



~ Request for Pilot Study Applications ~

July 1, 2010

I. INTRODUCTION

The South Central Mental Illness Research Education and Clinical Center (MIRECC) invites pilot study applications that support its mission:

To improve access to evidence-based practices in rural and other underserved populations, including recently returning war veterans, veterans experiencing natural disasters, and vulnerable elderly veterans.

Goals - The ultimate goal of the South Central MIRECC pilot study program is to stimulate research that can be used to develop clinical policy or programs that improve access, quality and outcomes of mental health and substance abuse treatment services for rural and underserved veterans. This request for pilot study applications is intended to increase both the *quantity* and *quality* of federally funded research that will help better understand the experiences of rural/underserved veterans and which supports the development and dissemination of evidence-based practices that can make a real difference in the lives of rural/underserved veterans. The South Central MIRECC encourages pilot study applications that will lead to federally funded research programs designed to improve the delivery of services by the Department of Veterans Affairs (VA), as well as help community partners better serve the behavioral health needs of rural/underserved veterans.

Background - According to the VA Office of Rural Health, nearly 3 million (37.8%) VHA enrollees live in rural areas across the country.¹ Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF) veterans are even more likely to come from rural areas.^{1,2} In VISN 16, over half (51.1%, n=328,387) of VHA enrollees reside in rural areas.¹ Compared to urban veterans who use the VA healthcare system, rural veterans face even more barriers to mental health and substance abuse care, and suffer from worse physical and mental health status.³ Potentially important barriers facing rural veterans include: longer travel times and higher travel costs, fewer community resources, poverty, stigma, culture of self-reliance, lack of anonymity, and lack of culturally acceptable treatments. These barriers may reduce access to behavioral healthcare services more than physical healthcare services due to a relative lack of perceived need for behavioral healthcare. For example, veterans are significantly less willing to travel long distances for the treatment of mental health and substance abuse disorders than for the treatment of physical health disorders.⁴ Rural veterans are likely to have different patterns of service utilization than urban veterans. For example, rural veterans are more likely to use Community Based Outpatient Clinics (CBOCs) that often lack mental health specialists such as psychiatrists and psychologists. Primary care providers in CBOCs may not have been extensively trained to deliver evidence-based mental health and

substance abuse treatments and may not have the time to adequately address these illnesses. Likewise, veterans using CBOCs are less reliant on the VA health care system than are veterans using VA Medical Centers. Thus, compared to urban veterans, rural veterans with mental health disorders may be less likely to receive all their mental health care from the VA.

Types of Studies - The South Central MIRECC invites three types of pilot study applications: *observational pilot studies*, *intervention pilot studies*, and *implementation pilot studies*. Pilot studies are needed to support the submission of highly competitive grant applications to federal agencies. Observational pilot studies include qualitative research, survey research, chart reviews, and analyses of administrative data. Observational pilot studies are needed to justify the objectives and validate the proposed methods of large scale observational studies. Observational pilot studies are also needed to help inform the design of interventions and implementation strategies for large scale intervention and implementation studies. Intervention pilot studies are needed to demonstrate the acceptability, safety, feasibility, and/or preliminary effectiveness of interventions to support grant applications proposing randomized trials. Implementation pilot studies are needed to cultivate partnerships, conduct needs assessments, develop educational tools and informatics applications, and conduct small scale feasibility demonstrations to support grant applications proposing regional demonstrations and national rollouts of evidence-based practices.

