**Memorandum of Understanding**

***Between***

**<Insert Name>, Principal Investigator,**

**University of Arkansas Medical Sciences, <Insert Department>**

***and the***

**UAMS Rural Research Network (RRN) – Regional Programs**

Study Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institutional Review Board (IRB) Number: \_\_\_\_\_\_\_\_\_\_

Funding Source: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participating Study Site(s)/Regional Programs: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

This Memorandum of Understanding (MOU) sets forth the terms and understanding between:

<Insert PI(s), University of Arkansas Medical Sciences, <Insert Department>, and the UAMS Rural Research Network – Regional Programs in support of study activities outlined herein.

**Background**

The University of Arkansas for Medical Sciences (UAMS) Rural Research Network (RRN) is a collaboration of the Translational Research Institute, Office of Community Health and Research, Winthrop P. Rockefeller Cancer Institute and Regional Programs.

The mission of the RRN is to engage individuals living in rural areas of Arkansas in clinical and translational research by implementing RRN-approved research studies within the UAMS Regional Campuses located across the State of Arkansas. The RRN supports and guides investigators and/or their research support team throughout the research process, as necessary and appropriate. Specifically, RRN staff provide support in:

* Study start-up activities
* Study coordination, providing research coordinators and clinical resources based on availability and funding provided by the requesting investigator
* Beta testing prior to launching studies, if applicable
* Study implementation and workflow within the clinical setting
* Research coordinator services (i.e., participant recruitment, screening for eligibility, consent, data collection and management including administration of survey instruments and collection of biometrics such as HbA1c, BMI, and blood pressure, management of study files, regulatory adherence, and day-to-day operations of the research projects including scheduling and appointment reminder calls
* Research oversight and facilitation of clinical research within regional programs

**Purpose**

This MOU outlines the roles and responsibilities of the RRN and the study PI and designees to achieve study objectives and study enrollment goals.

**Goals**

This MOU states each party’s roles and responsibilities throughout the duration of the research project, where applicable, with the joint goals of:

* Establishing and fostering professional relationships
* Obtaining all required approvals for study initiation
* Facilitating start-up of financially sound and fiscally compliant research studies
* Streamlining research processes and avoiding duplication of efforts
* Recruiting and enrolling study participants per approved protocols
* Maintaining research compliance
* Recording and reporting of study activities as appropriate

The above goals will be accomplished by undertaking the following activities related to the study referenced above:

RRN responsibilities (specifically, the Executive Director or RRN designee(s)):

1. Communicates with the study Principal Investigator (PI) and/or PI designee to obtain all required information and/or materials for initiating study start-up activities
2. Communicates with PI and/or PI designee to determine the responsibilities of individual study team members (i.e., screening, consent and recruitment activities, use of Epic, management of participant incentives, data and/or specimen collection, storage of supplies at sites if needed, transport and labeling of samples, etc.)
3. Provides PI with a cost estimate for RRN services using TRI’s established charges for clinical trials.
4. Identifies local regional study site leads (i.e., administrators, clinical service, and/or lab managers) to serve as point(s) of contact(s) with the RRN Director
5. In collaboration with regional study site(s), identifies and/or hires, trains and supervises designated research and/or clinical support staff (i.e., research coordinators/data collectors, diabetes educators, phlebotomists/laboratory personnel, social workers, etc.) located at participating study sites, when applicable
6. Provides ongoing oversight of project implementation within the regional study sites (i.e., at least monthly)
7. Meets monthly with PI and/or designated study personnel for study updates and progress reports

PI and/or designated study personnel responsibilities:

