metrocare.

METROCARE SERVICES IRB RELIANCE AGREEMENT

I. Purpose

This Reliance Agreement sets forth the agreement between Metrocare Services IRB and [Insert IRB of Record Here] concerning the agreed-upon arrangements for the Institutional Review Board ([Insert IRB of Record Here]).

- Name of Institution or Organization Providing IRB Review (Reviewing Institution): [Insert IRB of Record Here]
- Office for Human Research Protections (OHRP) Federal Wide Assurance (FWA)#: Please Complete
- Name of Institution Relying on the Designated IRB (Relying Institution): Metrocare Services IRB
- OHRP Federal Wide Assurance (FWA) #: FWA00009249

This agreement concerns the reliance of Metrocare Services IRB on the review and approval by [Insert IRB of Record Here], as specified in this agreement. This agreement sets forth the respective authorities, roles, and responsibilities of each party in such arrangement.

Those signing below agree that Metrocare Services IRB may rely on [Insert IRB of Record Here] for review, approval, and continuing oversight of the human subjects research described below.

II. Types of Research Covered by this Agreement

This agreement is limited to the following specific protocol(s):

Title of Study:
Principal Investigator:
Sponsor or Funding Agency:
Faculty Investigator(s):
Student Investigator(s):

This agreement applies to human subject research conducted by [Insert Principal Investigator] for this study listed above. Only human subjects research pertaining to this specific study will be included in this agreement.

III. Compliance with Federal and State Law and Metrocare Policy

Review and approval of human subjects research under this agreement shall be conducted in compliance with the federal regulations as codified in 45 CFR 46, other pertinent federal regulations, state and local laws, and all applicable Metrocare policies pertaining to the protection of human subjects participating in research.

IV. Informed Consent

Research subject to this agreement must employ a consent process, including a consent form, except when a waiver of informed consent is approved by the [Insert IRB of Record Here] and Metrocare Services IRB according to 45 CFR part 46.

V. Duties and Responsibilities of the [Insert IRB of Record Here]

a. Provide initial and continuing review in accordance with 45 CFR 46, including approval of consent forms for all sites, review of amendments to approved protocols, and review of

information that requires reporting (i.e. unanticipated problems involving risks to participants or others, non-compliance, protocol deviations, etc.) for all sites.

b. Suspend or terminate approval of research that is not being conducted in accordance with [Insert IRB of Record Here] policies, is not in compliance with Federal Regulations 45 CFR 46, or that has been associated with unexpected increased risk to participants.

c. Prompt reporting by the principal investigator to [Insert IRB of Record Here] of any unanticipated events or problems involving risk to subjects or others, serious or continuing non-compliance, or suspension/termination of IRB approval. A subsequent incident report must be submitted to Metrocare Services IRB via Cayuse.

d. Ensure principal investigators and other research personnel involved in the research are appropriately qualified, and meet its institutional standards for eligibility to conduct research including, but not limited to, having the proper training in the protection of human subjects.

VI. Duties and Responsibilities of Metrocare Services IRB

a. Metrocare Services IRB will review and approve submissions for the recruitment of, or access and use of, client or agency data.

b. Metrocare Services IRB will coordinate with Metrocare locations to schedule access to sites for researcher needs based upon approval.

c. Ensure that research activities at its site are in compliance with the IRB's determinations and with the terms of this Reliance Agreement. This includes retaining authority to conduct audits of the research being done at a Metrocare location to ensure compliance.

d. Evaluate the potential personal and financial conflicts of interest of its investigators, research staff, and institution in adherence to its institutional conflict of interest policies and procedures. The principal investigator is responsible for providing Metrocare Services IRB with any applicable conflicts of interest and corresponding management plans related to the study.

e. Maintain compliance oversight of the Metrocare Services IRB and report unanticipated problems involving risk to participants or others by submitting an event into the Metrocare Online Reporting Incident System (MORIS).

f. Once an incident report is received from the principal investigator, Metrocare Services IRB must submit the event into MORIS.

VII. Duties and Responsibilities of both the [Insert IRB of Record Here] and Metrocare Services IRB.

a. Agree to abide by all applicable regulations in the conduct of human subjects research at each facility as dictated by their FWA and 45 CFR 46.

b. Keep this Reliance Agreement on file at their respective institutions, per their policies and procedures, and to make it available upon request to OHRP or any U.S. federal department or agency conducting or supporting research to which the FWA applies.

c. Maintain effective communication and cooperation mechanisms sufficient to ensure adequate protections for human research subjects. Both institutions agree to fully cooperate with the reciprocal IRB including providing relevant documentation and records as needed.

d. Promptly inform the reciprocal institution of reports of serious or continuing noncompliance in the conduct of the study and unanticipated problems involving risks to participants or others, encountered in research as specified in this agreement.

VIII. Research Related Grievances

Any researcher related grievances can be emailed to acerresearch@metrocareservices.org.

IX. Notices and Primary Contacts

a. Any correspondence regarding this study should be addressed to:

Relying Institution: Metrocare Services
Name: John Bennett, MD
Title: Metrocare Services, Chief Medical Officer (CMO)
Address: 3242 Remond Dr., Dallas, TX 75211
Email: acerresearch@metrocareservices.org
Phone: (214) 743-1202

Reviewing Institution: [Insert IRB of Record Here]
Name:
Title:
Address:
Email:
Phone:

This agreement will become effective upon the date of the last signature by the institutional officials below and will remain in effect until the termination of the research study listed in Part II or until such time that either institution provides 30 days written notice of termination to the other institution.

Signature of Signatory Official for [Insert IRB of Record Here]**:**

Signature: _____ Date: _____

Print Full Name: _____
Institutional Title: _____

Signature of Principal Investigator:

Signature: _____ Date: _____

Print Full Name: _____

Co-Principal Investigator/Advisor: _____ Date: _____

Print Full Name: _____

Signature of Metrocare CMO:

Signature: _____ Date: _____

Print Full Name: John Bennett, MD
Institutional Title: _____

Signature of Metrocare IRB Chair:

Signature: _____ Date: _____

Print Full Name: Muralidhar Kannan, MD
Institutional Title: _____