II. RESEARCH AREAS

Observational Studies

Observational studies are needed to examine rural and underserved veterans' behavioral health needs, patterns of service utilization, and health beliefs prior to designing programs to improve outcomes for this population. Epidemiological research is needed to identify unmet behavioral health needs of rural/underserved veterans. Services research is needed to identify where and when rural/underserved veterans receive behavioral health services and whether their mental health and substance abuse disorders are detected and addressed with evidence-based practices. Rural/underserved veterans often come from cultures with different beliefs about self reliance, stigma, anonymity and treatment effectiveness. Cultural beliefs and values may shape veterans' definitions of mental illness and substance abuse and influence their decision to seek care and adhere to treatment. Beliefs and preferences among rural/underserved veterans may limit the acceptability of evidence-based practices designed and tested for delivery to urban veterans in urban settings. Observational research is needed to understand the barriers to care faced by rural and underserved veterans and how those barriers affect use, quality and outcomes of behavioral health care. Observational research is needed to better understand what factors influence the quality of care provided by clinicians treating rural/underserved veterans. Likewise, research is needed to understand providers' preferences for treating rural/underserved veterans and the organizational climate, culture and capacity of clinics delivering services to rural/underserved veterans. Understanding these issues can lead directly to new policies or help inform the design of interventions and implementation strategies.

Observational studies typically use data from four types of sources: 1) administrative files, 2) mail, telephone or email surveys, 3) chart reviews, and/or 4) qualitative interviews. Administrative data sources include the patient encounter files stored at the Corporate Franchise Data Center, performance measure data stored at the Veterans Service Support Center, pharmacy data stored at the Corporate Franchise Data Center and the Pharmacy Benefits Management files housed at the Strategic Healthcare Group, and clinical data stored at

the VISN 16 Data Warehouse. Rural/underserved veterans and their providers can be identified from administrative data sources and administered surveys via mail, email, or phone. Data can also be extracted directly from patient medical records via chart review of Computerized Patient Record System (CPRS) progress notes. Likewise, qualitative data can be collected from face-to-face, interactive video, telephone interviews or focus groups with rural/underserved veterans and/or their providers.

Observational pilot studies are needed to support competitive grant applications to federal agencies that propose to conduct large scale observational research. In addition, observational pilot studies can also support grant applications that propose to conduct intervention and implementation research. Observational pilot studies can be used to: 1) demonstrate that the proposed topic is clinically relevant (e.g., prevalent), 2) develop a sampling frame, 3) identify appropriate clinical settings for an intervention, and 4) identify potential barriers to the implementation of evidence-based practices. The following is a list of examples of the kinds of observational pilot studies that MIRECC investigators might propose. The following list of potential research topics is illustrative, not exhaustive. Researchers responding to this request for pilot study applications are invited to identify additional areas of inquiry that support the mission of the South Central MIRECC.

- Develop and psychometrically validate survey instruments and chart review protocols to be used in observational studies of rural/underserved veterans.
- Using administrative or survey data, document the prevalence of disorders, treatments (e.g., antipsychotic medications prescribed by primary care providers, tele-psychiatry encounters, suicide hotline telephone encounters, etc.) and/or adverse events (e.g., rehospitalization, attempted suicide, etc.) experienced by rural/underserved veterans. This information could be used to justify grant applications that propose to describe in more detail the quality and outcomes of care provided to rural/underserved veterans.
- Document patterns of service utilization among rural/underserved veterans. When, where, and how often do rural and underserved veterans use VA and non-VA services. In what types of settings (e.g., primary care, emergency department, Chaplin service) are mental health and substance abuse disorders first detected? What range of provider types treat mental health and substance abuse disorders? Where are quality of care problems most commonly found? This information could be used to develop *sampling frames* for grant applications proposing to administer patient/provider surveys or to conduct chart reviews.
- Identify structural barriers to care for rural/underserved veterans including travel time and cost. Identify cultural barriers to care for rural/underserved veterans including stigma, lack of perceived need, emphasis on self-reliance, concerns about anonymity, unacceptability of available treatments, and unavailability of treatments perceived to be acceptable and effective. This information could be used to design or modify interventions for grant applications proposing to evaluate interventions targeting rural/underserved veterans.
- Examine rural/underserved veterans' preferences for receiving behavioral health care. When and where do patients want to receive mental health and substance abuse care? Are distance technologies such as phones, interactive video, health buddies, internet, etc. acceptable? What type of treatments (e.g., pharmacotherapy versus psychotherapy) do rural/underserved veterans prefer? This information could be used

to design or modify interventions for grant applications proposing to evaluate interventions targeting rural/underserved veterans.