1. Prior to launch, communicates with RRN Director to outline the responsibilities of the study team
2. Directs the study’s implementation in collaboration with the RRN Director or designee(s)
3. Leads and responds to funding agency or Program Officer communications
4. Directs study-specific policies and standard operating procedures
5. Maintains and updates study protocol in CLARA/UAMS IRB
6. Approves cost estimate for RRN support *prior to* study start-up
7. Allocates assigned RRN study staff and if applicable, prior approved TRI core services, informatics and/or statistical support to the funded account
8. Oversees and manages the study budget and all purchasing related to the study
9. Covers all study-related costs and provides all study-required materials, supplies, equipment, etc.
10. Works with the RRN Director or designee to prepare the study launch plan with a detailed timeline
11. Adds assigned RRN support staff to the IRB protocol and provides access to the study’s SOPs
12. Develops a study database such as REDCap to manage the operations of the study and the data collection (must be developed or approved by the Comprehensive Informatics Resource Center led by Dr. Fred Prior)
13. Coordinates Investigator and Stakeholder Meetings required by the funder if applicable
14. Responds to questions from the RRN staff as needed
15. Presents the study to RRN stakeholders as requested
16. Provides opportunities for regional programs faculty and residents to participate and engage in scholarly activities that are a part of the research (i.e., presentations, publications, etc.)
17. Cite TRIusing [TRI.uams.edu/cite](https://tri.uams.edu/learn-more/cite-tri/)
18. Acknowledges RRN when publishing and/or presenting study and study results

**Funding**

The parties specifically acknowledge that this MOU is not an obligation of funds, nor does it constitute a legally binding commitment by the UAMS - <insert Department> PI or RRN – Regional Programs.

**Duration**

This MOU is at-will and may be modified by mutual consent of authorized official(s) from UAMS - <insert Department> and RRN – Regional Programs. This MOU shall become effective upon signature by the authorized officials from the UAMS - <insert Department> and RRN – Regional Programs and will remain in effect until modified or terminated by any one of the partners by mutual consent. In the absence of mutual agreement by the authorized officials from UAMS- <insert Department> and RRN – Regional Programs, this MOU shall be reviewed annually. The first review will be held one year from the date of original signatures.

**Contact Information**

**University of Arkansas for Medical Sciences – <Insert College or Institute>:**

<Insert PI Name, Title>

<Insert Department>

University of Arkansas for Medical Sciences

<Insert Address> | Little Rock, AR 72205

Office: <Insert Number> | Cell #: <Insert Number>

Email: <Insert Email>

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Principal Investigator (print name)

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Principal Investigator (signature) Date

**UAMS Rural Research Network:**

Veronica J. Smith, MBA, Executive Director

UAMS Rural Research Network

Translational Research Institute

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UAMS RRN Executive Director (print name)

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UAMS RRN Executive Director (signature) Date

**Agreement of Regional Programs - Participating Sites:**

**UAMS East Regional Campus – Helena-West Helena:**

Amber K. Norris, MD, Medical Director

1393 Hwy 242 South | Helena-West Helena, AR 72342

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UAMS East – Site Lead/Designee (print name)

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UAMS East – Site Lead (signature) Date

**UAMS North Central Regional Campus – Batesville:**

Jordan Weaver, MD

Medical and Residency Director

1993 Harrison Street | Batesville, AR 72501

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UAMS North Central – Site Lead/Designee (print name)

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UAMS North Central – Site Lead (signature) Date

**UAMS Northeast Regional Campus – Jonesboro**

Mark C. Brown, MD, Medical Director or Scott Dickson, MD, Residency Director

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UAMS Northeast – Site Lead/Designee (print name)

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UAMS Northeast – Site Lead (signature) Date

**UAMS Northwest Regional Campus – Fayetteville:**

Ronald Brimberry, MD, Medical Director or Michael Macechko, MD, Residency Director

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UAMS Northwest – Site Lead/Designee (print name)

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UAMS Northwest – Site Lead (signature) Date

**UAMS South Regional Campus – Magnolia**

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UAMS South – Site Lead/Designee (print name)

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UAMS South – Site Lead (signature) Date

**UAMS South Central Regional Campus – Pine Bluff:**

Darrell R. Over, MD, Medical Director or Toni Middleton, MD, Residency Director

1601 W. 40th | Pine Bluff, AR 71603

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UAMS South Central – Site Lead/Designee (print name)

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UAMS South Central – Site Lead (signature) Date

**UAMS Southwest Regional Campus – Texarkana:**

Russell Mayo, MD, Medical Director or Matthew Nix, MD, Residency Director

3417 U of A Way | Texarkana, AR 71854

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UAMS South Central – Site Lead/Designee (print name)

