a date.
Estimated Project End Date	Click to enter a date.

Principal Investigator			
Name	Click to enter text.		
Organization	Click to enter text.		
Mailing Address	Click to enter text.		
City, State, Zip	Click to enter text.		
Phone Number	Click to enter text.	Email	Click to enter text.
Secondary Contact			
Name	Click to enter text.		
Organization	Click to enter text.		
Phone Number	Click to enter text.	Email	Click to enter text.

Are you submitting this application as a student?
☐ Yes (Enter your faculty advisor as a secondary contact if submitting as a student).
☐ No

Protocol Title
Click to enter text.

DSHS and HHSC Program Contacts			
Program Name	Contact Name	Contact Information	
Click to enter text.	Click to enter text.	Phone	Click to enter text.
		Email	Click to enter text.
Click to enter text.	Click to enter text.	Phone	Click to enter text.
		Email	Click to enter text.
Click to enter text.	Click to enter text.	Phone	Click to enter text.
		Email	Click to enter text.

Click to enter text.	Click to enter text.	Phone	Click to enter text.
		Email	Click to enter text.

Funding Source			
☐ Federal Grant ☐ State Grant ☐ Another Grant ☐ No Grant			
Grant Number	Click to enter text.	Grant Amount	Click to enter text.
Agency	Click to enter text.		

Subject Population
Check the special population(s) this study targets
☐ Pregnant women, human fetuses, neonates ☐ Children (17 years and younger) ☐ Prisoners ☐ Cognitively impaired persons

Reviews by Non-DSHS Institutional Review Boards	
Submit copies of other IRB determination letters. Enter "pending" if applicable.	
Name of Organization	Determination
Click to enter text.	Click to enter text.
Click to enter text.	Click to enter text.
Click to enter text.	Click to enter text.
Click to enter text.	Click to enter text.

Acknowledgement of DSHS IRB Requirements	
By initialing the box next to each condition, checking the conflicts of interest box, and signing this application, I certify that I meet all requirements of the DSHS IRB.	
Communication with Program Contact	
	I have communicated with the appropriate Department of State Health Services (DSHS) and Health and Human Services Commission (HHSC) program contacts to verify their support and the availability of the data and/or biospecimens for the requested timeframe.
	The program contacts disclosed any relevant fees or cost reimbursement required for the requested data or biospecimens. Payment must be received before the data or biospecimens are provided.
Disclosure of Conflicts of Interest	
	Investigators and members of their research team must report immediately below if they, their spouse, or dependent children have any of the following disclosable financial interests: • Ownership interest, stock, stock options, or other financial interest of more than $10,000 that is related to the research. • Compensation (salary, consultant payments, honoraria, royalty payments dividends, loans, or other payments or consideration with value) of more than $10,000 in the past year when aggregated for the immediate family that is related to the research. • Proprietary interest including, but not limited to, a patent, trademark, copyright, or licensing agreement that is related to the research. • Board or executive relationship, regardless of compensation, that is related to the research.