- Examine how family and dense social networks influence rural/underserved veterans' health beliefs and treatment preferences. Determine the acceptability of clinicians engaging the social network members of rural/underserved veterans' in behavioral health decisions. Study the impact of social and community norms in rural areas on the engagement and effectiveness of behavioral health services. This information could be used to design or modify interventions for grant applications proposing to evaluate interventions targeting rural/underserved veterans.
- Measure the organizational climate, culture and capacity of clinics delivering care to rural/underserved veterans, especially CBOCs. Measure clinicians' preferences for improving the quality of behavioral health care delivered to rural/underserved veterans. This information could be used to describe implementation settings and develop pre-implementation strategies for grant applications proposing implementation research.
- Identify clinical barriers to delivering high quality behavioral health care to rural/underserved veterans. Potentially important barriers include lack of clinical resources, lack of provider training, and lack of provider time (e.g., competing demands). This information could be used to develop implementation strategies for grant applications proposing to implementation research.

Methodological Considerations - For studies using administrative data, investigators will have to measure rurality based on the geographic location of the veteran's zip code of residence. Zip codes can be used to calculate travel distance to VA facilities, so this dimension of rurality can and should be measured precisely as it is a consistent predictor of help seeking and continuity of care. Rurality can be measured from zip codes based on whether a veteran's residence is outside a Metropolitan Statistical Area or using more refined classification systems such as Rural Urban Continuum Codes, Rural Urban Commuting Area Codes, or Urban Influence Codes, many of which are based on adjacency and commuting to urban areas, as well as population. These rural typologies are often helpful for policy makers, but they only serve as a proxy measure for the underlying causal factors that lead to rural-urban differences in use, quality and outcomes. Most dimensions of rurality (e.g., needs, beliefs, preferences) cannot be measured from administrative data, and these rural typologies do not provide the necessary information to design effective interventions and implementation strategies. Surveys and qualitative interviews are needed to better understand such issues.

Intervention Studies

Due to differences between rural and urban patients and differences in rural and urban practice settings, interventions designed for rural/underserved veterans may need to be different from those designed for urban practice settings serving urban veterans. Many evidence-based practices proven to be effective in urban settings will need to be modified and reevaluated for rural settings. With observational data about service use patterns, needs, barriers, and preferences, South Central MIRECC investigators should be able to design acceptable and effective interventions for rural/underserved veterans.

Evidence-based practices can be modified in many ways to make them more acceptable and effective for rural/underserved veterans. For example, evidence-based practices can be

modified to be delivered by different *types* of providers. Interventions could be adapted to better match the capacity of clinical personnel available in rural settings. Because rural individuals are more likely to be treated by a general medical provider or informal caregiver, interventions are needed that can be delivered effectively by these types of providers, either alone or in collaboration with off-site mental health and/or addiction specialists. Novel distance education programs, medical informatics applications, and decision support systems will need to be developed to support these non-specialty providers. Internet-based applications may be a particularly effective way to train and support rural providers. Alternatively, the *mode* of delivering the evidence-based practice might need to be expanded beyond face-to-face encounters to include interactive video encounters in CBOCs and home-based telephone encounters. Likewise, internet-based applications (e.g., My HealtheVet) and telemonitoring devices (e.g., Health Buddy®) have the potential to improve outcomes via patient self-management activities such as education, health promotion, and better communication with providers. Research is needed to determine which types of technology (e.g., interactive video, phone, internet) are more effective, and what types (e.g., group versus individual therapy) and settings (home versus primary care clinic) are most appropriate. Finally, the *content* of the evidence-based practice can be modified to better match the beliefs and preferences of rural/underserved veterans.

