

Primary Care Research Institute



The North Texas Primary Care Practice-Based Research Network

**University of North Texas Health Science Center *at Fort Worth*
Texas College of Osteopathic Medicine**

Policy & Procedures

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Article 1. The North Texas Primary Care Practice-Based Research Network (hereafter referred to as NorTex) is housed in the Primary Care Research Institute of the University of North Texas Health Science Center at Fort Worth.

Section 1.01 Mission

- (a) Our mission is to provide a forum for researchers and clinical practitioners in Texas to collaborate in research activities with the ultimate goal to improve the health of the Texas community and to contribute to our country's scientific knowledge base.

Section 1.02 Vision

- (a) To be a top 10 primary care practice-based research network in the country.

Section 1.03 Goals

- (a) To maintain and grow NorTex by creating and maintaining relationships with researchers, primary care clinics, and clinicians throughout Texas.
 - (i) Objectives
 - 1) Maintain a working relationship with all schools of UNTHSC and outside partners as a source of study design and analysis expertise.
 - 2) Establish and develop new relationships with clinical practices and organizations that share the same purpose and mission of the network.
 - 3) Retain researchers, clinics, and practitioners as NorTex members.
- (b) To develop areas of research priorities based on the needs and interests of the Texas community and the members of NorTex.
 - (i) Objectives
 - 1) Create and maintain a database of all members of NorTex, including areas of research interest.
 - 2) Collect patient demographic and clinical data among participating clinics and entities of NorTex.

- (c) To offer research resources to researchers and clinicians of NorTex.
 - (i) Objectives
 - 1) Support scientific and community advisory committees for NorTex.
 - 2) Offer advice and expertise on all stages of research development, implementation, and dissemination.
- (d) To maintain a forum for members of NorTex to communicate and express research interests, including dissemination of research findings.
 - (i) Objectives
 - 1) Maintain and update a NorTex website and list serve that function as an avenue for communication and information dissemination.
 - 2) Distribute a quarterly electronic newsletter that will display ongoing activities and achievements of NorTex.
 - 3) Establish a yearly NorTex conference that allows members to participate in research activities.
- (e) To implement and maintain an electronic data management system that allows for a uniform standard of data collection for any and all research projects.
 - (i) Objectives
 - 1) Assess local resources in implementing a data management system.
 - 2) Work with the UNTHSC IT Department in developing a data management system.

Article 2. Scientific Review Board and Community Advisory Board

Section 2.01 Overview

- (a) The function of the Scientific Review Board (SRB) and the Community Advisory Board (CAB) will be to review and approve or disapprove any research proposal that has the intent to utilize

network resources. In addition, both boards will oversee and uphold the implementation of the policies and procedures of NorTex. All members of these boards are seated on a voluntary basis and may include representatives of any NorTex partner. Each board has its specific purposes as outlined in the following:

SRB - This board will be responsible for assessing a study proposal's feasibility, integrity, and overall study design and methodology. In essence, this board will assess if the study has sufficient resources to ensure its scientific rigor and successful completion. Additionally, the board will ensure that the purpose of any proposal has a significant primary care and public health emphasis that is consistent with the mission, vision, and goals of NorTex.

CAB – This board will be responsible for ensuring that a study's proposal is consistent with the mission, vision, and goals of NorTex. More importantly, the board represents the various communities of its members. Hence, these member advocates will assess the proposal's importance to their community and the community of the intended study, ensuring that the study is performed ethically and with the community in mind.

Section 2.02 Members

- (a) Members of the SRB and CAB will represent the various segments and partners of NorTex. Each member of both boards is serving on a voluntary basis. Each board will include one chairperson as well as members representing various communities and NorTex partners. Both the SRB and CAB chairs will be appointed by the NorTex Director and will serve as members of the Executive Advisory Board of the Primary Care Research Institute.

CAB – This board will consist of members from Texas communities and NorTex partners. There is no limit in the number of board members.

- (i) CAB Chair
- (ii) NorTex Director
- (iii) NorTex Assistant Director
- (iv) Community Members

SRB – This board is made up of any NorTex partner representative and persons representing the following fields:

- (i) SRB Chair
- (ii) NorTex Director
- (iii) NorTex Assistant Director
- (iv) Biostatistics
- (v) Epidemiology
- (vi) Social and Behavioral Sciences
- (vii) Health Management and Policy
- (viii) Biomedical Sciences
- (ix) Primary Care Physicians
- (x) External Members

Section 2.03 Governance

- (a) All meetings will follow Robert's Rules of Order. Each meeting will be led by the board's chairperson. Each board will have meetings at least twice per year.

