

STATE OF TEXAS §
 §
COUNTY OF TARRANT §

CONTRACT FOR SERVICES

This contract is entered into between Tarrant County, Texas hereinafter referred to as COUNTY, and University of North Texas Health Science Center at Fort Worth (UNTHSC), hereinafter referred to as PROVIDER pursuant to Chapter 791 of the Texas Government Code (Interlocal Cooperation Act) for the purpose of PROVIDER providing ethical research review of human subject protocols initiated by the Tarrant County Public Health Department (TCPH) which the Commissioners Court finds serves a public purpose and serves the public welfare of the citizens of Tarrant County.

**I.
SCOPE OF SERVICES**

1. PROVIDER agrees to provide ethical research review of human subject protocols initiated by employees and staff of Tarrant County Public Health Department (TCPH) in accordance with the terms of this Agreement.
2. COUNTY shall ensure the primary researcher (principal investigator) for any project at TCPH shall obtain prior written approval of the Director of TCPH for all IRB reviews to be conducted by PROVIDER. The Director of TCPH must be aware of and approve submission of TCPH human research protocols to be reviewed by PROVIDER'S IRB. No TCPH protocol can be reviewed by the PROVIDER'S IRB without TCPH Director approval.
3. COUNTY shall require the Principal Investigator, after obtaining TCPH Director approval as described above, submit to the PROVIDER-IRB a complete and appropriate number of copies of documents for review which shall contain at least the following items:
 - Title of Project (full title including any acronyms and subtitles)
 - Principal Investigator (name, title, degrees if any)
 - Contact Information
 - Facility / Agency (including any subdivisions)
 - Facility Administrator and Contact Information
 - Completed and Signed IRB Application Form
 - Complete Protocol Synopsis, following UNTHSC-IRB guidelines and format
 - Consent Forms(s) if any
 - Other Required Supporting Documents and Materials as needed for timely and effective review
4. The parties understand and agree that PROVIDER'S IRB has the authority to conduct oversight and human subject research review for a TCPH research protocol reviewed by the PROVIDER'S IRB, and COUNTY further agrees to follow, and shall ensure that its employees comply with all applicable laws and regulations and follow all PROVIDER'S IRB policies and procedures regarding the involvement of human subjects in research.
5. All TCPH research projects submitted for review by the PROVIDER-IRB must be reviewed and approved by TCPH personnel with respect to issues of appropriateness for its human subject population and TCPH's ability to perform the research procedures as approved by the PROVIDER'S IRB (i.e.,

the TCPH has the appropriate equipment and personnel to conduct the research in a manner reviewed and approved by the PROVIDER'S IRB).

6. COUNTY shall ensure that personnel from TCPH who are involved in data collection are responsible for implementing the research following PROVIDER'S IRB approved procedures. The Director of TCPH or his or her written designee is responsible for including written confirmation that facility personnel have the appropriate expertise to carry out the research procedures as reviewed and approved by the PROVIDER'S IRB.

7. TCPH shall provide verification that personnel from TCPH who are involved in data collection have completed appropriate training in the ethical conduct of human subject research (for example, CITI training), and TCPH shall submit copies of these training certificates to PROVIDER upon request.

8. For each research protocols initiated by TCPH under this agreement, the PROVIDER IRB will work with the TCPH principal investigator and TCPH to develop appropriate protocol and consent documents preparatory to IRB, arrange for IRB review including meeting materials, and coordinate all follow-up ethical reviews and regulatory requirements. In addition, the PROVIDER IRB will coordinate with the TCPH principal investigator for annual (continuing review) and all relevant federally mandated reporting requirements and documentation. The parties understand and agree it is the responsibility of COUNTY and its principal investigator to adhere to all IRB stipulations and requirements at all times, and to conduct the research project in accordance with high standards of research integrity and ethics and applicable law and regulations.

9. TCPH already has an existing Federal Wide Assurance (FWA) and FWA number from the Department of Health and Human Services (DHHS), and has previously designated that the IRB of record for TCPH will be that of PROVIDER. COUNTY acknowledges that PROVIDER IRB's reviews, do not assure the safety or freedom from injury of subjects participating in its studies. COUNTY and its principal investigators are responsible for compliance with protocols and the conduct of studies, and COUNTY and its personnel shall comply with all PROVIDER's IRB policies, procedures and directives and TCPH's FWA. The parties have already executed an Institutional Review Board (IRB)/Independent Ethics Committee (IEC) Authorization Agreement in the form of Exhibit A, which is attached hereto and incorporated herein by reference.

II. TERM

This contract will begin on November 1, 2023 and conclude on October 31, 2026. After this initial three (3) year term, this Agreement may be renewed for periods of three (3) year terms, unless sooner terminated in accordance with this Agreement.