Intervention studies can be categorized into three types: efficacy trials, equivalency trials, and effectiveness trials. Sometimes, it will be necessary to reestablish safety and efficacy using a randomized *efficacy* or demonstration trial. For example, is prolonged exposure therapy for posttraumatic stress disorder safe to deliver at a distance? Under what circumstances? Other times, it will be necessary to demonstrate that interventions designed for rural/underserved veterans result in *equivalent* outcomes as interventions designed for urban veterans. This will be especially important when the treatment as usual for rural veterans is typically no treatment. Studies should be designed which demonstrate that, with the intervention, rural veterans can expect to receive the same quality of care and experience the same outcomes as urban veterans. If the quality of treatment as usual for rural/underserved veterans meets current standards of excellence, randomized *effectiveness* studies can be used to compare enhanced care to usual care for rural/underserved veterans.

Intervention demonstration pilot studies are needed to support competitive grant applications proposing randomized trials. Intervention pilot studies can be used to: 1) demonstrate the acceptability of the intervention to patients and providers, 2) demonstrate the safety of the intervention for patients, 3) demonstrate the feasibility of delivering the intervention in the proposed setting, and 4) estimate the effect size of the intervention for power analysis. The following is a list of examples of the kinds of intervention pilot studies that MIRECC investigators might propose. The following list of potential research topics is illustrative, not exhaustive.

- Develop and test the feasibility, acceptability and preliminary effectiveness of new interventions (or intervention components/materials) designed to heighten awareness and perceived need for care, such as direct marketing and social network interventions. Can gatekeepers (e.g., clergy, police officers, educators, etc.) help facilitate entry into and sustained engagement in care for rural/underserved veterans?
- Develop and test the acceptability, safety, preliminary efficacy/equivalency/effectiveness of evidence-based practices delivered by mid-level practitioners and primary care providers instead of mental health and addiction specialists.
- Develop and test the acceptability, safety, preliminary efficacy/equivalency/effectiveness of evidence-based practices delivered to rural/underserved veterans via

telemedicine technologies. Compare delivery of telemedicine care in group versus individual encounter settings. Compare delivery of telemedicine care in home settings versus primary care clinics or nursing homes. Compare different telemedicine delivery modes (e.g., interactive video, phone, internet). Determine what types of mental health and substance abuse disorders are the most amenable to treatment via telemedicine.

- Develop and test the acceptability, feasibility and preliminary effectiveness of new interventions (or intervention components/materials) that incorporate spiritual components, traditions of indigenous populations, or other rural cultural elements, or which harness the influence of rural/underserved veterans' social networks.
- Develop and test the acceptability, safety, preliminary effectiveness of new interventions (or intervention components/materials) that address modifiable factors related to suicide risk. Develop and test interventions that identify and intervene with socially isolated, rural residents who experience frequent or serious suicidal ideation.

During intervention pilot studies, investigators may develop educational or treatment materials (e.g., brochures, DVDs, CDs, treatment manuals, etc). These products should be developed as exportable, independent clinical tools that can be disseminated at the end of the study. For product development, investigators should consult with educational experts (e.g., content and technology experts, production experts, graphic designers, copyeditors) and include production costs of materials.

Methodological Considerations - Efficacy studies are difficult to conduct in remote sites while maintaining high fidelity to the protocol and ensuring the safety of subjects. Equivalency studies comparing telemedicine-based care to face-to-face care are difficult because it often is not feasible to deliver specialty services face-to-face to patients in remote rural clinics. Likewise, equivalency studies comparing treatment delivered by mid-level providers to treatment delivered by more highly trained mental health and addiction specialists are difficult because it often is not always feasible to place highly trained specialists in remote rural clinics. Effectiveness studies are difficult to conduct in small rural clinics because it is difficult to obtain sufficient sample sizes to have adequate statistical power. Methods for improving statistical power should be considered such as recruiting from multiple sites, recruiting for long periods of time, using repeated measures and repeated-measures analysis techniques, and measuring outcomes with instruments that are sensitive to small changes in symptomatology.

