

## **1. ACADEMIC AND RESEARCH ENVIRONMENT**

### **The University of Arkansas for Medical Sciences (UAMS)**

UAMS is the only medical, nursing, pharmaceutical, and public health education university in Arkansas. UAMS is also the state's largest, most comprehensive facility for medical treatment and biomedical research. UAMS is part of the University of Arkansas system and has an enrollment of more than 2,500 students in five colleges (Medicine, Nursing, Pharmacy, Public Health, and Health Professions) and a Graduate School. Matrixed into the colleges are seven institutes of excellence: Cancer, Myeloma, Aging, Psychiatric Research, Eye, Spine & Neurosciences, and Translational Research. UAMS employs over 10,000 individuals, including clinical providers that deliver medical care to patients at UAMS and its affiliates, Arkansas Children's Hospital, and the VA Medical Center. UAMS Regional Clinics are located across Arkansas, and UAMS has eight satellite Centers on Aging. UAMS also provides an interactive video infrastructure throughout the state. In addition, UAMS has the largest biomedical library in the state. It serves students and faculty on all UAMS campuses by providing access to collections of basic and applied science and clinical materials.

**UAMS clinics through Arkansas.** The proposed research will be conducted at UAMS clinics, with primary sites in Fayetteville, Little Rock, Texarkana, and Pine Bluff. UAMS clinics served over 80,000 patients from across the state in the last year. There are 5,113 active T2DM patients at the primary clinics and another 2,251 in the secondary clinics for a total of 7,364 patients who meet the inclusion criteria. UAMS clinics are strategically located throughout Arkansas and are connected by telehealth technology with one another and to a Central Administration office on the UAMS campus in Little Rock. Such a broad and strategic network enables UAMS to translate the latest knowledge, skills, resources, and best healthcare practices to communities throughout Arkansas, both quickly and efficiently. The clinics have appropriate clinical and patient room space, as well as a private room for consent. Additional information is provided below.

**Research support services and infrastructure.** UAMS is the state's largest research institution and manages more than \$125 million in extramural research and programmatic funding each year. UAMS offers a number of key administrative and research support services to assist investigators. The UAMS Institutional Review Board (IRB) has been fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2005. The office is responsible for ensuring the rights and welfare of all human subjects' research conducted by UAMS research programs. The Office of Research Compliance coordinates UAMS' comprehensive research compliance program and offers compliance consultations and program reviews for the entire research community. They offer tools and templates to researchers who request assistance with assessment and evaluation of their own research processes. They also offer a free 28 credit hour Certified Research Specialist program (CRS) that includes CITI human subject protection training, and modules on research ethics and misconduct, research protocols, record keeping and regulatory compliance, research billing and grant management, and long-distance collaboration through webinars and workshops. The department includes four research compliance analysts, a research compliance education specialist, and the UAMS research compliance officer. The UAMS Office of Research and Sponsored Programs (ORSP) provides support during the acquisition, performance, and administration of programs and projects funded by extramural sources. The Office of Research Regulatory Affairs (ORRA) includes a staff of eleven regulatory specialists and research administrators that provide assistance with regulatory submissions to federal agencies, quality assurance and monitoring, research agreements, including material and data transfer, and other research support services. The Office of Clinical Programs Education supports research enhancement activities that include online staff training, continuing education, and consultation.

## **2. FACILITIES AND CENTRAL RESOURCES AT UAMS**

**Office Space and Equipment.** Each of the faculty and staff listed have adequate offices (~150 sq ft each) that can be securely locked and include a desk, phone, locking file cabinets, book cases, and several include conference tables. All offices are wired for high speed internet access and staff can also access the internet through the campus' wireless network. Additionally, as part of the UAMS response to COVID-19, all faculty and staff are set up and have been working remotely to reduce risk and transmission of COVID-19. This includes access to VPN as necessary and cloud-based collaboration and sharing solutions. Investigator and staff meetings will occur in the departments' ~550 square foot conference room and/or virtually through videoconference. Conference rooms have audiovisual equipment, including ceiling projectors that can be used

to project videoconferences, DVDs, and PowerPoint presentations onto a 110" tab-tensioned screen. These rooms are wired to hold videoconferences and can accommodate additional audiovisual equipment as needed. Study meetings and dissemination efforts can utilize the UAMS videoconference system to connect investigators at different locations. The research team also has access to three UAMS vans – a 2005 Dodge Caravan, a 2011 Dodge Caravan, and 2015 Dodge Caravan, that each seat seven people. These facilities and resources will contribute to the project's success by ensuring study personnel and activities have access to the space and functional equipment needed to conduct all work outlined in the proposal.