	☐ I do not have conflict(s) of interest to disclose. ☐ I have conflict(s) of interest to declare for myself or members of my research team and have included a Conflicts of Interest Letter in this submission.
Responsible Conduct of Research	
	I will meet exemplary standards of intellectual honesty in the formulation, conduct, reporting, and reviewing of this research study (as defined by the National Institutes of Health Office of Extramural Research https://grants.nih.gov/policy/research_integrity/what-is.htm).
	I declare that scientific integrity includes meticulous attention to the acquisition and maintenance of the research data or biospecimens.
	I will adhere to the applicable Federal laws and regulations; Texas state laws, regulations, statues and codes; and the Texas Health and Human Services system-wide, agency, and program policies to ensure compliance with the IRB approved protocol and the protection of the research subjects and their data, as communicated to me by the DSHS and HHSC program contact(s).
	I will adhere to the DSHS Human Subject Research Protection Training requirements and ensure all my research team members also comply.
Principles of Data Management	
	The electronic data will be stored in a secured and encrypted manner meeting applicable DSHS or HHSC-specified standards.
	Hard copies of all data or biospecimens will be stored in a secure location that meets DSHS or HHSC-specified standards.
	All data and biospecimens will be protected against unauthorized access, disclosure, transfer, modification, reproduction, and destruction.
	Data received from DSHS or HHSC will not be linked or matched to any other data without prior written permission from the DSHS or HHSC data source and approval from the DSHS IRB.
	For investigators who work for federal agencies which are subject to the Freedom of Information Act and the Privacy Act, the confidential identifying data will not be released except as required by those Acts. The respective DSHS or HHSC program contacts and the DSHS IRB must be notified of any potential release, consistent with applicable law.
Protection of Confidential Data or Biospecimens	
	No DSHS or HHSC provided data or biospecimens will be used for any purpose other than that specifically stated in this application and described in the IRB approved protocol.
	The data or biospecimens provided by the DSHS or HHSC programs for this study are the property of DSHS or HHSC. Ownership or ownership interest of the data or biospecimens does not transfer to the principal investigator, project partners, research team members, organization, or the sponsor.
	The data or biospecimens provided by DSHS or HHSC will be treated strictly as confidential.
	All data that directly or indirectly identifies a person will not be shared with any individual outside the research team, or any other entity, agency, institution, or firm.
	Data or biospecimens may not be used to discover personal identities unless prior written approval has been provided by the DSHS IRB.
Publication of Outcomes	
	Any results reported will comply with the suppression and aggregation rules specified by the program(s) or DSHS. Results will not identify any individuals, data providers, institutions, or firms unless prior written approval has been provided by the DSHS or HHSC data source and the DSHS IRB.

	All reports and other materials prepared for publishing from research using the data and biospecimens will be submitted to the program contact(s) and the DSHS IRB once they are accepted by the publisher.
	DSHS or HHSC will be credited as the source of the data or biospecimens as specified by the program(s). No statement will be made indicating or suggesting that interpretations drawn from DSHS or HHSC data and biospecimens are those of DSHS or HHSC.
Data Destruction	
	A certificate of destruction or other written verification will be submitted to the IRB when the data or biospecimens are no longer needed, such as data used as an intermediary linking step or variables no longer needed after initial analysis. The destruction process used will meet DSHS or HHSC-specified standards.
	At the end of the research study, any remaining data or biospecimens provided by DSHS or HHSC will be destroyed in the manner described in the IRB approved protocol unless specific prior written permission is granted by DSHS or HHSC for their retention. Upon completion, a certificate of destruction or other written verification will be submitted to the IRB.
Final Report	
	A Final Report of the study will be submitted to the DSHS IRB and program contact(s) within 60 days of completion of the study.
Submission	
	This application includes all the required and applicable documents outlined in the submission checklist.

Principal Investigator Signature

Date

ATTACHMENT A-1

Protocol Form

Study Information	
☐ Initial Review	
☐ Existing DSHS IRB#	
Principal Investigator	
Protocol Title	

Complete each section. Provide concise information or enter "not applicable" if a section does not apply to your study.

I. Summary
Provide a synopsis of the study using plain language. Limit it to 100 words or less.

II. Rationale and Background
A. Describe the purpose of the study.
B. State the hypotheses.
C. Describe the research question(s).
D. List no more than five relevant studies published on this topic.

III. Objectives and Goals
A. Describe the specific aim(s) and objective(s) of the study in context to the research question(s).
B. Describe the goal(s) of the study.

IV. Public Health Purpose
Briefly explain how the results will be used and what relevance the results will have to public health policies or public health practices.

V. Risks and Benefits
A. Describe the foreseeable risks involved in this study and how your protocol minimizes these risks.
B. Describe potential benefits and knowledge that can reasonably be expected from the study results.

VI. Subject Population
A. Describe the key demographic characteristics of the subject population(s), such as gender, race, ethnicity, and geography.
B. If a control group will be utilized, describe and justify this control group.
C. List the inclusion criteria of the subject population.
D. List the exclusion criteria of the subject population.