Implementation Studies

The VA often uses top-down strategies for disseminating evidence-based practices. The top-down approach can work successfully for relatively simple interventions such as screening programs. However, complex treatments require more intensive implementation strategies that facilitate local adaptation of the evidence-based practice to meet the needs, preferences and resources of patients and providers while maintaining fidelity to the evidence base. Bottom up or home grown quality improvement approaches are often very effective, but are subject to substantial variation in outcomes depending on local climate, culture, and capacity. Implementation experience suggests that both researchers (clinical experts, implementation experts) and local staff need to participate fully in the implementation of complex evidence-based practices, with researchers facilitating rather than dictating implementation efforts. Therefore, developing close partnerships with clinicians and administrators at target

implementation sites is critical. More research is needed to determine the best way to partner with clinicians and administrators serving rural/underserved veterans in order to facilitate the design and evaluation of strategies to implement complex evidence-based practices.

There are numerous barriers to implementing evidence-based practices for rural/underserved veterans. Unless the evidence-based practice was specifically designed for and tested in rural settings, a major barrier to implementation is that the rural clinical context is usually substantially different from the urban clinical context for which the evidence-based practice was originally designed and tested. Thus, considerable effort may be needed to tailor the evidence-based practice, and pilot it for acceptability and effectiveness. Another potential barrier to implementation is that small clinics in rural areas have less complex organizational structures and often lack the centralized infrastructure (e.g., dedicated staff with quality improvement expertise and evaluation skills) needed to coordinate implementation efforts. Other barriers to evidence-based practice adoption in rural areas include the geographic isolation of clinics, which impedes the natural spatial diffusion of innovations. Also, because rural clinics are often small, highly trained mental health and addiction specialists are not always co-located with primary care and mid-level providers. Consequently, primary care and mid-level providers tend not to be exposed to mental health and substance abuse evidence-based practices in their own clinical environment. There is little to no evidence in the literature about how these barriers impact implementation efforts in rural areas.

Implementation pilot studies are needed to support competitive grant applications proposing to implement or disseminate evidence-based practices. Three types of implementation pilot studies are needed to support implementation grant applications: pre-implementation pilot studies, educational pilot studies, and small scale demonstrations. *Pre-implementation* pilot studies include: 1) developing partnerships with clinicians and administrators, 2) conducting needs assessments, 3) measuring and testing methods to improve organizational culture and climate, and 4) developing implementation tools such as decision support systems. *Educational* pilot studies develop/validate methods and tools (e.g., web-based applications, PDAs etc.) for training mid-level and primary care providers to deliver evidence-based treatments for mental health and substance abuse disorders. Small scale *demonstration* projects test the feasibility and acceptability of implementing evidence-based practices and help uncover hidden barriers to adoption and sustainability. The following is a list of examples of the kinds of implementation pilot studies that MIRECC investigators might propose. The following list of potential research topics is illustrative, not exhaustive.

- Develop community-academic partnerships with VA and non-VA providers, gatekeepers and informal caregivers who provide services to rural/underserved veterans in preparation for conducting implementation research. Researchers are encouraged to explore community-based participatory methods that develop capacity among community partners to conduct and evaluate quality improvement initiatives.
- Assess site-specific information about needs, preferences, resources, facilitators, and barriers to local adaptation and adoption of evidence-based practices in settings that serve rural and underserved veterans. Assess current site-specific practice patterns and office workflow systems, and assess organizational readiness to change.
- Develop and evaluate methods to measure and improve the culture/climate of clinical organizations to enhance the quality of care delivered to rural/underserved veterans. Can strategies be developed which modify an organization's readiness and/or capacity to change?