**Computer and Technology Support.** All faculty and staff use Dell E6540 laptops, docking stations, and external monitors. The E6540 laptops have a memory upgrade, a processor upgrade, and a larger hard-drive to ensure there will be enough RAM, processing power, and file storage available to run multiple software applications. The E6540 laptops have a 9-cell battery to enable staff to work in multiple off-site locations where power sources may not be available. The data collection team will also have access to 35 13" Apple iPads for data entry. All computers are equipped with Windows 11 Professional, Microsoft Office products, and various software that allows investigators and administrative staff to perform job-specific tasks, including SAS, SPSS, and Adobe Creative Suite. UAMS investigators and staff have access to a shared drive, and all files on personal computers and the shared drive are backed up nightly to a protected server. All investigators and staff will stay connected through a SharePoint site that provides a secure, yet widely accessible, platform to distribute and store documents, such as meeting agendas, minutes, and curricula. We will also use SharePoint's shared calendar function to post the study calendar and information about all meetings and events. In addition, SharePoint allows users to exchange and store manuscripts during the collaborative interpretation and writing process as needed. UAMS information technology (IT) staff maintain all computers and drives, and provide technical support for the network, computers, and other technologies. The department currently has 167 employees, including IT specialists that serve on site at the regional clinic sites. Staff will have access to equipment that can be checked out through the UAMS IT department if needed, including additional laptop computers and several digital multimedia LCD projectors. These technologies and IT support will contribute to the project's success by assuring all investigators and staff have tools for optimal communication and productivity.

**Data Management and Storage.** UAMS Primary Data Center will provide five servers that will be utilized for this project. UAMS Primary Data Center is a state-of-the-art data center that resides in its own building on campus. It has approximately 3,500 square feet of raised floor space and redundant 1) air handlers; 2) uninterruptible power supplies (UPSs); 3) connectivity to main campus; and 4) generators. UAMS has two additional, geographically separated data centers for load-balancing and disaster recovery. In total, the three data centers host ~500 physical server machines running ~750 logical (or virtual) servers; ~50 physical servers are virtual machine hosts. The Primary Data Center houses the majority of servers, the primary storage area network (SAN) with a total of 1.2 petabytes of storage, and the mainframe. Power supply is guaranteed by multiple generators, including primary and backup. The secondary data center is the disaster recovery data center, which houses the backup SAN, COLD secondary servers, and passive nodes of active/passive clusters. It is equipped with cooling, two UPSs, and an emergency generator. The third data center is the load-balanced data center, which houses the second node of multi-server load balanced systems. It is equipped with cooling, in-cabinet UPSs, and an emergency generator. UAMS has implemented network and SAN redundancy across three core network switches (one per data center).

**REDCap.** The research team will use Research Electronic Data Capture suite (REDCap) for data capture and data management. REDCap is a comprehensive set of open source software tools for electronic management of clinical trials and associated data. REDCap supports data submission, validation, annotation, filtering, and extraction, as well as study oversight, auditing, and reporting. Quality control of the data entry process will be facilitated by institution range and logic checks. We have successfully completed required documentation and testing to be compliant with the 21 CFR part 11 guidelines. All components of the UAMS REDCap system are web-based, enabling sharing and integration of clinical research information for single- and multi-site trials. All applications are integrated into a portal that allows single point of access with a registered UAMS username and password. All REDCap applications reside on a cluster server with failover capability behind the UAMS firewall, and thus have the benefit of high security, fire protection, and routine backup. UAMS REDCap supports subject registration, study calendar management, participant recruitment, tracking regulatory events, reporting, and electronic data capture. The resources outlined above will contribute to the project's success by providing the research team with hardware and software systems needed to support the study's data collection and management plans.

**Laboratory Resources.** All biometric data will be collected using point of care tests. Systolic and diastolic blood pressure will be measured using a sphygmomanometer and stethoscope or digital blood pressure device with the participant seated and arm elevated. Finger stick blood collection will be used to test HbA1c using a Siemens DCA Vantage. BMI will be calculated using height and weight. Participants' weight will be measured in light clothing to the nearest 0.5 lb. (0.2 kg) using a calibrated digital scale. Height (without shoes) will be measured to the nearest 0.5 cm using a stadiometer. Weight and height will be used to compute a continuous measure of BMI using the Quetelet Index (kg/m<sup>2</sup>).