VII. Data and Biospecimens Request
A. Provide an estimated number of subjects whose records or biospecimens will be requested from the program(s).
B. Provide a description of the DSHS/ HHSC data or biospecimens required for this study. Specify if the data or biospecimens will be one record or sample per person or potentially more than one record or sample per person (e.g., one record per visit, one record per diagnosis).
C. Specify the time frame, including prospective years, requested for analysis. Consult with your program contact(s) to determine which years are available.

VIII. Informed Consent Process and Forms

Describe the informed consent process utilized to enroll subjects.

Check the documents included with the protocol.

☐ **Written informed consent document(s) to be signed by subjects.** The informed consent document(s), Informed Consent Document Checklist and Recruitment Protocol are included with the protocol submission.

☐ **Waiver or Alteration of Informed Consent Form.** In the section below, check the applicable request(s) completed on the form and include the document(s).

- ☐ **Waiver of Informed Consent.** The Waiver or Alteration of Informed Consent Form is included with the protocol submission.
- ☐ **Waiver of Documentation of Informed Consent.** The Waiver or Alteration of Informed Consent Form, the verbal, electronic or implied informed consent script(s), Informed Consent Document Checklist, and the Recruitment Protocol are included with the protocol submission.
- ☐ **Alteration of Informed Consent.** The Waiver or Alteration of Informed Consent Form, the altered informed consent document(s), and the Recruitment Protocol are included with the protocol submission.

IX. Design and Methodology

A. Describe the study design in context to the research question(s).

B. Detail the intervention or experimental procedures, if applicable.

Click to enter text.

C. Detail all information to be collected for analyses and their sources.

D. Provide the rationale for obtaining personally identifiable information about the living or deceased subjects.

X. Data Analysis

A. Describe the statistical analysis plan.

B. Justify the selected sample size. Detail the power of the study, level of significance, and accounting procedures for any missing or spurious data.

C. Describe statistical tests and/or the evaluation techniques that you anticipate using. Detail the pre-analysis data screening, reliability analyses, and assumption tests based on the chosen statistical tests.

D. Describe the results you expect to obtain from your analyses.

XI. Data Protection and Security Plan
A. Specify how the data or biospecimens will be transferred to your institution.
B. Specify all locations where the data or biospecimens will be stored.
C. Describe all data storage or biospecimens security strategies.

XII. Dissemination and Publication
A. Describe the governance plan to prepare and publish the results, such as time allocation, resources, management structure and advisory committees.
B. Describe the manner which the potential personally identifiable information will be protected in published results, such as through suppression of small counts.
C. Describe how the results will be disseminated.

XIII. Data Destruction Plan
A. Specify if any data will be destroyed when they are no longer needed, not just at the end of the study, such as data used as an intermediary linking step or variables no longer needed after initial analysis.
B. Specify the tools, including product names, and protocols you plan to use to destroy all copies of electronic data provided by DSHS/ HHSC.
C. Describe the destruction plan for hard copies and/or magnetic media mediums at all locations.
D. Describe the destruction plan for the biospecimens at all locations.
E. Provide the estimated destruction date for all copies of the DSHS/ HHSC data and biospecimens.

ATTACHMENT B

Research Team Log

☐ Initial Review	
☐ Existing DSHS IRB#	
Principal Investigator	
Protocol Title	

This log must include **all** research team members who**:**

- participate in the protocol design
- interact with any human subject for research purposes
- obtain the informed consent of human subjects for research purposes
- obtain identifiable information and biospecimens for research purposes
- access, use, study, and analyze identifiable information and biospecimens

Instructions:

1. Beginning with the Principal Investigator, enter the requested information for each team member.
   - The **Start Date** is when the member is added to the team.
   - The **End Date** is when the member was removed from the team. (Do not delete members from the log when they are removed from the team.)
2. Include a Human Subject Research (HSR) protection training certificate for **all active team members** on the log.
   - We do not accept expired HSR certificates.
   - HSR certificates must have been **issued within the last five years**
3. Submit this form with the initial review, renewals, and amendment applications making updates to the log.

Name & Credentials	Organization	Email	Role in Study	Start Date	End Date

Contact DSHS Institutional Review Board at InstitutionalReviewBoard@dshs.texas.gov with any questions.