- Develop and validate educational programs to help mid-level practitioners and primary care providers develop the clinical expertise to deliver evidence-based mental health and addiction treatments. What types of educational strategies are most effective for CBOC clinicians and other providers serving rural veterans? What distance technologies are effective for providing educational trainings to providers at remote sites?
- Develop and evaluate decision support systems for mid-level and primary care providers to help them provide evidence-based treatments to rural/underserved veterans. How is decision support best provided to clinicians when and where they need it (e.g., hardcopy materials such as pocket cards, CPRS reminders/alerts, PDA resources, or web-based applications)?
- Determine the acceptability and feasibility of adapting evidence-based practices for CBOCs and other clinical settings providing services to rural and underserved veterans. Determine how evidence-based practices need to be tailored for these settings to better meet the needs and preferences of rural/underserved veterans and their providers. Determine how evidence-based practices need to be tailored to account for the clinical capacity of settings providing services to rural/underserved veterans. Determine how evidence-based practices can be adapted to help clinics meet their organization goals (e.g., performance measures).

Methodological Considerations – Successful implementation research requires developing close relationships with community partners. However, it is difficult to establish participatory research partnerships with clinicians and administrators in multiple remote locations. The South Central MIRECC is working towards developing a CBOC Practice-Based Research Network which will link MIRECC investigators to rural sites interested in participating in their research. MIRECC investigators are encouraged to contact their MIRECC Project Officer for more information.

III. SUBMISSION REQUIREMENTS AND REVIEW PROCESS

Investigator Eligibility Criteria – South Central MIRECC Core and Affiliate Investigators are eligible to apply for pilot studies. Core investigators are researchers who receive salary support from the South Central MIRECC. Affiliate investigators are researchers (M.D., Ph.D., Ed.D., etc.) who have a VA affiliation (permanent, temporary or Without Compensation appointment), and have signed a South Central MIRECC Affiliate Investigator Agreement. You will need to provide a copy of your VA appointment letter or a memo from your site leader saying you have a VA appointment.

Junior Investigators – Medical students, interns, residents, and fellows with VA appointments are eligible to submit applications for pilot studies. Requested award amounts should reflect the experience of the investigator. All junior investigators must designate a mentor in the grant application and specify a mentoring plan for the proposed pilot study. Pilot study applications from Junior Investigators will be evaluated using the same review criteria described below, but their experience level will be taken into consideration. Reviewer expectations concerning the potential for future external funding will concentrate on the likelihood that the junior investigator will continue to engage in research with rural and underserved veterans.

Award amount - The maximum award under this *Request for Pilot Study Applications* is \$75,000. However, the average award is expected to be much less. Investigators may submit

a request for a waiver to exceed the maximum amount. To request a waiver, submit a letter to Melonie Shelton (SheltonMelonieS@uams.edu) at least 4 weeks prior to the pilot study submission date (see below) justifying why additional funds are needed. The request for a waiver will be reviewed by a Project Officer and the Associate Director for Research, and the investigator will be notified within 2 weeks whether the waiver has been approved. Pilot funds awarded in the current fiscal year must be *spent* or *obligated* by the end of the next fiscal year (September 30th). For example, pilot study funds awarded on October 15, 2008 must be *spent* or *obligated* by September 30, 2010. Likewise, pilot study funds awarded on September 15th 2009 must be spent or obligated by September 30, 2010. Thus, a pilot study awarded earlier in the fiscal year can have a longer duration than a pilot study awarded later in the fiscal year. There are no exceptions to the requirement that funds must be spent or obligated by September 30th of the fiscal year immediately following the fiscal year in which the pilot study funds were awarded. Note that the ability to rollover MIRECC pilot funds from one fiscal year to the next is subject to changes in VISN policy.