Section 2.04 Selection

- (a) Each member of the boards will hold at least 3-year terms. There is no limit to the number of terms each member may hold. Selection will be based on invitation by board members and the NorTex Director to ensure adequate representation of NorTex. The Chair of the CAB and SRB will serve 1-year terms. There is no limit to the number of terms each member may hold.

Article 3. NorTex Organization

Section 3.01 The organization of NorTex is shown in Appendix I. All members listed will be selected by the NorTex Director. This organizational structure may change at the discretion of the NorTex Director.

Article 4. NorTex Membership

Section 4.01 Overview

- (a) Membership to NorTex is completely voluntary. All members must meet the criteria listed below.

Section 4.02 Definition/Criteria

- (a) A member must be:
 - (i) A clinician (DO, MD, PA, NP, RN) in primary care which includes family medicine, general internal medicine, geriatrics, general pediatrics, obstetrics/gynecology, or a research/health care professional (PhD, DrPH).
 - (ii) Willing to fill out the required member form to provide information about their training, demographic characteristics, and experience.
 - (iii) Willing to designate one member of the practice or system as the contact member who must fill out a second form describing characteristics of the practice.
 - (iv) Willing to display a furnished certificate and patient formation brochures in the waiting room of the practice that identifies the site as a NorTex member clinic.
 - (v) In agreement that participation in NorTex studies affects practice routines in varying degrees. Studies may ask for completion of brief data collection forms (only part of which needs to be filled out by the practitioner). Some studies require informed consent from parents and/or patients. However, minimal disruption to the clinician's busy clinic schedule is one of NorTex's highest priorities.
 - (vi) In agreement that NorTex practices are not required to participate in all studies, but are expected to remain active in the network by participating on a regular basis when available and requested.
 - (vii) Willing to sign a memorandum of understanding if the member is not a faculty member of the University of North Texas Health Science Center at Fort Worth. In addition, a member must sign a separate sub-agreement for each research project in which the member will be involved.

Section 4.03 Recruitment

- (a) All clinicians contacted by NorTex will have the option to join on a voluntary basis. NorTex continually recruits all practices located in the North Texas region.

Section 4.04 Adjunct Faculty Assignment

- (a) Members who are not part of the staff at the University of North Texas Health Science Center at Fort Worth may have the opportunity to apply for an adjunct faculty position with the Texas College of Osteopathic Medicine. Any member who has interest in applying for adjunct status may initiate the process by sending a letter of intent to the NorTex Director and the Chairperson for the Department of Family & Community Medicine.

Section 4.05 Retainment

- (a) Retention of members will be a high priority for NorTex. This will be accomplished by ensuring that the resources for members are available and adapted over time as the needs of members change.

Section 4.06 Withdrawal from NorTex

- (a) Any member may withdraw from NorTex at any time. It is preferable that a member withdraw when there are not active studies at their site. Withdrawal may occur by simply contacting any staff member of NorTex. A confirmation letter regarding intent to withdraw participation will be sent to the member.

Article 5. Research Policy

Section 5.01 Research Priorities

- (a) The NorTex Director, staff, member clinicians/partners, and board members determine the research agenda of NorTex. The interest and dedication of the member clinicians are crucial for research projects to succeed. The opinions of member clinicians will be regularly solicited over time through surveys, e-mails, and meetings.
- (b) Study proposals submitted to NorTex by principal investigators must be aligned with NorTex's mission, vision, goals, and current research objectives. The total body of work undertaken by NorTex will be consistent with the following principles. Projects must:

- (i) be designed and implemented collaboratively with NorTex
- (ii) address a question of importance to primary care and public health
- (iii) have the potential to influence practice and health care delivery
- (iv) have the support and interest of the clinician members and partners of NorTex
- (v) be led by an experienced principal investigator or co-investigator
- (vi) have adequate funding as determined by NorTex
- (vii) have the potential for publication in a peer-reviewed journal and additional funding

Section 5.02 Submitting a Research Proposal

- (a) All potential research projects must be formally proposed to the NorTex Director or designated staff member in writing. All projects must be screened by the NorTex Director or designated staff member in order to utilize the resources provided by NorTex. The NorTex Director or designated staff member has the ability to refuse or accept any research proposals. Once a proposal is screened and allowed to proceed, the proposal, using the appropriate forms, will be sent to the SRB and CAB members for final review.
- (b) Research proposals will be reviewed and voted upon by both the SRB and CAB. A proposal must be approved by a majority of members from both the SRB and CAB to become a NorTex project. Voting may take place at regular board meetings or by e-mail. If a member is not present at the board meeting, he/she will be asked to vote by e-mail such that all board members will be given the opportunity to vote on all proposals. Board members will be given a set deadline to return their vote. A non-response in the designated time for returning a vote is recorded as no objections to the study proposal.
- (c) Unless permitted by the NorTex Director or designated staff, all research must be funded by a grant. At times, the NorTex Director or designated staff member understands that preliminary data must be collected for grant application purposes. Nonetheless, approval

must be obtained from the NorTex Director or designated staff member when there is no funding.