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UAMS South Central – Site Lead (signature) Date

**UAMS West Regional Campus – Fort Smith:**

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UAMS West – Site Lead/Designee (print name)

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UAMS West – Site Lead (signature) Date

**Addendum**

***Between***

**<Insert Name), Principal Investigator,**

**University of Arkansas Medical Sciences, <Insert Department>**

***and the***

**UAMS Rural Research Network (RRN) – Regional Programs**

Study Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institutional Review Board (IRB) Number: \_\_\_\_\_\_\_\_\_\_

Funding Source: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participating Study Site(s)/Regional Programs: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Specifications:**

1. **Charge Rate(s):**
	1. Salary support for RRN Services in support of the study is outlined within the approved budget awarded by the funder.
2. **Implementation of approved study protocol:**

<A brief summary of study design related to recruitment, enrollment, data collection, etc. will be inserted here.>

< In collaboration with PI, specific tasks, roles and responsibilities related to the implementation and study activities will be included.>

For Example….. The specified study data will be collected by the Rural Research Network (RRN) coordinators at the participating study sites. The analysis will be done by the project investigator’s analyst.

* 1. Up to XX # of participants will be enrolled and consented by the RRN Research Coordinators from Regional Programs’ participating clinical study sites.
	2. A list of potential participants will be provided by AR-CDR (specify how, by whom, frequency, use of REDCap).
		1. The list will be provided by the PI or designee (i.e., data manager) via a secure Box account and uploaded to the study database by the PI’s designated team member.
		2. A REDCap study database will be provided by the PI to store participants’ information and measurements. Only team members and site coordinators will have access to the data collected. Only the necessary staff within Regional Programs participating sites will be aware of participants scheduled for research appointments.
			1. Prior to the launch of the study, the PI will ensure all forms of data collection have been reviewed and approved by the Comprehensive Informatics Resource Center (CIRC) led by Dr. Fred Prior.
		3. Only the necessary staff within Regional Programs’ participating study sites will be aware of participants scheduled for research appointments (including CSM, Telehealth Nurse when applicable, RRN Coordinator, and front desk access staff).
	3. All data collection appointments within the regional sites will be scheduled and conducted by the RRN Coordinators. The following will be collected by the RRN Coordinators:
		1. BMI and demographics including weight, height, age and ethnicity.
		2. Food Frequency Questionnaire (FFQ)
	4. For studies involving clinical and/or telehealth appointments, clinic operational support will be provided by the UAMS Regional Program clinic staff and the Integrated Medicine Service Line Epic Template Management team. Technical support for these visits will be provided by UAMS IT, and the Institute for Digital Health and Innovation (IDHI).
		1. For scheduled telehealth appointments, Telehealth nurses from each regional site will provide normal standard of care (i.e., billable) procedures upon arrival of the patient and prior to the research appointment.
	5. A monetary incentive in the amount of $XX will be offered to the participants upon completion of the data collection event. The monetary incentives will be managed and distributed by the Research Coordinators using Tango®, an electronic gift card system (established by the PI or their designee in collaboration with the UAMS Treasurer’s Office).
	6. Prior to launch, the PI’s study team will provide access to the study protocol within CLARA and all study-related standard operating procedures and workflows.
		1. General Details and Workflow – Regional Site Visit(s)
			1. Outlines PI’s study team, the RRN Coordinators’ and if applicable, the Regional Sites’ clinical responsibilities.
	7. Throughout the project period, the PI’s study team will provide:
		1. Study supplies at each participating site
		2. Training on data collection
		3. List of participants to schedule for data collection
		4. REDCap framework for data entry and management of the study operations as approved by CIRC.
	8. All training required to perform the study activities will be provided by the PI’s study team [and/or Telehealth support team].
	9. All regulatory requirements will be maintained by [the PI’s study team or TRI Regulatory Service Unit].
		1. Onsite quality control and regulatory oversight visits may be conducted in collaboration with the RRN Director. These will be performed by PI and/or a designated member delegated within the study to perform regulatory oversight if needed.
	10. PI and/or study team will participate in routine meetings with the RRN and local study sites (i.e., at least monthly) to address any questions or obstacles and report on quality control measures.