Submission Process – Pilot study applications will be accepted four times per year (July 1, October 1, January 1, and April 1). Applications must be submitted by 5:00PM CT on the due date. If the due date falls on a Saturday or Sunday, applications will be due the following Monday by 5:00PM CT. Pilot study applications must be approved by *either* the Site Leader at a South Central MIRECC anchor site (VAMCs in Houston, Jackson, Little Rock, New Orleans and Oklahoma) or by the Associate Director for Research. Specifically, investigators at anchor sites will need to have their Site Leader sign the face page (see Attachment A). Investigators must request approval from their Site Leader to submit the pilot study application at least one month prior to the submission date. In fact, investigators are *strongly* encouraged to work with their Site Leaders as early as possible in the application process. If the Site Leader is not willing to approve the submission of a pilot study application, an investigator may submit a letter of intent to submit a MIRECC pilot study application to Melonie Shelton (SheltonMelonieS@uams.edu) stating the type of pilot study (observation, intervention or implementation), briefly describing the objectives and methods of the pilot study, and how the proposed research supports the South Central MIRECC mission. The letter of intent will be reviewed by a South Central MIRECC Project Officer and the South Central MIRECC Associate Director for Research, and the investigator will be notified within 4 weeks whether they have been approved to submit the pilot study application. However, pilot studies submitted from anchor sites without Site Leader approval are expected to have a low probability of being funded. Investigators at non-anchor sites must also submit a letter of intent to submit a MIRECC pilot study application to Melonie Shelton (SheltonMelonieS@uams.edu) stating the type of pilot study, briefly describing the objectives and methods of the pilot study, and how the proposed research supports the South Central MIRECC mission. Letters of intent must be submitted 4 weeks prior to the pilot study submission date. Applicants should submit the pilot study application electronically (via email) to Melonie Shelton (SheltonMelonieS@uams.edu) at the South Central MIRECC Office in Little Rock, AR. Applicants will be notified in writing of approval or disapproval within six weeks of the submission date.

Application - The pilot study application should include a face page (See Attachment A), the grant narrative, citations, budget (form VAF 10-1313-3), and a VA biosketch (form VAF 10-1313-5/6) or a NIH biosketch for the principal investigator and other key personnel. The budget should provide projected costs associated with staffing, supplies, etc. Funds for investigator salary, travel, or IT equipment may not be included. The grant narrative should be no longer than 4 pages (single-spaced, half inch margins, and Arial 11pt font), exclusive of references. The grant narrative should include the following sections:

1. Specific Aims (1/2 page) – State concisely and realistically what the research is intended to accomplish. Indicate how the research relates to the overall mission of the South Central MIRECC.
2. Background and Significance (1 page) – Briefly sketch the scientific literature pertinent to the proposed pilot study (and future grant application), critically evaluating existing knowledge, and identifying the gaps that the pilot study are intended to fill.
3. Methods (2 pages) – Briefly describe the study design and the procedures to be used to accomplish the specific aims of the project. Include the means by which the data will be collected, analyzed, and interpreted.
4. Research Team, Timeline, and Future Plans (1/2 page) – Briefly describe the qualifications and roles of the research team. Include a timeline for the work planned, including a projected completion date. Describe any new instruments, tools, or materials that will be generated. Describe plans for how the proposed pilot study will support a grant application to the VA, NIH, SAMSHA, or other federal funding agency. If the applicant is a junior investigator (e.g., medical student, resident, intern, or fellow), designate a mentor and describe the mentoring plan.

MIRECC Implementation Design and Analysis Support (MIDAS) – Investigators with methodological questions are encouraged to contact Melonie Shelton (SheltonMelonieS@uams.edu) to schedule a consultation with MIDAS. MIDAS experts can provide advice on issues of study design, instrument selection, sampling, subject recruitment, data extraction, statistical analysis, as well as qualitative data collection and analysis. MIDAS experts are available to assist investigators during the proposal development phase, as well as during the course of the pilot study. If investigators propose to use MIDAS during the course of the pilot study, MIDAS should to be consulted prior to submitting the pilot study application.