- (d) All members of NorTex who are participating in research projects must complete Human Subjects Training.
- (e) When possible, the Principal Investigator of the research project should submit a summary of any grant application(s) which intends to use NorTex resources prior to submitting the grant.

Section 5.03 Human Subjects Training

- (a) Any individual who participates in research projects as deemed appropriate, including all NorTex member clinic sites, must complete Human Subjects Training which will be available through the UNTHSC website.

Section 5.04 Study Conduct

- (a) Every study that is accepted by the NorTex Director or designated staff member as well as the SRB and CAB must have a research team assigned with sufficient expertise in research methods and adequate statistical analysis.
- (b) An external member principal investigator memorandum of understanding must be signed before the commencement of a study.
- (c) Once a study proposal is accepted by the NorTex Director or designated staff member as well as the SRB and CAB, the member investigator must first meet with the NorTex Director or designated staff member and the appropriate NorTex members to identify NorTex assistance/resources required for the project. This meeting will include discussions on budgets, study design, timeline, grant writing processes, IRB processes, study methods, and publication/presentation procedures for the accepted research proposal. At any time, if deemed warranted, the NorTex Director, designated staff member, SRB or CAB may terminate NorTex's involvement (resources, assistance, subjects, etc.) in a research project if patient safety is at risk, inappropriate or unethical research methods are being conducted, or if the best interests of the NorTex are neglected or unattainable at the time of the research project.
- (d) Clear lines of authority and responsibility are necessary to facilitate communication among all members of the project team. This is particularly important when the project's principal investigators are

geographically separated. Day-to-day operation of a NorTex project will be guided by the following policies:

- (i) For each funded project, the Principal Investigator and NorTex Director will jointly develop a specific implementation plan. Implementation planning will include clear lines of accountability for defined portions of the budget. Each individual with responsibility for a portion of the budget will be accountable to the NorTex Director for proper management of that budget in accordance with the NorTex policies and appropriate federal regulations.
- (ii) Modifications and reallocations within a project budget (even those permitted under expanded authorities) will be documented by the Principal Investigator and summarized in the annual progress report to the funding agency.

Section 5.05 Data Collection and Maintenance

(a) Clinic Sites

- (i) Anyone who is active in data collection, informed consent, or any part of a research study must have completed the Human Subjects Training.
- (ii) Every effort must be made to maintain a participant's confidentiality. When possible, no personal identifying information should be collected or be made accessible to non-research staff.

(b) Data Storage

- (i) All data will be entered, summarized, and analyzed in centralized NorTex offices. At times, analysis may be done in a consultant's or partner's location with whom an agreement of confidentiality is understood.
- (ii) All sensitive material will be located and stored in files located in a centralized NorTex location or an approved partner location.

Section 5.06 Secondary Data

- (a) NorTex will support and encourage researchers in the development, acquisition, and analysis of external data. The purposes may be for primary or preliminary studies including

student research.

Section 5.07 IRB

- (a) All research projects that are accepted and performed within NorTex will be approved by the Institutional Review Board (IRB) of the University of North Texas Health Science Center and any other IRB board representing any outside partner. The policy and procedures of each IRB will be followed for any research projects with human subjects that will be conducted within NorTex.

Section 5.08 Grants and Funding

- (a) All research projects must be funded unless permitted by the NorTex Director or designated staff. All grants must designate NorTex and the University of North Texas Health Science Center at Fort Worth and any collaborating partner as the institute(s) that the research is being conducted through. Any disbursement of funds that are designated within the initial grant will be completed through the Office of Grant and Contract Management of the University of North Texas Health Science Center at Fort Worth or equivalent office at a partner's institution if the Principal Investigator is from another institution. An external agreement must be signed and completed through such an office if such funds must be distributed.
- (b) The NorTex Director is ultimately responsible for the success of each project and the overall well-being of NorTex. The following policies are intended to provide the NorTex Director with adequate oversight of project activities.
 - (i) The NorTex Director, SRB, and CAB must approve modifications in study protocols.
 - (ii) Modification in the budget that moves funds from one project component (as defined in the implementation plan) to another must be agreed upon by the NorTex Director and the PI to ensure feasibility and completion of the project.
 - (iii) The NorTex Director has the authority to establish and enforce administrative procedures that minimize the vulnerability of NorTex in the financial and administrative management of federal research grants.
 - (iv) The Principal Investigator can appeal the NorTex Director's decision in writing. The appeal should be sent to the NorTex Director and will be reviewed by the SRB and CAB.