III. COST

All parties acknowledge that regulatory compliance and oversight, involving, preparatory, initial, and ongoing review is personnel and resource intensive. As such, appropriate fees will be required to offset the costs to provide the services described in this Agreement. COUNTY agrees to pay PROVIDER, within thirty days of the commencement of this Agreement, TWO THOUSAND DOLLARS (\$2,000.00) as an annual fee for all TCPH-initiated reviews of Exempt Category protocols as described by OHRP regulation 45 CFR 46. For each TCHP protocol that requires Expedited Category Review (as defined

by 45 CFR 46.110) TCPH agrees to pay PROVIDER IRB SEVEN HUNDRED FIFTY DOLLARS (\$750) per protocol. For studies involving more than minimal risk and requiring review by a convened IRB, TCPH agrees to pay PROVIDER ONE THOUSAND FIVE HUNDRED DOLLARS (\$1500) per protocol, which will cover all review activity for a given protocol for the life of that specific protocol, payable within thirty (30) days of COUNTY's receipt of PROVIDER's invoice for such review. Payment to PROVIDER shall not exceed \$5,000.

**IV.
SUPERVISION**

COUNTY and PROVIDER agree that COUNTY has no right under this contract to supervise or to direct the actual performance of PROVIDER'S services as PROVIDER is an independent contractor.

PROVIDER agrees to be responsible for the negligent acts and omissions of its agents, servants, and employees pursuant to the Constitution and laws of the State of Texas, particularly the Texas Tort Claims Act. COUNTY agrees to be responsible for the negligent acts and omissions of its agents, servants, and employees pursuant to the Constitution and laws of the State of Texas, particularly the Texas Tort Claims Act.

**V.
AGENCY-INDEPENDENT CONTRACTOR**

Neither COUNTY nor any employee thereof is an agent of PROVIDER and neither PROVIDER nor any employee thereof is an agent of COUNTY. This agreement does not and shall not be construed to entitle either party or any of their respective employees, if applicable, to any benefit, privilege or other amenities of employment by the other amenities of employment by the other party.

To the extent permitted by the Constitution and the laws of the State of Texas, PROVIDER agrees to indemnify and hold harmless the COUNTY against any and all claims, lawsuits, settlements, judgments, costs, penalties and expenses, including attorney's fees, with respect to PROVIDER'S performance under this contract to the extent permitted by law. To the extent permitted by the Constitution and the laws of the State of Texas, COUNTY agrees to indemnify and hold harmless the PROVIDER against any and all claims, lawsuits, settlements, judgments, costs, penalties and expenses, including attorney's fees, with respect to COUNTY'S performance of research which is reviewed by PROVIDER's IRB under this contract.

**VI.
ASSIGNMENT**

Neither party may assign, in whole or in part, any interest it may have in this contract without the prior written consent of the other party.

**VII.
THIRD PARTY BENEFICIARY EXCLUDED**

No person not a party to this contract may bring a cause of action pursuant to this contract as a third party beneficiary. This contract may not be interpreted to waive the sovereign immunity of any party to this contract to the extent such party may have immunity under Texas law.

**VIII.
ENTIRE AGREEMENT**

This contract represents the entire understanding of and between the parties and supersedes all prior representations. This contract may not be varied orally, but must be amended by written document of subsequent date duly executed by the duly authorized parties. This contract shall be governed by the laws of the State of Texas and venue for any action under this contract shall be in the district courts of Tarrant County, Texas.

**IX.
TERMINATION**

This contract may be terminated by either party by providing written notice to the other party at least thirty (30) days prior to the intended date of termination. Any notice or other writing required by this contract shall be deemed given when personally delivered or mailed by certified or registered United States mail, postage prepaid, addressed as follows:

COUNTY
Tarrant County Public Health
1101 South Main Street
Fort Worth, Texas 76104

PROVIDER
University of North Texas Health
Science Center at Fort Worth (UNTHSC)
3500 Camp Bowie Blvd.
Fort Worth, Texas 76107

Approved on this the _____ by Commissioners Court Order No. _____ **N-13882b**

**TARRANT COUNTY
STATE OF TEXAS**

PROVIDER

Tim O'Hare, County Judge
Authorized Signature Authority
Tarrant County

DocuSigned by:
Brian Gladue 10/11/2023

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Brian Gladue, PhD
Executive Vice President for Research

DocuSigned by:
Ruth Roman 10/4/2023

60BFD635B4424B3...
Ruth Roman
Executive Vice President & Chief Operating
Officer

APPROVED AS TO FORM:

Kimberly Colliet Wesley
Criminal District Attorney's Office*

Certification of Funds Available for the amount of \$ _____.

Auditor's Office

* By law, the Criminal District Attorney's Office may only advise or approve contacts or legal documents on behalf of its clients. It may not advise or approve a contract or legal document on behalf of other parties. Our review of this document was conducted solely from the legal perspective of our client. Our approval of this document was offered solely for the benefit of our client. Other parties should not rely on this approval, and should seek review and approval by their own respective attorney(s).

This Addendum relates to the following contract: UNTHSC IRB - 2023

Compliance with Laws. In providing the services required by this Agreement, Entity must observe and comply with all applicable federal, state, and local statutes, ordinances, rules, and regulations, including, without limitation, workers' compensation laws, minimum and maximum salary and wage statutes and regulations, and non-discrimination laws and regulations. Vendor shall be responsible for ensuring its compliance with any laws and regulations applicable to its business, including maintaining any necessary licenses and permits.

DocuSigned by:

8AA25B77E1FB41A...
Signature

Brian Gladue, PhD
Printed Name

Executive Vice President for Research
Title

University of North Texas Health Science Center
Entity/Company Name

10/26/2023
Date signed