Review Process and Criteria - Pilot study applications will be reviewed by a South Central MIRECC Project Officer for scientific merit. Project Officers may consult with content or methodological experts as needed. Review criteria will include: 1) clinical or public health significance, 2) methodological approach, 3) innovation, 4) investigator qualifications, 5) local research environment and 6) potential for external funding.

- **Clinical or Public Health Significance:** Does this study address an important problem facing rural and underserved veterans?
- **Methodological Approach:** Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well-integrated, well-reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?
- **Innovation:** Is the project original and innovative? Does the project challenge existing paradigms or clinical practice? Does the project develop or employ novel concepts, approaches or methodologies, tools, or technologies?
- **Investigator qualifications:** Are the investigators and other key personnel appropriately trained and well suited to carry out this work? Is the work proposed

appropriate to the experience of the principal investigator? Do the investigators have a demonstrated track record of peer-reviewed publications commensurate with past funding?

- **Research Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Is there evidence of institutional support?
- **Potential for External Funding:** If successful, will the proposed pilot study lead to a competitive grant application for external funding from federal funding agencies (e.g., VA, NIH, SAMSHA), or private foundation (e.g., Robert Wood Johnson Foundation). If the applicant is a junior investigator (e.g., medical student, resident, intern, or fellow), what is the likelihood that they will conduct research with rural and underserved veterans in the future.

Note that an application does not need to be strong in all categories to be judged likely to have strong scientific merit. For example, an investigator may propose to carry out important work that by its nature is not innovative, but is essential to move a field forward. South Central MIRECC Project Officers may raise concerns, request clarifications and/or recommend changes to the pilot study application.

- Investigators submitting pilot study applications not considered to have *strong scientific merit*, will not be asked to revise and resubmit the application.
- Investigators submitting pilot study applications considered to have strong scientific merit, but also considered to have *major* weaknesses, will be asked to revise their application (including a 1 page introduction to the revised application) and resubmit it for the next submission cycle (July 1, October 1, January 1, and April 1).
- Investigators submitting pilot study applications considered to have strong scientific merit, but also considered to have *moderate* weaknesses, will be asked to submit a 1 page modification letter prior to the next submission cycle.
- Pilot study applications considered to have strong scientific merit and only *minor* weaknesses will compete for available pilot funds. Based on recommendations from the South Central MIRECC Project Officers, the Director and Associate Director for Research will make funding decisions, at their discretion, based on scientific merit, availability of funds, and contribution to the South Central MIRECC mission.

Note that pilot study applications will be subject to three levels of review. At the first level, Site Leaders will determine when pilot studies are ready for submission. At the second level, South Central MIRECC Project Officers will review the pilot study applications and recommend that those determined to have strong scientific merit and only minor weaknesses be considered for funding. At the third level, the South Central MIRECC Director and Associate Director for Research will decide which pilot studies should be prioritized for funding. By relying on the explicitly stated review criteria during each level of the review process, the South Central MIRECC pilot study program will emphasize scientific *objectivity* during each level of review.

Funding Requirements

Once the Pilot Study application is approved for funding, the following items must be completed and presented to the local MIRECC Program Specialist (if from an anchor site) or to Melonie Shelton (if from a non-anchor site). These items must be received **before your research begins**. Funds will be transferred upon receipt of all required documentation.

- South Central MIRECC Funding Agreement (see Attachment B)
- Local certificates of training in Human Subjects Protection and Data Security
- Local IRB and VA R&D approval letters
- Local Data Security Forms
 - o Data Security Checklist for Principal Investigators
 - o Principal Investigator's Certification: Storage & Security of VA Research Information
- Documentation of VA appointment
- Proof of Clinical Trials Registry (or statement of N/A from South Central MIRECC Associate Director of Research)

IV. CONTACTS

Associate Director for Research

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Project Officers

Observation Studies

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Project Officers (continued)

Intervention Studies

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Anchor Site Leaders

Houston

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Jackson

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Anchor Site Leaders (continued)

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