### **Clinical Resources**

**UAMS clinics throughout Arkansas.** The proposed research will be conducted in UAMS clinics located throughout Arkansas (See **Figure 1**). UAMS has primary care clinics located in Batesville, Fayetteville, Fort Smith, Helena, Jonesboro, Little Rock, Magnolia, Pine Bluff, and Texarkana. UAMS clinics served over 80,000 patients from across the state in the last year. Approximately 7,364 of those patients have type 2 diabetes mellitus and meet the study's inclusion criteria according to our EMR query. UAMS clinics are connected by telehealth technology with one another and to a Central Administration office on the main UAMS campus in Little Rock. Such a broad and strategic network enables UAMS to translate the latest knowledge, skills, resources, and best healthcare practices to communities throughout Arkansas, both quickly and efficiently. The clinics have appropriate clinical, patient care space as well as a private room for consent. The main UAMS campus and the regional clinics have the same DUNs number; and all sites operate under a Federal Wide Assurance of the protection of human subjects and comply with 45 CFR part 46 and other NIH human subjects' related policies.

We have selected four primary sites (Little Rock, Fayetteville, Pine Bluff, and Texarkana). Secondary sites will serve as backup if the team encounters challenges in recruitment and accrual. UAMS clinics will help contribute to the study's success by providing clinical environments and access to patient populations.

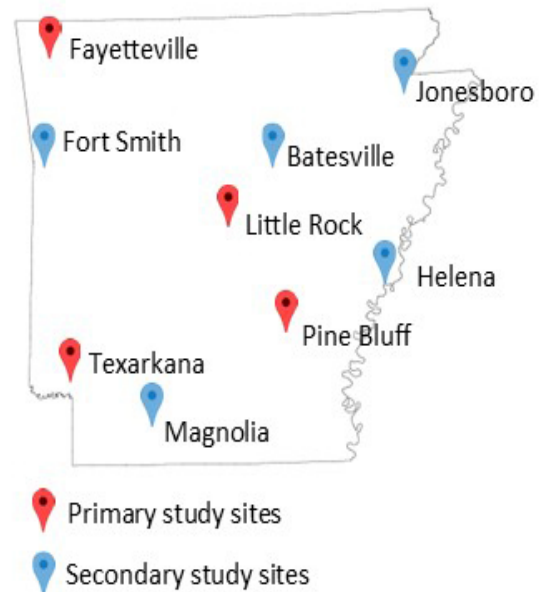
**Equipment.** Not applicable.

**Animal.** Not applicable.

### **3. OTHER RESOURCES AT UAMS**

**Translational Research Institute (TRI).** The TRI provides innovative resources and key infrastructure to support research activities at UAMS. Expert staff help investigators navigate UAMS' research infrastructure and facilitate access to UAMS and TRI resources, ensuring that researchers receive timely and appropriate support. The institute fosters long-term partnerships with communities to guide the development of meaningful research projects. In other words, the TRI is helping "translate" our most relevant knowledge and discoveries to the clinics and people who need it most. TRI will provide shared core resources that will strengthen the project. Specifically, the TRI has a Biomedical Informatics Core and a Biostatistics Core that will provide expertise and service to support the proposed work. The Biostatistics Core, through the TRI, is jointly administered by the Colleges of Medicine and Public Health. While administered by two colleges, the unit functions as one department. The department has 10 full-time faculty members, 11 faculty members with secondary or adjunct appointments, and seven research associates with master's degrees in biostatistics. In addition, the TRI supports a Biomedical Informatics Core that can provide support in managing the data collection and database for the project. The Biomedical Informatics Core has six full-time faculty, a post-doctoral fellow, three FTE of administrative staff, and three information technology (IT) staff. They work closely with UAMS Information Technology (IT) and share in the oversight of IT staff working on joint initiatives. The TRI's shared core resources will contribute to the project's success by providing the research team with expertise and consulting in biostatistics and biomedical informatics as needed.