Section 5.09 Student Research

- (a) NorTex promotes UNTHSC student and resident primary care related research projects
- (b) Predoctoral, medical, and public health students, as well as postdoctoral fellows and residents of UNTHSC may utilize NorTex resources under the following conditions:
 - (i) A proposal defining the goals of the research project shall be completed by the student or resident.
 - (ii) The proposal may be submitted for approval to the SRB and CAB if the student's project is an original study utilizing NorTex resources.
 - (iii) All research activities related to the approved research project shall adhere to the policies governing NorTex research (Article V) and publication and presentations (Article VI).

Article 6. Publication and Presentation Policy

Section 6.01 Published Reports

- (a) NorTex expects all of its research to result in publishable reports in the academic press. All Principal Investigators must adhere to the following:
 - (i) The NorTex Director and Principal Investigator must meet to establish a reasonable timeline to submit a publishable manuscript to a peer reviewed journal for each NorTex project. The timeline will take into account project specific circumstances such as data collection and analysis.
 - (ii) All manuscripts must be reviewed and approved by the NorTex Director or designated staff member to ensure NorTex is credited for its involvement and the quality of the manuscript is appropriate. The Principal Investigator, however, retains all rights and privileges to the manuscript.
 - (iii) The Principal Investigator is responsible for the accuracy of the data results and its interpretation.
 - (iv) All manuscripts, publications, and presentations must acknowledge NorTex in their work.

Article 7. Communication and Exchange

Section 7.01 Website/Internet/List-Serve Services

- (a) A website for NorTex provides information and enables the exchange of data with members of the NorTex community, prospective members, and the general public.
 - (i) The NorTex website will:
 - 1) Be maintained by a faculty or staff member on the NorTex team to ensure that the website remains dynamic.
 - 2) Provide a link to primary care related resources.
 - 3) Provide appropriate security for institutional information. It shall be the duty and responsibility of NorTex to develop and recommend policies and establish procedures and practices necessary to ensure the security of all information resource assets against unauthorized or accidental modification, destruction, or disclosure.
 - 4) Facilitate better institutional and community communication both internally and externally via the web.
 - (ii) The List Serve
 - 1) The NorTex Listserv is a moderated, electronic mail distribution list for NorTex members. It is used to disseminate notices regarding conferences and workshops, data availability, calls for papers, positions available, etc., as well as requests for information.
 - 2) The purpose of the NorTex Listserv is to foster discussion of primary care research among NorTex members and serve as a means of disseminating NorTex information. Information provided by members is for reference purposes only and is not to be used for research projects, books, or other potentially profit-making endeavors without written permission of the author of the original post. The messages posted are the opinions of individual members and not the opinions of NorTex.

Section 7.02 Meetings

- (a) The SRB and CAB meeting are utilized to review NorTex research activities and any other NorTex business.
 - (i) It is the responsibility of the board chairpersons to convene meetings of NorTex and to keep minutes of NorTex meetings as well as documentation of NorTex decisions.
 - (ii) It is the responsibility of NorTex board members to attend regularly convened meetings.
 - (iii) The Administrative Coordinator is responsible but not limited to coordinating the SRB, CAB, and other NorTex meetings. It is also the Coordinator's responsibility to record and transcribe minutes as well as maintain records of all meetings.

Section 7.03 Other Forms of Communication

- (a) NorTex will openly communicate with its members on what research and scholarly activities are being done within NorTex.
 - (i) NorTex will maintain an electronic journal (The Primary Care Research Journal) to be mailed out regularly to all members and partners of NorTex.
 - (ii) Per Section 6.01, NorTex will develop and maintain a Listserv for its members.
 - (iii) NorTex has created a website, www.hsc.unt.edu/NorTex, to disseminate research information and provide resources.

Article 8. Library Liaison

- (a) NorTex will have a designated library liaison to help in the dissemination of library services to network members.

Article 9. The Policy and Procedures of NorTex are consistent with the University of North Texas Health Science Center policies and of the State of Texas and federal regulations.