**Figure 1. Arkansas study sites**



**UAMS Rural Research Network.** The UAMS Rural Research Network was established in January 2020 in response to the stark health disparities for rural populations. Forty-two percent of Arkansans live in rural areas compared to just 15% for the United States. Rural Americans are more likely to die from five leading causes of death than urban Americans, with many deaths preventable for heart disease, cancer, unintentional injuries, chronic lower respiratory disease and stroke. The problems of poverty and health care inequity are particularly concentrated in rural, minority populations. The network comprises UAMS' eight Regional Campuses across the state and is supported by an intra-institutional partnership. Its partners are UAMS Community Health & Research, Translational Research Institute, Regional Programs, and Winthrop P. Rockefeller Cancer Institute. At the end of December 2021, UAMS had more than 1,400 active clinical and behavioral research studies. The Network's mission is to engage rural Arkansans in the extensive clinical and translational research led by UAMS researchers. Our practice partners and colleagues share in this commitment to improve health outcomes for Arkansans living in rural and underserved areas. The Rural Research Network will contribute to this project's success by providing an existing infrastructure for communication and collaboration.

**UAMS Center for Health Literacy (CHL).** The UAMS CHL is dedicated to improving individual, provider, systems, and community health literacy at the local, state, and national level in order to improve health outcomes and population health. The CHL provides services and training, research, and policy initiatives to improve literacy on the individual, organization, community, and health systems levels. The CHL works with healthcare providers, health agencies, individuals in communities, and researchers throughout the region. The CHL will contribute to the study's success by providing expertise in developing materials that use understandable language and concepts.

**Office of Community Health and Research (OCHR).** OCHR is a multidisciplinary department that focuses on patient-centered research, community programs, training, and policy to address health disparities. OCHR initiatives integrate clinical- and community-based research with interprofessional education and service learning on the UAMS Northwest campus. The OCHR addresses needs identified by Arkansas patients' and family members, and all work is based on principles of community-based participatory research. Dr. Pearl McElfish (PI/PD) serves as the director of OCHR and leads a team that includes 30 project managers and research support professionals. OCHR is currently conducting several pilot studies evaluating family models of chronic disease management and prevention and is completing a PCORI-funded comparative effectiveness trial of Family DSMES and Standard DSMES among Pacific Islanders. OCHR offers unique resources that will help facilitate the success of this study, including a community engagement core and a methodology core. The community engagement core within the OCHR is committed to nurturing productive partnerships with a broad group of academic and community stakeholders that are committed to using a collaborative approach to prevent chronic disease and improve health equity among diverse patient populations. The community engagement core is led by Dr. McElfish and includes three full-time project managers and coordinators and two community co-investigators. The community engagement core works closely with community members and helps keep community stakeholders engaged in all phases of the project. The community engagement core will help coordinate and support effective communication between the community, investigators, and study staff. Community engagement core communication strategies are based on a commitment to transparency and inclusive dialogue. The methodology core consists of six highly qualified academic and community investigators that provide ongoing methodological support and expertise in health literacy, data management, biostatistics, engaged research methods, implementation research, social network analysis, and qualitative methods. Methodology core team members will work with investigators to help ensure rigorous methods and measures by developing and evaluating key approaches and methods used in the study (recruitment, consent, data collection, implementation, IRB compliance, and evaluation). The team works closely with patients and family members to plan studies that include relevant and meaningful variables, and they help implement strategies that protect study participants and communities from unintended harms and stigma. The OCHR contributes to the study's success by providing: 1) an existing infrastructure with shared cores and highly qualified staff to support the project; 2) academic and community investigators with experience conducting large multi-site trials; and 3) strong collaborative relationships with national and regional community stakeholders that will help plan, implement, evaluate, and disseminate the proposed study.

**Arkansas Center for Health Disparities Research (ARCHD).** ARCHD develops research intended to improve access to quality prevention and healthcare programs for racial and ethnic minorities with the goal of reducing health disparities. The ARCHD focuses on chronic disease disparities with an emphasis on cardiovascular disease, diabetes, obesity, and cancer. The ARCHD serves as a resource and collaborative partner to the campus community with expertise in engaging academic and community partners in research and programs to address health disparities. The ARCHD Research Core focuses its efforts on working to

increase the capacity of UAMS departments, centers, partnering institutions, and communities to engage in health disparities research. They serve as a resource for documenting community needs and assets, assisting with the identification of academic and community partners, and providing consultation on community research and dissemination methods. ARCHD helps research teams increase access to and participation in UAMS research, health services, and service learning partnerships. The ARCHD will contribute to the study's success by providing expertise and consulting in health disparities research.